Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Hello Michele

Thank you for your support on our questions below. Its been invaluable to our team to get this crucial feedback in such a short timeline.

After reading your response (provided in red font below) we have provided a response on points 2 and 4 which have been provided in blue font to which we would like to get clarification on.

Supporting evidence is provided below if required.

Additionally, please also find the finalised meeting minutes below

Thank you in advance for all your support.

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 24/11/2021 18:00
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Please find the responses to your questions below in red font and revised meeting minutes attached. Hope this is helpful!

Best,
Michele

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Friday, November 12, 2021 10:15 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

Regarding the timeline clarification i've taken a look on the customer collaboration portal but there was only an email to provide feedback on the portal. Nevertheless i've emailed as i'm a little concerned about what may happen if the portal shows that the 180 day hold periods has expired and we haven't yet submitted our response..... is there a risk that the 510(k) may be inadvertently withdrawn?

We have prepared our response to your question below which I hope you find helpful.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 08/11/2021 22:05

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thanks for your message. Iâ€™ll need some time to review the teleconference minutes with my team and also obtain some feedback from our consulting toxicologist about the follow up questions. But I wanted to let you know I

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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received your email and you may feel free to check in again next week.

(b)(4)

Thank you,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov

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provide feedback regarding the customer service you have received:

https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Friday, November 5, 2021 12:07 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: helen.topping@admedsol.com; k211878@docs.fda.gov

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

I hope you had a nice holiday!

Following on from the teleconference we had a few actions to complete and get back to you with.

1) Teleconference minutes

Please find a draft of the the teleconference minutes below. Could you review and confirm if you require any changes made?

2) Follow-up questions on the teleconference discussion

As suggested during the teleconference there was the opportunity for a followup email clarification on a few minor points.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Thank you again for your assistance

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>, "Liu, Lixin" <Lixin.Liu@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 20/10/2021 22:43
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Michele

Thank you for the prompt response to the clarifications! We'll take your points on board regarding future shelf life studies.

I do have a minor clarification question regarding our response timeline

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 20/10/2021 14:55

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you to you and your team for attending the teleconference yesterday. I wanted to follow up on two things I was discussing with my team:

(b)(4)

I will be on leave for the next two weeks and you may contact our team management (Lixin.Liu@fda.hhs.gov) if you have questions during that time.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Best,

Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Lee, Michele
Sent: Friday, October 15, 2021 4:47 PM
To: Martin.Mitchell@admedsol.com
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you for providing your questions in advance of the meeting. We look forward to discussing our responses with you next week.

Have a good weekend,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Friday, October 15, 2021 12:00 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Please find the list of questions/clarifications attached below.

I hope you have a good weekend. I'm looking forwards to our discussion next week!

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 13/10/2021 22:35
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

I have scheduled the teleconference for next Tuesday October 19that 9am

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EST/ 2pm BST. Per your request, I can be on the call for 1 hour but our biocompatibility consultant/ team management needs to drop off for another call at 9:30am. Please send me the questions for discussion in advance of the meeting so that we can plan to discuss biocompatibility/ regulatory questions first before the relevant parties need to drop off.

Join Zoom Meeting

One tap mobile:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Thanks,

Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
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Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 13, 2021 4:46 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Apologies Michele, one final thing I missed off my email... could you clarify how long the teleconference would be by default? Could we request 1 hour just incase some of the points end up taking longer to discuss?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 13/10/2021 20:35

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hi Michele

We're currently preparing our questions for the teleconference and will send these through in due course, however to assist with scheduling the relevant parties at FDA, I should let you know that we would definitely like to discuss the questions related to biocompatibility.

After discussion with the team we would like to request the teleconference on the Tuesday 19th October if that is possible? As we are based in the UK, we would also like to request that this is arranged between the hours of 2-5pm BST.

If this time slot is not available could you outline any alternative days/times which would be possible?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 08/10/2021 22:14

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Hi Michele

Thank you for the offer. I think after today's meeting we may need a little more time to be better prepared for the teleconference.

We are reaching out to the (b)(4) for us as we feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible dates for you early next week.

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 06/10/2021 13:49
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference deadline up to October 19th. Let me know if you would like to select a date later than the 14thand I can check our management schedules.

Regarding review timelines, we are still on the 90 day review cycle and are planning to complete the review of your response with the 20 calendar days left on the clock. While we retain the right to add additional days, we are doing our best with the resources that we have to avoid delaying review timelines if possible.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Best,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>

Sent: Wednesday, October 6, 2021 6:00 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: helen.topping@admedsol.com

Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Thank you again for your review. Our team are busy discussing the questions and we would definitely like to have a teleconference with the FDA. We're currently consolidating our understanding of the deficiencies and are determining what our potential questions to you would be. I hope to get the questions to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we look to schedule a teleconference with the FDA on Wednesday 13th or Thursday 14th? As we're based in the UK we would appreciate a timeslot within our working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines for this project.... regarding the FDA timeline I can see on the CCP tracker

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website that the FDA timeline is on day 70.

Will FDA be sticking to the 90 day target and as a result only have 20 days left on the clock?

Or, due to the current situation with the unprecedented resource limitations..... will you will assume 30 days to review the response as standard? Or perhaps stick to the 20 days but retain the right to add additional days?

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
To: <martin.mitchell@admedsol.com>, <helen.topping@admedsol.com>
Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
Date: 04/10/2021 21:44
Subject: K211878/S001 is on Hold Pending Your Response

October 4, 2021
We have reviewed your submission. Please see attached.
If you have any questions, please contact the lead reviewer assigned to your submission, Michele Lee.

*** This is a system-generated email notification ***[attachment "K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Hello Michele

Thank you for your support on our questions

below. Its been invaluable to our team to get this crucial feedback in

such a short timeline.

After reading your response (provided

in red fontbelow) we have provided a response on points 2 and 4 which have been

provided in blue font

to which we would like to get

clarification on.

Supporting evidence is provided below

if required.

Additionally, please also find the finalised

meeting minutes below

Thank you in advance for all your support.

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions

Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From:

 "Lee, Michele"

<Michele.Lee@fda.hhs.gov>
To:

 "Martin.Mitchell@admedsol.com"

<Martin.Mitchell@admedsol.com>
Cc:

 "helen.topping@admedsol.com"

<helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date:

 24/11/2021 18:00
Subject:

   RE: [EXTERNAL]

Re: K211878/S001 is on Hold Pending Your Response
<hr noshade>

Hello Martin,

Please find the responses to your questions

below in red font and

revised meeting minutes attached. Hope this is helpful!

Best,
Michele

1.   In

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

face="Calibri">
Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices

Team
DHT4B: Division of Infection Control and

Plastic Surgery Devices
OHT4: Office of Surgical and Infection

Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue

| Silver Spring, MD 20993
<u>Michele.Lee@fda.hhs.gov</u>

<img src=cid:_4_0BE35CF80BE35998005E21D6802587A4 width=192 height=43 style="border:0px solid;">
<u>
</u><img src=cid:_2_0BE361880BE35998005E21D6802587A4 style="border:0px solid;"> <img src=cid:_2_0BE365D40BE35998005E21D6802587A4 style="border:0px solid;"> <img src=cid:_2_0BE36A200BE35998005E21D6802587A4 style="border:0px solid;"> <img src=cid:_2_0BE36E6C0BE35998005E21D6802587A4 style="border:0px solid;"> <img src=cid:_2_0BE372B80BE35998005E21D6802587A4 style="border:0px solid;">
Excellent customer

service is important to us. Please take a moment to provide feedback

regarding the customer service you have received: <font size=2 color=#0082bf

face="Helvetica"><u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u><
/font>

<font size=2
face="Calibri">From: Martin.Mitchell@admedsol.com

<Martin.Mitchell@admedsol.com>
Sent: Friday, November 12, 2021 10:15
AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc:
helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re:
K211878/S001 is on Hold Pending Your Response
<font size=2
face="Calibri">
<font size=2 color=#806210
face="Calibri">CAUTION:This email originated from
outside of the organization. Do not click links

or open attachments unless you recognize the sender and know the content

is safe.

<font size=2
face="Arial">Hello Michele
<font size=2
face="Arial">
Regarding the timeline clarification i've taken a look on the customer

collaboration portal but there was only an email to provide feedback on

the portal. Nevertheless i've emailed as i'm a little concerned about what

may happen if the portal shows that the 180 day hold periods has expired

and we haven't yet submitted our response..... is there a risk that the

510(k) may be inadvertently withdrawn?<font size=2
face="Calibri">

We have prepared our response
to your question below which I hope you find

helpful.<p><table width=100% style="border-collapse:collapse;"><tr height=8><td
width=18% style="border-style:none solid solid none;border-color:#000000;border-
width:0px 1px 1px 0px;padding:0px 0px;"><td colspan=3 style="border-style:none solid
solid none;border-color:#000000;border-width:0px 1px 1px 0px;padding:0px 0px;"><div
align=center>(b)(4)

(b)(4)

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

face="Arial">
Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>
To: "<u>Martin.Mitchell@admedsol.com</u>"

<<u>Martin.Mitchell@admedsol.com</u>>
Cc: "<u>helen.topping@admedsol.com</u>"

<<u>helen.topping@admedsol.com</u>>,

"<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 08/11/2021

22:05
Subject: RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hello Martin,

Thanks for your message. Iâ€™ll need some time to review the teleconference

minutes with my team and also obtain some feedback from our consulting

toxicologist about the follow up questions. But I wanted to let you know

I received your email and you may feel free to check in again next week.

(b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

would allow you an additional 180 days for the hold period. I have reached

out to the 510(k) Staff multiple times to confirm and am still waiting

on their response. Is there a customer service contact email for the customer

collaboration portal specifically? You may try contacting them as well

to have the date corrected on your end.

Thank you,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993<u>
</u><u>Michele.Lee@fda.hhs.gov</u>
 <u>
</u><img src=cid:_4_0B943A580B942A5C005E21D6802587A4 width=192 height=43 style="border:0px solid;"><u>
</u><u>
</u><img src=cid:_2_0B943EE80B942A5C005E21D6802587A4 style="border:0px solid;"><img src=cid:_2_0B9443340B942A5C005E21D6802587A4 style="border:0px solid;"> <img src=cid:_2_0B9447800B942A5C005E21D6802587A4 style="border:0px solid;"><img src=cid:_2_0B944BCC0B942A5C005E21D6802587A4 style="border:0px solid;"> <img src=cid:_2_0B9450180B942A5C005E21D6802587A4 style="border:0px solid;">
Excellent customer service is important to us. Please take a moment

to provide feedback regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

From: <u>Martin.Mitchell@admedsol.com</u><font size=2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

face="Calibri"><<u>Martin.Mitchell@admedsol.com</u>>

Sent: Friday, November 5, 2021 12:07 PM
To: Lee, Michele <<u>Michele.Lee@fda.hhs.gov</u>>
Cc: <u>helen.topping@admedsol.com</u>;

<u>k211878@docs.fda.gov</u>
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

CAUTION:This email originated from outside

of the organization. Do not click links or open attachments unless you

recognize the sender and know the content is safe.

Hello Michele

I hope you had a nice holiday!

Following on from the teleconference we had a few actions to complete and

get back to you with.

1) Teleconference minutes

Please find a draft of the the teleconference minutes below. Could you

review and confirm if you require any changes made?

2) Follow-up questions on the teleconference discussion

As suggested during the teleconference there was the opportunity for a

followup email clarification on a few minor points.
1.   In

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

face="Calibri">

3) Timeline clarification as per previous email

I can see on the customer collaboration portal that we have a 180 day hold

period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below

was active which would provide us with an additional 180 day hold period?
<u>https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices</u>
Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Thank you again for

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

your assistance

Best regards,<font size=2 color=#000080
face="Arial">

Martin Mitchell
Regulatory Affairs
Manager

Advanced Medical Solutions Ltd.
E-mail: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=2 color=#000080
face="Arial">
Tel: +44 (0) 1752 30 9360<font size=2
face="Calibri">

From:
       Martin

Mitchell/WIN/UK/AMS
To:
   "Lee,

Michele" <<font size=1 color=blue
face="Arial"><u>Michele.Lee@fda.hhs.gov</u>>,

"Liu, Lixin" <<font size=1
color=blue face="Arial"><u>Lixin.Liu@fda.hhs.gov</u><font size=1
face="Arial">>
Cc:
   "<a
href=mailto:helen.topping@admedsol.com><font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">>,

"<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u>"

<<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u><font size=1
face="Arial">>
Date:
   20/10/2021

22:43
Subject:
 RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response<font size=2
face="Calibri"> <hr noshade>
<font size=2
face="Calibri">

Hello Michele

Thank
you for the prompt response to the clarifications! We'll take your

points on board regarding future shelf life studies.

I do have a minor
clarification question regarding our response timeline

I can see on the customer
collaboration portal that we have a 180 day hold

period which ends on the 2nd of April 2022.

However, I was under the
understanding that the guidance document below

was active which would provide us with an additional 180 day hold period?<u>
</u><font size=2 color=blue
face="Calibri"><u>
</u><a href="https://www.fda.gov/regulatory-
information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-
formal-meetings-and-user-fee-applications-medical-devices"><font size=2 color=blue
face="Arial"><u>https://www.fda.gov/regulatory-information/search-fda-guidance-
documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-
applications-medical-devices</u>

Could you
clarify if we have 180 days or 360 days to respond to the deficiencies?

Best
regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-
mail: <font size=2 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=2 color=#000080
face="Arial">
Tel: +44 (0) 1752 30 9360<font size=2
face="Calibri">

<font size=1 color=#5f5f5f
face="Arial">

From: <font size=1
face="Arial">"Lee,

Michele" <<font size=1 color=blue
face="Arial"><u>Michele.Lee@fda.hhs.gov</u><font size=1

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

face="Arial">>
To: "<u>Martin.Mitchell@admedsol.com</u>"

<<u>Martin.Mitchell@admedsol.com</u>>
Cc: "<u>helen.topping@admedsol.com</u>"

<<u>helen.topping@admedsol.com</u>>,

"<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 20/10/2021

14:55
Subject: RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hello Martin,

Thank you to you and your team for attending the teleconference yesterday.

(b)(4)

management (<u>Lixin.Liu@fda.hhs.gov</u>)

if you have questions during that time.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993<u>
</u><u>Michele.Lee@fda.hhs.gov</u><font size=2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

color=blue face="Calibri"><u>
</u><u>
</u><img src=cid:_4_0C34442C0C343524005E21D6802587A4 style="border:0px solid;"><u>
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</u><img src=cid:_2_0C3448BC0C343524005E21D6802587A4 style="border:0px solid;"><img src=cid:_2_0C344CF00C343524005E21D6802587A4 style="border:0px solid;"><img src=cid:_2_0C34513C0C343524005E21D6802587A4 style="border:0px solid;"><img src=cid:_2_0C3455700C343524005E21D6802587A4 style="border:0px solid;"> <img src=cid:_2_0C3459BC0C343524005E21D6802587A4 style="border:0px solid;">
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to provide feedback regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

From: Lee, Michele
Sent: Friday, October 15, 2021 4:47 PM
To: <u>Martin.Mitchell@admedsol.com</u>
Cc: <u>helen.topping@admedsol.com</u>;

<u>k211878@docs.fda.gov</u>
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you for providing your questions in advance of the meeting. We look

forward to discussing our responses with you next week.

Have a good weekend,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993<u>
</u><u>Michele.Lee@fda.hhs.gov</u><u>
</u><u>
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</u><img src=cid:_2_0C3473D40C343524005E21D6802587A4 style="border:0px solid;"><img src=cid:_2_0C3478080C343524005E21D6802587A4 style="border:0px solid;"><img src=cid:_2_0C7A75BC0C343524005E21D6802587A4 style="border:0px solid;"><img src=cid:_2_0C7A78600C343524005E21D6802587A4 style="border:0px solid;"> <img src=cid:_2_0C7A7C940C343524005E21D6802587A4 style="border:0px solid;">
Excellent customer service is important to us. Please take a moment

to provide feedback regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u></fon

t>

From: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri"><<font size=2
color=blue face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri">>

Sent: Friday, October 15, 2021 12:00 PM
To: Lee, Michele
<<font size=2 color=blue
face="Calibri"><u>Michele.Lee@fda.hhs.gov</u><font size=2
face="Calibri">>
Cc: <a
href=mailto:helen.topping@admedsol.com><font size=2 color=blue
face="Calibri"><u>helen.topping@admedsol.com</u><font size=2
face="Calibri">;

<font size=2 color=blue
face="Calibri"><u>k211878@docs.fda.gov</u><font size=2
face="Calibri">
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending
Your Response<font size=2 color=#806210
face="Calibri">

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from outside

of the organization. Do not click links or open attachments unless you

recognize the sender and know the content is safe.<font size=2
face="Arial">

Hi Michele

Please find the list of questions/clarifications
attached below.

I hope you have a good weekend. I'm looking forwards to our
discussion

next week!
<font size=2
face="Arial">

Best regards,<font size=2 color=#000080
face="Arial">

Martin Mitchell
Regulatory Affairs
Manager

Advanced Medical Solutions Ltd.
E-mail: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=2 color=#000080
face="Arial">
Tel: +44 (0) 1752 30 9360<font size=2
face="Calibri">

From:
       "Lee,

Michele" <<font size=1 color=blue
face="Arial"><u>Michele.Lee@fda.hhs.gov</u><font size=1
face="Arial">>
To:
   "<a
href=mailto:Martin.Mitchell@admedsol.com><font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">>
Cc:
   "<a
href=mailto:helen.topping@admedsol.com><font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">>,

"<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u>"

<<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u><font size=1
face="Arial">>
Date:
   13/10/2021

22:35
Subject:
 RE:

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hello Martin,

I have scheduled the teleconference for next Tuesday October 19that

9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour but

our biocompatibility consultant/ team management needs to drop off for

another call at 9:30am. Please send me the questions for discussion in

advance of the meeting so that we can plan to (b)(4)

(b)(4)

<p><table width=100% style="border-collapse:collapse;"><tr height=8><td colspan=2 bgcolor=white style="border-style:none none none none;border-color:#000000;border-width:0px 0px 0px 0px;padding:0px 0px;"><u>Join

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

size=2>

Thanks,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993<u>
</u><u>Michele.Lee@fda.hhs.gov</u><u>

</u><img src=cid:_4_0DBF5A7C0C7AB6C0005E21D8802587A4 style="border:0px solid;"><u>

</u><img src=cid:_2_0DBF5DC00C7AB6C0005E21D8802587A4 style="border:0px solid;"><img src=cid:_2_0DBF61740C7AB6C0005E21D8802587A4

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

style="border:0px solid;"><a
href=http://www.youtube.com/user/USFoodandDrugAdmin><img
src=cid:_2_0DBF65A80C7AB6C0005E21D8802587A4 style="border:0px solid;"><a
href=http://www.flickr.com/photos/fdaphotos/><img
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color=#4f4f4f face="Arial"><a
href=http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm><img
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color=#4f4f4f>
Excellent customer service is important to us. Please
take a moment

to provide feedback regarding the customer service you have received: <a
href="https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E"
target=_blank><font size=2 color=#0082bf
face="Arial"><u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u></fon
t>

From: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2
color=blue><u>Martin.Mitchell@admedsol.com</u><<a
href=mailto:Martin.Mitchell@admedsol.com><font size=2
color=blue><u>Martin.Mitchell@admedsol.com</u>>

Sent: Wednesday, October 13, 2021 4:46 PM
To: Lee, Michele
<<font size=2
color=blue><u>Michele.Lee@fda.hhs.gov</u>>
Cc:
<font size=2
color=blue><u>helen.topping@admedsol.com</u>;

<font size=2
color=blue><u>k211878@docs.fda.gov</u>
Subject: RE:
[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response<font size=2
color=#806210>

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the organization.

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and know the content is safe.

Apologies
Michele, one final thing I missed off my email... could you clarify

how long the teleconference would be by default? Could we request 1 hour

just incase some of the points end up taking longer to discuss?

Best
regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-
mail: <font size=2 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=2 color=#000080
face="Arial">
Tel: +44 (0) 1752 30 9360
<font size=1
color=#5f5f5f face="Arial">

From:
 Martin

Mitchell/WIN/UK/AMS
To:
   "Lee,

Michele" <<font size=1 color=blue
face="Arial"><u>Michele.Lee@fda.hhs.gov</u><font size=1
face="Arial">>
Cc:
   "<a
href=mailto:helen.topping@admedsol.com><font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">>,

"<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u>"

<<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u><font size=1
face="Arial">>
Date:

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
   13/10/2021

20:35
Subject:
 RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response<div
align=center><hr noshade>

<font size=2
face="Arial">

Hi Michele

We're currently preparing our questions
for the teleconference and will

send these through in due course, however to assist with scheduling the

relevant parties at FDA, I should let you know that we would definitely

like to discuss the questions related to (b)(4) discussion with
the team we would like to request the teleconference

on the Tuesday 19th October

if that is possible? As we are based in

the UK, we would also like to request that this is arranged between the

hours of 2-5pm BST<font size=2
face="Arial">.

If this time slot is not available could you outline any alternative days/times

which would be possible?

Best regards,<font size=2 color=#000080
face="Arial">

Martin Mitchell
Regulatory Affairs
Manager

Advanced Medical Solutions Ltd.
E-mail: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=2 color=#000080
face="Arial">
Tel: +44 (0) 1752 30 9360<font size=2
face="Calibri">

<font size=1 color=#5f5f5f
face="Arial">

From: <font size=1
face="Arial">Martin

Mitchell/WIN/UK/AMS
To:
   "Lee,

Michele" <<font size=1 color=blue
face="Arial"><u>Michele.Lee@fda.hhs.gov</u><font size=1
face="Arial">>
Cc:
   "<a
href=mailto:helen.topping@admedsol.com><font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">>,

"<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u>"

<<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u><font size=1
face="Arial">>
Date:
   08/10/2021

22:14
Subject:
 RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response<font size=2
face="Calibri"> <hr noshade>
<font size=2
face="Calibri">

Hi
Michele

Thank you for the offer. I think after today's meeting we may need a
little

more time to be better prepared for the teleconference.

We are reaching out to
the toxicologist who wrote the TRA for us as we

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible

dates for you early next week.

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>
To: "<u>Martin.Mitchell@admedsol.com</u>"

<<u>Martin.Mitchell@admedsol.com</u>>
Cc: "<u>helen.topping@admedsol.com</u>"

<<u>helen.topping@admedsol.com</u>>,

"<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 06/10/2021

13:49
Subject: RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference

deadline up to October 19th. Let me know if you would like to

select a date later than the 14thand I can check our management

schedules.

Regarding review timelines, we are still on the 90 day review cycle and

are planning to complete the review of your response with the 20 calendar

days left on the clock. While we retain the right to add additional days,

we are doing our best with the resources that we have to avoid delaying

review timelines if possible.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993<u>
</u><u>Michele.Lee@fda.hhs.gov</u><font size=2
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

color=blue face="Calibri"><u>
</u><u>
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</u><img src=cid:_2_015851100158411C005E21D8802587A4 style="border:0px solid;"><img src=cid:_2_015855440158411C005E21D8802587A4 style="border:0px solid;"><img src=cid:_2_015859780158411C005E21D8802587A4 style="border:0px solid;"><img src=cid:_2_01585DAC0158411C005E21D8802587A4 style="border:0px solid;"><img src=cid:_2_015861E00158411C005E21D8802587A4 style="border:0px solid;">
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to provide feedback regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

From: <u>Martin.Mitchell@admedsol.com</u><<u>Martin.Mitchell@admedsol.com</u>>

Sent: Wednesday, October 6, 2021 6:00 AM
To: Lee, Michele <<u>Michele.Lee@fda.hhs.gov</u>>
Cc: <u>helen.topping@admedsol.com</u>
Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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of the organization. Do not click links or open attachments unless you

recognize the sender and know the content is safe.

Hi Michele

Thank you again for your review. Our team are busy discussing the questions

and we would definitely like to have a teleconference with the FDA. We're

currently consolidating our understanding of the deficiencies and are determining

what our potential questions to you would be. I hope to get the questions

to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we

look to schedule a teleconference with the FDA on Wednesday 13th or Thursday

14th? As we're based in the UK we would appreciate a timeslot within our

working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines

for this project.... regarding the FDA timeline I can see on the CCP tracker

website that the FDA timeline is on day 70.
Will FDA be sticking to the 90 day target

and as a result only have 20 days left on the clock?<li>Or, due to the current situation with the

unprecedented resource limitations..... will you will assume 30 days to

review the response as standard? Or perhaps stick to the 20 days but retain

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
the right to add additional days?
Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Michele

Lee [MICHELE.LEE]" <<u>michele.lee@fda.hhs.gov</u>>
To: <<u>martin.mitchell@admedsol.com</u>>,

<<u>helen.topping@admedsol.com</u>>
Cc: "Michele

Lee [MICHELE.LEE]" <<u>michele.lee@fda.hhs.gov</u>>
Date: 04/10/2021

21:44
Subject: K211878/S001

is on Hold Pending Your Response <hr noshade>

October 4, 2021 <p>We have reviewed your submission. Please see attached.

<p>If you have any questions, please contact the lead reviewer

assigned to your submission, Michele Lee. <p> <p>*** This is a system-generated email notification ***[attachment

"K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin

Mitchell/WIN/UK/AMS] <p>

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color=blue><u>http://www.admedsol.com</u>.

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color=blue><u>http://www.admedsol.com</u>.

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recipient, please notify the sender immediately and delete it from your

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Meeting Minutes.FDAEdit.docx" deleted by Martin Mitchell/WIN/UK/AMS]

<p><p>

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Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
Hi Michelle,

I realise we're

in unprecedented times and I do want to be respectful to FDA's challenges.

As this project is business critical for us, could you reassure me that

Monday's timeframe will not move again?

Best regards
Helen

Helen Topping

 Senior Regulatory Affairs Manager

 Advanced Medical Solutions

 Tel: +44 (0) 7721261214

 Email: helen.topping@admedsol.com<table width=850 style="border-collapse:collapse;"><tr height=8><td width=848 style="border-style:none none none none;border-color:#000000;border-width:0px 0px 0px 0px;padding:1px 1px;"></table>

From:

       "Lee,

Michele" <Michele.Lee@fda.hhs.gov>
To:

       "Martin.Mitchell@admedsol.com"

<Martin.Mitchell@admedsol.com>, "Helen.Topping@admedsol.com"

<Helen.Topping@admedsol.com>, "Rose.Guang@admedsol.com"

<Rose.Guang@admedsol.com>
Cc:

       "k211878@docs.fda.gov"

<k211878@docs.fda.gov>
Date:

       28/09/2021

16:45
Subject:

       RE:

[EXTERNAL] Re: K211878/S001 Review Status
<hr noshade>

 Hello

Martin, Helen, & Rose: I

am writing to inform you of a revision to the review timeline for your

510(k) Submission K211878/S001. Unfortunately, we are unable to complete

the substantive review by the previously revised timeline of September

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

29th. We now anticipate completion of the substantive review

by next Monday, October 4th. We apologize for any inconveniences

caused because of the multiple extensions of review timeline and appreciate

your understanding as the Agency works through resource limitations during

this time.   Best

Regards, Michele   Michele

Lee, Ph.D. Lead

Reviewer / Materials Engineer   Plastic

Surgery Skin and Wound Devices Team DHT4B:

Division of Infection Control and Plastic Surgery Devices OHT4:

Office of Surgical and Infection Control Devices Office

of Product Evaluation and Quality   CDRH

| Food and Drug Administration White

Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993 <u>Michele.Lee@fda.hhs.gov</u>   <img src=cid:_4_13ACA08013AC9D10006742AB8025875E style="border:0px solid;">
<u>
</u><img src=cid:_2_13ACA51813AC9D10006742AB8025875E style="border:0px solid;"> <img src=cid:_2_13ACA98013AC9D10006742AB8025875E style="border:0px solid;"> <img src=cid:_2_13ACADE813AC9D10006742AB8025875E style="border:0px solid;"> <img src=cid:_2_13ACB25013AC9D10006742AB8025875E style="border:0px solid;"> <img src=cid:_2_13ACB6B813AC9D10006742AB8025875E style="border:0px solid;"> Excellent

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feedback regarding the customer service you have received: </i><a
href="https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E"
target=_blank><span style=" font-size:10pt;color:#0082bf;font-
family:Helvetica"><u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>
 <span style=" font-
size:11pt;font-family:Calibri"> <p style="margin-top:0px;margin-
Bottom:0px"><span style=" font-size:11pt;font-
family:Calibri">From:Martin.Mitchell@admedsol.com
<Martin.Mitchell@admedsol.com>
Sent: Tuesday, September 21, 2021 10:03
AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc:
k211878@docs.fda.gov; Helen.Topping@admedsol.com;
Rose.Guang@admedsol.com
Subject: [EXTERNAL] Re: K211878/S001 Review
Status <span style=" font-
size:11pt;font-family:Calibri"> <p style="margin-top:0px;margin-
Bottom:0px"><span style=" font-size:10pt;color:#806210;font-
family:Calibri">CAUTION:This
email originated from outside of the organization. Do not click links

or open attachments unless you recognize the sender and know the content

is safe. <span style=" font-
size:11pt;font-family:Calibri"> <p style="margin-top:0px;margin-
Bottom:0px">Hello

Michele
<span
style=" font-size:10pt;font-family:Arial">
Thank you for your email to keep us
updated with progress.<span style=" font-size:11pt;font-
family:Calibri">

Please
note that next week i'll be out on annual leave... therefore, could

you also place Helen and Rose (on this email) on copy with any further

communication you send over.<span style=" font-size:11pt;font-
family:Calibri">

Best
regards,
<span
style=" font-size:10pt;color:#000080;font-family:Arial">
Martin Mitchell

Senior Regulatory Affairs Associate <span style=" font-size:11pt;font-
family:Calibri">
<span style=" font-size:10pt;color:#000080;font-
family:Arial">
Advanced Medical Solutions Ltd.
E-mail: <a
href=mailto:Martin.Mitchell@admedsol.com><span style=" font-size:10pt;color:blue;font-
family:Arial"><u>Martin.Mitchell@admedsol.com</u><span style=" font-
size:10pt;color:#000080;font-family:Arial">
Tel: +44 (0) 1752 30 9360<span
style=" font-size:11pt;font-family:Calibri">

<span style=" font-
size:8pt;color:#5f5f5f;font-family:Arial">
From:
 "Lee,

Michele" <<span style=" font-
size:8pt;color:blue;font-family:Arial"><u>Michele.Lee@fda.hhs.gov</u><span
style=" font-size:8pt;font-family:Arial">><span style=" font-
size:8pt;color:#5f5f5f;font-family:Arial">
To:
 "<a
href=mailto:Martin.Mitchell@admedsol.com><span style=" font-size:8pt;color:blue;font-
family:Arial"><u>Martin.Mitchell@admedsol.com</u><span style=" font-
size:8pt;font-family:Arial">"

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size:8pt;color:blue;font-
family:Arial"><u>Martin.Mitchell@admedsol.com</u><span style=" font-
size:8pt;font-family:Arial">><span style=" font-size:8pt;color:#5f5f5f;font-
family:Arial">
Cc: <span style=" font-
size:8pt;font-family:Arial">"<span
style=" font-size:8pt;color:blue;font-
family:Arial"><u>k211878@docs.fda.gov</u><span style=" font-size:8pt;font-
family:Arial">"

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size:8pt;color:blue;font-family:Arial"><u>k211878@docs.fda.gov</u><span
style=" font-size:8pt;font-family:Arial">><span style=" font-
size:8pt;color:#5f5f5f;font-family:Arial">
Date:

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 20/09/2021

22:31
Subject:
       <span style=" font-size:8pt;font-
family:Arial">K211878/S001

Review Status <hr noshade> <p style="margin-
top:0px;margin-Bottom:0px"><span style=" font-size:11pt;font-
family:Calibri">

<span style=" font-size:10pt;font-
family:Calibri">
Hello Martin:

I want to inform you of a slightly revised
review timeline for your 510(k)

submission K211878/S001. Due to a limitation of Agency resources, we are

unable to complete the substantive review by September 24th.

We want to inform you that we expect to complete the review by next Wednesday,

September 29th. We apologize for any inconveniences because

of the extension of timeline.

Best Regards,
Michele
 <span
style=" font-size:10pt;color:#0082bf;font-family:Segoe UI">
Michele Lee,
Ph.D.
Lead Reviewer
/ Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B:
Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality

CDRH
| Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver
Spring, MD 20993<span style=" font-size:11pt;color:blue;font-
family:Calibri"><u>
</u><span style="
font-size:10pt;color:blue;font-family:Segoe
UI"><u>Michele.Lee@fda.hhs.gov</u><span style=" font-size:12pt;font-
family:Segoe UI">
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family:Calibri"><u>
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family:Calibri"><u>
</u><span style=" font-size:11pt;color:blue;font-
family:Calibri"><u>
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font-size:8pt;color:#4f4f4f;font-family:Arial"><a
href=https://twitter.com/US_FDA><img src=cid:_2_142E1148142DFB08006742AB8025875E
style="border:0px solid;"><span style=" font-size:8pt;color:#4f4f4f;font-
family:Arial"> <img
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href=http://www.flickr.com/photos/fdaphotos/><img
src=cid:_2_142E1A18142DFB08006742AB8025875E style="border:0px solid;"><span style="
font-size:8pt;color:#4f4f4f;font-family:Arial"> <a
href=http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm><img
src=cid:_2_142E1E80142DFB08006742AB8025875E style="border:0px solid;"><span style="
font-size:10pt;color:#4f4f4f;font-family:Calibri">
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target=_blank><span style=" font-size:10pt;color:#0082bf;font-
family:Arial"><u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u></sp
an>
 <span style="
font-size:11pt;font-family:Calibri">

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href=http://www.admedsol.com/><span style=" font-size:11pt;color:blue;font-
family:Calibri"><u>http://www.admedsol.com</u><span style=" font-
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Bottom:0px">

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Hello Martin, Helen, & Rose:

I am writing to inform you of a revision to the review timeline for your 510(k) Submission K211878/S001. Unfortunately, we are unable to complete the substantive review by the previously revised timeline of September 29th. We now anticipate completion of the substantive review by next Monday, October 4th. We apologize for any inconveniences caused because of the multiple extensions of review timeline and appreciate your understanding as the Agency works through resource limitations during this time.

Best Regards,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D7B45E.3B4A9CB0]<http://www.fda.gov/>

[cid:image002.jpg@01D7B45E.3B4A9CB0]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D7B45E.3B4A9CB0] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7B45E.3B4A9CB0] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7B45E.3B4A9CB0] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D7B45E.3B4A9CB0]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Tuesday, September 21, 2021 10:03 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: k211878@docs.fda.gov; Helen.Topping@admedsol.com; Rose.Guang@admedsol.com

Subject: [EXTERNAL] Re: K211878/S001 Review Status

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Hello Michele

Thank you for your email to keep us updated with progress.

Please note that next week i'll be out on annual leave... therefore, could you also place Helen and Rose (on this email) on copy with any further communication you send over.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Best regards,

Martin Mitchell

Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 20/09/2021 22:31

Subject: K211878/S001 Review Status

Hello Martin:

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Best Regards,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D7B45E.3B4A9CB0]<http://www.fda.gov/>

[cid:image002.jpg@01D7B45E.3B4A9CB0]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D7B45E.3B4A9CB0] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7B45E.3B4A9CB0] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7B45E.3B4A9CB0] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D7B45E.3B4A9CB0]

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<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Dear both,

Yes, that would work for me as well.
Many thanks.

Kind regards.

(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov>
Sent: Freitag, 5. November 2021 17:19
To: (b)(4) k211878@docs.fda.gov
Cc:
Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

This message is from an EXTERNAL SENDER – be CAUTIOUS, particularly with links and attachments

---

Hello (b)(4)

Yes, I was thinking 1:30pm EST on Wednesday 11/10.

Thanks,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: (b)(4)
Sent: Friday, November 5, 2021 11:57 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>; (b)(4)
Cc: (b)(4)
Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Michele:

Just confirming you are looking at 1:30 pm Eastern time.

(b)(4) That time would work for me; please confirm your availability.

(b)(4)

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov>
Sent: Friday, November 5, 2021 11:08 AM
To: (b)(4) k211878@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

This message is from an EXTERNAL SENDER – be CAUTIOUS, particularly with links and attachments

---

Hello (b)(4)

I have another meeting before that scheduled time. I can do a half hour earlier (6:30pm UTC+1) on Wednesday or a different time on another day next week?

Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/odhcustomerservice?ID=1624&S=E

From: (b)(4)
Sent: Friday, November 5, 2021 11:02 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>; k211878@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Dear Michele,

many thanks for sending the invite.

I fear, I´ve made a mistake, when communicating the time.
Could we schedule one hour earlier?

Kind regards.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov>
Sent: Freitag, 5. November 2021 15:59
To: (b)(4) k211878@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello (b)(4)

Sure, we can discuss via teleconference on 10 Nov 2021 at 7pm UTC+1/ 2pm EDT. I sent a ZoomGov invite via email and also copied the call-in information below.

Image removed

Hi there,

Michele.Lee@fda.hhs.gov is inviting you to a scheduled ZoomGov meeting.

Join Zoom Meeting

(b)(4)

Best Regards,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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From: (b)(4)
Sent: Friday, November 5, 2021 10:10 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>; k211878@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Dear Michele,

Many thanks for your message.
Martin, thank you for the connection.

Michele, would you be available next Wednesday, 10 November 2021, at 7 pm (UTC+1)?
Then I would send an invitation.

Kind regards.

(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov>
Sent: Freitag, 5. November 2021 14:33
To: Martin.Mitchell@admedsol.com; k211878@docs.fda.gov
Cc: (b)(4)
Subject: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

This message is from an EXTERNAL SENDER -- be CAUTIOUS, particularly with links and attachments

---

Hello all,

Thank you, Martin, for the connection.

(b)(4)

Best Regards,

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Michele.Lee@fda.hhs.gov



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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Thursday, November 4, 2021 11:29 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>; k211378@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hello Michele

Regarding the recent deficiency question on our medical device submission which is currently under review with the FDA:

(b)(4)

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

Visit us at: http://www.admedsol.com. This e-mail, including any attached files, is confidential and intended for the exclusive use of the addressee(s) only. If you are not the intended recipient, please notify the sender immediately and delete it from your mailbox or any other storage mechanism.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hi Michele

Please find the list of questions/clarifications attached below.

I hope you have a good weekend. I'm looking forwards to our discussion next week!

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 13/10/2021 22:35
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

I have scheduled the teleconference for next Tuesday October 19th at 9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour but our biocompatibility consultant/ team management needs to drop off for another call at 9:30am. Please send me the questions for discussion in advance of the meeting so that we can plan to discuss biocompatibility/ regulatory questions first before the relevant parties need to drop off.

Join Zoom Meeting
One tap mobile:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Thanks,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

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Michele.Lee@fda.hhs.gov

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Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 13, 2021 4:46 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Apologies Michele, one final thing I missed off my email... could you clarify how long the teleconference would be by default? Could we request 1 hour just incase some of the points end up taking longer to discuss?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 13/10/2021 20:35
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hi Michele

We're currently preparing our questions for the teleconference and will send these through in due course, however to assist with scheduling the relevant parties at FDA, I should let you know that we would definitely like to discuss the questions related to biocompatibility.

After discussion with the team we would like to request the teleconference on the Tuesday 19th October if that is possible? As we are based in the

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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UK, we would also like to request that this is arranged between the hours of 2-5pm BST.

If this time slot is not available could you outline any alternative days/times which would be possible?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 08/10/2021 22:14
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hi Michele

Thank you for the offer. I think after today's meeting we may need a little more time to be better prepared for the teleconference.

We are reaching out to the (b)(4) for us as we feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible dates for you early next week.

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 06/10/2021 13:49
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference deadline up to October 19th. Let me know if you would like to select a date later than the 14thand I can check our management schedules.

Regarding review timelines, we are still on the 90 day review cycle and are planning to complete the review of your response with the 20 calendar days left on the clock. While we retain the right to add additional days, we are doing our best with the resources that we have to avoid delaying review timelines if possible.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
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Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 6, 2021 6:00 AM

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: helen.topping@admedsol.com

Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Thank you again for your review. Our team are busy discussing the questions and we would definitely like to have a teleconference with the FDA. We're currently consolidating our understanding of the deficiencies and are determining what our potential questions to you would be. I hope to get the questions to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we look to schedule a teleconference with the FDA on Wednesday 13th or Thursday 14th? As we're based in the UK we would appreciate a timeslot within our working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines for this project.... regarding the FDA timeline I can see on the CCP tracker website that the FDA timeline is on day 70.
Will FDA be sticking to the 90 day target and as a result only have 20 days left on the clock?
Or, due to the current situation with the unprecedented resource limitations..... will you will assume 30 days to review the response as standard? Or perhaps stick to the 20 days but retain the right to add additional days?

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>

To: <martin.mitchell@admedsol.com>, <helen.topping@admedsol.com>

Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Date: 04/10/2021 21:44

Subject: K211878/S001 is on Hold Pending Your Response

October 4, 2021

We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Michele Lee.

*** This is a system-generated email notification ***[attachment "K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Hi Michele

I'd like to provide an update on our

progress with responding to the deficiencies raised on K211878

We were on track to have a deficiency

response submitted to the FDA by the 180 day hold period deadline of 2nd

April 2022.

However, the organisation performing

the (b)(4) have

been affected (b)(4) . As a result, they were unable to complete

the testing by our targeted timeline.

Therefore, I just want to confirm that

we are still intending to respond to the deficiencies, but we would need

to use the second 180 day hold period granted to us through the COVID-19

situation.

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions

Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From:

 "Lee, Michele"

<Michele.Lee@fda.hhs.gov>
To:

 "Martin.Mitchell@admedsol.com"

<Martin.Mitchell@admedsol.com>
Cc:

 "helen.topping@admedsol.com"

<helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date:

 08/11/2021 22:05
Subject:

   RE: [EXTERNAL]

Re: K211878/S001 is on Hold Pending Your Response
<hr noshade>

Hello Martin,

Thanks for your message. Iâ€™ll need some

time to review the teleconference minutes with my team and also obtain

some feedback from our consulting toxicologist about the follow up questions.

But I wanted to let you know I received your email and you may feel free

to check in again next week.

I do have a clarification question about

(b)(4)

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(b)(4)

Regarding the timeline clarification- I

am also under the understanding that the COVID-19 guidance document you

cited was still active and that would allow you an additional 180 days

for the hold period. I have reached out to the 510(k) Staff multiple times

to confirm and am still waiting on their response. Is there a customer

service contact email for the customer collaboration portal specifically?

You may try contacting them as well to have the date corrected on your

end.

Thank you,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices

Team
DHT4B: Division of Infection Control and

Plastic Surgery Devices
OHT4: Office of Surgical and Infection

Control Devices
Office of Product Evaluation and Quality

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White Oak | 10903 New Hampshire Avenue

| Silver Spring, MD 20993
<u>Michele.Lee@fda.hhs.gov</u>

<img src=cid:_4_0DA1CB300DA1C7B40054EB4480258810 width=192 height=43 style="border:0px solid;">
<u>
</u><img src=cid:_2_0DA1CFC00DA1C7B40054EB4480258810 style="border:0px solid;"> <img src=cid:_2_0DA1D40C0DA1C7B40054EB4480258810 style="border:0px solid;"> <img src=cid:_2_0DA1D8580DA1C7B40054EB4480258810 style="border:0px solid;"> <img src=cid:_2_0DA1DCA40DA1C7B40054EB4480258810 style="border:0px solid;"> <img src=cid:_2_0DA1E0F00DA1C7B40054EB4480258810 style="border:0px solid;">
<font

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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size=2 color=#4f4f4f face="Calibri">Excellent customer

service is important to us. Please take a moment to provide feedback

regarding the customer service you have received: <a
href="https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E"
target=_blank><font size=2 color=#0082bf
face="Helvetica"><u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u><
/font>

<font size=2
face="Calibri">From: Martin.Mitchell@admedsol.com

<Martin.Mitchell@admedsol.com>
Sent: Friday, November 5, 2021 12:07
PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc:
helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re:
K211878/S001 is on Hold Pending Your Response
<font size=2
face="Calibri">
<font size=2 color=#806210
face="Calibri">CAUTION:This email originated from
outside of the organization. Do not click links

or open attachments unless you recognize the sender and know the content

is safe.

<font size=2
face="Arial">Hello Michele

I hope you had a nice holiday!<font size=2
face="Calibri">

Following on from the
teleconference we had a few actions to complete and

get back to you with.
<font size=2
face="Arial">
1) Teleconference minutes<font size=2
face="Calibri">

Please find a draft of the the
teleconference minutes below. Could you

review and confirm if you require any changes made?<font size=2
face="Calibri">

2) Follow-up
questions on the teleconference discussion<font size=2
face="Calibri">

As suggested during the
teleconference there was the opportunity for a

followup email clarification on a few minor points.
<font size=2 face="sans-
serif">1.   In

alignment with FDA recommendation, (b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

face="Arial">
The supporting information which provides further clarity on the questions

above has been attached if required.

3) Timeline clarification as per previous email

I can see on the customer collaboration portal that we have a 180 day hold

period which ends on the 2nd of April 2022.

However, I was under the

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

understanding that the guidance document below

was active which would provide us with an additional 180 day hold period?
<u>https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices</u>
Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Thank you again for your assistance

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: Martin

Mitchell/WIN/UK/AMS
To: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>,

"Liu, Lixin" <<u>Lixin.Liu@fda.hhs.gov</u>>
Cc: "<u>helen.topping@admedsol.com</u>"

<<u>helen.topping@admedsol.com</u>>,

"<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 20/10/2021

22:43
Subject: RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hello Michele

Thank you for the prompt response to the clarifications! We'll take your

points on board regarding future shelf life studies.

I do have a minor clarification question regarding our response timeline

I can see on the customer collaboration portal that we have a 180 day hold

period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below

was active which would provide us with an additional 180 day hold period?
<u>
</u><a href="https://www.fda.gov/regulatory-

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information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices"><u>https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices</u>

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>
To: "<u>Martin.Mitchell@admedsol.com</u>"

<<u>Martin.Mitchell@admedsol.com</u>>
Cc: "<u>helen.topping@admedsol.com</u>"

<<u>helen.topping@admedsol.com</u>>,

"<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 20/10/2021

14:55
Subject: RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hello Martin,

Thank you to you and your team for attending the teleconference yesterday.

I wanted to follow up on two things I was discussing with my team:
1.   Regarding

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

(b)(4)

I will be on leave for the next two weeks and you may contact our team

management (<u>Lixin.Liu@fda.hhs.gov</u>)

if you have questions during that time.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993<u>
</u><u>Michele.Lee@fda.hhs.gov</u>
 <u>
</u><img src=cid:_4_0CF2CE880CF2BF140054EB4580258810 style="border:0px solid;"><u>
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</u><img src=cid:_2_0CF2D3180CF2BF140054EB4580258810 style="border:0px solid;"><img src=cid:_2_0CF2D7640CF2BF140054EB4580258810 style="border:0px solid;"> <img src=cid:_2_0CF2DBB00CF2BF140054EB4580258810 style="border:0px solid;"><img src=cid:_2_0CF2DFFC0CF2BF140054EB4580258810 style="border:0px solid;"> <img src=cid:_2_0CF2E4480CF2BF140054EB4580258810 style="border:0px solid;">
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to provide feedback regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

From: Lee, Michele
Sent: Friday, October 15, 2021 4:47 PM
To: <u>Martin.Mitchell@admedsol.com</u>
Cc: <u>helen.topping@admedsol.com</u>;

<u>k211878@docs.fda.gov</u>
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you for providing your questions in advance of the meeting. We look

forward to discussing our responses with you next week.

Have a good weekend,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993<u>
</u><u>Michele.Lee@fda.hhs.gov</u>
 <u>
</u><a

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

href=http://www.fda.gov/><img src=cid:_4_0CF2FA200CF2BF140054EB4580258810
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face="Calibri"><u>
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color=#4f4f4f face="Arial"><img
src=cid:_2_0D7AC6B40CF2BF140054EB4580258810 style="border:0px solid;"><font size=1
color=#4f4f4f face="Arial"> <a
href=http://www.youtube.com/user/USFoodandDrugAdmin><img
src=cid:_2_0D7ACB000CF2BF140054EB4580258810 style="border:0px solid;"><font size=1
color=#4f4f4f face="Arial"><img
src=cid:_2_0D7ACF4C0CF2BF140054EB4580258810 style="border:0px solid;"><font size=1
color=#4f4f4f face="Arial"> <a
href=http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm><img
src=cid:_2_0D7AD3980CF2BF140054EB4580258810 style="border:0px solid;"><font size=2
color=#4f4f4f face="Calibri">
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 Please take a moment

to provide feedback regarding the customer service you have received: <a
href="https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E"
target=_blank><font size=2 color=#0082bf
face="Helvetica"><u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u><
/font>

From: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri"><<font size=2
color=blue face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri">>

Sent: Friday, October 15, 2021 12:00 PM
To: Lee, Michele
<<font size=2 color=blue
face="Calibri"><u>Michele.Lee@fda.hhs.gov</u><font size=2
face="Calibri">>
Cc: <a
href=mailto:helen.topping@admedsol.com><font size=2 color=blue
face="Calibri"><u>helen.topping@admedsol.com</u><font size=2
face="Calibri">;

<font size=2 color=blue
face="Calibri"><u>k211878@docs.fda.gov</u><font size=2
face="Calibri">
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending
Your Response
 <font size=2 color=#806210
face="Calibri">
CAUTION:This email originated
from outside

of the organization. Do not click links or open attachments unless you

recognize the sender and know the content is safe.
 <font size=2
face="Arial">
Hi Michele

Please find the list of questions/clarifications
attached below.

I hope you have a good weekend. I'm looking forwards to our
discussion

next week!

<font size=2
face="Arial">

Best regards,<font size=2 color=#000080
face="Arial">

Martin Mitchell
Regulatory Affairs
Manager

Advanced Medical Solutions Ltd.
E-mail: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=2 color=#000080
face="Arial">
Tel: +44 (0) 1752 30 9360<font size=2
face="Calibri">

From:
       "Lee,

Michele" <<font size=1 color=blue
face="Arial"><u>Michele.Lee@fda.hhs.gov</u><font size=1
face="Arial">>
To:
   "<a
href=mailto:Martin.Mitchell@admedsol.com><font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">"

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

<<u>Martin.Mitchell@admedsol.com</u>>
Cc: "<u>helen.topping@admedsol.com</u>"

<<u>helen.topping@admedsol.com</u>>,

"<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 13/10/2021

22:35
Subject: RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hello Martin,

I have scheduled the teleconference for next Tuesday October 19that

9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour but

our biocompatibility consultant/ team management needs to drop off for

another call at 9:30am. Please send me the questions for discussion in

advance of the meeting so that we can plan to discuss biocompatibility/

regulatory questions first before the relevant parties need to drop off.

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Zoom Meeting</u> <tr valign=top height=8><td style="border-style:none none none none;border-color:#000000;border-width:0px 0px 0px 0px;padding:0px 0px;">One

tap mobile: <td style="border-style:none none none none;border-

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

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Records processed under FOIA Request 2023-7342, Released by CDRH on 04-11-2024

(b)(4)

size=2>

Thanks,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993<u>
</u><u>Michele.Lee@fda.hhs.gov</u><u>

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</u><img src=cid:_2_0C5AE2800D7B0E140054EB4580258810 style="border:0px solid;"><img src=cid:_2_0C5AE5C40D7B0E140054EB4580258810 style="border:0px solid;"><img src=cid:_2_0C5AE9A40D7B0E140054EB4580258810 style="border:0px solid;"><img src=cid:_2_0C5AEDD80D7B0E140054EB4580258810 style="border:0px solid;"> <img src=cid:_2_0C5AF2240D7B0E140054EB4580258810 style="border:0px solid;">
Excellent customer service is important to us. Please take a moment

to provide feedback regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

From: <u>Martin.Mitchell@admedsol.com</u><<u>Martin.Mitchell@admedsol.com</u>>

Sent: Wednesday, October 13, 2021 4:46 PM
To: Lee, Michele <<u>Michele.Lee@fda.hhs.gov</u>>
Cc: <u>helen.topping@admedsol.com</u>;

<u>k211878@docs.fda.gov</u>
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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and know the content is safe.

Apologies Michele, one final thing I missed off my email... could you clarify

how long the teleconference would be by default? Could we request 1 hour

just incase some of the points end up taking longer to discuss?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: Martin

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Mitchell/WIN/UK/AMS
To: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>
Cc: "<u>helen.topping@admedsol.com</u>"

<<u>helen.topping@admedsol.com</u>>,

"<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 13/10/2021

20:35
Subject: RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hi Michele

We're currently preparing our questions for the teleconference and will

send these through in due course, however to assist with scheduling the

relevant parties at FDA, I should let you know that we would definitely

like to discuss the questions related to biocompatibility.

After discussion with the team we would like to request the teleconference

on the Tuesday 19th October

if that is possible? As we are based in

the UK, we would also like to request that this is arranged between the

hours of 2-5pm BST.

If this time slot is not available could you outline any alternative days/times

which would be possible?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: Martin

Mitchell/WIN/UK/AMS
To: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>
Cc: "<u>helen.topping@admedsol.com</u>"

<<u>helen.topping@admedsol.com</u><font size=1

face="Arial">>,

"<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 08/10/2021

22:14
Subject: RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hi Michele

Thank you for the offer. I think after today's meeting we may need a little

more time to be better prepared for the teleconference.

We are reaching out to the (b)(4) for us as we

feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible

dates for you early next week.

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>
To: "<u>Martin.Mitchell@admedsol.com</u>"

<<u>Martin.Mitchell@admedsol.com</u>>
Cc: "<u>helen.topping@admedsol.com</u>"

<<u>helen.topping@admedsol.com</u>>,

"<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 06/10/2021

13:49
Subject: RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference

deadline up to October 19th. Let me know if you would like to

select a date later than the 14thand I can check our management

schedules.

Regarding review timelines, we are still on the 90 day review cycle and

are planning to complete the review of your response with the 20 calendar

days left on the clock. While we retain the right to add additional days,

we are doing our best with the resources that we have to avoid delaying

review timelines if possible.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993<u>
</u><u>Michele.Lee@fda.hhs.gov</u><u>
</u><u>
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</u><img src=cid:_2_0E44D4140E44C4240054EB4580258810 style="border:0px solid;"><img src=cid:_2_0E44D8480E44C4240054EB4580258810 style="border:0px solid;"><img src=cid:_2_04E78F000E44C4240054EB4580258810 style="border:0px solid;"><img src=cid:_2_04E792B40E44C4240054EB4580258810 style="border:0px solid;"><img src=cid:_2_04E797000E44C4240054EB4580258810 style="border:0px solid;">
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to provide feedback regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

From: <u>Martin.Mitchell@admedsol.com</u><<u>Martin.Mitchell@admedsol.com</u>>

Sent: Wednesday, October 6, 2021 6:00 AM
To: Lee, Michele <<u>Michele.Lee@fda.hhs.gov</u>>
Cc: <u>helen.topping@admedsol.com</u>
Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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of the organization. Do not click links or open attachments unless you

recognize the sender and know the content is safe.

Hi Michele

Thank you again for your review. Our team are busy discussing the questions

and we would definitely like to have a teleconference with the FDA. We're

currently consolidating our understanding of the deficiencies and are determining

what our potential questions to you would be. I hope to get the questions

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to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we

look to schedule a teleconference with the FDA on Wednesday 13th or Thursday

14th? As we're based in the UK we would appreciate a timeslot within our

working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines

for this project.... regarding the FDA timeline I can see on the CCP tracker

website that the FDA timeline is on day 70.
Will FDA be sticking to the 90 day target

and as a result only have 20 days left on the clock?<li>Or, due to the current situation with the

unprecedented resource limitations..... will you will assume 30 days to

review the response as standard? Or perhaps stick to the 20 days but retain

the right to add additional days?
Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Michele

Lee [MICHELE.LEE]" <<u>michele.lee@fda.hhs.gov</u>>
To: <<u>martin.mitchell@admedsol.com</u>>,

<<u>helen.topping@admedsol.com</u>>
Cc: "Michele

Lee [MICHELE.LEE]" <<u>michele.lee@fda.hhs.gov</u>>
Date: 04/10/2021

21:44
Subject: K211878/S001

is on Hold Pending Your Response <hr noshade>

October 4, 2021 <p>We have reviewed your submission. Please see attached.

<p>If you have any questions, please contact the lead reviewer

assigned to your submission, Michele Lee. <p> <p>*** This is a system-generated email notification ***[attachment

"K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin

Mitchell/WIN/UK/AMS] <p>

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for the exclusive use of the addressee(s) only. If you are not the intended

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

recipient, please notify the sender immediately and delete it from your

mailbox or any other storage mechanism.<p>

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color=blue><u>http://www.admedsol.com</u>.

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color=blue><u>http://www.admedsol.com</u>.

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Hi Michele

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today's meeting we may need a little more time to be better prepared for

the teleconference.

We are reaching out to the (b)(4)

(b)(4) for us as we feel that it may be beneficial to have them

join us on the teleconference.

As such we need to check their availability.

I hope to have list of possible dates for you early next week.

Best regards,

Martin Mitchell
Senior Regulatory Affairs

Associate

Advanced Medical Solutions

Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From:

 "Lee, Michele"

<Michele.Lee@fda.hhs.gov>
To:

 "Martin.Mitchell@admedsol.com"

<Martin.Mitchell@admedsol.com>
Cc:

 "helen.topping@admedsol.com"

<helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date:

 06/10/2021 13:49
Subject:

   RE: [EXTERNAL]

Re: K211878/S001 is on Hold Pending Your Response
<hr noshade>

Hello Martin,

If it makes it easier for your team, we

are able to extend the 10 day teleconference deadline up to October 19th.

Let me know if you would like to select a date later than the 14thand I can check our management schedules.

Regarding review timelines, we are still

on the 90 day review cycle and are planning to complete the review of your

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Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices

Team
DHT4B: Division of Infection Control and

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Plastic Surgery Devices
OHT4: Office of Surgical and Infection

Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue

| Silver Spring, MD 20993
<u>Michele.Lee@fda.hhs.gov</u>

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</u><img src=cid:_2_0C9412740C940A840074AD6080258768 style="border:0px solid;"> <img src=cid:_2_0C9416C00C940A840074AD6080258768 style="border:0px solid;"> <img src=cid:_2_0C941B0C0C940A840074AD6080258768 style="border:0px solid;"> <img src=cid:_2_0C941F580C940A840074AD6080258768 style="border:0px solid;"> <img src=cid:_2_0C9423A40C940A840074AD6080258768 style="border:0px solid;">
Excellent customer

service is important to us. Please take a moment to provide feedback

regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

From: Martin.Mitchell@admedsol.com

<Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 6, 2021 6:00 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com
Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Michele

Lee [MICHELE.LEE]" <<u>michele.lee@fda.hhs.gov</u>>
To: <<u>martin.mitchell@admedsol.com</u>>,

<<u>helen.topping@admedsol.com</u>>
Cc: "Michele

Lee [MICHELE.LEE]" <<u>michele.lee@fda.hhs.gov</u>>
Date: 04/10/2021

21:44
Subject: K211878/S001

is on Hold Pending Your Response <hr noshade>

October 4, 2021 <p>We have reviewed your submission. Please see attached.

<p>If you have any questions, please contact the lead reviewer

assigned to your submission, Michele Lee. <p> <p>*** This is a system-generated email notification ***[attachment

"K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin

Mitchell/WIN/UK/AMS] <p>

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Hi Sam

Please find a response to the two points

(b)(4)

serif">Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions

Ltd.
E-mail:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From:

 "Arepalli, Sambasiva"

<Sambasiva.Arepalli@fda.hhs.gov>
To:

 "Martin.Mitchell@admedsol.com"

<Martin.Mitchell@admedsol.com>
Cc:

 "Arepalli, Sambasiva"

<Sambasiva.Arepalli@fda.hhs.gov>, "K211878@docs.fda.gov"

<K211878@docs.fda.gov>
Date:

 16/05/2022 14:39
Subject:

   K211878-s002
<hr noshade>

Hi Mr. Martin:
Please address the following:
<font size=2 face="Calibri"[(b)(4)]:
<font size=2 face="Calibri"

[(b)(4)]

face="Calibri">Thx
Sam

Sam Arepalli, Ph.D.
FDA/CDRH/OPEQ/OHT4/PRSB2
Ph: 301 796 6434

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Hello Martin,

Thanks for the update and good to know this information. I also received your previous email with additional information about the (b)(4) (b)(4) I am still waiting on feedback from our consulting toxicologist but hope to have more information to provide you mid next week.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Monday, November 15, 2021 3:54 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Subject: Fw: [EXTERNAL] K211878 timeline - COVID-19

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Hi Michele

I got an update regarding timeline from the CCP email address.

FYI we are exploring a number of backup strategies to resolve the 510(k) deficiencies.... and some of these take us past the 180 day hold period.

As per the request below, I'll let you know closer to the time if we end up needing to request the additional 180 days.

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

---- Forwarded by Martin Mitchell/WIN/UK/AMS on 15/11/2021 08:31 ----

From: "CCP" <CCP@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Date: 12/11/2021 21:08
Subject: RE: [EXTERNAL] K211878 timeline - COVID-19

Good day to you Martin,

The extra 180 days for response are added as needed, and then only shortly before the original 180 days expires.

--
Happy trails,
~N els A nder son
Regulatory Systems & Data Management Staff
Center for Devices and Radiological Health | Office of Product Evaluation and Quality| Office of Regulatory Programs

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Friday, November 12, 2021 09:49
To: CCP <CCP@fda.hhs.gov>
Subject: [EXTERNAL] K211878 timeline - COVID-19

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Hello

Regarding the timeline showing for K211878 I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I (and the lead reviewer Michele Lee) were under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify that the 180 timeline in the customer collaboration portal won't trigger premature closure of the 510(k) before the actual 360 day timeline expires?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

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Hello (b)(4)

Ok, I have changed the Zoom call time to 1:30pm EST on Wednesday. The call in information should still be the same.

Thanks,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D7D47F.5A972930]<http://www.fda.gov/>

[cid:image002.jpg@01D7D47F.5A972930]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D7D47F.5A972930] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7D47F.5A972930] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7D47F.5A972930] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D7D47F.5A972930]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: (b)(4)

Sent: Monday, November 8, 2021 3:19 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>; (b)(4)
k211878@docs.fda.gov

Cc: (b)(4)

Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Dear both,

Yes, that would work for me as well.

Many thanks.

Kind regards.

(b)(4)

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(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Sent: Freitag, 5. November 2021 17:19

To: (b)(4)
(b)(4)
k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Cc: (b)(4)

Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello (b)(4)

Yes, I was thinking 1:30pm EST on Wednesday 11/10.

Thanks,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

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Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D7D47F.5A972930]<http://www.fda.gov/>

[cid:image002.jpg@01D7D47F.5A972930]<https://www.facebook.com/FDA>

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[cid:image003.jpg@01D7D47F.5A972930] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7D47F.5A972930] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7D47F.5A972930] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D7D47F.5A972930]
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From: (b)(4)

Sent: Friday, November 5, 2021 11:57 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>; (b)(4)
(b)(4)
k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Cc: (b)(4)

Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Michele:

Just confirming you are looking at 1:30 pm Eastern time.

(b)(4) That time would work for me; please confirm your availability.

(b)(4)

(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Sent: Friday, November 5, 2021 11:08 AM

To: (b)(4);
k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Cc: (b)(4)
(b)(4)

Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello (b)(4)

I have another meeting before that scheduled time. I can do a half hour earlier (6:30pm UTC+1) on Wednesday or a different time on another day next week?

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

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Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

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[cid:image002.jpg@01D7D47F.5A972930]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D7D47F.5A972930] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7D47F.5A972930] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7D47F.5A972930] <http://www.flickr.com/photos/fdaphotos/>
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From: (b)(4)

Sent: Friday, November 5, 2021 11:02 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Cc: (b)(4)
(b)(4)

Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Dear Michele,

many thanks for sending the invite.

I fear, IÂ´ve made a mistake, when communicating the time.

Could we schedule one hour earlier?

Kind regards.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Sent: Freitag, 5. November 2021 15:59

To: (b)(4)
k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Cc: (b)(4)
(b)(4)

Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello (b)(4)

Sure, we can discuss via teleconference on 10 Nov 2021 at 7pm UTC+1/ 2pm EDT. I sent a ZoomGov invite via email and also copied the call-in information below.

[Image removed by sender.]<https://zoom.us/>

Hi there,

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov> is inviting you to a scheduled ZoomGov meeting.

Join Zoom

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Best Regards,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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[cid:image004.jpg@01D7D47F.5A972930] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7D47F.5A972930] <http://www.flickr.com/photos/fdaphotos/>
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From: (b)(4)

Sent: Friday, November 5, 2021 10:10 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Cc: (b)(4)

(b)(4)

Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Dear Michele,

Many thanks for your message.

Martin, thank you for the connection.

Michele, would you be available next Wednesday, 10 November 2021, at 7 pm (UTC+1)?

Then I would send an invitation.

Kind regards.

(b)(4)

_____

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Sent: Freitag, 5. November 2021 14:33

To: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Cc: (b)(4)

(b)(4)

Subject: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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_____

Hello all,

Thank you, Martin, for the connection.

(b)(4)

Best Regards,

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

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Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

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[cid:image002.jpg@01D7D47F.5A972930]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D7D47F.5A972930] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7D47F.5A972930] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7D47F.5A972930] <http://www.flickr.com/photos/fdaphotos/>
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From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>
<Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Thursday, November 4, 2021 11:29 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>;

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Cc: (b)(4)

(b)(4)

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

Regarding the recent deficiency question on our medical device submission which is currently under review with the FDA:

(b)(4)

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

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(b)(4)

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Hi Michele

We're currently preparing our questions

for the teleconference and will send these through in due course, however

to assist with scheduling the relevant parties at FDA, (b)(4)

(b)(4)

(b)(4)

After discussion with the team we would

like to request the teleconference on the Tuesday

19th October if that is possible?

As we are based in the UK, we would also like to request that this is arranged

between the hours of 2-5pm

BST.

If this time slot is not available could

you outline any alternative days/times which would be possible?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions

Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From:

 Martin Mitchell/WIN/UK/AMS
To:

 "Lee, Michele"

<Michele.Lee@fda.hhs.gov>
Cc:

 "helen.topping@admedsol.com"

<helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date:

 08/10/2021 22:14
Subject:

   RE: [EXTERNAL]

Re: K211878/S001 is on Hold Pending Your Response
<hr noshade>

Hi Michele

Thank you for the offer. I think after

today's meeting we may need a little more time to be better prepared for

the teleconference.

We are reaching out to the (b)(4)

(b)(4) for us as we feel that it may be beneficial to have them

join us on the teleconference.

As such we need to check their availability.

I hope to have list of possible dates for you early next week.

Best regards,

Martin Mitchell
Senior Regulatory Affairs

Associate

Advanced

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Medical Solutions

Ltd.
E-mail:
Martin.Mitchell@admedsol.com
<font size=2 color=#000080 face="sans-
serif">Tel: +44 (0) 1752 30 9360

<font size=1
color=#5f5f5f face="sans-serif">From:

 "Lee, Michele"

<Michele.Lee@fda.hhs.gov>
<font size=1 color=#5f5f5f face="sans-
serif">To:

 "Martin.Mitchell@admedsol.com"

<Martin.Mitchell@admedsol.com>
<font size=1 color=#5f5f5f face="sans-
serif">Cc:

 "helen.topping@admedsol.com"

<helen.topping@admedsol.com>, "k211878@docs.fda.gov"
<k211878@docs.fda.gov>
<font size=1 color=#5f5f5f face="sans-
serif">Date:

 06/10/2021 13:49
<font size=1
color=#5f5f5f face="sans-serif">Subject:

   RE: [EXTERNAL]

Re: K211878/S001 is on Hold Pending Your Response
<hr
noshade>

Hello Martin,
<font size=2
face="Calibri">
If it makes it easier for
your team, we

are able to extend the 10 day teleconference deadline up to October 19th.

Let me know if you would like to select a date later than the 14thand I can
check our management schedules.
<font size=2
face="Calibri">
Regarding review timelines,
we are still

on the 90 day review cycle and are planning to complete the review of your

response with the 20 calendar days left on the clock. While we retain the

right to add additional days, we are doing our best with the resources

that we have to avoid delaying review timelines if possible.
<font size=2
face="Calibri">
Best,
Michele
<font size=2
face="Calibri">
Michele
Lee, Ph.D.
Lead Reviewer / Materials
Engineer

<font size=2
face="Segoe UI">Plastic Surgery Skin and Wound Devices

Team
DHT4B: Division of Infection Control and

Plastic Surgery Devices
OHT4: Office of
Surgical and Infection

Control Devices
Office of Product Evaluation and
Quality

<font size=2 face="Segoe
UI">CDRH | Food and Drug Administration
White
Oak | 10903 New Hampshire Avenue

| Silver Spring, MD 20993
<font size=2
color=blue face="Segoe UI"><u>Michele.Lee@fda.hhs.gov</u><font size=2
face="Segoe UI">

<a
href=http://www.fda.gov/><img src=cid:_4_0E4551080E454DA8006B93A78025876D
style="border:0px solid;">
<u>
</u><a
href=https://www.facebook.com/FDA><img src=cid:_2_0B2AD6900E454DA8006B93A78025876D

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

style="border:0px solid;"> <a
href=https://twitter.com/US_FDA><img src=cid:_2_0B2ADADC0E454DA8006B93A78025876D
style="border:0px solid;"> <a
href=http://www.youtube.com/user/USFoodandDrugAdmin><img
src=cid:_2_0B2ADF280E454DA8006B93A78025876D style="border:0px solid;"><font size=1
color=#4f4f4f face="Arial"> <a
href=http://www.flickr.com/photos/fdaphotos/><img
src=cid:_2_0B2AE3740E454DA8006B93A78025876D style="border:0px solid;"><font size=1
color=#4f4f4f face="Arial"> <a
href=http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm><img
src=cid:_2_0B2AE7C00E454DA8006B93A78025876D style="border:0px solid;">
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service is important to us. Please take a moment to provide feedback

regarding the customer service you have received: <a
href="https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E"
target=_blank><font size=2 color=#0082bf face="sans-
serif"><u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

<font size=2
face="Calibri">From: Martin.Mitchell@admedsol.com

<Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 6, 2021 6:00
AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc:
helen.topping@admedsol.com
Subject: [EXTERNAL] Re: K211878/S001 is on Hold
Pending Your Response

CAUTION:This
email originated from outside of the organization. Do not click links

or open attachments unless you recognize the sender and know the content

is safe.

<font size=2
face="Arial">Hi Michele
<font size=2
face="Arial">
Thank you again for your review. Our team are busy discussing the
questions

and we would definitely like to have a teleconference with the FDA. We're

currently consolidating our understanding of the deficiencies and are determining

what our potential questions to you would be. I hope to get the questions

to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind....
could we

look to schedule a teleconference with the FDA on Wednesday 13th or Thursday

14th? As we're based in the UK we would appreciate a timeslot within our

working hours which finish at 17:00 BST.<font size=2
face="Calibri">

Additionally, I have a small
question to allow us to predict timelines

for this project.... regarding the FDA timeline I can see on the CCP tracker

website that the FDA timeline is on day 70.<font size=2
face="Calibri">
Will FDA be sticking to the 90
day target

and as a result only have 20 days left on the clock?
<font size=2
face="Arial">Or, due to the current situation with the

unprecedented resource limitations..... will you will assume 30 days to

review the response as standard? Or perhaps stick to the 20 days but retain

the right to add additional days?
Best
regards,
<font size=2 color=#000080
face="Arial">
Martin Mitchell
Senior Regulatory Affairs Associate

<font size=2 color=#000080
face="Arial">
Advanced Medical Solutions Ltd.
E-mail: <a

href=mailto:Martin.Mitchell@admedsol.com><u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Michele

Lee [MICHELE.LEE]" <<u>michele.lee@fda.hhs.gov</u>>
To: <<u>martin.mitchell@admedsol.com</u>>,

<<u>helen.topping@admedsol.com</u>>
Cc: "Michele

Lee [MICHELE.LEE]" <<u>michele.lee@fda.hhs.gov</u>>
Date: 04/10/2021

21:44
Subject: K211878/S001

is on Hold Pending Your Response <hr noshade>

October 4, 2021 <p>We have reviewed your submission. Please see attached.

<p>If you have any questions, please contact the lead reviewer

assigned to your submission, Michele Lee. <p> <p>*** This is a system-generated email notification ***[attachment

"K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin

Mitchell/WIN/UK/AMS] <p>

Visit us at: <u>http://www.admedsol.com</u>.

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recipient, please notify the sender immediately and delete it from your

mailbox or any other storage mechanism.<p><p><p>

Visit us at: http://www.admedsol.com. This e-mail, including any attached files, is confidential and intended for the exclusive use of the addressee(s) only. If you are not the intended recipient, please notify the sender immediately and delete it from your mailbox or any other storage mechanism.

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Morning Sam

I hope you've had a nice weekend.

I'm just following up on my previous

email from last Friday....we believe that the information we provided satisfied

your request; however we would like to check on the feedback from management.

Please feel free to contact me if you

require further assistance. As there is now only 1 day left of the review

(completing on the 24th May) myself and the project team are fully available

to provide you with any assistance to support you in the review.

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions

Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From:

 Martin Mitchell/WIN/UK/AMS
To:

 "Arepalli, Sambasiva"

<Sambasiva.Arepalli@fda.hhs.gov>
Date:

 20/05/2022 11:07
Subject:

   RE: [EXTERNAL]

Re: K211878-s002
<hr noshade>

Good morning Sam!

Do you think we can expect feedback

from management today?

If we don't get feedback; as the FDA review is performed on calendar days....

should we be prepared to deal with any further requests during the weekend?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions

Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From:

 "Arepalli, Sambasiva"

<Sambasiva.Arepalli@fda.hhs.gov>
To:

 "Martin.Mitchell@admedsol.com"

<Martin.Mitchell@admedsol.com>
Date:

 19/05/2022 16:44
Subject:

   RE: [EXTERNAL]

Re: K211878-s002
<hr noshade>

Being reviewed by mgt

Sam Arepalli, Ph.D.
<font size=2
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

face="Calibri">FDA/CDRH/OPEQ/OHT4/PRSB2
Ph: 301
796 6434

<font size=2
color=#4f4f4f face="Calibri">Excellent customer

service is important to us. Please take a moment to provide feedback

regarding the customer service you have received: <a
href="https://secure-web.cisco.com/1JJS7do9IwVAYX_w_aX-
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cdkanEQUP6BFHszQXi4HjrcCqPst5Gh0ma8o1RNA3c1lgzYJ1i5hbM1L15bDKn8BHblDYBsASQXVTfF5_oyLbf7
2pHOKiRZRahmWq5XFT2RXTJCq5uZTSBUHNZ9fcGZNHye7afRXgsMkTXKVbLNxGL9ePKfw/https%3A%2F%2Fwww
.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1624%26S%3DE"><font size=2 color=#0082bf
face="Calibri"><u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u></f
ont><u></u>

<font size=2
face="Calibri">
From:
Martin.Mitchell@admedsol.com

<Martin.Mitchell@admedsol.com>
Sent: Thursday, May 19, 2022 11:37
AM
To: Arepalli, Sambasiva
<Sambasiva.Arepalli@fda.hhs.gov>
Subject: RE: [EXTERNAL] Re: K211878-
s002

<font size=2 color=#806210
face="Calibri">CAUTION:This email originated from
outside of the organization. Do not click links

or open attachments unless you recognize the sender and know the content

is safe.

<font size=2
face="Arial">Hi Sam
<font size=2
face="Arial">
Sorry, i'm not following your response... Was it implying that
Its been discussed and the issue is
resolved?<li>Or you need more clarification and want a

teleconference?
It's almost 5pm here so I
just wanted to make sure I can offer the most

support I can before I go home and try to juggle family and checking my

emails

Best
regards,
<font size=2 color=#000080
face="Arial">
Martin Mitchell
Regulatory Affairs Manager
<font size=2 color=#000080
face="Arial">
Advanced Medical Solutions Ltd.
E-mail: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=2 color=#000080
face="Arial">
Tel: +44 (0) 1752 30 9360<font size=2
face="Calibri">

From:
       "Arepalli,

Sambasiva" <<font size=1
color=blue face="Arial"><u>Sambasiva.Arepalli@fda.hhs.gov</u><font size=1
face="Arial">>
To:
   "<a
href=mailto:Martin.Mitchell@admedsol.com><font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">>
Date:
   19/05/2022

16:32
Subject:
 RE:

[EXTERNAL] Re: K211878-s002 <hr noshade>
<font size=2
face="Calibri">

yes

Sam Arepalli,
Ph.D.
FDA/CDRH/OPEQ/OHT4/PRSB2
Ph: 301 796 6434
 <font size=2
color=#4f4f4f face="Calibri">
Excellent customer service is important to us.
 Please take a moment

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to provide feedback regarding the customer service you have received: </i><a
href="https://secure-
web.cisco.com/1wHYuIBzTaMJflQ4NWiRl_LrDWTay2JCyNed5miqxxnrMlY01UXmExqhF_XZxGmayyFC0Hv2x
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if7XjPQgBR4lJQ/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1624%26S
%3DE"><font size=2 color=#0082bf
face="Calibri"><u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u></f
ont>

From: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri"><<font size=2
color=blue face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri">>

Sent: Thursday, May 19, 2022 11:30 AM
To: Arepalli, Sambasiva
<<font size=2 color=blue
face="Calibri"><u>Sambasiva.Arepalli@fda.hhs.gov</u><font size=2
face="Calibri">>
Cc: <u>K211878@docs.fda.gov</u><font size=2
face="Calibri">;

<font size=2 color=blue
face="Calibri"><u>Rose.Guang@admedsol.com</u><font size=2
face="Calibri">
Subject: RE: [EXTERNAL] Re: K211878-s002

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email originated from outside

of the organization. Do not click links or open attachments unless you

recognize the sender and know the content is safe.
 <font size=2
face="Arial">
Hello Sam

Regarding your deadline where you planned to have
completed versions of

the IFU and 510(k) Summary by COB today.

Have you managed to discuss the issue
in your department?

I'm wondering if there is any further clarification we can
provide to assist

in the discussion; or perhaps a call could be scheduled quickly to resolve

the matter?

Best regards,<font size=2 color=#000080
face="Arial">

Martin Mitchell
Regulatory Affairs
Manager

Advanced Medical Solutions Ltd.
E-mail: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=2 color=#000080
face="Arial">
Tel: +44 (0) 1752 30 9360<font size=2
face="Calibri">

From:
       Martin

Mitchell/WIN/UK/AMS
To:
   "Arepalli,

Sambasiva" <<font size=1
color=blue face="Arial"><u>Sambasiva.Arepalli@fda.hhs.gov</u><font size=1
face="Arial">>
Cc:
   "<a
href=mailto:K211878@docs.fda.gov><font size=1 color=blue
face="Arial"><u>K211878@docs.fda.gov</u>"

<<font size=1 color=blue
face="Arial"><u>K211878@docs.fda.gov</u>>,

Rose Guang/WIN/UK/AMS@ams
Date:
       19/05/2022

11:28
Subject:
 RE:

[EXTERNAL] Re: K211878-s002 <div
align=center><hr noshade>

<font size=2
face="Arial">

Hi Sam

For your ease of reference, please find our response
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Martin Mitchell/WIN/UK/AMS]

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: Martin

Mitchell/WIN/UK/AMS
To: "Arepalli,

Sambasiva" <<u>Sambasiva.Arepalli@fda.hhs.gov</u>>
Cc: "<u>K211878@docs.fda.gov</u>"

<<u>K211878@docs.fda.gov</u>>,

Rose Guang/WIN/UK/AMS@ams
Date: 19/05/2022

10:17
Subject: RE:

[EXTERNAL] Re: K211878-s002 <hr noshade>

Hi Sam

I'll call you today at 6am (11am UK time); we thought it would be better

to send you the updated documents to help aid the discussion during the

call.

The IFU has been updated with your comments (and as per our modifications

we suggest below). I've provided a redlined and clean copy of this:
[attachment "IFU - LiquiBand XL.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

[attachment "IFU - LiquiBand XL - Tracked.pdf" deleted by Martin

Mitchell/WIN/UK/AMS]

The 510(k) summary has been updated with your comments
[attachment "510K Summary.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

<font size=1 color=#5f5f5f

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

face="Arial">

From: Martin

Mitchell/WIN/UK/AMS
To: "Arepalli,

Sambasiva" <<u>Sambasiva.Arepalli@fda.hhs.gov</u>>
Cc: "<u>K211878@docs.fda.gov</u>"

<<u>K211878@docs.fda.gov</u>>,

Rose Guang/WIN/UK/AMS@ams
Date: 18/05/2022

22:37
Subject: RE:

[EXTERNAL] Re: K211878-s002 <hr noshade>

Hi Sam

Firstly, thank you for staying late to continue to work with us on in the

final stages of this submission. It is much appreciated.

Please find attached the IFU with updated comments from ourselves

[attachment "K211878-S002 - Revised labeling received on 5-16-2022.jam.pdf"

deleted by Martin Mitchell/WIN/UK/AMS]

For most of the proposed updates we will accept to make the changes. However

there are two points we would wish to clarify

(b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

As discussed I'll call you tomorrow to discuss your email below

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Arepalli,

Sambasiva" <<u>Sambasiva.Arepalli@fda.hhs.gov</u>>
To: "<u>Martin.Mitchell@admedsol.com</u>"

<<u>Martin.Mitchell@admedsol.com</u>>
Cc: "Arepalli,

Sambasiva" <<u>Sambasiva.Arepalli@fda.hhs.gov</u>>,

"<u>K211878@docs.fda.gov</u>"

<<u>K211878@docs.fda.gov</u>>
Date: 18/05/2022

20:39
Subject: RE:

[EXTERNAL] Re: K211878-s002 <hr noshade>

Hi Mr. Mitchell:
Please see attached for the (b)(4) with FDA edits.

Please address these edits and send me both the edited versions and clean

copies of the (b)(4) by COB tomorrow (5-19-2022).

Please cc your response to <u>K211878@docs.fda.gov</u>.

Thx
Sam

Sam Arepalli, Ph.D.
FDA/CDRH/OPEQ/OHT4/PRSB2
Ph: 301 796 6434

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to provide feedback regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

From: <u>Martin.Mitchell@admedsol.com</u><<u>Martin.Mitchell@admedsol.com</u>>

Sent: Tuesday, May 17, 2022 6:39 AM
To: Arepalli, Sambasiva <<u>Sambasiva.Arepalli@fda.hhs.gov</u><font size=2

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

face="Calibri">>
Subject: RE: [EXTERNAL] Re: K211878-s002

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recognize the sender and know the content is safe.

Hi Sam

Just to be safe for the email trail.... so that your email has a response

The email with this information was send yesterday; however it is also

(b)(4)

face="Calibri">

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u><font size=2 color=#000080

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

face="Arial">
Tel: +44 (0) 1752 30 9360<font size=2
face="Calibri">

From:
       "Arepalli,

Sambasiva" <<font size=1
color=blue face="Arial"><u>Sambasiva.Arepalli@fda.hhs.gov</u><font size=1
face="Arial">>
To:
   "<a
href=mailto:Martin.Mitchell@admedsol.com><font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">>
Date:
   17/05/2022

10:32
Subject:
 RE:

[EXTERNAL] Re: K211878-s002 <div
align=center><hr noshade>

Hi
Mr. Mitchell:
Can you please give an update on the (b)(4) request? Could
you

please send the information cob today? Please give me a call when you have

a minute.
Thx
Sam

Sam Arepalli, Ph.D.
FDA/CDRH/OPEQ/OHT4/PRSB2
Ph:
301 796 6434

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to provide feedback regarding the customer service you have received: <a
href="https://secure-
web.cisco.com/1v_0OwI01XyYIrR5QdcqPvkNkCoDtTGQHdIwHOyFmN5FDUBpuZ7wV3E9sq3sVmjZ84S9zyo-
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lBPTtkLNiJ-
nvaNSabNX2MdWjf4pFySXsD/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3
D1624%26S%3DE"><font size=2 color=#0082bf
face="Calibri"><u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u></f
ont>

From: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri"><<font size=2
color=blue face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri">>

Sent: Monday, May 16, 2022 12:06 PM
To: Arepalli, Sambasiva
<<font size=2 color=blue
face="Calibri"><u>Sambasiva.Arepalli@fda.hhs.gov</u><font size=2
face="Calibri">>
Subject: [EXTERNAL] Re: K211878-s002<font size=2
color=#806210 face="Calibri">

CAUTION:This
email originated from outside

of the organization. Do not click links or open attachments unless you

recognize the sender and know the content is safe.<font size=2
face="Arial">

Hi Sam

Just so you're aware it's 17:00 now so i'll be
heading home; however i'll

try to make myself available outside of hours so please don't hesitate

to get in touch if you have any further questions.

Additionally i'll be working
from home the next few days so I won't pick

up calls from my office number you used previously.

If you have any further
questions please email me or call me on my personal

mobile number (b)(6)

Best regards,<font size=2
color=#000080 face="Arial">

Martin Mitchell
Regulatory Affairs
Manager

Advanced Medical Solutions Ltd.
E-mail: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

face="Arial"><u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: Martin

Mitchell/WIN/UK/AMS
To: "Arepalli,

Sambasiva" <<u>Sambasiva.Arepalli@fda.hhs.gov</u>>
Cc: "<u>K211878@docs.fda.gov</u>"

<<u>K211878@docs.fda.gov</u>>,

Rose Guang/WIN/UK/AMS@ams, Helen Topping/WIN/UK/AMS@ams
Date: 16/05/2022

16:28
Subject: Re:

K211878-s002 <hr noshade>

Hi Sam

Please find a response to the two points we

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Arepalli,

Sambasiva" <<u>Sambasiva.Arepalli@fda.hhs.gov</u>>
To: "<u>Martin.Mitchell@admedsol.com</u>"

<<u>Martin.Mitchell@admedsol.com</u>>
Cc: "Arepalli,

Sambasiva" <<u>Sambasiva.Arepalli@fda.hhs.gov</u>>,

"<u>K211878@docs.fda.gov</u>"

<<u>K211878@docs.fda.gov</u>>
Date: 16/05/2022

14:39
Subject: K211878-s002 <hr noshade>

Hi Mr. Martin:
Please address the following:

(b)(4)

(b)(4)

Ph.D.
FDA/CDRH/OPEQ/OHT4/PRSB2
Ph: 301 796 6434

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Visit us at: <a href="http://secure-web.cisco.com/1z4ZIykl5rMf5xXkALZcFSaXARBHFfphXL5zOAOiOaFtvE8rdY5JYvsTpy63fXgD5KSI_rGj7-aHATeSlXNwVnAKJKnY7yVMWXr-0Es9pZT0ulTOx1cFfiAYC1I3nRCVxMJf8iskBHWn6Ug19jXGx8WmrkiOr81pVHaY4bJbZ9kqpmcpTLiLCOIEWQL

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

e1hapZ/http%3A%2F%2Fwww.admedsol.com%2F"><u>http://www.admedsol.com</u>.

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From: Seearam, Tulsidai * [Tulsidai.Seearam@fda.hhs.gov]
Sent: 6/21/2021 4:19:23 PM
To: martin.mitchell@admedsol.com
Subject: K211878 Acknowledgement Notification
Attachments: K211878 Letter.pdf

Respectfully,

Tulsidai Seearam

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

U.S. FOOD & DRUG ADMINISTRATION

Acknowledgment Letter

6/21/2021

Martin Mitchell, Senior Regulatory Affairs Associate
Advanced Medical Solutions Limited
Western Wood Way , Langage Science Park
Plymouth, Devon PL7 5BG
UNITED KINGDOM

Dear Martin Mitchell:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the address listed below. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please contact the Office of Product Evaluation and Quality (OPEQ) submission support at (301) 796-5640 or OPEQSubmissionSupport@fda.hhs.gov.

Submission Number: K211878
Received: 6/21/2021
Applicant: Advanced Medical Solutions Limited
Device: LiquiBand XL

We will notify you when the review of this document has been completed or if any additional information is required. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Hello (b)(4)

Yes, I was thinking 1:30pm EST on Wednesday 11/10.

Thanks,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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From: (b)(4)
Sent: Friday, November 5, 2021 11:57 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>; (b)(4) k211878@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Michele:

Just confirming you are looking at 1:30 pm Eastern time.

(b)(4) That time would work for me; please confirm your availability.

(b)(4)

(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov>
Sent: Friday, November 5, 2021 11:08 AM
To: (b)(4) k211878@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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---

Hello (b)(4)

I have another meeting before that scheduled time. I can do a half hour earlier (6:30pm UTC+1) on Wednesday or a different time on another day next week?

Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: (b)(4)
Sent: Friday, November 5, 2021 11:02 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>; k211878@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Dear Michele,

many thanks for sending the invite.

I fear, I´ve made a mistake, when communicating the time.
Could we schedule one hour earlier?

Kind regards.

(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov>
Sent: Freitag, 5. November 2021 15:59
To: (b)(4); k211878@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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---

Hello (b)(4)

Sure, we can discuss via teleconference on 10 Nov 2021 at 7pm UTC+1/ 2pm EDT. I sent a ZoomGov invite via email and also copied the call-in information below.

Image removed

Hi there,

Michele.Lee@fda.hhs.gov is inviting you to a scheduled ZoomGov meeting.

Join Zoom Meeting

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Best Regards,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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Michele.Lee@fda.hhs.gov

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From: (b)(4)
Sent: Friday, November 5, 2021 10:10 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>; k211878@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Dear Michele,

Many thanks for your message.
Martin, thank you for the connection.

Michele, would you be available next Wednesday, 10 November 2021, at 7 pm (UTC+1)?
Then I would send an invitation.

Kind regards.

(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov>
Sent: Freitag, 5. November 2021 14:33
To: Martin.Mitchell@admedsol.com; k211878@docs.fda.gov
Cc: (b)(4)
Subject: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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---

Hello all,

Thank you, Martin, for the connection.

(b)(4)

Best Regards,

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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Michele.Lee@fda.hhs.gov

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https://www.research.net/s/oirhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Thursday, November 4, 2021 11:29 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>; k211878@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

Regarding the recent deficiency question on our medical device submission which is currently under review with the FDA:

(b)(4)

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(b)(4)

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

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(b)(4)

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Hi Sam

(b)(4)

Please don't hesitate to contact me if you need any further information.

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: (b)(4)

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>,

(b)(4)>

Cc: (b)(4),

"Sambasiva.Arepalli@fda.hhs.gov" <Sambasiva.Arepalli@fda.hhs.gov>,

"Rose.Guang@admedsol.com" <Rose.Guang@admedsol.com>

Date: 23/05/2022 12:34

Subject: AW: [EXT] Re: URGENT: (b)(4) request

Hi Martin, all,

My US colleague (b)(4) resent it just now to Sam.

Thank you.

Best Regards / Mit freundlichen GrÃ¼ÃŸen / SincÃ¨res salutations

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Von: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Gesendet: Montag, 23. Mai 2022 13:17

An: (b)(4)

(b)(4)

Cc: (b)(4); Sambasiva.Arepalli@fda.hhs.gov; Rose.Guang@admedsol.com

Betreff: [EXT] Re: URGENT: (b)(4) request

PrioritÃ¤t: Hoch

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Hi all

(b)(4)

(b)(4)

(b)(4)

I've just found your contact details so bringing you into the email chain below

(b)(4)

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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To: (b)(4)

Cc: (b)(4) Sambasiva.Arepalli@fda.hhs.gov

Date: 23/05/2022 10:59

Subject: URGENT: (b)(4) request

Hi (b)(4)

FDA have changed lead reviewer from Michele (who you dealt with previously) to Sam (who is on copy)

(b)(4)

Thanks in advance for your support.

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

(b)(4)

From: (b)(4)

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: (b)(4)

Date: 22/11/2021 10:44

Subject: AW: AW: AW: AW: [EXT] Re: Fw: URGENT: (b)(4) request

Hello Martin,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Thank you.

Best Regards / Mit freundlichen GrÃ¼Ÿen / SincÃ¨res salutations

(b)(4)

Von: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>

Gesendet: Mittwoch, 17. November 2021 17:24

An: (b)(4)

Cc: (b)(4)

Betreff: Re: AW: AW: AW: [EXT] Re: Fw: URGENT: (b)(4) request

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Hello (b)(4)

Thank you for the update. Could you target the end of November to get this information to the FDA?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

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From: (b)(4)

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: (b)(4)

Date: 15/11/2021 12:45

Subject: AW: AW: AW: [EXT] Re: Fw: URGENT: (b)(4) request

Hi Martin,

(b)(4)

Thank you.

Best Regards / Mit freundlichen GrÃ¼Ÿen / SincÃ¨res salutations

(b)(4)

Von: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>

Gesendet: Dienstag, 2. November 2021 09:33

An: (b)(4)

Cc: (b)(4)

Betreff: Re: AW: AW: [EXT] Re: Fw: URGENT: (b)(4) request

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Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Hello

(b)(4)

Shall we set up a meeting to discuss the point?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: (b)(4)

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: (b)(4)

Date: 02/11/2021 07:50

Subject: AW: AW: [EXT] Re: Fw: URGENT: (b)(4) request

Good morning Martin,

(b)(4)

Thank you.

Best Regards / Mit freundlichen GrÃ¼ÃŸen / SincÃ¨res salutations

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Von: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>

Gesendet: Montag, 1. November 2021 12:42

An: (b)(4)

Cc: (b)(4)

Betreff: Re: AW: [EXT] Re: Fw: URGENT: (b)(4) request

This message is from an EXTERNAL SENDER â€" be CAUTIOUS, particularly with links and attachments

Good morning (b)(4)

(b)(4)

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: (b)(4)

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: (b)(4)

Date: 27/10/2021 10:08

Subject: AW: [EXT] Re: Fw: URGENT: (b)(4) request

Good morning Martin,

Nice to meet you.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

(b)(4)

Thank you.

Best Regards / Mit freundlichen GrÃ¼ÃŸen / SincÃ¨res salutations

(b)(4)

Von: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>

Gesendet: Mittwoch, 27. Oktober 2021 10:46

An: (b)(4)

Cc: (b)(4)

Betreff: [EXT] Re: Fw: URGENT: (b)(4) request

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Hello (b)(4)

I'd like to introduce myself as a member of Advanced Medical Solutions who

(b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

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(b)(4)

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Hi Sam

Please find a response to the two points we discussed over the phone

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>,

"K211878@docs.fda.gov" <K211878@docs.fda.gov>

Date: 16/05/2022 14:39

Subject: K211878-s002

Hi Mr. Martin:

Please address the following:

(b)(4)

Thx

Sam

Sam Arepalli, Ph.D.

FDA/CDRH/OPEQ/OHT4/PRSB2

Ph: 301 796 6434

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Visit us at: http://secure-web.cisco.com/1n0drXVJuNlvTjuyCimhb9ZkGyoVZbPPPr3jSAAf8A-7BMZshFG_4Cg-5YQ5dC5gxYAwXjBwYwffSISgmEpKUfvCP-fP3xfoayqFWTaI3OIIiSVLCFP9qR7uaQv4CHOHr2QGleK63e6RTt-oC1PmXzN1wbLAkzZVkHEkkLeQcmdgqJqSik9DKNHZJtnLbbzMW/http%3A%2F%2Fwww.admedsol.com This e-mail, including any attached files, is confidential and intended for the exclusive use of the addressee(s) only. If you are not the intended recipient, please notify the sender immediately and delete it from your mailbox or any other storage mechanism.

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Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

From: Rua, Diego
To: Lee, Michele
Subject: RE: toxicology consult request
Date: Thursday, September 30, 2021 9:04:22 AM
Attachments: image001.png
TRA deficiency dr.docx
image008.png

Hi Michele,

(b)(5)

Thanks,
Diego

From: Lee, Michele <Michele.Lee@fda.hhs.gov>
Sent: Wednesday, September 29, 2021 2:04 PM
To: Rua, Diego <Diego.Rua@fda.hhs.gov>
Subject: RE: toxicology consult request

Hi Diego,

(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Thanks,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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Michele.Lee@fda.hhs.gov





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From: Rua, Diego <Diego.Rua@fda.hhs.gov>
Sent: Tuesday, September 7, 2021 7:46 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Subject: RE: toxicology consult request

Hi Michele,

(b)(5)

Best,
Diego

From: Lee, Michele <Michele.Lee@fda.hhs.gov>
Sent: Sunday, September 05, 2021 12:23 PM
To: Rua, Diego <Diego.Rua@fda.hhs.gov>
Subject: RE: toxicology consult request

Hi Diego,

Thanks for letting me know **(b)(5)**

(b)(5)

Best,
Michele

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
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Michele.Lee@fda.hhs.gov





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From: Rua, Diego <Diego.Rua@fda.hhs.gov>
Sent: Friday, September 3, 2021 3:54 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Subject: RE: toxicology consult request

Hi Michele,

Attached is my memo. **(b)(5)**

(b)(5)

Thanks,

Diego Rua, PhD MBA
Research Biologist
Division of Biology, Chemistry, and Materials Science (DBCMS)
Office of Science and Engineering Laboratories (OSEL)
Center for Devices and Radiological Health (CDRH)
10903 New Hampshire Avenue
Building 64, Room 4074
Silver Spring, Maryland 20993
diego.rua@fda.hhs.gov



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Lee, Michele <Michele.Lee@fda.hhs.gov>
Sent: Monday, August 16, 2021 11:32 AM
To: Rua, Diego <Diego.Rua@fda.hhs.gov>
Subject: RE: toxicology consult request

Thanks, Diego! I have assigned the consult in CTS and also attached the relevant documents to this email since they're hard to find in the submission. **(b)(5)**

(b)(5)

Thanks,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov





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From: Rua, Diego <Diego.Rua@fda.hhs.gov>
Sent: Friday, August 13, 2021 3:04 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Subject: RE: toxicology consult request

Hi Michele,

Yes, I'm available and happy to help you with a **(b)(5)**

Best,
Diego

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From: Lee, Michele <Michele.Lee@fda.hhs.gov>
Sent: Friday, August 13, 2021 2:57 PM
To: Rua, Diego <Diego.Rua@fda.hhs.gov>
Subject: toxicology consult request

Hi Diego,

Would you be available to provide a consult of a **(b)(5)** **(b)(5)** but can allow more time if needed. Please let me know.

Thanks!
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
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Michele.Lee@fda.hhs.gov





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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(5)

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Dear Michele,

many thanks for sending the invite.

I fear, I´ve made a mistake, when communicating the time.
Could we schedule one hour earlier?

Kind regards.

(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov>
Sent: Freitag, 5. November 2021 15:59
To: (b)(4) ; k211878@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

This message is from an EXTERNAL SENDER -- be CAUTIOUS, particularly with links and attachments

---

Hello (b)(4)

Sure, we can discuss via teleconference on 10 Nov 2021 at 7pm UTC+1/ 2pm EDT. I sent a ZoomGov invite via email and also copied the call-in information below.

Image removed

Hi there,

Michele.Lee@fda.hhs.gov is inviting you to a scheduled ZoomGov meeting.

Join Zoom Meeting

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Best Regards,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
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OHT4: Office of Surgical and Infection Control Devices
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Michele.Lee@fda.hhs.gov

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https://www.research.net/s/odhcustomerservice?ID=1624&S=E

From: (b)(4)
Sent: Friday, November 5, 2021 10:10 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>; k211878@docs.fda.gov
Cc: (b)(4) ;Martin.Mitchell@admedsol.com
Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Dear Michele,

Many thanks for your message.
Martin, thank you for the connection.

Michele, would you be available next Wednesday, 10 November 2021, at 7 pm (UTC+1)?
Then I would send an invitation.

Kind regards.

(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Sent: Freitag, 5. November 2021 14:33
To: Martin.Mitchell@admedsol.com; k211878@docs.fda.gov
Cc: (b)(4)
Subject: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

This message is from an EXTERNAL SENDER -- be CAUTIOUS, particularly with links and attachments

Hello all,

Thank you, Martin, for the connection.

(b)(4)

Best Regards,

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
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Michele.Lee@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/odhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Thursday, November 4, 2021 11:29 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>; k211878@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

Regarding the recent deficiency question on our medical device submission which is currently under review with the FDA:

(b)(4)

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

Visit us at: http://www.admedsol.com. This e-mail, including any attached files, is confidential and intended for the exclusive use of the addressee(s) only. If you are not the intended recipient, please notify the sender immediately and delete it from your mailbox or any other storage mechanism.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

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Good morning Michele

I was just emailing to ask if you picked up this email and forwarded this onto your consulting toxicologist?

If so do you think it may be possible to expect feedback before the end of this year?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 07/12/2021 17:08
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Michele

Thank you for your support on our questions below. Its been invaluable to our team to get this crucial feedback in such a short timeline.

After reading your response (provided in red font below) we have provided a response on points 2 and 4 which have been provided in blue font to which we would like to get clarification on.

Supporting evidence is provided below if required.

[attachment "Supporting evidence.pdf" deleted by Martin Mitchell/WIN/UK/AMS] [attachment "(b)(4)" deleted by Martin Mitchell/WIN/UK/AMS]

Additionally, please also find the finalised meeting minutes below

[attachment "K211878 - 19Oct2021 Meeting Minutes - Final.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

Thank you in advance for all your support.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 24/11/2021 18:00

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Please find the responses to your questions below in red font and revised meeting minutes attached. Hope this is helpful!

Best,

Michele

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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will also be provided within the future supplement in addition to the rationale above.

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Friday, November 12, 2021 10:15 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

Regarding the timeline clarification i've taken a look on the customer collaboration portal but there was only an email to provide feedback on the portal. Nevertheless i've emailed as i'm a little concerned about what may happen if the portal shows that the 180 day hold periods has expired and we haven't yet submitted our response..... is there a risk that the 510(k) may be inadvertently withdrawn?

We have prepared our response to your question below which I hope you find helpful.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 08/11/2021 22:05

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thanks for your message. Iâ€™ll need some time to review the teleconference minutes with my team and also obtain some feedback from our consulting toxicologist about the follow up questions. But I wanted to let you know I received your email and you may feel free to check in again next week.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Regarding the timeline clarification- I am also under the understanding that the COVID-19 guidance document you cited was still active and that would allow you an additional 180 days for the hold period. I have reached out to the 510(k) Staff multiple times to confirm and am still waiting on their response. Is there a customer service contact email for the customer collaboration portal specifically? You may try contacting them as well to have the date corrected on your end.

Thank you,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Friday, November 5, 2021 12:07 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

I hope you had a nice holiday!

Following on from the teleconference we had a few actions to complete and get back to you with.

1) Teleconference minutes

Please find a draft of the the teleconference minutes below. Could you review and confirm if you require any changes made?

2) Follow-up questions on the teleconference discussion

As suggested during the teleconference there was the opportunity for a followup email clarification on a few minor points.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

The supporting information which provides further clarity on the questions above has been attached if required.

3) Timeline clarification as per previous email

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Thank you again for your assistance

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>, "Liu, Lixin" <Lixin.Liu@fda.hhs.gov>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 20/10/2021 22:43

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Michele

Thank you for the prompt response to the clarifications! We'll take your points on board regarding future shelf life studies.

I do have a minor clarification question regarding our response timeline

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 20/10/2021 14:55

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you to you and your team for attending the teleconference yesterday. I wanted to follow up on two things I was discussing with my team:

(b)(4)

I will be on leave for the next two weeks and you may contact our team management (Lixin.Liu@fda.hhs.gov) if you have questions during that time.

Best,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

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Michele.Lee@fda.hhs.gov

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From: Lee, Michele
Sent: Friday, October 15, 2021 4:47 PM
To: Martin.Mitchell@admedsol.com
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you for providing your questions in advance of the meeting. We look forward to discussing our responses with you next week.

Have a good weekend,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
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Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Friday, October 15, 2021 12:00 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Please find the list of questions/clarifications attached below.

I hope you have a good weekend. I'm looking forwards to our discussion next week!

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 13/10/2021 22:35
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

I have scheduled the teleconference for next Tuesday October 19that 9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour but our biocompatibility consultant/ team management needs to drop off for another call at 9:30am. Please send me the questions for discussion in advance of the meeting so that we can plan to discuss biocompatibility/ regulatory questions first before the relevant parties need to drop off.

Join Zoom Meeting
One tap mobile:

(b)(4)

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Meeting URL:

(b)(4)

Thanks,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

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Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>

Sent: Wednesday, October 13, 2021 4:46 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: helen.topping@admedsol.com; k211878@docs.fda.gov

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Apologies Michele, one final thing I missed off my email... could you clarify how long the teleconference would be by default? Could we request 1 hour just incase some of the points end up taking longer to discuss?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 13/10/2021 20:35

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hi Michele

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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We're currently preparing our questions for the teleconference and will send these through in due course, however to assist with scheduling the relevant parties at FDA, I should let you know that we would definitely like to discuss the questions related to biocompatibility.

After discussion with the team we would like to request the teleconference on the Tuesday 19th October if that is possible? As we are based in the UK, we would also like to request that this is arranged between the hours of 2-5pm BST.

If this time slot is not available could you outline any alternative days/times which would be possible?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 08/10/2021 22:14
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hi Michele

Thank you for the offer. I think after today's meeting we may need a little more time to be better prepared for the teleconference.

We are reaching out to the (b)(4) for us as we feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible dates for you early next week.

Best regards,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 06/10/2021 13:49
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference deadline up to October 19th. Let me know if you would like to select a date later than the 14thand I can check our management schedules.

Regarding review timelines, we are still on the 90 day review cycle and are planning to complete the review of your response with the 20 calendar days left on the clock. While we retain the right to add additional days, we are doing our best with the resources that we have to avoid delaying review timelines if possible.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 6, 2021 6:00 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com
Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Thank you again for your review. Our team are busy discussing the questions and we would definitely like to have a teleconference with the FDA. We're currently consolidating our understanding of the deficiencies and are determining what our potential questions to you would be. I hope to get the questions to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we look to schedule a teleconference with the FDA on Wednesday 13th or Thursday 14th? As we're based in the UK we would appreciate a timeslot within our working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines for this project.... regarding the FDA timeline I can see on the CCP tracker website that the FDA timeline is on day 70.
Will FDA be sticking to the 90 day target and as a result only have 20 days left on the clock?
Or, due to the current situation with the unprecedented resource limitations..... will you will assume 30 days to review the response as standard? Or perhaps stick to the 20 days but retain the right to add additional days?

Best regards,

Martin Mitchell

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>

To: <martin.mitchell@admedsol.com>, <helen.topping@admedsol.com>

Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>

Date: 04/10/2021 21:44

Subject: K211878/S001 is on Hold Pending Your Response

October 4, 2021

We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Michele Lee.

*** This is a system-generated email notification ***[attachment "K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hello Martin,

I am sorry to hear about (b)(4). I hope all is able to be resolved soon.

Thank you for the update. I am actually working in a different division within FDA and no longer the primary contact for this submission. I believe that the 180 days is automatically granted for responses to AINN hold but you can also confirm with the 510(k) Program staff (510k_Program@fda.hhs.gov<mailto:510k_Program@fda.hhs.gov>, telephone: 301-796-5640) to make sure.

Best,

Michele

Michele Lee, Ph.D. (she/her/hers)

Regulatory Science Program Manager

Partnerships to Advance Innovation and Regulatory Science (PAIRS)

Center for Devices and Radiological Health

Office of Strategic Partnerships and Technology Innovation

Division of All Hazards Response, Science, and Strategic Partnerships

U.S. Food and Drug Administration

michele.lee@fda.hhs.gov<mailto:michele.lee@fda.hhs.gov>

[cid:image001.png@01D8403E.C13A19B0]<http://www.fda.gov/>

[cid:image002.jpg@01D8403E.C13A19B0]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D8403E.C13A19B0] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D8403E.C13A19B0] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D8403E.C13A19B0] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D8403E.C13A19B0]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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https://www.research.net/s/cdrhcustomerservice?ID=7013&S=E.

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Friday, March 25, 2022 11:28 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: k211878@docs.fda.gov

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

I'd like to provide an update on our progress with responding to the deficiencies raised on K211878

We were on track to have a deficiency response submitted to the FDA by the 180 day hold period deadline of 2nd April 2022.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

However, the organisation performing the (b)(4) (b)(4) (b)(4). As a result, they were unable to complete the testing by our targeted timeline.

Therefore, I just want to confirm that we are still intending to respond to the deficiencies, but we would need to use the second 180 day hold period granted to us through the COVID-19 situation.

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 08/11/2021 22:05

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

Thanks for your message. Iâ€™ll need some time to review the teleconference minutes with my team and also obtain some feedback from our consulting toxicologist about the follow up questions. But I wanted to let you know I received your email and you may feel free to check in again next week.

(b)(4)

Regarding the timeline clarification- I am also under the understanding that the COVID-19 guidance document you cited was still active and that would allow you an additional 180 days for the hold period. I have reached out to the 510(k) Staff multiple times to confirm and am still waiting on their response. Is there a customer service contact

email for the customer collaboration portal specifically? You may try contacting them as well to have the date corrected on your end.

Thank you,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D8403E.C13A19B0]<http://www.fda.gov/>

[cid:image002.jpg@01D8403E.C13A19B0]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D8403E.C13A19B0] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D8403E.C13A19B0] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D8403E.C13A19B0] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D8403E.C13A19B0]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>
<Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Friday, November 5, 2021 12:07 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>;
k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

I hope you had a nice holiday!

Following on from the teleconference we had a few actions to complete and get back to you with.

1) Teleconference minutes

Please find a draft of the the teleconference minutes below. Could you review and confirm if you require any changes made?

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2) Follow-up questions on the teleconference discussion

As suggested during the teleconference there was the opportunity for a followup email clarification on a few minor points.

(b)(4)

The supporting information which provides further clarity on the questions above has been attached if required.

3) Timeline clarification as per previous email

I can see on the customer collaboration portal that we have a 180 day hold period which

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Thank you again for your assistance

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>, "Liu, Lixin" <Lixin.Liu@fda.hhs.gov<mailto:Lixin.Liu@fda.hhs.gov>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 20/10/2021 22:43

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Michele

Thank you for the prompt response to the clarifications! We'll take your points on board regarding future shelf life studies.

I do have a minor clarification question regarding our response timeline

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

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Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 20/10/2021 14:55

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

Thank you to you and your team for attending the teleconference yesterday. I wanted to follow up on two things I was discussing with my team:

(b)(4)

I will be on leave for the next two weeks and you may contact our team management (Lixin.Liu@fda.hhs.gov<mailto:Lixin.Liu@fda.hhs.gov>) if you have questions during that time.

Best,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

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[cid:image002.jpg@01D8403E.C13A19B0]<https://www.facebook.com/FDA>[cid:image003.jpg@01D8403E.C13A19B0]<https://twitter.com/US_FDA> [cid:image004.jpg@01D8403E.C13A19B0]<http://www.youtube.com/user/USFoodandDrugAdmin> [cid:image005.jpg@01D8403E.C13A19B0]<http://www.flickr.com/photos/fdaphotos/> [cid:image006.jpg@01D8403E.C13A19B0]<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: Lee, Michele

Sent: Friday, October 15, 2021 4:47 PM

To: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you for providing your questions in advance of the meeting. We look forward to discussing our responses with you next week.

Have a good weekend,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

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Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

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[cid:image002.jpg@01D8403E.C13A19B0]<https://www.facebook.com/FDA>[cid:image003.jpg@01D8403E.C13A19B0]<https://twitter.com/US_FDA> [cid:image004.jpg@01D8403E.C13A19B0]<http://www.youtube.com/user/USFoodandDrugAdmin> [cid:image005.jpg@01D8403E.C13A19B0]<http://www.flickr.com/photos/fdaphotos/> [cid:image006.jpg@01D8403E.C13A19B0]<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From:
Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Friday, October 15, 2021 12:00 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>;
k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Please find the list of questions/clarifications attached below.

I hope you have a good weekend. I'm looking forwards to our discussion next week!

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>"
<Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>"
<helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>,
"k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>"
<k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 13/10/2021 22:35

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

I have scheduled the teleconference for next Tuesday October 19that 9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour but our biocompatibility consultant/ team management needs to drop off for another call at 9:30am. Please send me the questions for discussion in advance of the meeting so that we can plan to discuss biocompatibility/ regulatory questions first before the relevant parties need to drop

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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off.

Join Zoom

(b)(4)

Thanks,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

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Office of Product Evaluation and Quality

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Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

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[cid:image002.jpg@01D8403E.C13A19B0]<https://www.facebook.com/FDA>[cid:image003.jpg@01D8403E.C13A19B0]<https://twitter.com/US_FDA>[cid:image004.jpg@01D8403E.C13A19B0]<http://www.youtube.com/user/USFoodandDrugAdmin>[cid:image005.jpg@01D8403E.C13A19B0]<http://www.flickr.com/photos/fdaphotos/> [cid:image006.jpg@01D8403E.C13A19B0]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From:
Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Wednesday, October 13, 2021 4:46 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Apologies Michele, one final thing I missed off my email... could you clarify how long the teleconference would be by default? Could we request 1 hour just incase some of the points end up taking longer to discuss?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>"

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
<k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 13/10/2021 20:35

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hi Michele

We're currently preparing our questions for the teleconference and will send these through in due course, however to assist with scheduling the relevant parties at FDA, I should let you know that we would definitely like to discuss the questions related to biocompatibility.

After discussion with the team we would like to request the teleconference on the Tuesday 19th October if that is possible? As we are based in the UK, we would also like to request that this is arranged between the hours of 2-5pm BST.

If this time slot is not available could you outline any alternative days/times which would be possible?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 08/10/2021 22:14

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hi Michele

Thank you for the offer. I think after today's meeting we may need a little more time to be better prepared for the teleconference.

We are reaching out to the (b)(4) for us as we feel that it may be beneficial to have them join us on the teleconference.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
As such we need to check their availability. I hope to have list of possible dates for you early next week.

Best regards,

Martin Mitchell

Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 06/10/2021 13:49

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference deadline up to October 19th. Let me know if you would like to select a date later than the 14thand I can check our management schedules.

Regarding review timelines, we are still on the 90 day review cycle and are planning to complete the review of your response with the 20 calendar days left on the clock. While we retain the right to add additional days, we are doing our best with the resources that we have to avoid delaying review timelines if possible.

Best,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D8403E.C13A19B0]<http://www.fda.gov/>

[cid:image002.jpg@01D8403E.C13A19B0]<https://www.facebook.com/FDA>[cid:image003.jpg@01D8403E.C13A19B0]<https://twitter.com/US_FDA>[cid:image004.jpg@01D8403E.C13A19B0]<http://www.youtube.com/user/USFoodandDrugAdmin>[cid:image005.jpg@01D8403E.C13A19B0]<http://www.flickr.com/photos/fdaphotos/>[cid:image006.jpg@01D8403E.C13A19B0]<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Wednesday, October 6, 2021 6:00 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>

Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Thank you again for your review. Our team are busy discussing the questions and we would definitely like to have a teleconference with the FDA. We're currently consolidating our understanding of the deficiencies and are determining what our potential questions to you would be. I hope to get the questions to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we look to schedule a teleconference with the FDA on Wednesday 13th or Thursday 14th? As we're based in the UK we would appreciate a timeslot within our working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines for this project.... regarding the FDA timeline I can see on the CCP tracker website that the FDA timeline is on day 70.

* Will FDA be sticking to the 90 day target and as a result only have 20 days left on the clock?

* Or, due to the current situation with the unprecedented resource limitations..... will you will assume 30 days to review the response as standard? Or perhaps stick to the 20 days but retain the right to add additional days?

Best regards,

Martin Mitchell

Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
Tel: +44 (0) 1752 30 9360

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov<mailto:michele.lee@fda.hhs.gov>>

To: <martin.mitchell@admedsol.com<mailto:martin.mitchell@admedsol.com>>, <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>

Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov<mailto:michele.lee@fda.hhs.gov>>

Date: 04/10/2021 21:44

Subject: K211878/S001 is on Hold Pending Your Response

October 4, 2021

We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Michele Lee.

*** This is a system-generated email notification ***[attachment "K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

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Hi Martin,

(b)(4)

Best,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

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Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Friday, November 26, 2021 6:41 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: k211878@docs.fda.gov

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

(b)(4)

Best regards,

Martin Mitchell

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Cc: (b)(4)", (b)(4),

Date: 05/11/2021 13:34

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello all,

Thank you, Martin, for the connection.

(b)(4)

Best Regards,

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

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Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

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[cid:image004.jpg@01D7E480.5D173DB0] <http://www.youtube.com/user/USFoodandDrugAdmin>

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[cid:image005.jpg@01D7E480.5D173DB0] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D7E480.5D173DB0]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>
<Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Thursday, November 4, 2021 11:29 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>;
k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Cc: (b)(4)

(b)(4)

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

Regarding the recent deficiency question on our medical device submission which is currently under review with the FDA:

(b)(4)

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hello Michele

Thank you for the prompt response to the clarifications! We'll take your points on board regarding future shelf life studies.

I do have a minor clarification question regarding our response timeline

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 20/10/2021 14:55

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you to you and your team for attending the teleconference yesterday. I wanted to follow up on two things I was discussing with my team:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

I will be on leave for the next two weeks and you may contact our team management (Lixin.Liu@fda.hhs.gov) if you have questions during that time.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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Michele.Lee@fda.hhs.gov

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From: Lee, Michele
Sent: Friday, October 15, 2021 4:47 PM
To: Martin.Mitchell@admedsol.com
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you for providing your questions in advance of the meeting. We look forward to discussing our responses with you next week.

Have a good weekend,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

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Office of Product Evaluation and Quality

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Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Friday, October 15, 2021 12:00 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: helen.topping@admedsol.com; k211878@docs.fda.gov

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Please find the list of questions/clarifications attached below.

I hope you have a good weekend. I'm looking forwards to our discussion next week!

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 13/10/2021 22:35

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

I have scheduled the teleconference for next Tuesday October 19th at 9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour but our biocompatibility consultant/ team management needs to drop off for another call at 9:30am. Please send me the questions for discussion in advance of the meeting so that we can plan to discuss biocompatibility/ regulatory questions first before the relevant parties need to drop off.

Join Zoom Meeting

One tap mobile:

(b)(4)

Join by Telephone

For higher quality, dial a number based on your current location.

Dial:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Thanks,

Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 13, 2021 4:46 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Apologies Michele, one final thing I missed off my email... could you clarify how long the teleconference would be by default? Could we request 1 hour just incase some of the points end up taking longer to discuss?

Best regards,

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Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 13/10/2021 20:35

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hi Michele

We're currently preparing our questions for the teleconference and will send these through in due course, however to assist with scheduling the relevant parties at FDA, I should let you know that we would definitely like to discuss the questions related to biocompatibility.

After discussion with the team we would like to request the teleconference on the Tuesday 19th October if that is possible? As we are based in the UK, we would also like to request that this is arranged between the hours of 2-5pm BST.

If this time slot is not available could you outline any alternative days/times which would be possible?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 08/10/2021 22:14

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hi Michele

Thank you for the offer. I think after today's meeting we may need a little more time to be better prepared for the teleconference.

We are reaching out to the toxicologist who wrote the TRA for us as we feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible dates for you early next week.

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 06/10/2021 13:49

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference deadline up to October 19th. Let me know if you would like to select a date later than the 14thand I can check our management schedules.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Regarding review timelines, we are still on the 90 day review cycle and are planning to complete the review of your response with the 20 calendar days left on the clock. While we retain the right to add additional days, we are doing our best with the resources that we have to avoid delaying review timelines if possible.

Best,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>

Sent: Wednesday, October 6, 2021 6:00 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: helen.topping@admedsol.com

Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Thank you again for your review. Our team are busy discussing the questions and we would definitely like to have a teleconference with the FDA. We're currently consolidating our understanding of the deficiencies and are determining what our potential questions to you would be. I hope to get the questions to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we

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look to schedule a teleconference with the FDA on Wednesday 13th or Thursday 14th? As we're based in the UK we would appreciate a timeslot within our working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines for this project.... regarding the FDA timeline I can see on the CCP tracker website that the FDA timeline is on day 70.
Will FDA be sticking to the 90 day target and as a result only have 20 days left on the clock?
Or, due to the current situation with the unprecedented resource limitations..... will you will assume 30 days to review the response as standard? Or perhaps stick to the 20 days but retain the right to add additional days?

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
To: <martin.mitchell@admedsol.com>, <helen.topping@admedsol.com>
Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
Date: 04/10/2021 21:44
Subject: K211878/S001 is on Hold Pending Your Response

October 4, 2021
We have reviewed your submission. Please see attached.
If you have any questions, please contact the lead reviewer assigned to your submission, Michele Lee.

*** This is a system-generated email notification ***[attachment "K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

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Hello Martin,

I have forwarded your question on to my management and will let you know when I receive their feedback.

Best,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D7E767.AA213630]<http://www.fda.gov/>

[cid:image002.jpg@01D7E767.AA213630]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D7E767.AA213630] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7E767.AA213630] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7E767.AA213630] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D7E767.AA213630]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Wednesday, December 1, 2021 12:05 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: k211878@docs.fda.gov

Subject: RE: [EXTERNAL] K211878 timeline - COVID-19

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Hi Michele

I have a further question regarding how COVID affects timelines below.

Knowing that FDA have are allowing a further 180 day timeline to respond to deficiencies due to COVID.... is there any scope or provision for timeline adjustments relating to a SIR review time?

More specifically, regarding an SIR submission i've seen in the guidance document that if the SIR is received before the 60 day timepoint after issuance of the deficiency letter, this would result in a 21 day FDA review time; whereas if we submit the SIR after this date this results in a 70 day FDA review time.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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We have faced some delays in being able to meet the deadline of submitting an SIR before the 60 day timepoint. Where, we've spent some time liasing with yourselves through teleconference and email about the issues noted and covid has impacted our ability and our toxicologists ability to move quickly on these matters.

Therefore I'd like to enquire as to whether the FDA are allowing extensions to the time to receive an SIR (currently 60 days after issuance of the deficiency) where the SIR would still receive a 21 day FDA review time?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 16/11/2021 19:03

Subject: RE: [EXTERNAL] K211878 timeline - COVID-19

Hello Martin,

Thanks for the update and good to know this information. I also received your previous email with additional information about the test parameters of the degradation & extraction studies. I am still waiting on feedback from our consulting toxicologist but hope to have more information to provide you mid next week.

Best,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

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Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D7E767.AA213630]<http://www.fda.gov/>

[cid:image002.jpg@01D7E767.AA213630]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D7E767.AA213630] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7E767.AA213630] <http://www.youtube.com/user/USFoodandDrugAdmin>
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[cid:image006.jpg@01D7E767.AA213630]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>
<Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Monday, November 15, 2021 3:54 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Subject: Fw: [EXTERNAL] K211878 timeline - COVID-19

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Hi Michele

I got an update regarding timeline from the CCP email address.

FYI we are exploring a number of backup strategies to resolve the 510(k) deficiencies.... and some of these take us past the 180 day hold period.

As per the request below, I'll let you know closer to the time if we end up needing to request the additional 180 days.

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

----- Forwarded by Martin Mitchell/WIN/UK/AMS on 15/11/2021 08:31 -----

From: "CCP" <CCP@fda.hhs.gov<mailto:CCP@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>"
<Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Date: 12/11/2021 21:08

Subject: RE: [EXTERNAL] K211878 timeline - COVID-19

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Good day to you Martin,

The extra 180 days for response are added as needed, and then only shortly before the original 180 days expires.

--

Happy trails,

~Nels Anderson

Regulatory Systems & Data Management Staff

Center for Devices and Radiological Health | Office of Product Evaluation and Quality| Office of Regulatory Programs

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From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Friday, November 12, 2021 09:49

To: CCP <CCP@fda.hhs.gov<mailto:CCP@fda.hhs.gov>>

Subject: [EXTERNAL] K211878 timeline - COVID-19

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Hello

Regarding the timeline showing for K211878 I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I (and the lead reviewer Michele Lee) were under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify that the 180 timeline in the customer collaboration portal won't trigger premature closure of the 510(k) before the actual 360 day timeline expires?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Dear Michelle,

Thank you for informing us, we look forward to hearing from you on Monday.

Best regards

Helen

Helen Topping

Senior Regulatory Affairs Manager

Advanced Medical Solutions

Tel: +44 (0) 7721261214

Email: helen.topping@admedsol.com

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>, "Helen.Topping@admedsol.com" <Helen.Topping@admedsol.com>, "Rose.Guang@admedsol.com" <Rose.Guang@admedsol.com>

Cc: "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 28/09/2021 16:45

Subject: RE: [EXTERNAL] Re: K211878/S001 Review Status

Hello Martin, Helen, & Rose:

I am writing to inform you of a revision to the review timeline for your 510(k) Submission K211878/S001. Unfortunately, we are unable to complete the substantive review by the previously revised timeline of September 29 th. We now anticipate completion of the substantive review by next Monday, October 4th. We apologize for any inconveniences caused because of the multiple extensions of review timeline and appreciate your understanding as the Agency works through resource limitations during this time.

Best Regards,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Tuesday, September 21, 2021 10:03 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: k211878@docs.fda.gov; Helen.Topping@admedsol.com; Rose.Guang@admedsol.com

Subject: [EXTERNAL] Re: K211878/S001 Review Status

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Hello Michele

Thank you for your email to keep us updated with progress.

Please note that next week i'll be out on annual leave... therefore, could you also place Helen and Rose (on this email) on copy with any further communication you send over.

Best regards,

Martin Mitchell

Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 20/09/2021 22:31

Subject: K211878/S001 Review Status

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Hello Martin:

I want to inform you of a slightly revised review timeline for your 510(k) submission K211878/S001. Due to a limitation of Agency resources, we are unable to complete the substantive review by September 24th. We want to inform you that we expect to complete the review by next Wednesday, September 29th. We apologize for any inconveniences because of the extension of timeline.

Best Regards,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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Hi Mr. Martin:

Please address the following:

(b)(4)

Thx

Sam

Sam Arepalli, Ph.D.

FDA/CDRH/OPEQ/OHT4/PRSB2

Ph: 301 796 6434

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Hello (b)(4)

Sure, we can discuss via teleconference on 10 Nov 2021 at 7pm UTC+1/ 2pm EDT. I sent a ZoomGov invite via email and also copied the call-in information below.

Hi there,

Michele.Lee@fda.hhs.gov is inviting you to a scheduled ZoomGov meeting.

Join Zoom Meeting

(b)(4)

Best Regards,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: (b)(4)
Sent: Friday, November 5, 2021 10:10 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>; k211878@docs.fda.gov
Cc: (b)(4) Martin.Mitchell@admedsol.com
Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Dear Michele,

Many thanks for your message.
Martin, thank you for the connection.

Michele, would you be available next Wednesday, 10 November 2021, at 7 pm (UTC+1)?
Then I would send an invitation.

Kind regards.

(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov>
Sent: Freitag, 5. November 2021 14:33
To: Martin.Mitchell@admedsol.com; k211878@docs.fda.gov
Cc: (b)(4)
Subject: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

This message is from an EXTERNAL SENDER – be CAUTIOUS, particularly with links and attachments

Hello all,

Thank you, Martin, for the connection.

(b)(4)

Best Regards,

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Thursday, November 4, 2021 11:29 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>; k211878@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

Regarding the recent deficiency question on our medical device submission which is currently under review with the FDA:

(b)(4)

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

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(b)(4)

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Hello Michele

Thank you for your email to keep us

updated with progress.

Please note that next week i'll be out

on annual leave... therefore, could you also place Helen and Rose (on this

email) on copy with any further communication you send over.

Best regards,

Martin Mitchell
Senior Regulatory Affairs

Associate

Advanced Medical Solutions

Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From:

 "Lee, Michele"

<Michele.Lee@fda.hhs.gov>
To:

 "Martin.Mitchell@admedsol.com"

<Martin.Mitchell@admedsol.com>
Cc:

 "k211878@docs.fda.gov"

<k211878@docs.fda.gov>
Date:

 20/09/2021 22:31
Subject:

   K211878/S001

Review Status
<hr noshade>

Hello Martin:

I want to inform you of a slightly revised

review timeline for your 510(k) submission K211878/S001. Due to a limitation

of Agency resources, we are unable to complete the substantive review by

September 24th. We want to inform you that we expect to complete

the review by next Wednesday, September 29th. We apologize for

any inconveniences because of the extension of timeline.

Best Regards,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices

Team
DHT4B: Division of Infection Control and

Plastic Surgery Devices
OHT4: Office of Surgical and Infection

Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue

| Silver Spring, MD 20993
<font size=2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

color=blue face="Segoe UI"><u>Michele.Lee@fda.hhs.gov</u><font size=2
face="Segoe UI">

<a
href=http://www.fda.gov/><img src=cid:_4_0DC176140DC172DC004D328C80258757 width=192
height=43 style="border:0px solid;"><font size=1 color=#4f4f4f
face="Arial">
<u>
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href=https://www.facebook.com/FDA><img src=cid:_2_0DD7561C0DC172DC004D328C80258757
style="border:0px solid;"> <a
href=https://twitter.com/US_FDA><img src=cid:_2_0DD758EC0DC172DC004D328C80258757
style="border:0px solid;"> <a
href=http://www.youtube.com/user/USFoodandDrugAdmin><img
src=cid:_2_0DD75D200DC172DC004D328C80258757 style="border:0px solid;"><font size=1
color=#4f4f4f face="Arial"> <a
href=http://www.flickr.com/photos/fdaphotos/><img
src=cid:_2_0DD7616C0DC172DC004D328C80258757 style="border:0px solid;"><font size=1
color=#4f4f4f face="Arial"> <a
href=http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm><img
src=cid:_2_0DD765B80DC172DC004D328C80258757 style="border:0px solid;">
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target=_blank><font size=2 color=#0082bf face="sans-
serif"><u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

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Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Hello Martin:

I want to inform you of a slightly revised review timeline for your 510(k) submission K211878/S001. Due to a limitation of Agency resources, we are unable to complete the substantive review by September 24th. We want to inform you that we expect to complete the review by next Wednesday, September 29th. We apologize for any inconveniences because of the extension of timeline.

Best Regards,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D7AE43.84EC9CE0]<http://www.fda.gov/>

[cid:image002.jpg@01D7AE43.84EC9CE0]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D7AE43.84EC9CE0] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7AE43.84EC9CE0] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7AE43.84EC9CE0] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D7AE43.84EC9CE0]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Department of Health and Human Services

Food & Drug Administration
Center of Device & Radiological Health
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

Consult Memorandum

Date: 09/27/2021

From: Yu-Chieh Chiu, PhD; CDRH\OHT4\DHT4b\THT4B4
To: Michele Lee, PhD; CDRH\OHT4\DHT4b\THT4B4
Cc: Lixin Liu , PhD; AD, CDRH\OHT4\DHT4b\THT4B4

Subject: **K211878/S001** – Biocompatibility(wound healing study) Consult
Sponsor: Advanced Medical Solutions Limited
Device: LiquiBand XL

Scope

(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(5)

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Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Hello Michele

Regarding the recent deficiency question

on our medical device submission which is currently under review with the

FDA:

<i>(b)(4)

(b)(4)

Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

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Hi Mr. Mitchell:
Please see attached for the (b)(4) with FDA edits.

Please address these edits and send me both the edited versions and clean copies of the (b)(4) by COB tomorrow (5-19-2022).

Please cc your response to K211878@docs.fda.gov.

Thx
Sam

Sam Arepalli, Ph.D.
FDA/CDRH/OPEQ/OHT4/PRSB2
Ph: 301 796 6434

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Tuesday, May 17, 2022 6:39 AM
To: Arepalli, Sambasiva <Sambasiva.Arepalli@fda.hhs.gov>
Subject: RE: [EXTERNAL] Re: K211878-s002

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Hi Sam

Just to be safe for the email trail.... so that your email has a response

The email with this information was send yesterday; however it is also provided again below:

Please find a response to the two points we discussed over the phone

(b)(4)

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Date: 17/05/2022 10:32
Subject: RE: [EXTERNAL] Re: K211878-s002

Hi Mr. Mitchell:
Can you please give an update on the **(b)(4)** request? Could you please send the information cob today? Please give me a call when you have a minute.
Thx
Sam

Sam Arepalli, Ph.D.
FDA/CDRH/OPEQ/OHT4/PRSB2
Ph: 301 796 6434

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Monday, May 16, 2022 12:06 PM
To: Arepalli, Sambasiva <Sambasiva.Arepalli@fda.hhs.gov>
Subject: [EXTERNAL] Re: K211878-s002

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Hi Sam

Just so you're aware it's 17:00 now so i'll be heading home; however i'll try to make myself available outside of hours so please don't hesitate to get in touch if you have any further questions.

Additionally i'll be working from home the next few days so I won't pick up calls from my office number you used previously.

If you have any further questions please email me or call me on my personal mobile number **(b)(6)**

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>
Cc: "K211878@docs.fda.gov" <K211878@docs.fda.gov>, Rose Guang/WIN/UK/AMS@ams, Helen Topping/WIN/UK/AMS@ams
Date: 16/05/2022 16:28
Subject: Re: K211878-s002

Hi Sam

Please find a response to the two points we discussed over the phone

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>, "K211878@docs.fda.gov" <K211878@docs.fda.gov>
Date: 16/05/2022 14:39
Subject: K211878-s002

Hi Mr. Martin:
Please address the following:

(b)(4)

Thx
Sam

Sam Arepalli, Ph.D.
FDA/CDRH/OPEQ/OHT4/PRSB2
Ph: 301 796 6434

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Hello Martin,

Thank you for providing your questions in advance of the meeting. We look forward to discussing our responses with you next week.

Have a good weekend,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

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[cid:image002.jpg@01D7C1E4.47502D20]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D7C1E4.47502D20] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7C1E4.47502D20] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7C1E4.47502D20] <http://www.flickr.com/photos/fdaphotos/>
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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Friday, October 15, 2021 12:00 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: helen.topping@admedsol.com; k211878@docs.fda.gov

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Please find the list of questions/clarifications attached below.

I hope you have a good weekend. I'm looking forwards to our discussion next week!

Best regards,

Martin Mitchell

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 13/10/2021 22:35

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

I have scheduled the teleconference for next Tuesday October 19th at 9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour but our biocompatibility consultant/ team management needs to drop off for another call at 9:30am. Please send me the questions for discussion in advance of the meeting so that we can plan to discuss biocompatibility/ regulatory questions first before the relevant parties need to drop off.

Join Zoom

(b)(4)

Join by Telephone

For higher quality, dial a number based on your current location.

Dial:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Thanks,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

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Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D7C1E4.47502D20]<http://www.fda.gov/>

[cid:image002.jpg@01D7C1E4.47502D20]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D7C1E4.47502D20] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7C1E4.47502D20] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7C1E4.47502D20] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D7C1E4.47502D20]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>
<Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Wednesday, October 13, 2021 4:46 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>;
k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Apologies Michele, one final thing I missed off my email... could you clarify how long the teleconference would be by default? Could we request 1 hour just incase some of the points end up taking longer to discuss?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 13/10/2021 20:35

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hi Michele

We're currently preparing our questions for the teleconference and will send these through in due course, however to assist with scheduling the relevant parties at FDA, I should let you know that we would definitely like to discuss the questions related to biocompatibility.

After discussion with the team we would like to request the teleconference on the Tuesday 19th October if that is possible? As we are based in the UK, we would also like to request that this is arranged between the hours of 2-5pm BST.

If this time slot is not available could you outline any alternative days/times which would be possible?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 08/10/2021 22:14

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hi Michele

Thank you for the offer. I think after today's meeting we may need a little more time to be better prepared for the teleconference.

We are reaching out to the **(b)(4)** for us as we feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible dates for you early next week.

Best regards,

Martin Mitchell

Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 06/10/2021 13:49

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference deadline up to October 19th. Let me know if you would like to select a date later than the 14thand I can check our management schedules.

Regarding review timelines, we are still on the 90 day review cycle and are planning to complete the review of your response with the 20 calendar days left on the clock. While we retain the right to add additional days, we are doing our best with the resources that we have to avoid delaying review timelines if possible.

Best,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D7C1E4.47502D20]<http://www.fda.gov/>

[cid:image002.jpg@01D7C1E4.47502D20]<https://www.facebook.com/FDA>[cid:image003.jpg@01D7C1E4.47502D20]<https://twitter.com/US_FDA> [cid:image004.jpg@01D7C1E4.47502D20] <http://www.youtube.com/user/USFoodandDrugAdmin> [cid:image005.jpg@01D7C1E4.47502D20] <http://www.flickr.com/photos/fdaphotos/> [cid:image006.jpg@01D7C1E4.47502D20] <http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Wednesday, October 6, 2021 6:00 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>

Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Thank you again for your review. Our team are busy discussing the questions and we would definitely like to have a teleconference with the FDA. We're currently consolidating our understanding of the deficiencies and are determining what our

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potential questions to you would be. I hope to get the questions to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we look to schedule a teleconference with the FDA on Wednesday 13th or Thursday 14th? As we're based in the UK we would appreciate a timeslot within our working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines for this project.... regarding the FDA timeline I can see on the CCP tracker website that the FDA timeline is on day 70.

* Will FDA be sticking to the 90 day target and as a result only have 20 days left on the clock?

* Or, due to the current situation with the unprecedented resource limitations..... will you will assume 30 days to review the response as standard? Or perhaps stick to the 20 days but retain the right to add additional days?

Best regards,

Martin Mitchell

Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov<mailto:michele.lee@fda.hhs.gov>>

To: <martin.mitchell@admedsol.com<mailto:martin.mitchell@admedsol.com>>, <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>

Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov<mailto:michele.lee@fda.hhs.gov>>

Date: 04/10/2021 21:44

Subject: K211878/S001 is on Hold Pending Your Response

October 4, 2021

We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Michele Lee.

*** This is a system-generated email notification ***[attachment "K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

Visit us at: http://www.admedsol.com<http://www.admedsol.com/>. This e-mail, including
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Hello Martin,

Sure, I will also put Helen and Rose on future communication for this submission.

Take care,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Tuesday, September 21, 2021 10:03 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: k211878@docs.fda.gov; Helen.Topping@admedsol.com; Rose.Guang@admedsol.com
Subject: [EXTERNAL] Re: K211878/S001 Review Status

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Hello Michele

Thank you for your email to keep us updated with progress.

Please note that next week i'll be out on annual leave... therefore, could you also place Helen and Rose (on this email) on copy with any further communication you send over.

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 20/09/2021 22:31
Subject: K211878/S001 Review Status

Hello Martin:

I want to inform you of a slightly revised review timeline for your 510(k) submission K211878/S001. Due to a limitation of Agency resources, we are unable to complete the substantive review by September 24th. We want to inform you that we expect to complete the review by next Wednesday, September 29th. We apologize for any inconveniences because of the extension of timeline.

Best Regards,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov



* * * * *

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Hi Sam

I'll call you today at 6am (11am UK time); we thought it would be better to send you the updated documents to help aid the discussion during the call.

The IFU has been updated with your comments (and as per our modifications we suggest below). I've provided a redlined and clean copy of this:

The (b)(4) has been updated with your comments

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>
Cc: "K211878@docs.fda.gov" <K211878@docs.fda.gov>, Rose Guang/WIN/UK/AMS@ams
Date: 18/05/2022 22:37
Subject: RE: [EXTERNAL] Re: K211878-s002

Hi Sam

Firstly, thank you for staying late to continue to work with us on in the final stages of this submission. It is much appreciated.

Please find attached the IFU with updated comments from ourselves

[attachment "K211878-S002 - (b)(4) (b)(4)" deleted by Martin Mitchell/WIN/UK/AMS]

For most of the proposed updates we will accept to make the changes. However there are two points we would wish to clarify

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

As discussed I'll call you tomorrow to discuss your email below

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>, "K211878@docs.fda.gov" <K211878@docs.fda.gov>
Date: 18/05/2022 20:39
Subject: RE: [EXTERNAL] Re: K211878-s002

Hi Mr. Mitchell:

Please see attached for the (b)(4) with FDA edits.

Please address these edits and send me both the edited versions and clean copies of the (b)(4) by COB tomorrow (5-19-2022).

Please cc your response to K211878@docs.fda.gov.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Thx

Sam

Sam Arepalli, Ph.D.

FDA/CDRH/OPEQ/OHT4/PRSB2

Ph: 301 796 6434

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Tuesday, May 17, 2022 6:39 AM

To: Arepalli, Sambasiva <Sambasiva.Arepalli@fda.hhs.gov>

Subject: RE: [EXTERNAL] Re: K211878-s002

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Hi Sam

Just to be safe for the email trail.... so that your email has a response

The email with this information was send yesterday; however it is also provided again below:

Please find a response to the two points we discussed over the phone

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Date: 17/05/2022 10:32

Subject: RE: [EXTERNAL] Re: K211878-s002

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Hi Mr. Mitchell:

Can you please give an update on the revised labeling request? Could you please send the information cob today? Please give me a call when you have a minute.

Thx

Sam

Sam Arepalli, Ph.D.

FDA/CDRH/OPEQ/OHT4/PRSB2

Ph: 301 796 6434

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Monday, May 16, 2022 12:06 PM

To: Arepalli, Sambasiva <Sambasiva.Arepalli@fda.hhs.gov>

Subject: [EXTERNAL] Re: K211878-s002

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Hi Sam

Just so you're aware it's 17:00 now so i'll be heading home; however i'll try to make myself available outside of hours so please don't hesitate to get in touch if you have any further questions.

Additionally i'll be working from home the next few days so I won't pick up calls from my office number you used previously.

If you have any further questions please email me or call me on my personal mobile number (b)(6)

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>

Cc: "K211878@docs.fda.gov" <K211878@docs.fda.gov>, Rose Guang/WIN/UK/AMS@ams, Helen Topping/WIN/UK/AMS@ams

Date: 16/05/2022 16:28

Subject: Re: K211878-s002

Hi Sam

Please find a response to the two points we discussed over the phone

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>, "K211878@docs.fda.gov" <K211878@docs.fda.gov>

Date: 16/05/2022 14:39

Subject: K211878-s002

Hi Mr. Martin:

Please address the following:

(b)(4)

Thx

Sam

Sam Arepalli, Ph.D.

FDA/CDRH/OPEQ/OHT4/PRSB2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Ph: 301 796 6434

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug
Administration

Memorandum

Title of Memo Toxicological Risk Assessment Consult, 510k Original

Date: Memo: 9/03/2021
Due: 9/03/2021
Requested: 8/16/2021

To: Michele Lee, PhD
CDRH\OHT4\DHT4B\THT4B4

From: Diego Rua, PhD MBA
CDRH/OSEL/DBCMS
240-402-2454

Diego Rua -S
Digitally signed by Diego Rua -S
Date: 2021.09.03 15:41:17 -04'00'

Re: K211878/S001
Advanced Medical Solutions Limited
LiquiBand XL

(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(5)

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(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Hello Martin,

A new lead reviewer will not be assigned until a follow up submission is received. So there is currently not a primary contact unless there is an active submission under FDA review. All of our correspondence and the prior related review have been documented internally, so you can be assured that the history of the prior review and contact is available to the future lead reviewer.

Best,

Michele

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Friday, March 25, 2022 12:21 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: k211878@docs.fda.gov

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

I've seen on the FDA customer collaboration portal that the time has automatically been added, but just thought it would be prudent to also inform you of the situation.

Could I ask who the primary contact is now? Will you be assisting or have any involvement with the review of our response?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 25/03/2022 15:59

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

I am sorry to hear about (b)(4). I hope all is able to be resolved soon.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Thank you for the update. I am actually working in a different division within FDA and no longer the primary contact for this submission. I believe that the 180 days is automatically granted for responses to AINN hold but you can also confirm with the 510(k) Program staff (510k_Program@fda.hhs.gov<mailto:510k_Program@fda.hhs.gov>, telephone: 301-796-5640) to make sure.

Best,

Michele

Michele Lee, Ph.D.(she/her/hers)

Regulatory Science Program Manager

Partnerships to Advance Innovation and Regulatory Science (PAIRS)

Center for Devices and Radiological Health

Office of Strategic Partnerships and Technology Innovation

Division of All Hazards Response, Science, and Strategic Partnerships

U.S. Food and Drug Administration

michele.lee@fda.hhs.gov<mailto:michele.lee@fda.hhs.gov>

[cid:image001.png@01D84046.82E713E0]<http://www.fda.gov/>

[cid:image002.jpg@01D84046.82E713E0]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D84046.82E713E0] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D84046.82E713E0] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D84046.82E713E0] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D84046.82E713E0]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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https://www.research.net/s/cdrhcustomerservice?ID=7013&S=E.

From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>
<Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Friday, March 25, 2022 11:28 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

I'd like to provide an update on our progress with responding to the deficiencies raised on K211878

We were on track to have a deficiency response submitted to the FDA by the 180 day hold period deadline of 2nd April 2022.

However, the organisation performing the **(b)(4)**

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(b)(4) (b)(4). As a result, they were unable to complete the testing by our targeted timeline.

Therefore, I just want to confirm that we are still intending to respond to the deficiencies, but we would need to use the second 180 day hold period granted to us through the COVID-19 situation.

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 08/11/2021 22:05

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

Thanks for your message. Iâ€™ll need some time to review the teleconference minutes with my team and also obtain some feedback from our consulting toxicologist about the follow up questions. But I wanted to let you know I received your email and you may feel free to check in again next week.

(b)(4)

Regarding the timeline clarification- I am also under the understanding that the COVID-19 guidance document you cited was still active and that would allow you an additional 180 days for the hold period. I have reached out to the 510(k) Staff multiple times to confirm and am still waiting on their response. Is there a customer service contact email for the customer collaboration portal specifically? You may try contacting them

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

as well to have the date corrected on your end.

Thank you,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D84046.82E713E0]<http://www.fda.gov/>

[cid:image002.jpg@01D84046.82E713E0]<https://www.facebook.com/FDA>[cid:image003.jpg@01D84046.82E713E0]<https://twitter.com/US_FDA> [cid:image004.jpg@01D84046.82E713E0]<http://www.youtube.com/user/USFoodandDrugAdmin> [cid:image005.jpg@01D84046.82E713E0]<http://www.flickr.com/photos/fdaphotos/> [cid:image006.jpg@01D84046.82E713E0]<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Friday, November 5, 2021 12:07 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

I hope you had a nice holiday!

Following on from the teleconference we had a few actions to complete and get back to you with.

1) Teleconference minutes

Please find a draft of the the teleconference minutes below. Could you review and confirm if you require any changes made?

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2) Follow-up questions on the teleconference discussion

As suggested during the teleconference there was the opportunity for a followup email clarification on a few minor points.

(b)(4)

The supporting information which provides further clarity on the questions above has been attached if required.

3) Timeline clarification as per previous email

I can see on the customer collaboration portal that we have a 180 day hold period which

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Thank you again for your assistance

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>, "Liu, Lixin" <Lixin.Liu@fda.hhs.gov<mailto:Lixin.Liu@fda.hhs.gov>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 20/10/2021 22:43

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Michele

Thank you for the prompt response to the clarifications! We'll take your points on board regarding future shelf life studies.

I do have a minor clarification question regarding our response timeline

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 20/10/2021 14:55

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

_____

Hello Martin,

Thank you to you and your team for attending the teleconference yesterday. I wanted to follow up on two things I was discussing with my team:

(b)(4)

I will be on leave for the next two weeks and you may contact our team management (Lixin.Liu@fda.hhs.gov<mailto:Lixin.Liu@fda.hhs.gov>) if you have questions during that time.

Best,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

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[cid:image002.jpg@01D84046.82E713E0]<https://www.facebook.com/FDA>[cid:image003.jpg@01D84046.82E713E0]<https://twitter.com/US_FDA>[cid:image004.jpg@01D84046.82E713E0]<http://www.youtube.com/user/USFoodandDrugAdmin>[cid:image005.jpg@01D84046.82E713E0]<http://www.flickr.com/photos/fdaphotos/> [cid:image006.jpg@01D84046.82E713E0]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: Lee, Michele

Sent: Friday, October 15, 2021 4:47 PM

To: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you for providing your questions in advance of the meeting. We look forward to discussing our responses with you next week.

Have a good weekend,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

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Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D84046.82E713E0]<http://www.fda.gov/>

[cid:image002.jpg@01D84046.82E713E0]<https://www.facebook.com/FDA>[cid:image003.jpg@01D84046.82E713E0]<https://twitter.com/US_FDA>[cid:image004.jpg@01D84046.82E713E0]<http://www.youtube.com/user/USFoodandDrugAdmin>[cid:image005.jpg@01D84046.82E713E0]<http://www.flickr.com/photos/fdaphotos/> [cid:image006.jpg@01D84046.82E713E0]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Friday, October 15, 2021 12:00 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Please find the list of questions/clarifications attached below.

I hope you have a good weekend. I'm looking forwards to our discussion next week!

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 13/10/2021 22:35

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

I have scheduled the teleconference for next Tuesday October 19that 9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour but our biocompatibility consultant/ team management needs to drop off for another call at 9:30am. Please send me the

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questions for discussion in advance of the meeting so that we can plan to discuss biocompatibility/ regulatory questions first before the relevant parties need to drop off.

Join Zoom

(b)(4)

Thanks,

Michele

Michele Lee, Ph.D.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

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[cid:image002.jpg@01D84046.82E713E0]<https://www.facebook.com/FDA>[cid:image003.jpg@01D84046.82E713E0]<https://twitter.com/US_FDA>[cid:image004.jpg@01D84046.82E713E0]<http://www.youtube.com/user/USFoodandDrugAdmin>[cid:image005.jpg@01D84046.82E713E0]<http://www.flickr.com/photos/fdaphotos/>[cid:image006.jpg@01D84046.82E713E0]<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Wednesday, October 13, 2021 4:46 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Apologies Michele, one final thing I missed off my email... could you clarify how long the teleconference would be by default? Could we request 1 hour just incase some of the points end up taking longer to discuss?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>"

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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<helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>,
"k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>"
<k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 13/10/2021 20:35

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hi Michele

We're currently preparing our questions for the teleconference and will send these through in due course, however to assist with scheduling the relevant parties at FDA, I should let you know that we would definitely like to discuss the questions related to biocompatibility.

After discussion with the team we would like to request the teleconference on the Tuesday 19th October if that is possible? As we are based in the UK, we would also like to request that this is arranged between the hours of 2-5pm BST.

If this time slot is not available could you outline any alternative days/times which would be possible?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>"
<helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>,
"k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>"
<k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 08/10/2021 22:14

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hi Michele

Thank you for the offer. I think after today's meeting we may need a little more time to be better prepared for the teleconference.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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We are reaching out to (b)(4) for us as we feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible dates for you early next week.

Best regards,

Martin Mitchell

Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 06/10/2021 13:49

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference deadline up to October 19th. Let me know if you would like to select a date later than the 14thand I can check our management schedules.

Regarding review timelines, we are still on the 90 day review cycle and are planning to complete the review of your response with the 20 calendar days left on the clock. While we retain the right to add additional days, we are doing our best with the resources that we have to avoid delaying review timelines if possible.

Best,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

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[cid:image002.jpg@01D84046.82E713E0]<https://www.facebook.com/FDA>[cid:image003.jpg@01D84046.82E713E0]<https://twitter.com/US_FDA>[cid:image004.jpg@01D84046.82E713E0]<http://www.youtube.com/user/USFoodandDrugAdmin>[cid:image005.jpg@01D84046.82E713E0]<http://www.flickr.com/photos/fdaphotos/>[cid:image006.jpg@01D84046.82E713E0]<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Wednesday, October 6, 2021 6:00 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>

Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Thank you again for your review. Our team are busy discussing the questions and we would definitely like to have a teleconference with the FDA. We're currently consolidating our understanding of the deficiencies and are determining what our potential questions to you would be. I hope to get the questions to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we look to schedule a teleconference with the FDA on Wednesday 13th or Thursday 14th? As we're based in the UK we would appreciate a timeslot within our working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines for this project.... regarding the FDA timeline I can see on the CCP tracker website that the FDA timeline is on day 70.

* Will FDA be sticking to the 90 day target and as a result only have 20 days left on the clock?

* Or, due to the current situation with the unprecedented resource limitations..... will you will assume 30 days to review the response as standard? Or perhaps stick to the 20 days but retain the right to add additional days?

Best regards,

Martin Mitchell

Senior Regulatory Affairs Associate

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Michele Lee [MICHELE.LEE]"
<michele.lee@fda.hhs.gov<mailto:michele.lee@fda.hhs.gov>>

To: <martin.mitchell@admedsol.com<mailto:martin.mitchell@admedsol.com>>,
<helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>

Cc: "Michele Lee [MICHELE.LEE]"
<michele.lee@fda.hhs.gov<mailto:michele.lee@fda.hhs.gov>>

Date: 04/10/2021 21:44

Subject: K211878/S001 is on Hold Pending Your Response

October 4, 2021

We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Michele Lee.

*** This is a system-generated email notification ***[attachment "K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

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Hello Michele

I hope you had a nice holiday!

Following on from the teleconference we had a few actions to complete and get back to you with.

1) Teleconference minutes

Please find a draft of the the teleconference minutes below. Could you review and confirm if you require any changes made?

2) Follow-up questions on the teleconference discussion

As suggested during the teleconference there was the opportunity for a followup email clarification on a few minor points.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

3) Timeline clarification as per previous email

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Thank you again for your assistance

Best regards,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>, "Liu, Lixin" <Lixin.Liu@fda.hhs.gov>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 20/10/2021 22:43

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Michele

Thank you for the prompt response to the clarifications! We'll take your points on board regarding future shelf life studies.

I do have a minor clarification question regarding our response timeline

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

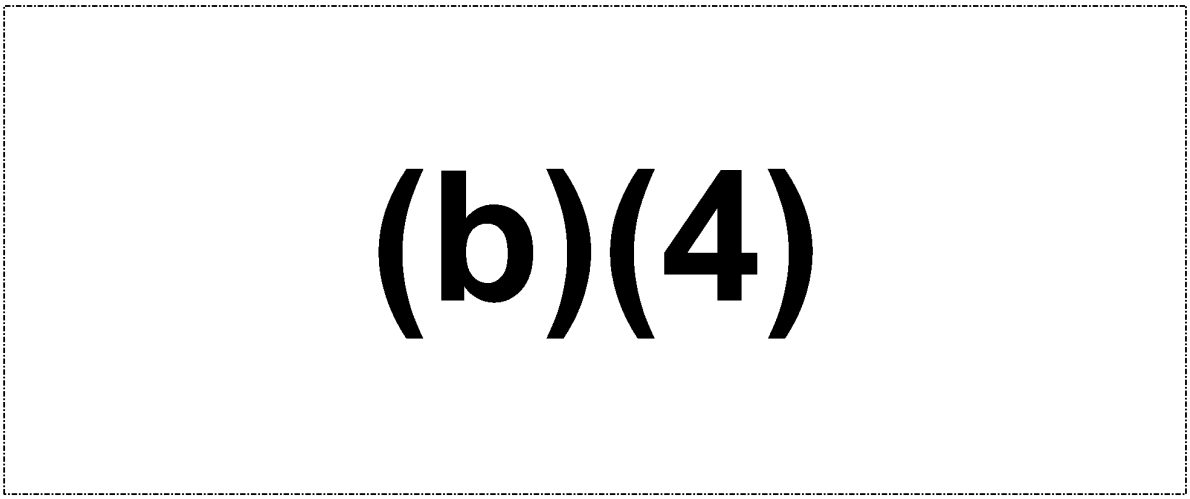
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 20/10/2021 14:55

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you to you and your team for attending the teleconference yesterday. I wanted to follow up on two things I was discussing with my team:



I will be on leave for the next two weeks and you may contact our team management (Lixin.Liu@fda.hhs.gov) if you have questions during that time.

Best,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

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Michele.Lee@fda.hhs.gov

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From: Lee, Michele
Sent: Friday, October 15, 2021 4:47 PM
To: Martin.Mitchell@admedsol.com
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you for providing your questions in advance of the meeting. We look forward to discussing our responses with you next week.

Have a good weekend,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
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Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Friday, October 15, 2021 12:00 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

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Please find the list of questions/clarifications attached below.

I hope you have a good weekend. I'm looking forwards to our discussion next week!

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 13/10/2021 22:35
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

I have scheduled the teleconference for next Tuesday October 19th at 9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour but our biocompatibility consultant/ team management needs to drop off for another call at 9:30am. Please send me the questions for discussion in advance of the meeting so that we can plan to discuss biocompatibility/ regulatory questions first before the relevant parties need to drop off.

Join Zoom Meeting

(b)(4)

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(b)(4)

Thanks,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Wednesday, October 13, 2021 4:46 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: helen.topping@admedsol.com; k211878@docs.fda.gov

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Apologies Michele, one final thing I missed off my email... could you clarify how long the teleconference would be by default? Could we request 1 hour just incase some of the points end up taking longer to discuss?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 13/10/2021 20:35

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hi Michele

We're currently preparing our questions for the teleconference and will send these through in due course, however to assist with scheduling the relevant parties at FDA, I should let you know that we would definitely like to discuss the questions related to biocompatibility.

After discussion with the team we would like to request the teleconference on the Tuesday 19th October if that is possible? As we are based in the UK, we would also like to request that this is arranged between the hours

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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of 2-5pm BST.

If this time slot is not available could you outline any alternative days/times which would be possible?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 08/10/2021 22:14
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hi Michele

Thank you for the offer. I think after today's meeting we may need a little more time to be better prepared for the teleconference.

We are reaching out to (b)(4) for us as we feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible dates for you early next week.

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 06/10/2021 13:49

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference deadline up to October 19th. Let me know if you would like to select a date later than the 14thand I can check our management schedules.

Regarding review timelines, we are still on the 90 day review cycle and are planning to complete the review of your response with the 20 calendar days left on the clock. While we retain the right to add additional days, we are doing our best with the resources that we have to avoid delaying review timelines if possible.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
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Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 6, 2021 6:00 AM

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: helen.topping@admedsol.com

Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Thank you again for your review. Our team are busy discussing the questions and we would definitely like to have a teleconference with the FDA. We're currently consolidating our understanding of the deficiencies and are determining what our potential questions to you would be. I hope to get the questions to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we look to schedule a teleconference with the FDA on Wednesday 13th or Thursday 14th? As we're based in the UK we would appreciate a timeslot within our working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines for this project.... regarding the FDA timeline I can see on the CCP tracker website that the FDA timeline is on day 70.
Will FDA be sticking to the 90 day target and as a result only have 20 days left on the clock?
Or, due to the current situation with the unprecedented resource limitations..... will you will assume 30 days to review the response as standard? Or perhaps stick to the 20 days but retain the right to add additional days?

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>

To: <martin.mitchell@admedsol.com>, <helen.topping@admedsol.com>

Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Date: 04/10/2021 21:44

Subject: K211878/S001 is on Hold Pending Your Response

October 4, 2021

We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Michele Lee.

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Hi Martin,

I received information that the FDA review timeline is strongly dependent on available review resources at the time that the q-submission is received. While the Agency is trying our best to meet review timeline goals, we are currently experiencing many delays due to lack of resources and unavailability of personnel to review. We encourage you to submit the SIR as early as you are able to try to get the feedback earlier. You may consider submitting multiple q-submissions if you are not able to compile all of the information in time.

Best,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

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Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

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From: Lee, Michele

Sent: Thursday, December 2, 2021 10:31 AM

To: Martin.Mitchell@admedsol.com

Cc: k211878@docs.fda.gov

Subject: RE: [EXTERNAL] K211878 timeline - COVID-19

Hello Martin,

I have forwarded your question on to my management and will let you know when I receive their feedback.

Best,

Michele

Michele Lee, Ph.D.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

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Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

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[cid:image003.jpg@01D7E851.7BA3B400] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7E851.7BA3B400] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7E851.7BA3B400] <http://www.flickr.com/photos/fdaphotos/>
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From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>
<Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Wednesday, December 1, 2021 12:05 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] K211878 timeline - COVID-19

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Hi Michele

I have a further question regarding how COVID affects timelines below.

Knowing that FDA have are allowing a further 180 day timeline to respond to deficiencies due to COVID.... is there any scope or provision for timeline adjustments relating to a SIR review time?

More specifically, regarding an SIR submission i've seen in the guidance document that if the SIR is received before the 60 day timepoint after issuance of the deficiency letter, this would result in a 21 day FDA review time; whereas if we submit the SIR after this date this results in a 70 day FDA review time.

We have faced some delays in being able to meet the deadline of submitting an SIR before the 60 day timepoint. Where, we've spent some time liasing with yourselves through teleconference and email about the issues noted and covid has impacted our ability and our toxicologists ability to move quickly on these matters.

Therefore I'd like to enquire as to whether the FDA are allowing extensions to the time to receive an SIR (currently 60 days after issuance of the deficiency) where the SIR would still receive a 21 day FDA review time?

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Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 16/11/2021 19:03

Subject: RE: [EXTERNAL] K211878 timeline - COVID-19

Hello Martin,

Thanks for the update and good to know this information. I also received your previous email with additional information about the test parameters of the degradation & extraction studies. I am still waiting on feedback from our consulting toxicologist but hope to have more information to provide you mid next week.

Best,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

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Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

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From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com> <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Monday, November 15, 2021 3:54 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Subject: Fw: [EXTERNAL] K211878 timeline - COVID-19

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Hi Michele

I got an update regarding timeline from the CCP email address.

FYI we are exploring a number of backup strategies to resolve the 510(k) deficiencies.... and some of these take us past the 180 day hold period.

As per the request below, I'll let you know closer to the time if we end up needing to request the additional 180 days.

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

----- Forwarded by Martin Mitchell/WIN/UK/AMS on 15/11/2021 08:31 -----

From: "CCP" <CCP@fda.hhs.gov<mailto:CCP@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Date: 12/11/2021 21:08

Subject: RE: [EXTERNAL] K211878 timeline - COVID-19

Good day to you Martin,

The extra 180 days for response are added as needed, and then only shortly before the original 180 days expires.

--

Happy trails,

~Nels Anderson

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Regulatory Systems & Data Management Staff

Center for Devices and Radiological Health | Office of Product Evaluation and Quality| Office of Regulatory Programs

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From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Friday, November 12, 2021 09:49

To: CCP <CCP@fda.hhs.gov<mailto:CCP@fda.hhs.gov>>

Subject: [EXTERNAL] K211878 timeline - COVID-19

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Hello

Regarding the timeline showing for K211878 I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I (and the lead reviewer Michele Lee) were under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify that the 180 timeline in the customer collaboration portal won't trigger premature closure of the 510(k) before the actual 360 day timeline expires?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

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Hello (b)(4)

I have another meeting before that scheduled time. I can do a half hour earlier (6:30pm UTC+1) on Wednesday or a different time on another day next week?

Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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From: (b)(4)
Sent: Friday, November 5, 2021 11:02 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>; k211878@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Dear Michele,

many thanks for sending the invite.

I fear, I´ve made a mistake, when communicating the time.
Could we schedule one hour earlier?

Kind regards.

(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov>
Sent: Freitag, 5. November 2021 15:59
To: (b)(4); k211878@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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---

Hello (b)(4)

Sure, we can discuss via teleconference on 10 Nov 2021 at 7pm UTC+1/ 2pm EDT. I sent a ZoomGov invite via email and also copied the call-in information below.

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Image removed

Hi there,

Michele.Lee@fda.hhs.gov is inviting you to a scheduled ZoomGov meeting.

Join Zoom Meeting

(b)(4)

Best Regards,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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From: (b)(4)
Sent: Friday, November 5, 2021 10:10 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>; k211878@docs.fda.gov

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Cc: (b)(4) Martin.Mitchell@admedsol.com
Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Dear Michele,

Many thanks for your message.
Martin, thank you for the connection.

Michele, would you be available next Wednesday, 10 November 2021, at 7 pm (UTC+1)?
Then I would send an invitation.

Kind regards.

(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov>
Sent: Freitag, 5. November 2021 14:33
To: Martin.Mitchell@admedsol.com; k211878@docs.fda.gov
Cc: (b)(4)
Subject: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello all,

Thank you, Martin, for the connection.

(b)(4)

Best Regards,

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Thursday, November 4, 2021 11:29 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>; k211878@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hello Michele

Regarding the recent deficiency question on our medical device submission which is currently under review with the FDA:

(b)(4)

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

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Sent: Freitag, 5. November 2021 14:33

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Cc: (b)(4)

(b)(4)

Subject: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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(b)(4)

Best Regards,

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[cid:image001.png@01D7D257.03B043B0]<http://www.fda.gov/>

[cid:image002.jpg@01D7D257.03B043B0]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D7D257.03B043B0] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7D257.03B043B0] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7D257.03B043B0] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D7D257.03B043B0]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>;
k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Cc: (b)(4)

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Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

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FINAL GLP REPORT: (b)(4)

RABBIT PYROGEN TEST (MATERIAL MEDIATED) – ISO

Test Article
LIQUIBAND XL (Complete Device)

21 CFR Part 58 Compliance
Good Laboratory Practice for Nonclinical Laboratory Studies

Final Report Date
3/2/2021

Study Director
(b)(4)

Sponsor
Advanced Medical Solutions Limited
2 Western Wood Way, Langage Science Park
Plymouth PL7 5BG
U.K.

Questions? Contact FDA/CDRH/OIE/DI at CDRH-FOI-TA...da.hhs.gov or 301-796-8118

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(b)(4)

(b)(4)
FDA GLP REGULATIONS
FILE COPY/CONFIDENTIAL PROPERTY (b)(4)

RABBIT PYROGEN TEST (MATERIAL MEDIATED) - ISO

(b)(4) PROTOCOL NUMBER: (b)(4)

21 CFR Part 58 Compliance
Good Laboratory Practice for Nonclinical Laboratory Studies

MANAGEMENT OF THE STUDY

(b)(4)

Sponsor
Advanced Medical Solutions Limited
2 Western Wood Way,
Langage Science Park
Plymouth, PL7 5BG
United Kingdom

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

FINAL GLP REPORT: (b)(4)

SYSTEMIC INJECTION TEST – ISO

Test Article
LIQUIBAND XL (Complete Device)

21 CFR Part 58 Compliance
Good Laboratory Practice for Nonclinical Laboratory Studies

Final Report Date
3/2/2021

Study Director
(b)(4)

Sponsor
Advanced Medical Solutions Limited
2 Western Wood Way, Langage Science Park
Plymouth, PL7 5BG
United Kingdom

Questions? Contact FDA/CDRH/OCE/ID; CDRHFOIASTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

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FDA GLP REGULATIONS
FILE COPY/CONFIDENTIAL PROPERTY (b)(4)

SYSTEMIC INJECTION TEST - ISO

(b)(4) PROTOCOL NUMBER: (b)(4)

21 CFR Part 58 Compliance
Good Laboratory Practice for Nonclinical Laboratory Studies

MANAGEMENT OF THE STUDY

(b)(4)

Sponsor
Advanced Medical Solutions Limited
2 Western Wood Way,
Langage Science Park
Plymouth, PL7 5BG
United Kingdom

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FINAL NON-GLP REPORT: (b)(4)

CHEMICAL CHARACTERIZATION OF THE EXTRACTABLE AMOUNT OF CHEMICAL COMPOUNDS FROM SPONSOR COMPONENTS (LIQUIBAND XL (COMPLETE DEVICE))

Test Article
LIQUIBAND XL (Complete Device)

Final Report Date
5/21/2021

Study Director
(b)(4)

Sponsor
Advanced Medical Solutions Limited
2 Western Wood Way,
Langage Science Park
Plymouth, PL7 5BG
United Kingdom

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(b)(4)	Title: Toxicological risk assessment LIQUIBAND XL	Id: (b)(4)

CONFIDENTIAL
Toxicological risk assessment LIQUIBAND XL

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Test Protocol

SOLVENT COMPATIBILITY ASSESSMENT FOR LIQUIBAND XL DEVICE	Doc No: (b)(4)
	Rev No:

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General Report

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	Rev No:	

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General Report

SOLVENT COMPATIBILITY ASSESSMENT FOR LIQUIBAND XL DEVICE

Doc No:	(b)(4)
Rev No:	

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Hello Martin,

Thank you to you and your team for attending the teleconference yesterday. I wanted to follow up on two things I was discussing with my team:

(b)(4)

I will be on leave for the next two weeks and you may contact our team management (Lixin.Liu@fda.hhs.gov) if you have questions during that time.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
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From: Lee, Michele
Sent: Friday, October 15, 2021 4:47 PM
To: Martin.Mitchell@admedsol.com
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you for providing your questions in advance of the meeting. We look forward to discussing our responses with you next week.

Have a good weekend,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Friday, October 15, 2021 12:00 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Please find the list of questions/clarifications attached below.

I hope you have a good weekend. I'm looking forwards to our discussion next week!

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 13/10/2021 22:35
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

I have scheduled the teleconference for next Tuesday October 19th at 9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour but our biocompatibility consultant/ team management needs to drop off for another call at 9:30am. Please send me the questions for discussion in advance of the meeting so that we can plan to discuss biocompatibility/ regulatory questions first before the relevant parties need to drop off.

Join Zoom Meeting

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international numbers

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H.323:

Meeting ID:
Passcode:
SIP:
Passcode:
(b)(4)

Thanks,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Sent: Wednesday, October 13, 2021 4:46 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Apologies Michele, one final thing I missed off my email... could you clarify how long the teleconference would be by default? Could we request 1 hour just incase some of the points end up taking longer to discuss?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 13/10/2021 20:35
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hi Michele

We're currently preparing our questions for the teleconference and will send these through in due course, however to assist with scheduling the relevant parties at FDA, I should let you know that we would definitely like to discuss the questions related to biocompatibility.

After discussion with the team we would like to request the teleconference on the Tuesday 19th October if that is possible? As we are based in the UK, we would also like to request that this is arranged between the hours of 2-5pm BST.

If this time slot is not available could you outline any alternative days/times which would be possible?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 08/10/2021 22:14
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hi Michele

Thank you for the offer. I think after today's meeting we may need a little more time to be better prepared for the teleconference.

We are reaching out to [redacted] (b)(4) for us as we feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible dates for you early next week.

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 06/10/2021 13:49
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference deadline up to October 19th. Let me know if you would like to select a date later than the 14thand I can check our management schedules.

Regarding review timelines, we are still on the 90 day review cycle and are planning to complete the review of your response with the 20 calendar days left on the clock. While we retain the right to add additional days, we are doing our best with the resources that we have to avoid delaying review timelines if possible.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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Michele.Lee@fda.hhs.gov

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https://www.research.net/s/odhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 6, 2021 6:00 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com
Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Thank you again for your review. Our team are busy discussing the questions and we would definitely like to have a teleconference with the FDA. We're currently consolidating our understanding of the deficiencies and are determining what our potential questions to you would be. I hope to get the questions to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we look to schedule a teleconference with the FDA on Wednesday 13th or Thursday 14th? As we're based in the UK we would appreciate a timeslot within our working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines for this project.... regarding the FDA timeline I can see on the CCP tracker website that the FDA timeline is on day 70.

- Will FDA be sticking to the 90 day target and as a result only have 20 days left on the clock?
- Or, due to the current situation with the unprecedented resource limitations..... will you will assume 30 days to review the response as standard? Or perhaps stick to the 20 days but retain the right to add additional days?

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
To: <martin.mitchell@admedsol.com>, <helen.topping@admedsol.com>
Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
Date: 04/10/2021 21:44
Subject: K211878/S001 is on Hold Pending Your Response

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

October 4, 2021

We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Michele Lee.

*** This is a system-generated email notification ***[attachment "K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

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Hello Martin,

Thanks for your message. Iâ€™ll need some time to review the teleconference minutes with my team and also obtain some feedback from our consulting (b)(4) about the follow up questions. But I wanted to let you know I received your email and you may feel free to check in again next week.

(b)(4)

Regarding the timeline clarification- I am also under the understanding that the COVID-19 guidance document you cited was still active and that would allow you an additional 180 days for the hold period. I have reached out to the 510(k) Staff multiple times to confirm and am still waiting on their response. Is there a customer service contact email for the customer collaboration portal specifically? You may try contacting them as well to have the date corrected on your end.

Thank you,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

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Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D7D4C2.CA3E8D80]<http://www.fda.gov/>

[cid:image002.jpg@01D7D4C2.CA3E8D80]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D7D4C2.CA3E8D80] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7D4C2.CA3E8D80] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7D4C2.CA3E8D80] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D7D4C2.CA3E8D80]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Sent: Friday, November 5, 2021 12:07 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: helen.topping@admedsol.com; k211878@docs.fda.gov

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

I hope you had a nice holiday!

Following on from the teleconference we had a few actions to complete and get back to you with.

1) Teleconference minutes

Please find a draft of the the teleconference minutes below. Could you review and confirm if you require any changes made?

2) Follow-up questions on the teleconference discussion

As suggested during the teleconference there was the opportunity for a followup email clarification on a few minor points.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1.

(b)(4)

3) Timeline clarification as per previous email

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Thank you again for your assistance

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>, "Liu, Lixin" <Lixin.Liu@fda.hhs.gov<mailto:Lixin.Liu@fda.hhs.gov>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>"

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<helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>,
"k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>"
<k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 20/10/2021 22:43

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Michele

Thank you for the prompt response to the clarifications! We'll take your points on board regarding future shelf life studies.

I do have a minor clarification question regarding our response timeline

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>"
<Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>"
<helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>,
"k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>"
<k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 20/10/2021 14:55

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

Thank you to you and your team for attending the teleconference yesterday. I wanted to follow up on two things I was discussing with my team:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

I will be on leave for the next two weeks and you may contact our team management (Lixin.Liu@fda.hhs.gov<mailto:Lixin.Liu@fda.hhs.gov>) if you have questions during that time.

Best,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D7D4C2.CA3E8D80]<http://www.fda.gov/>

[cid:image002.jpg@01D7D4C2.CA3E8D80]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D7D4C2.CA3E8D80] <https://twitter.com/US_FDA>
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[cid:image005.jpg@01D7D4C2.CA3E8D80] <http://www.flickr.com/photos/fdaphotos/>
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From: Lee, Michele

Sent: Friday, October 15, 2021 4:47 PM

To: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you for providing your questions in advance of the meeting. We look forward to discussing our responses with you next week.

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Have a good weekend,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

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Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D7D4C2.CA3E8D80]<http://www.fda.gov/>

[cid:image002.jpg@01D7D4C2.CA3E8D80]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D7D4C2.CA3E8D80] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7D4C2.CA3E8D80] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7D4C2.CA3E8D80] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D7D4C2.CA3E8D80]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From:
Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Friday, October 15, 2021 12:00 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Please find the list of questions/clarifications attached below.

I hope you have a good weekend. I'm looking forwards to our discussion next week!

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 13/10/2021 22:35

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

I have scheduled the teleconference for next Tuesday October 19that 9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour but our (b)(4) team management needs to drop off for another call at 9:30am. Please send me the questions for discussion in advance of the meeting so that we can plan to discuss (b)(4) questions first before the relevant parties need to drop off.

Join Zoom

(b)(4)

Join by Telephone

For higher quality, dial a number based on your current location.

Dial:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Join from an H.323/SIP room system

(b)(4)

Thanks,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

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Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D7D4C2.CA3E8D80]<http://www.fda.gov/>

[cid:image002.jpg@01D7D4C2.CA3E8D80]<https://www.facebook.com/FDA>[cid:image003.jpg@01D7D4C2.CA3E8D80]<https://twitter.com/US_FDA> [cid:image004.jpg@01D7D4C2.CA3E8D80]<http://www.youtube.com/user/USFoodandDrugAdmin> [cid:image005.jpg@01D7D4C2.CA3E8D80]<http://www.flickr.com/photos/fdaphotos/> [cid:image006.jpg@01D7D4C2.CA3E8D80]<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Wednesday, October 13, 2021 4:46 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Apologies Michele, one final thing I missed off my email... could you clarify how long the teleconference would be by default? Could we request 1 hour just incase some of the points end up taking longer to discuss?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 13/10/2021 20:35

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hi Michele

We're currently preparing our questions for the teleconference and will send these through in due course, however to assist with scheduling the relevant parties at FDA, I should let you know that we would definitely like to discuss the questions related to **(b)(4)**.

After discussion with the team we would like to request the teleconference on the Tuesday 19th October if that is possible? As we are based in the UK, we would also like to request that this is arranged between the hours of 2-5pm BST.

If this time slot is not available could you outline any alternative days/times which would be possible?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 08/10/2021 22:14

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Thank you for the offer. I think after today's meeting we may need a little more time to be better prepared for the teleconference.

We are reaching out to the **(b)(4)** for us as we feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible dates for you early next week.

Best regards,

Martin Mitchell

Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 06/10/2021 13:49

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference deadline up to October 19th. Let me know if you would like to select a date later than the 14thand I can check our management schedules.

Regarding review timelines, we are still on the 90 day review cycle and are planning to complete the review of your response with the 20 calendar days left on the clock. While we retain the right to add additional days, we are doing our best with the resources that we have to avoid delaying review timelines if possible.

Best,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D7D4C2.CA3E8D80]<http://www.fda.gov/>

[cid:image002.jpg@01D7D4C2.CA3E8D80]<https://www.facebook.com/FDA>[cid:image003.jpg@01D7D4C2.CA3E8D80]<https://twitter.com/US_FDA>[cid:image004.jpg@01D7D4C2.CA3E8D80]<http://www.youtube.com/user/USFoodandDrugAdmin>[cid:image005.jpg@01D7D4C2.CA3E8D80]<http://www.flickr.com/photos/fdaphotos/> [cid:image006.jpg@01D7D4C2.CA3E8D80]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From:
Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Wednesday, October 6, 2021 6:00 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>

Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

CAUTION:This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Michele

Thank you again for your review. Our team are busy discussing the questions and we would definitely like to have a teleconference with the FDA. We're currently consolidating our understanding of the deficiencies and are determining what our

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potential questions to you would be. I hope to get the questions to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we look to schedule a teleconference with the FDA on Wednesday 13th or Thursday 14th? As we're based in the UK we would appreciate a timeslot within our working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines for this project.... regarding the FDA timeline I can see on the CCP tracker website that the FDA timeline is on day 70.

* Will FDA be sticking to the 90 day target and as a result only have 20 days left on the clock?

* Or, due to the current situation with the unprecedented resource limitations..... will you will assume 30 days to review the response as standard? Or perhaps stick to the 20 days but retain the right to add additional days?

Best regards,

Martin Mitchell

Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov<mailto:michele.lee@fda.hhs.gov>>

To: <martin.mitchell@admedsol.com<mailto:martin.mitchell@admedsol.com>>, <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>

Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov<mailto:michele.lee@fda.hhs.gov>>

Date: 04/10/2021 21:44

Subject: K211878/S001 is on Hold Pending Your Response

October 4, 2021

We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Michele Lee.

*** This is a system-generated email notification ***[attachment "K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration
CDRH/OPEQ/OHTIV/DHTIVB
WO66 RM4529
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-5130

Premarket Notification 510(k) Review

Date: October 1, 2021

Reviewer: Michele Lee

Subject: Traditional 510(k)# K211878/S001

Applicant: Advanced Medical Solutions Limited	**Device Trade Name:** LiquiBand XL
Contact Name: Martin Mitchell	**Contact Title:** Senior Regulatory Affairs Associate
Correspondent Firm: Advanced Medical Solutions Limited	**Phone:** **Email:** martin.mitchell@admedsol.com
Received Date: July 26, 2021	**Due Date:** October 24, 2021
Pro Code(s): OMD **Class:** II **Reg #:** 878.4011	**Reg Name:** Tissue Adhesive With Adjunct Wound Closure Device For Topical Approximation Of Skin

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K191461	OMD	Exofin Fusion Skin Closure System	Chemence Medical, Inc.
K183570	MPN	LiquiBand Plus	Advanced Medical Solutions Limited

Recommendation

(b)(5)

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Advanced Medical Solutions Limited
Martin Mitchell
Senior Regulatory Affairs Associate
Western Wood Way , Langage Science Park
Plymouth, Devon PL7 5BG
United Kingdom

Re: K211878
Trade/Device Name: LiquiBand® XL
Regulation Number: 21 CFR 878.4011
Regulation Name: Tissue Adhesive With Adjunct Wound Closure Device For Topical Approximation Of Skin
Regulatory Class: Class II
Product Code: OMD
Dated: May 4, 2022
Received: May 4, 2022

Dear Martin Mitchell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

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requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

LETTER SHOULD BE DATED BEFORE SIGNING, AND MUST BE SIGNED OUT OF CTS ON THE DATE INDICATED ON THE LETTER.

Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Hello Martin,

Thanks for reaching out. I'll be glad to assist in answering your questions.

- Will there be any delays in assigning a new reviewer?
  We do not anticipate a delay in assigning a new reviewer.

- Are there still resource constraints at the FDA?
  Speaking regarding our team, we are still working through resource constraints and doing our best to meet deadlines.

- Would a new reviewer who is not familiar with the product/deficiencies require a longer period of time to perform the review?
  We will do our best to align the new reviewer that is familiar and experienced with the review product, to limit delay to the extent possible.

I hope this is helpful, but please let me know if you'd like to discuss further.

Best,
Julie

Julie Morabito, PhD, RAC (she/her/hers)
Assistant Director

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4666 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (240) 402-3839 | Cell: (b)(6)
julie.morabito@fda.hhs.gov

Formerly:
Assistant Director, Outreach and Partnerships Team 2 (MedSun)
DCEA1: Division of Clinical Science and Quality | OCEA: Office of Clinical Evidence and Analysis
Office of Product Evaluation and Quality

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received here.

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Wednesday, April 13, 2022 3:32 PM
To: Morabito, Julie <Julie.Morabito@fda.hhs.gov>
Cc: Helen.Topping@admedsol.com; k211878@docs.fda.gov; Rose.Guang@admedsol.com; Lee, Michele <Michele.Lee@fda.hhs.gov>
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele and Julie

Thank you Michele for providing further clarification on the matter regarding maintenance of a lead reviewer. We are sad to lose you as our lead reviewer and wish you the best in your new role within the FDA.

During the initial review of the 510(k) it was flagged that the FDA had resource challenges which resulted in the review taking 70 days instead of the targeted 60 days....When we discussed this previously it was stated that when we submit our deficiency response the FDA would still target to complete the review within the remaining 20 days, however.... it was also flagged that if resource constraints still existed this could take longer than 20 days.

To keep the FDA informed about our progress we are planning to submit our response to the deficiency questions in around 3 weeks time. We would like to enquire about FDA's ability to complete the review within 20 days?

- Will there be any delays in assigning a new reviewer?
- Are there still resource constraints at the FDA?
- Would a new reviewer who is not familiar with the product/deficiencies require a longer period of time to perform the review?

The timely completion of your review would be massively appreciated as the large wound market is critical to urgent patient demand, AMS and our partners who are very keen to provide the improved product to hospitals across the United States.

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "k211878@docs.fda.gov" <k211878@docs.fda.gov>, "Rose.Guang@admedsol.com" <Rose.Guang@admedsol.com>, "Helen.Topping@admedsol.com" <Helen.Topping@admedsol.com>, "Morabito, Julie" <Julie.Morabito@fda.hhs.gov>
Date: 05/04/2022 14:47
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Unfortunately, it is not possible for me to take on lead review of this submission. As previously mentioned, I am currently working in another Office within FDA and do not conduct premarket reviews of medical devices in my current role.

It is not uncommon for new lead reviewers to be assigned to submissions returning from hold. The internal documentation serves as a complete record of the previous interactions during prior review of a submission. If you have further questions regarding the review process for your submission, you may contact the Assistant Director for the Plastic Surgery Skin & Wound Devices Team, Dr. Julie Morabito (Julie.Morabito@fda.hhs.gov).

Best,
Michele

Michele Lee, Ph.D. *(she/her/hers)*
Regulatory Science Program Manager
Partnerships to Advance Innovation and Regulatory Science (PAIRS)

Center for Devices and Radiological Health
Office of Strategic Partnerships and Technology Innovation
Division of All Hazards Response, Science, and Strategic Partnerships
U.S. Food and Drug Administration
michele.lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Tuesday, April 5, 2022 8:31 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: k211878@docs.fda.gov; Rose.Guang@admedsol.com; Helen.Topping@admedsol.com
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele,

We have been pleased to have you as the lead reviewer for RTA review, technical review, and responses to deficiency discussions since July 2021, as well as having you for the review for our previous 510(k) submission of the same product.

(b)(4)

- Jun 2021 - We submitted K211878 i **(b)(4)**
- Oct 2021 - Further deficiencies were raised on the new K211878 submission

We currently have only 20 days of FDA review time left on our product and have been advised that we will now be assigned a new reviewer. As you can imagine this causing us a high level of concern given you have a detailed knowledge of our submissions and of the current outstanding questions. Our concern being that a new reviewer will not have the same detailed knowledge of our submission or of the outstanding questions and hence this may cause unnecessary further delay.

We have been very satisfied with the support we have received from yourself and we would ask that you remain on our file for the final 20 days if at all possible, or an explanation of why this is not possible with some reassurances that a new assessor will not cause unnecessary delays whilst they gain detailed knowledge of our file.

Your expedited response to this request would be appreciated.

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

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From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 25/03/2022 16:47
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

A new lead reviewer will not be assigned until a follow up submission is received. So there is currently not a primary contact unless there is an active submission under FDA review. All of our correspondence and the prior related review have been documented internally, so you can be assured that the history of the prior review and contact is available to the future lead reviewer.

Best,
Michele

From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Friday, March 25, 2022 12:21 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

I've seen on the FDA customer collaboration portal that the time has automatically been added, but just thought it would be prudent to also inform you of the situation.

Could I ask who the primary contact is now? Will you be assisting or have any involvement with the review of our response?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 25/03/2022 15:59
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

I am sorry to hear about the cyber attack. I hope all is able to be resolved soon.

Thank you for the update. I am actually working in a different division within FDA and no longer the primary contact for this submission. I believe that the 180 days is automatically granted for responses to AINN hold but you can also confirm with the 510(k) Program staff (510k_Program@fda.hhs.gov, telephone: 301-796-5640) to make sure.

Best,
Michele

Michele Lee, Ph.D.*(she/her/hers)*
Regulatory Science Program Manager
Partnerships to Advance Innovation and Regulatory Science (PAIRS)

Center for Devices and Radiological Health
Office of Strategic Partnerships and Technology Innovation
Division of All Hazards Response, Science, and Strategic Partnerships
U.S. Food and Drug Administration
michele.lee@fda.hhs.gov



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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Friday, March 25, 2022 11:28 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Cc: k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

I'd like to provide an update on our progress with responding to the deficiencies raised on K211878

We were on track to have a deficiency response submitted to the FDA by the 180 day hold period deadline of 2nd April 2022.

However, the organisation performing (b)(4) have been affected (b)(4) As a result, they were unable to complete the testing by our targeted timeline.

Therefore, I just want to confirm that we are still intending to respond to the deficiencies, but we would need to use the second 180 day hold period granted to us through the COVID-19 situation.

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 08/11/2021 22:05
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thanks for your message. I'll need some time to review the teleconference minutes with my team and also obtain some feedback from our consulting toxicologist about the follow up questions. But I wanted to let you know I received your email and you may feel free to check in again next week.

(b)(4)

Regarding the timeline clarification- I am also under the understanding that the COVID-19 guidance document you cited was still active and that would allow you an additional 180 days for the hold period. I have reached out to the 510(k) Staff multiple times to confirm and am still waiting on their response. Is there a customer service contact email for the customer collaboration portal specifically? You may try contacting them as well to have the date corrected on your end.

Thank you,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Friday, November 5, 2021 12:07 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hello Michele

I hope you had a nice holiday!

Following on from the teleconference we had a few actions to complete and get back to you with.

1) Teleconference minutes

Please find a draft of the the teleconference minutes below. Could you review and confirm if you require any changes made?

2) Follow-up questions on the teleconference discussion

As suggested during the teleconference there was the opportunity for a followup email clarification on a few minor points.

(b)(4)

The supporting information which provides further clarity on the questions above has been attached if required.

3) Timeline clarification as per previous email

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Thank you again for your assistance

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>, "Liu, Lixin" <Lixin.Liu@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 20/10/2021 22:43
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hello Michele

Thank you for the prompt response to the clarifications! We'll take your points on board regarding future shelf life studies.

I do have a minor clarification question regarding our response timeline

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 20/10/2021 14:55
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you to you and your team for attending the teleconference yesterday. I wanted to follow up on two things I was discussing with my team:

(b)(4)

I will be on leave for the next two weeks and you may contact our team management (Lixin.Liu@fda.hhs.gov) if you have questions during that time.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/odhcustomerservice?ID=1624&S=E

From: Lee, Michele
Sent: Friday, October 15, 2021 4:47 PM
To: Martin.Mitchell@admedsol.com
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Thank you for providing your questions in advance of the meeting. We look forward to discussing our responses with you next week.

Have a good weekend,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/odhcustomerservice?ID=16244&S=E

From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Friday, October 15, 2021 12:00 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Please find the list of questions/clarifications attached below.

I hope you have a good weekend. I'm looking forwards to our discussion next week!

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 13/10/2021 22:35
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Martin,

I have scheduled the teleconference for next Tuesday October 19th at 9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour but our biocompatibility consultant/ team management needs to drop off for another call at 9:30am. Please send me the questions for discussion in advance of the meeting so that we can plan to discuss biocompatibility/ regulatory questions first before the relevant parties need to drop off.

Join Zoom Meeting

One tap mobile:
Meeting URL:
Meeting ID:
Passcode:

(b)(4)

Join by Telephone

For higher quality, dial a number based on your current location.
Dial:

Meeting ID:
Passcode:

(b)(4)

International numbers

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Join from an H.323/SIP room system
H.323:

Meeting ID:
Passcode:
SIP:
Passcode:

(b)(4)

Thanks,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 13, 2021 4:46 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Apologies Michele, one final thing I missed off my email... could you clarify how long the teleconference would be by default? Could we request 1 hour just incase some of the points end up taking longer to discuss?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 13/10/2021 20:35
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hi Michele

We're currently preparing our questions for the teleconference and will send these through in due course, however to assist with scheduling the relevant parties at FDA, I should let you know that we would definitely like to discuss the questions related to biocompatibility.

After discussion with the team we would like to request the teleconference on the Tuesday 19th October if that is possible? As we are based in the UK, we would also like to request that this is arranged between the hours of 2-5pm BST.

If this time slot is not available could you outline any alternative days/times which would be possible?

Best regards,

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Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 08/10/2021 22:14
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hi Michele

Thank you for the offer. I think after today's meeting we may need a little more time to be better prepared for the teleconference.

We are reaching out to the **(b)(4)** for us as we feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible dates for you early next week.

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 06/10/2021 13:49
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference deadline up to October 19th. Let me know if you would like to select a date later than the 14thand I can check our management schedules.

Regarding review timelines, we are still on the 90 day review cycle and are planning to complete the review of your response with the 20 calendar days left on the clock. While we retain the right to add additional days, we are doing our best with the resources that we have to avoid delaying review timelines if possible.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 6, 2021 6:00 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com
Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Thank you again for your review. Our team are busy discussing the questions and we would definitely like to have a teleconference with the FDA. We're currently consolidating our understanding of the deficiencies and are determining what our potential questions to you would be. I hope to get the questions to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we look to schedule a teleconference with the FDA on Wednesday 13th or Thursday 14th? As we're based in the UK we would appreciate a timeslot within our working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines for this project.... regarding the FDA timeline I can see on the CCP tracker website that the FDA timeline is on day 70.

- Will FDA be sticking to the 90 day target and as a result only have 20 days left on the clock?
- Or, due to the current situation with the unprecedented resource limitations..... will you will assume 30 days to review the response as standard? Or perhaps stick to the 20 days but retain the right to add additional days?

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
To: <martin.mitchell@admedsol.com>, <helen.topping@admedsol.com>
Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
Date: 04/10/2021 21:44
Subject: K211878/S001 is on Hold Pending Your Response

October 4, 2021

We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Michele Lee.

*** This is a system-generated email notification ***[attachment "K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Hi Sam

For your ease of reference, please find

our response to deficiency (b)(4)

(b)(4)

(b)(4)

As requested I've highlighted the teleconference

meeting minutes showing the FDA agreement to use the more clinically relevant

(b)(4)

IFU

I've also highlighted and provided the

pertinent pages from the (b)(4)

(b)(4)

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions

Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From:

 Martin Mitchell/WIN/UK/AMS
To:

 "Arepalli, Sambasiva"

<Sambasiva.Arepalli@fda.hhs.gov>
Cc:

 "K211878@docs.fda.gov"

<K211878@docs.fda.gov>, Rose Guang/WIN/UK/AMS@ams
Date:

 19/05/2022 10:17
Subject:

   RE: [EXTERNAL]

Re: K211878-s002
<hr noshade>

Hi Sam

I'll call you today at 6am (11am UK

time); we thought it would be better to send you the updated documents

to help aid the discussion during the call.

The IFU has been updated with your comments

(and as per our modifications we suggest below). I've provided a redlined

and clean copy of this:
[attachment "IFU - LiquiBand XL.pdf"

deleted by Martin Mitchell/WIN/UK/AMS] [attachment "IFU - LiquiBand

XL - Tracked.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

The 510(k) summary has been updated

with your comments
[attachment "510K Summary.pdf"

deleted by Martin Mitchell/WIN/UK/AMS]

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions

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Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From:

 Martin Mitchell/WIN/UK/AMS
To:

 "Arepalli, Sambasiva"

<Sambasiva.Arepalli@fda.hhs.gov>
Cc:

 "K211878@docs.fda.gov"

<K211878@docs.fda.gov>, Rose Guang/WIN/UK/AMS@ams
Date:

 18/05/2022 22:37
Subject:

   RE: [EXTERNAL]

Re: K211878-s002
<hr noshade>

Hi Sam

Firstly, thank you for staying late

to continue to work with us on in the final stages of this submission.

It is much appreciated.

Please find attached the IFU with updated

comments from ourselves

[attachment "K211878-S002 - Revised

labeling received on 5-16-2022.jam.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

For most of the proposed updates we

will accept to make the changes. However there are two points we would

wish to clarify
Regarding the comment on

(b)(4)

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(b)(4)

(b)(4)
As discussed I'll call you tomorrow

to discuss your email below

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions

Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From:

 "Arepalli, Sambasiva"

<Sambasiva.Arepalli@fda.hhs.gov>
To:

 "Martin.Mitchell@admedsol.com"

<Martin.Mitchell@admedsol.com>
Cc:

 "Arepalli, Sambasiva"

<Sambasiva.Arepalli@fda.hhs.gov>, "K211878@docs.fda.gov"

<K211878@docs.fda.gov>
Date:

 18/05/2022 20:39
Subject:

   RE: [EXTERNAL]

Re: K211878-s002
<hr noshade>

Hi Mr. Mitchell:
Please see attached for the (b)(4) and

(b)(4) with FDA edits.

Please address these edits and send me

both the edited versions and clean copies of the (b)(4)

by COB tomorrow (5-19-2022).

Please cc your response to K211878@docs.fda.gov.

Thx
Sam

Sam Arepalli, Ph.D.
FDA/CDRH/OPEQ/OHT4/PRSB2
Ph: 301 796 6434

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regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u><u></u>

<font size=2

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face="Calibri">
From:
Martin.Mitchell@admedsol.com

<Martin.Mitchell@admedsol.com>
Sent: Tuesday, May 17, 2022 6:39
AM
To: Arepalli, Sambasiva
<Sambasiva.Arepalli@fda.hhs.gov>
Subject: RE: [EXTERNAL] Re: K211878-
s002

<font size=2 color=#806210
face="Calibri">CAUTION:This email originated from
outside of the organization. Do not click links

or open attachments unless you recognize the sender and know the content

is safe.

<font size=2
face="Arial">Hi Sam
<font size=2
face="Arial">
Just to be safe for the email trail.... so that your email has a
response

The
email with this information was send yesterday; however it is also

provided again below:
<font size=2
face="Arial">
Please find a response to the two points we discussed over the
phone

FDA
deficiency 13
<font size=2
face="Arial">
As discussed over the call it can be clarified (b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

face="Calibri">

Best
regards,
<font size=2 color=#000080
face="Arial">
Martin Mitchell
Regulatory Affairs Manager
<font size=2 color=#000080
face="Arial">
Advanced Medical Solutions Ltd.
E-mail: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=2 color=#000080
face="Arial">
Tel: +44 (0) 1752 30 9360<font size=2
face="Calibri">

From:
       "Arepalli,

Sambasiva" <<font size=1
color=blue face="Arial"><u>Sambasiva.Arepalli@fda.hhs.gov</u><font size=1
face="Arial">>
To:
   "<a
href=mailto:Martin.Mitchell@admedsol.com><font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">>
Date:
   17/05/2022

10:32
Subject:
 RE:

[EXTERNAL] Re: K211878-s002 <hr noshade>
<font size=2
face="Calibri">

Hi Mr. Mitchell:
Can
you please give an update on the (b)(4) request? Could you

please send the information cob today? Please give me a call when you have

a minute.
Thx
Sam

Sam Arepalli, Ph.D.
FDA/CDRH/OPEQ/OHT4/PRSB2
Ph:
301 796 6434

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to provide feedback regarding the customer service you have received: <a
href="https://secure-
web.cisco.com/1v_0OwI01XyYIrR5QdcqPvkNkCoDtTGQHdIwHOyFmN5FDUBpuZ7wV3E9sq3sVmjZ84S9zyo-
1AgUmtlHaHzRPrVzusabtYklNemledc4HXtEHQ5xuvnggUn_UozBChwj4Ax2HmZ0FPJQAoj0c4yj4TSsiTFAame
lBPTtkLNiJ-
nvaNSabNX2MdWjf4pFySXsD/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3
D1624%26S%3DE"><font size=2 color=#0082bf
face="Calibri"><u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u></f
ont>

From: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri"><<font size=2
color=blue face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri">>

Sent: Monday, May 16, 2022 12:06 PM
To: Arepalli, Sambasiva
<<font size=2 color=blue
face="Calibri"><u>Sambasiva.Arepalli@fda.hhs.gov</u><font size=2
face="Calibri">>
Subject: [EXTERNAL] Re: K211878-s002

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recognize the sender and know the content is safe.

Hi Sam

Just so you're aware it's 17:00 now so i'll be heading home; however i'll

try to make myself available outside of hours so please don't hesitate

to get in touch if you have any further questions.

Additionally i'll be working from home the next few days so I won't pick

up calls from my office number you used previously.

If you have any further questions please email me or call me on my personal

mobile number (b)(6)

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: Martin

Mitchell/WIN/UK/AMS
To: "Arepalli,

Sambasiva" <<u>Sambasiva.Arepalli@fda.hhs.gov</u>>
Cc: "<u>K211878@docs.fda.gov</u>"

<<u>K211878@docs.fda.gov</u>>,

Rose Guang/WIN/UK/AMS@ams, Helen Topping/WIN/UK/AMS@ams
Date: 16/05/2022

16:28
Subject: Re:

K211878-s002 <hr noshade>

Hi Sam

Please find a response to the two points we discussed over the phone

FDA deficiency 13

As discussed over the call it can be clarified that (b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Arepalli,

Sambasiva" <<u>Sambasiva.Arepalli@fda.hhs.gov</u>>
To: "<u>Martin.Mitchell@admedsol.com</u>"

<<u>Martin.Mitchell@admedsol.com</u>>
Cc: "Arepalli,

Sambasiva" <<u>Sambasiva.Arepalli@fda.hhs.gov</u>>,

"<u>K211878@docs.fda.gov</u>"

<<u>K211878@docs.fda.gov</u>>
Date: 16/05/2022

14:39
Subject: K211878-s002 <hr noshade>

Hi Mr. Martin:
Please address the following:
Please revise the (b)(4) to say: (b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Ph.D.
FDA/CDRH/OPEQ/OHT4/PRSB2
Ph: 301 796 6434

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to provide feedback regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

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recipient, please notify the sender immediately and delete it from your

mailbox or any other storage mechanism.[attachment "K211878-S002 -

Revised labeling received on 5-16-2022.jam.pdf" deleted by Martin

Mitchell/WIN/UK/AMS] [attachment "K211878.510kSummary(Final).jam.pdf"

deleted by Martin Mitchell/WIN/UK/AMS]

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(b)(4)

CONFIDENTIAL

Pre Clinical Evaluation of the Safety and Performance of the Advanced Medical Solutions Device LiquiBand XL in a (b)(4)

STUDY REPORT

STUDY NO.

(b)(4)

ETHICAL APPROVAL NO.

(b)(4)

Study Sponsor:

Advanced Medical Solutions Ltd

2 Western Wood Way | Langage Science Park | Plymouth | PL7 5BG | UK

Testing Facility:

(b)(4)

Issue date: May 16, 2021

Total No. of Pages: 74

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Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Hi Martin,

Yes, this file landed in the Teamâ€™s queue today, and Iâ€™ll assign a new Lead Reviewer today.

Regards,

Julie

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Thursday, May 5, 2022 5:43 AM

To: Morabito, Julie <Julie.Morabito@fda.hhs.gov>

Cc: Helen.Topping@admedsol.com; k211878@docs.fda.gov; Rose.Guang@admedsol.com

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Julie

I've seen on the customer collaboration portal that our response has been acknowledged by the FDA and the clock has started moving.

Can we assume that a new reviewer has been successfully assigned?

[cid:image001.gif@01D8605F.A8A7D2C0]

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Morabito, Julie" <Julie.Morabito@fda.hhs.gov<mailto:Julie.Morabito@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "Helen.Topping@admedsol.com<mailto:Helen.Topping@admedsol.com>" <Helen.Topping@admedsol.com<mailto:Helen.Topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>, "Rose.Guang@admedsol.com<mailto:Rose.Guang@admedsol.com>" <Rose.Guang@admedsol.com<mailto:Rose.Guang@admedsol.com>>, "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Date: 14/04/2022 01:01

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Hello Martin,

Thanks for reaching out. Iâ€™ll be glad to assist in answering your questions.

* Will there be any delays in assigning a new reviewer?

We do not anticipate a delay in assigning a new reviewer.

* Are there still resource constraints at the FDA?

Speaking regarding our team, we are still working through resource constraints and doing our best to meet deadlines.

* Would a new reviewer who is not familiar with the product/deficiencies require a longer period of time to perform the review?

We will do our best to align the new reviewer that is familiar and experienced with the review product, to limit delay to the extent possible.

I hope this is helpful, but please let me know if youâ€™d like to discuss further.

Best,

Julie

Julie Morabito, PhD, RAC (she/her/hers)

Assistant Director

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4668 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (240) 402-3839 | Cell: (b)(6)

julie.morabito@fda.hhs.gov<mailto:julie.morabito@fda.hhs.gov>

Formerly:

Assistant Director, Outreach and Partnerships Team 2 (MedSun)

DCEA1: Division of Clinical Science and Quality | OCEA: Office of Clinical Evidence and Analysis

Office of Product Evaluation and Quality

[cid:image002.png@01D8605F.A8A7D2C0]<http://www.fda.gov/>

[cid:image003.jpg@01D8605F.A8A7D2C0]<https://www.facebook.com/FDA>
[cid:image004.jpg@01D8605F.A8A7D2C0] <https://twitter.com/US_FDA>
[cid:image005.jpg@01D8605F.A8A7D2C0] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image006.jpg@01D8605F.A8A7D2C0] <http://www.flickr.com/photos/fdaphotos/>
[cid:image007.jpg@01D8605F.A8A7D2C0]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>
<Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Wednesday, April 13, 2022 3:32 PM

To: Morabito, Julie <Julie.Morabito@fda.hhs.gov<mailto:Julie.Morabito@fda.hhs.gov>>

Cc: Helen.Topping@admedsol.com<mailto:Helen.Topping@admedsol.com>;
k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>;
Rose.Guang@admedsol.com<mailto:Rose.Guang@admedsol.com>; Lee, Michele
<Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele and Julie

Thank you Michele for providing further clarification on the matter regarding maintenance of a lead reviewer. We are sad to lose you as our lead reviewer and wish you the best in your new role within the FDA.

During the initial review of the 510(k) it was flagged that the FDA had resource challenges which resulted in the review taking 70 days instead of the targeted 60 days....When we discussed this previously it was stated that when we submit our deficiency response the FDA would still target to complete the review within the remaining 20 days, however.... it was also flagged that if resource constraints still existed this could take longer than 20 days.

To keep the FDA informed about our progress we are planning to submit our response to the deficiency questions in around 3 weeks time. We would like to enquire about FDA's ability to complete the review within 20 days?

* Will there be any delays in assigning a new reviewer?

* Are there still resource constraints at the FDA?

* Would a new reviewer who is not familiar with the product/deficiencies require a longer period of time to perform the review?

The timely completion of your review would be massively appreciated as the large wound market is critical to urgent patient demand, AMS and our partners who are very keen to provide the improved product to hospitals across the United States.

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>"
<Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>"

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
<k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>,
"Rose.Guang@admedsol.com<mailto:Rose.Guang@admedsol.com>"
<Rose.Guang@admedsol.com<mailto:Rose.Guang@admedsol.com>>,
"Helen.Topping@admedsol.com<mailto:Helen.Topping@admedsol.com>"
<Helen.Topping@admedsol.com<mailto:Helen.Topping@admedsol.com>>, "Morabito, Julie"
<Julie.Morabito@fda.hhs.gov<mailto:Julie.Morabito@fda.hhs.gov>>

Date: 05/04/2022 14:47

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

Unfortunately, it is not possible for me to take on lead review of this submission. As previously mentioned, I am currently working in another Office within FDA and do not conduct premarket reviews of medical devices in my current role.

It is not uncommon for new lead reviewers to be assigned to submissions returning from hold. The internal documentation serves as a complete record of the previous interactions during prior review of a submission. If you have further questions regarding the review process for your submission, you may contact the Assistant Director for the Plastic Surgery Skin & Wound Devices Team, Dr. Julie Morabito (Julie.Morabito@fda.hhs.gov<mailto:Julie.Morabito@fda.hhs.gov>).

Best,

Michele

Michele Lee, Ph.D.(she/her/hers)

Regulatory Science Program Manager

Partnerships to Advance Innovation and Regulatory Science (PAIRS)

Center for Devices and Radiological Health

Office of Strategic Partnerships and Technology Innovation

Division of All Hazards Response, Science, and Strategic Partnerships

U.S. Food and Drug Administration

michele.lee@fda.hhs.gov<mailto:michele.lee@fda.hhs.gov>

[cid:image002.png@01D8605F.A8A7D2C0]<http://www.fda.gov/>

[cid:image003.jpg@01D8605F.A8A7D2C0]<https://www.facebook.com/FDA>[cid:image004.jpg@01D8605F.A8A7D2C0]<https://twitter.com/US_FDA> [cid:image005.jpg@01D8605F.A8A7D2C0]
<http://www.youtube.com/user/USFoodandDrugAdmin> [cid:image006.jpg@01D8605F.A8A7D2C0]
<http://www.flickr.com/photos/fdaphotos/> [cid:image007.jpg@01D8605F.A8A7D2C0]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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https://www.research.net/s/cdrhcustomerservice?ID=7013&S=E.

From:
Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Sent: Tuesday, April 5, 2022 8:31 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>;
Rose.Guang@admedsol.com<mailto:Rose.Guang@admedsol.com>;
Helen.Topping@admedsol.com<mailto:Helen.Topping@admedsol.com>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele,

We have been pleased to have you as the lead reviewer for RTA review, technical review, and responses to deficiency discussions since July 2021, as well as having you for the review for our previous 510(k) submission of the same product.

(b)(4)

* Jun 2021 - We submitted K211878 (b)(4)

(b)(4)

* Oct 2021 - Further deficiencies were raised on the new K211878 submission

We currently have only 20 days of FDA review time left on our product and have been advised that we will now be assigned a new reviewer. As you can imagine this causing us a high level of concern given you have a detailed knowledge of our submissions and of the current outstanding questions. Our concern being that a new reviewer will not have the same detailed knowledge of our submission or of the outstanding questions and hence this may cause unnecessary further delay.

We have been very satisfied with the support we have received from yourself and we would ask that you remain on our file for the final 20 days if at all possible, or an explanation of why this is not possible with some reassurances that a new assessor will not cause unnecessary delays whilst they gain detailed knowledge of our file.

Your expedited response to this request would be appreciated.

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>"
<Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Cc: "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 25/03/2022 16:47

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Martin,

A new lead reviewer will not be assigned until a follow up submission is received. So there is currently not a primary contact unless there is an active submission under FDA review. All of our correspondence and the prior related review have been documented internally, so you can be assured that the history of the prior review and contact is available to the future lead reviewer.

Best,

Michele

From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Friday, March 25, 2022 12:21 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

I've seen on the FDA customer collaboration portal that the time has automatically been added, but just thought it would be prudent to also inform you of the situation.

Could I ask who the primary contact is now? Will you be assisting or have any involvement with the review of our response?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Cc: "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 25/03/2022 15:59

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Martin,

I am sorry to hear about (b)(4). I hope all is able to be resolved soon.

Thank you for the update. I am actually working in a different division within FDA and no longer the primary contact for this submission. I believe that the 180 days is automatically granted for responses to AINN hold but you can also confirm with the 510(k) Program staff (510k_Program@fda.hhs.gov<mailto:510k_Program@fda.hhs.gov>, telephone: 301-796-5640) to make sure.

Best,

Michele

Michele Lee, Ph.D.(she/her/hers)

Regulatory Science Program Manager

Partnerships to Advance Innovation and Regulatory Science (PAIRS)

Center for Devices and Radiological Health

Office of Strategic Partnerships and Technology Innovation

Division of All Hazards Response, Science, and Strategic Partnerships

U.S. Food and Drug Administration

michele.lee@fda.hhs.gov<mailto:michele.lee@fda.hhs.gov>

[cid:image002.png@01D8605F.A8A7D2C0]<http://www.fda.gov/>

[cid:image003.jpg@01D8605F.A8A7D2C0]<https://www.facebook.com/FDA>[cid:image004.jpg@01D8605F.A8A7D2C0]<https://twitter.com/US_FDA>[cid:image005.jpg@01D8605F.A8A7D2C0]<http://www.youtube.com/user/USFoodandDrugAdmin>[cid:image006.jpg@01D8605F.A8A7D2C0]<http://www.flickr.com/photos/fdaphotos/>[cid:image007.jpg@01D8605F.A8A7D2C0]<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Friday, March 25, 2022 11:28 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

I'd like to provide an update on our progress with responding to the deficiencies raised on K211878

We were on track to have a deficiency response submitted to the FDA by the 180 day hold period deadline of 2nd April 2022.

However, the organisation performing (b)(4) have been affected (b)(4). As a result, they were unable to complete the testing by our targeted timeline.

Therefore, I just want to confirm that we are still intending to respond to the deficiencies, but we would need to use the second 180 day hold period granted to us through the COVID-19 situation.

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 08/11/2021 22:05

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Martin,

Thanks for your message. Iâ€™ll need some time to review the teleconference minutes with my team and also obtain some feedback from our consulting toxicologist about the follow up questions. But I wanted to let you know I received your email and you may feel free to check in again next week.

I do have a clarification question about Follow Up Question #4: Could you please

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Regarding the timeline clarification- I am also under the understanding that the COVID-19 guidance document you cited was still active and that would allow you an additional 180 days for the hold period. I have reached out to the 510(k) Staff multiple times to confirm and am still waiting on their response. Is there a customer service contact email for the customer collaboration portal specifically? You may try contacting them as well to have the date corrected on your end.

Thank you,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image002.png@01D8605F.A8A7D2C0]<http://www.fda.gov/>

[cid:image003.jpg@01D8605F.A8A7D2C0]<https://www.facebook.com/FDA>[cid:image004.jpg@01D8605F.A8A7D2C0]<https://twitter.com/US_FDA>[cid:image005.jpg@01D8605F.A8A7D2C0]<http://www.youtube.com/user/USFoodandDrugAdmin>[cid:image006.jpg@01D8605F.A8A7D2C0]<http://www.flickr.com/photos/fdaphotos/>[cid:image007.jpg@01D8605F.A8A7D2C0]<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Friday, November 5, 2021 12:07 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

I hope you had a nice holiday!

Following on from the teleconference we had a few actions to complete and get back to you with.

1) Teleconference minutes

Please find a draft of the the teleconference minutes below. Could you review and confirm if you require any changes made?

2) Follow-up questions on the teleconference discussion

As suggested during the teleconference there was the opportunity for a followup email clarification on a few minor points.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

The supporting information which provides further clarity on the questions above has been attached if required.

3) Timeline clarification as per previous email

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Thank you again for your assistance

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>, "Liu, Lixin" <Lixin.Liu@fda.hhs.gov<mailto:Lixin.Liu@fda.hhs.gov>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 20/10/2021 22:43

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hello Michele

Thank you for the prompt response to the clarifications! We'll take your points on board regarding future shelf life studies.

I do have a minor clarification question regarding our response timeline

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 20/10/2021 14:55

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

Thank you to you and your team for attending the teleconference yesterday. I wanted to follow up on two things I was discussing with my team:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

I will be on leave for the next two weeks and you may contact our team management (Lixin.Liu@fda.hhs.gov<mailto:Lixin.Liu@fda.hhs.gov>) if you have questions during that time.

Best,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image002.png@01D8605F.A8A7D2C0]<http://www.fda.gov/>

[cid:image003.jpg@01D8605F.A8A7D2C0]<https://www.facebook.com/FDA>[cid:image004.jpg@01D8605F.A8A7D2C0]<https://twitter.com/US_FDA>[cid:image005.jpg@01D8605F.A8A7D2C0]<http://www.youtube.com/user/USFoodandDrugAdmin>[cid:image006.jpg@01D8605F.A8A7D2C0]<http://www.flickr.com/photos/fdaphotos/>[cid:image007.jpg@01D8605F.A8A7D2C0]<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: Lee, Michele

Sent: Friday, October 15, 2021 4:47 PM

To: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you for providing your questions in advance of the meeting. We look forward to discussing our responses with you next week.

Have a good weekend,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

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[cid:image003.jpg@01D8605F.A8A7D2C0]<https://www.facebook.com/FDA>[cid:image004.jpg@01D8605F.A8A7D2C0]<https://twitter.com/US_FDA>[cid:image005.jpg@01D8605F.A8A7D2C0]<http://www.youtube.com/user/USFoodandDrugAdmin>[cid:image006.jpg@01D8605F.A8A7D2C0]<http://www.flickr.com/photos/fdaphotos/>[cid:image007.jpg@01D8605F.A8A7D2C0]<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Friday, October 15, 2021 12:00 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Please find the list of questions/clarifications attached below.

I hope you have a good weekend. I'm looking forwards to our discussion next week!

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 13/10/2021 22:35

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

I have scheduled the teleconference for next Tuesday October 19that 9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour but our biocompatibility consultant/ team management needs to drop off for another call at 9:30am. Please send me the questions for discussion in advance of the meeting so that we can plan to discuss biocompatibility/ regulatory questions first before the relevant parties need to drop off.

Join Zoom

(b)(4)

Join by Telephone

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Thanks,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

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Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

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[cid:image003.jpg@01D8605F.A8A7D2C0]<https://www.facebook.com/FDA>[cid:image004.jpg@01D8605F.A8A7D2C0]<https://twitter.com/US_FDA>[cid:image005.jpg@01D8605F.A8A7D2C0]<http://www.youtube.com/user/USFoodandDrugAdmin>[cid:image006.jpg@01D8605F.A8A7D2C0]<http://www.flickr.com/photos/fdaphotos/>[cid:image007.jpg@01D8605F.A8A7D2C0]<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Wednesday, October 13, 2021 4:46 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Apologies Michele, one final thing I missed off my email... could you clarify how long the teleconference would be by default? Could we request 1 hour just incase some of the points end up taking longer to discuss?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 13/10/2021 20:35

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hi Michele

We're currently preparing our questions for the teleconference and will send these through in due course, however to assist with scheduling the relevant parties at FDA, I should let you know that we would definitely like to discuss the questions related to biocompatibility.

After discussion with the team we would like to request the teleconference on the Tuesday 19th October if that is possible? As we are based in the UK, we would also like to request that this is arranged between the hours of 2-5pm BST.

If this time slot is not available could you outline any alternative days/times which would be possible?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 08/10/2021 22:14

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hi Michele

Thank you for the offer. I think after today's meeting we may need a little more time to be better prepared for the teleconference.

We are reaching out to the **(b)(4)** for us as we feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible dates for you early next week.

Best regards,

Martin Mitchell

Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 06/10/2021 13:49

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference deadline up to October 19th. Let me know if you would like to select a date later than the 14thand I can check our management schedules.

Regarding review timelines, we are still on the 90 day review cycle and are planning to complete the review of your response with the 20 calendar days left on the clock. While we retain the right to add additional days, we are doing our best with the resources that we have to avoid delaying review timelines if possible.

Best,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

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[cid:image003.jpg@01D8605F.A8A7D2C0]<https://www.facebook.com/FDA>[cid:image004.jpg@01D8605F.A8A7D2C0]<https://twitter.com/US_FDA>[cid:image005.jpg@01D8605F.A8A7D2C0]<http://www.youtube.com/user/USFoodandDrugAdmin>[cid:image006.jpg@01D8605F.A8A7D2C0]<http://www.flickr.com/photos/fdaphotos/>[cid:image007.jpg@01D8605F.A8A7D2C0]<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Wednesday, October 6, 2021 6:00 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>

Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Thank you again for your review. Our team are busy discussing the questions and we would definitely like to have a teleconference with the FDA. We're currently consolidating our understanding of the deficiencies and are determining what our potential questions to you would be. I hope to get the questions to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we look to schedule a teleconference with the FDA on Wednesday 13th or Thursday 14th? As we're based in the UK we would appreciate a timeslot within our working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines for this project.... regarding the FDA timeline I can see on the CCP tracker website that the FDA timeline is on day 70.

* Will FDA be sticking to the 90 day target and as a result only have 20 days left on the clock?

* Or, due to the current situation with the unprecedented resource limitations..... will you will assume 30 days to review the response as standard? Or perhaps stick to the 20 days but retain the right to add additional days?

Best regards,

Martin Mitchell

Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov<mailto:michele.lee@fda.hhs.gov>>

To: <martin.mitchell@admedsol.com<mailto:martin.mitchell@admedsol.com>>, <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>

Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov<mailto:michele.lee@fda.hhs.gov>>

Date: 04/10/2021 21:44

Subject: K211878/S001 is on Hold Pending Your Response

October 4, 2021

We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Michele Lee.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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*** This is a system-generated email notification ***[attachment "K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

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Dear Michele,

many thanks for sending the invite.

I fear, IÂ´ve made a mistake, when communicating the time.

Could we schedule one hour earlier?

Kind regards.

(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov>

Sent: Freitag, 5. November 2021 15:59

To: (b)(4) k211878@docs.fda.gov

Cc: (b)(4)

(b)(4)

Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

This message is from an EXTERNAL SENDER â€" be CAUTIOUS, particularly with links and attachments

---

Hello (b)(4)

Sure, we can discuss via teleconference on 10 Nov 2021 at 7pm UTC+1/ 2pm EDT. I sent a ZoomGov invite via email and also copied the call-in information below.

[Image removed by sender.]<https://zoom.us/>

Hi there,

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov> is inviting you to a scheduled ZoomGov meeting.

Join Zoom

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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One tap mobile:

(b)(4)

Join by Telephone

For higher quality, dial a number based on your current location.

(b)(4)

Best Regards,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

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[cid:image005.jpg@01D7D25E.66D7DAA0] <http://www.flickr.com/photos/fdaphotos/>
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From: (b)(4)

Sent: Friday, November 5, 2021 10:10 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>; k211878@docs.fda.gov

Cc: (b)(4)
(b)(4); Martin.Mitchell@admedsol.com

Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Dear Michele,

Many thanks for your message.

Martin, thank you for the connection.

Michele, would you be available next Wednesday, 10 November 2021, at 7 pm (UTC+1)?

Then I would send an invitation.

Kind regards.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Sent: Freitag, 5. November 2021 14:33

To: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Cc: (b)(4)

(b)(4)

Subject: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

This message is from an EXTERNAL SENDER â€" be CAUTIOUS, particularly with links and attachments

---

Hello all,

Thank you, Martin, for the connection.

(b)(4)

Best Regards,

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

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[cid:image005.jpg@01D7D25E.66D7DAA0] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D7D25E.66D7DAA0]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com> <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Thursday, November 4, 2021 11:29 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Cc: (b)(4)

(b)(4)

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

Regarding the recent deficiency question on our medical device submission which is currently under review with the FDA:

(b)(4)

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
your mailbox or any other storage mechanism.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hello (b)(4)

(b)(4)

Best Regards,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: (b)(4)
Sent: Friday, November 12, 2021 4:39 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>; k211878@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211878

Device Name
LiquiBand® XL

Indications for Use *(Describe)*
LiquiBand® XL is intended for topical application only to hold closed easily approximated skin edges of wounds from surgical incisions, including incisions from minimally invasive surgery, and simple, thoroughly cleansed, trauma-induced lacerations. LiquiBand® XL should be used in conjunction with, but not in place of, deep dermal stitches. Additionally, the adjunct wound closure device component maintains temporary skin edge alignment along the length of the wound during application of the liquid adhesive.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Hello Martin:

I want to inform you of a slightly revised review timeline for your 510(k) submission K211878/S001. Due to a limitation of Agency resources, we are unable to complete the substantive review by September 24th. We want to inform you that we expect to complete the review by next Wednesday, September 29th. We apologize for any inconveniences because of the extension of timeline.

Best Regards,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov



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Hello Martin,

I have forwarded your question on to my management and will let you know when I receive their feedback.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
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CDRH | Food and Drug Administration
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Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Wednesday, December 1, 2021 12:05 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: k211878@docs.fda.gov
Subject: RE: [EXTERNAL] K211878 timeline - COVID-19

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Hi Michele

I have a further question regarding how COVID affects timelines below.

Knowing that FDA have are allowing a further 180 day timeline to respond to deficiencies due to COVID.... is there any scope or provision for timeline adjustments relating to a SIR review time?

More specifically, regarding an SIR submission i've seen in the guidance document that if the SIR is received before the 60 day timepoint after issuance of the deficiency letter, this would result in a 21 day FDA review time; whereas if we submit the SIR after this date this results in a 70 day FDA review time.

We have faced some delays in being able to meet the deadline of submitting an SIR before the 60 day timepoint. Where, we've spent some time liasing with yourselves through teleconference and email about the issues noted and covid has impacted our ability and our toxicologists ability to move quickly on these matters.

Therefore I'd like to enquire as to whether the FDA are allowing extensions to the time to receive an SIR (currently 60 days after issuance of the deficiency) where the SIR would still receive a 21 day FDA review time?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 16/11/2021 19:03
Subject: RE: [EXTERNAL] K211878 timeline - COVID-19

Hello Martin,

Thanks for the update and good to know this information. I also received your previous email with additional information about the test parameters of the degradation & extraction studies. I am still waiting on feedback from our consulting toxicologist but hope to have more information to provide you mid next week.

Best,

Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov



* * * * *

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https://www.research.net/s/odhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Monday, November 15, 2021 3:54 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Subject: Fw: [EXTERNAL] K211878 timeline - COVID-19

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Hi Michele

I got an update regarding timeline from the CCP email address.

FYI we are exploring a number of backup strategies to **(b)(4)**. and some of these take us past the 180 day hold period.

As per the request below, I'll let you know closer to the time if we end up needing to request the additional 180 days.

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

---- Forwarded by Martin Mitchell/WIN/UK/AMS on 15/11/2021 08:31 ----

From: "CCP" <CCP@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Date: 12/11/2021 21:08
Subject: RE: [EXTERNAL] K211878 timeline - COVID-19

Good day to you Martin,

The extra 180 days for response are added as needed, and then only shortly before the original 180 days expires.

--
Happy trails,
~Nels Anderson
Regulatory Systems & Data Management Staff
Center for Devices and Radiological Health | Office of Product Evaluation and Quality| Office of Regulatory Programs

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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Friday, November 12, 2021 09:49
To: CCP <CCP@fda.hhs.gov>
Subject: [EXTERNAL] K211878 timeline - COVID-19

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Hello

Regarding the timeline showing for K211878 I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I (and the lead reviewer Michele Lee) were under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify that the 180 timeline in the customer collaboration portal won't trigger premature closure of the 510(k) before the actual 360 day timeline expires?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

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Advanced Medical Solutions Ltd

Advanced Medical Solutions Ltd
Western Wood Way,
Langage Science Park,
Plympton, Plymouth,
Devon, PL7 5BG, UK
Tel : +44 (0)1752 209955 **Fax :** +44 (0)1752 209956
Web : www.admedsol.com

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center (DCC) – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
USA

FDA/CDRH/DCC
JUN 21 2021
RECEIVED

K211878

Dear Sir/Madam,

Advanced Medical Solutions Limited (AMS) hereby submits this 510(k) Notification for the "LiquiBand® XL Skin Closure System" device in which it is demonstrated that it is substantially equivalent to the predicate "Exofin Fusion Skin Closure System" which was cleared under K191461. This is a new device and as such we have opted to submit this through the traditional 510(k) route.

The history of this device in prior correspondence with the FDA is below:

- (b)(4)
- (b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Advanced Medical Solutions Ltd
Western Wood Way,
Langage Science Park,
Plympton, Plymouth,
Devon, PL7 5BG, UK
Tel : +44 (0)1752 209955 **Fax** : +44 (0)1752 209956
Web : www.admedsol.com

Administrative Information

510(k) type:	Traditional
Device type:	Cutaneous Tissue Adhesive With Mesh
Confidentiality:	AMS Ltd considers the intent to market this device as confidential commercial information and request that it be treated as such by the FDA. AMS Ltd has taken precautions to protect the confidentiality of the intent to market the subject device. We understand the submission of false information is prohibited by 10 U.S.C. 1001 and 21 U.S.C. 331(q).
Regulatory Classification:	21 CFR 878.4011 – Tissue adhesive with adjunct wound closure device for topical approximation of skin
Device Class:	Class II
Panel	General and plastic surgery devices
Product Code:	OMD – Cutaneous tissue adhesive with mesh
FDA document numbers associated with prior formal correspondence	(b)(4)

Primary Correspondent Information

510(k) submitter	Advanced Medical Solutions Limited
Name	Martin Mitchell
Title	Senior Regulatory Affairs Associate
Phone number	+44 (0) 1752 30 9360
Email address	Martin.Mitchell@admedsol.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Advanced Medical Solutions Ltd

Advanced Medical Solutions Ltd
Western Wood Way,
Langage Science Park,
Plympton, Plymouth,
Devon, PL7 5BG, UK
Tel : +44 (0)1752 209955 **Fax :** +44 (0)1752 209956
Web : www.admedsol.com

Design and Use of the Device

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	✓	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		✓
Does the device contain components derived from a tissue or other biologic source?		✓
Is the device provided sterile?	✓	
Is the device intended for single use?	✓	
Is the device a reprocessed single use device?		✓
If yes, does this device type require reprocessed validation data?		N/A
Does the device contain a drug?		✓
Does the device contain a biologic?		✓
Does the device use software?		✓
Does the submission include clinical information?		✓
Is the device implanted?		✓

All of the information necessary for a substantial equivalence determination is included herein. In accordance with 745A(b)(3) of the FD&C Act, this submission has been provided solely in electronic format on a CD.

Thank you in advance for your consideration of our application and if you should you require any additional data in order to reach a determination of substantial equivalence, please do not hesitate to contact me at the contact information provided.

Sincerely,

(b)(6)

14 - JUNE - 2021

Martin Mitchell
Senior Regulatory Affairs Associate

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hello Michele

Thank you for your clarification; we

have reviewed your feedback in line with the (b)(4)

(b)(4)

point.

Could you provide a small clarification

regarding the FDA timeline with regards the RTA issued
I've read a statement in a MDFUA performance

goals document which states "FDA Days begin on the date of receipt

of the submission or of the amendment to the submission that enables the

submission to be accepted 510(k)" Once the RTA is closed and the 510(k)

is accepted.... would Day 1 of the FDA clock remain as the "acknowledgment"

notification date (21st June 2021) or would now change to be the date of

the 510(k) "acceptance" notification?
Best regards,

Martin Mitchell
Senior Regulatory Affairs

Associate

Advanced Medical Solutions

Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From:

 "Lee, Michele"

<Michele.Lee@fda.hhs.gov>
To:

 "Martin.Mitchell@admedsol.com"

<Martin.Mitchell@admedsol.com>
Cc:

 "k211878@docs.fda.gov"

<k211878@docs.fda.gov>
Date:

 09/07/2021 20:12
Subject:

   RE: [EXTERNAL]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Re: K211878 is on Hold Pending Your Response
<hr noshade>

Hello Martin,

Thank you for the additional clarification

requests. If, in (b)(4)

(b)(4)

(b)(4) . Thank

you for bringing this report to my attention.

Best Regards,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices

Team
DHT4B: Division of Infection Control and

Plastic Surgery Devices
OHT4: Office of Surgical and Infection

Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue

| Silver Spring, MD 20993
<u>Michele.Lee@fda.hhs.gov</u>

<img src=cid:_4_0BF0B9EC0BF0B6700050534280258713 width=192 height=43 style="border:0px solid;">
<u>
</u><img src=cid:_2_0BF0BE7C0BF0B6700050534280258713 style="border:0px solid;"> <img src=cid:_2_0BF0C2C80BF0B6700050534280258713 style="border:0px solid;"> <img src=cid:_2_0BF0C7140BF0B6700050534280258713 style="border:0px solid;"> <img src=cid:_2_0BF0CB600BF0B6700050534280258713 style="border:0px solid;"> <img src=cid:_2_0BF0CFAC0BF0B6700050534280258713 style="border:0px solid;">
Excellent customer

service is important to us. Please take a moment to provide feedback

regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

From: Martin.Mitchell@admedsol.com

<Martin.Mitchell@admedsol.com>
Sent: Wednesday, July 7, 2021 11:19 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Subject: [EXTERNAL] Re: K211878 is on Hold Pending Your Response

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is safe.

<font size=2
face="Arial">Hi Michele
<font size=2
face="Arial">
Nice to see we're working with you again.<font size=2
face="Calibri">

I was a little surprised
regarding the RTA decision as the level of information

we've provided is the same as that which was provided in previous submissions,

where we didn't receive an RTA from yourself. Therefore, I just wanted

to reach out to you to ensure that I correctly answer the issue so as to

avoid any further delays.
<font size=2
face="Arial">
Regarding the RTA on question B.12(a) <font size=2
face="Calibri">

In section 15.3 of the 510(k),
we reference (b)(4)

(b)(4). I am wondering if

this would be sufficient to address the point which you raised? <font size=2
face="Calibri">

Regarding the RTA on
(b)(4)

We require no clarification on this point and can
provide the documents

as requested.
<font size=2
face="Arial">
Thanks in advance for your assistance<font size=2
face="Calibri">

Best regards,

Martin Mitchell

Senior Regulatory Affairs Associate
Advanced Medical Solutions Ltd.

Tel: +44 (0) 1752 30 9360
E-mail: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri">

From:
       "Michele

Lee [MICHELE.LEE]" <<font size=1
color=blue face="Arial"><u>michele.lee@fda.hhs.gov</u><font size=1
face="Arial">>
To:
   <<a
href=mailto:martin.mitchell@admedsol.com><font size=1 color=blue
face="Arial"><u>martin.mitchell@admedsol.com</u><font size=1
face="Arial">>
Cc:
   "Michele

Lee [MICHELE.LEE]" <<font size=1
color=blue face="Arial"><u>michele.lee@fda.hhs.gov</u><font size=1
face="Arial">>
Date:
   06/07/2021

20:49
Subject:
 K211878

is on Hold Pending Your Response <hr noshade>

July 6,
2021Acceptance Review Notification

- Refuse To Accept (RTA) <p>We have completed the
administrative acceptance review

of your submission K211878. Our review indicates that your submission does

not meet the criteria established for administrative completeness. Thus,

we regret to inform you that we are unable to conduct a substantive review

of your submission at this time and are placing it on RTA hold. <p>Please submit one eCopy of your response, referencing your

submission K211878, addressing the elements identified as missing or inconsistent

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in the attached checklist to:<p>U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002<p>Your submission will remain on hold for a maximum of 180

days from the date of this email. If you do not correct the missing or

inconsistent elements identified in the checklist by 01/02/2022, we will

consider this submission to be withdrawn, and we will delete it from our

review system.<p>Upon receipt of the requested information, FDA will conduct

another administrative review of your submission. We will contact you if

we require any additional information during the course of our administrative

review. FDA aims to apply <u>the

least burdensome principles</u> when requesting

additional information. <p>The lead reviewer assigned to your submission is me, Michele

Lee. The file is being reviewed in Office of Health Technology 4, Division

of Health Technology 4 B. The first line supervisor is the Assistant Director,

Plastic Surgery Skin and Wound Devices. You may contact me at any point

during the review if you have questions or concerns. You can provide valuable

support for CDRH to continue to improve our programs by raising to the

attention of management relevant issues that arise during the course of

this review. If you feel there is an unresolved issue or a matter that

requires additional attention, you should contact the Assistant Director.

If your concern or issue is not addressed by the Assistant Director, you

should contact the Division Director or OHT Director. The contact information

for each management level can be found in the <u>CDRH

Management Directory</u>.<p>For additional information about the Refuse to Accept Policy

for for 510(k)s please refer to the guidance document available at <u>http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf</u>.

<p>If you have general questions about the review process

for your submission, you should contact <u>OPEQSubmissionSupport@fda.hhs.gov</u>.

<p> <p>*** This is a system-generated email notification ***[attachment

"K211878.RTAChecklist.RTA1.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

<p>

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

May 23, 2022

Advanced Medical Solutions Limited
Martin Mitchell
Senior Regulatory Affairs Associate
Western Wood Way , Langage Science Park
Plymouth, Devon PL7 5BG
United Kingdom

Re: K211878
Trade/Device Name: LiquiBand® XL
Regulation Number: 21 CFR 878.4011
Regulation Name: Tissue Adhesive With Adjunct Wound Closure Device For Topical Approximation Of Skin
Regulatory Class: Class II
Product Code: OMD
Dated: May 4, 2022
Received: May 4, 2022

Dear Martin Mitchell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Julie A. Morabito -S

Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Apologies Michele, one final thing I missed

off my email... could you clarify how long the teleconference would be

by default? Could we request 1 hour just incase some of the points end

up taking longer to discuss?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions

Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From:

 Martin Mitchell/WIN/UK/AMS
To:

 "Lee, Michele"

<Michele.Lee@fda.hhs.gov>
Cc:

 "helen.topping@admedsol.com"

<helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date:

 13/10/2021 20:35
Subject:

   RE: [EXTERNAL]

Re: K211878/S001 is on Hold Pending Your Response
<hr noshade>

Hi Michele

We're currently preparing our questions

for the teleconference and will send these through in due course, however

to assist with scheduling the relevant parties at FDA, I should let you

know that we would definitely like to discuss the questions related to

biocompatibility.

After discussion with the team we would

like to request the teleconference on the Tuesday

19th October if that is possible?

As we are based in the UK, we would also like to request that this is arranged

between the hours of 2-5pm

BST.

If this time slot is not available could

you outline any alternative days/times which would be possible?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions

Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From:

 Martin Mitchell/WIN/UK/AMS
To:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

 "Lee, Michele"

<Michele.Lee@fda.hhs.gov>
Cc:

 "helen.topping@admedsol.com"

<helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date:

 08/10/2021 22:14
Subject:

   RE: [EXTERNAL]

Re: K211878/S001 is on Hold Pending Your Response
<hr noshade>

Hi Michele

Thank you for the offer. I think after

today's meeting we may need a little more time to be better prepared for

the teleconference.

We are reaching out to the (b)(4)

(b)(4) for us as we feel that it may be beneficial to have them

join us on the teleconference.

As such we need to check their availability.

I hope to have list of possible dates for you early next week.

Best regards,

Martin Mitchell
Senior Regulatory Affairs

Associate

Advanced Medical Solutions

Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From:

 "Lee, Michele"

<Michele.Lee@fda.hhs.gov>
To:

 "Martin.Mitchell@admedsol.com"

<Martin.Mitchell@admedsol.com>
Cc:

 "helen.topping@admedsol.com"

<helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date:

 06/10/2021 13:49
Subject:

   RE: [EXTERNAL]

Re: K211878/S001 is on Hold Pending Your Response
<hr noshade>

Hello Martin,

If it makes it easier for your team, we

are able to extend the 10 day teleconference deadline up to October 19th.

Let me know if you would like to select a date later than the 14thand I can check our management schedules.

Regarding review timelines,

we are still

on the 90 day review cycle and are planning to complete the review of your

response with the 20 calendar days left on the clock. While we retain the

right to add additional days, we are doing our best with the resources

that we have to avoid delaying review timelines if possible.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices

Team
DHT4B: Division of Infection Control and

Plastic Surgery Devices
OHT4: Office of Surgical and Infection

Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue

| Silver Spring, MD 20993
<u>Michele.Lee@fda.hhs.gov</u>

<img src=cid:_4_0B4FB7900B4FB4300072127A8025876D style="border:0px solid;">
<u>
</u><img src=cid:_2_0B4FBC200B4FB4300072127A8025876D style="border:0px solid;"> <img src=cid:_2_0B4FC06C0B4FB4300072127A8025876D style="border:0px solid;"> <img src=cid:_2_0B4FC4B80B4FB4300072127A8025876D style="border:0px solid;"> <img src=cid:_2_0B4FC9040B4FB4300072127A8025876D style="border:0px solid;"> <img src=cid:_2_0B4FCD500B4FB4300072127A8025876D style="border:0px solid;">
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service is important to us. Please take a moment to provide feedback

regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

From: Martin.Mitchell@admedsol.com

<Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 6, 2021 6:00 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com
Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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is safe.

Hi Michele

Thank you again for your review. Our team are busy discussing the questions

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and we would definitely like to have a teleconference with the FDA. We're

currently consolidating our understanding of the deficiencies and are determining

what our potential questions to you would be. I hope to get the questions

to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we

look to schedule a teleconference with the FDA on Wednesday 13th or Thursday

14th? As we're based in the UK we would appreciate a timeslot within our

working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines

for this project.... regarding the FDA timeline I can see on the CCP tracker

website that the FDA timeline is on day 70.
Will FDA be sticking to the 90 day target

and as a result only have 20 days left on the clock?<li>Or, due to the current situation with the

unprecedented resource limitations..... will you will assume 30 days to

review the response as standard? Or perhaps stick to the 20 days but retain

the right to add additional days?
Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Michele

Lee [MICHELE.LEE]" <<u>michele.lee@fda.hhs.gov</u>>
To: <<u>martin.mitchell@admedsol.com</u>>,

<<u>helen.topping@admedsol.com</u>>
Cc: "Michele

Lee [MICHELE.LEE]" <<u>michele.lee@fda.hhs.gov</u>>
Date: 04/10/2021

21:44
Subject: K211878/S001

is on Hold Pending Your Response <hr noshade>

October 4, 2021 <p>We have reviewed your submission. Please see attached.

<p>If you have any questions, please contact the lead reviewer

assigned to your submission, Michele Lee. <p> <p>*** This is a system-generated email notification ***[attachment

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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"K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin

Mitchell/WIN/UK/AMS] <p>

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color=#0082bf><u>http://www.admedsol.com</u>.

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Hello Michele

Hope you have a nice thanksgiving tomorrow!

Just checking how things are going with

your toxicologist. Are we still on track to get an update this week to

our questions?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions

Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From:

 "Lee, Michele"

<Michele.Lee@fda.hhs.gov>
To:

 "Martin.Mitchell@admedsol.com"

<Martin.Mitchell@admedsol.com>
Cc:

 "k211878@docs.fda.gov"

<k211878@docs.fda.gov>
Date:

 16/11/2021 19:03
Subject:

   RE: [EXTERNAL]

K211878 timeline - COVID-19
<hr noshade>

Hello Martin,

Thanks for the update and good to know

this information. I also received your previous email with additional information

about the test parameters of the degradation & extraction studies.

I am still waiting on feedback from our consulting toxicologist but hope

to have more information to provide you mid next week.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices

Team
DHT4B: Division of Infection Control and

Plastic Surgery Devices
OHT4: Office of Surgical and Infection

Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue

| Silver Spring, MD 20993
<u>Michele.Lee@fda.hhs.gov</u>

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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</u><img src=cid:_2_0C716ED80C7166E8005D2B0480258797 style="border:0px solid;"> <img src=cid:_2_0C7173240C7166E8005D2B0480258797 style="border:0px solid;"> <img src=cid:_2_0C7177700C7166E8005D2B0480258797 style="border:0px solid;"> <img src=cid:_2_0C717BBC0C7166E8005D2B0480258797 style="border:0px solid;"> <img src=cid:_2_0C7180080C7166E8005D2B0480258797 style="border:0px solid;">
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regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

From: Martin.Mitchell@admedsol.com

<Martin.Mitchell@admedsol.com>
Sent: Monday, November 15, 2021 3:54 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Subject: Fw: [EXTERNAL] K211878 timeline - COVID-19

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is safe.

Hi Michele

I got an update regarding timeline from the CCP email address.

FYI we are exploring a number of backup strategies to resolve the 510(k)

deficiencies.... and some of these take us past the 180 day hold period.

As per the request below, I'll let you know closer to the time if we end

up needing to request the additional 180 days.

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

----- Forwarded by Martin Mitchell/WIN/UK/AMS on 15/11/2021 08:31 -----

From: "CCP"

<<u>CCP@fda.hhs.gov</u>>
To: "<u>Martin.Mitchell@admedsol.com</u>"

<<u>Martin.Mitchell@admedsol.com</u>>
Date:

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
   12/11/2021

21:08
Subject:
 RE:

[EXTERNAL] K211878 timeline - COVID-19 <hr
noshade>

<font size=2
face="Calibri">
Good day to you Martin,

The extra 180 days for response are
added as needed, and then only shortly

before the original 180 days expires.

--
Happy trails,
~Nels Anderson<font size=2
face="Calibri">
Regulatory Systems & Data Management Staff
Center for Devices
and Radiological Health | Office of Product Evaluation

and Quality| Office of Regulatory Programs

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From: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri"><<font size=2
color=blue face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri">>

Sent: Friday, November 12, 2021 09:49
To: CCP <<a
href=mailto:CCP@fda.hhs.gov><font size=2 color=blue
face="Calibri"><u>CCP@fda.hhs.gov</u><font size=2
face="Calibri">>
Subject: [EXTERNAL] K211878 timeline - COVID-19

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face="Calibri">This email originated from outside

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 <font size=2
face="Arial">
Hello

Regarding the timeline showing for K211878 I can see on
the customer collaboration

portal that we have a 180 day hold period which ends on the 2nd of April

2022.

However, I (and the lead reviewer Michele Lee) were under the
understanding

that the guidance document below was active which would provide us with

an additional 180 day hold period? <a
href="https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-
covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-
devices"><u>https://www.fda.gov/regulatory-
information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-
formal-meetings-and-user-fee-applications-medical-devices</u>
Could you clarify that the 180 timeline in the customer
collaboration portal

won't trigger premature closure of the 510(k) before the actual 360 day

timeline expires?

Best regards,<font size=2 color=#000080
face="Arial">

Martin Mitchell
Regulatory Affairs
Manager

Advanced Medical Solutions Ltd.
E-mail: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=2 color=#000080
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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face="Arial">
Tel: +44 (0) 1752 30 9360<font size=2
face="Calibri">

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face="Calibri"><u>http://www.admedsol.com</u>.

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(b)(4)

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hello Michele,

We have been pleased to have you as the lead reviewer for RTA review, technical review, and responses to deficiency discussions since July 2021, as well as having you for the review for our previous 510(k) submission of the same product.

(b)(4)

Jun 2021 - We submitted K211878 in response the (b)(4)

(b)(4)

Oct 2021 - Further deficiencies were raised on the new K211878 submission

We currently have only 20 days of FDA review time left on our product and have been advised that we will now be assigned a new reviewer. As you can imagine this causing us a high level of concern given you have a detailed knowledge of our submissions and of the current outstanding questions. Our concern being that a new reviewer will not have the same detailed knowledge of our submission or of the outstanding questions and hence this may cause unnecessary further delay.

We have been very satisfied with the support we have received from yourself and we would ask that you remain on our file for the final 20 days if at all possible, or an explanation of why this is not possible with some reassurances that a new assessor will not cause unnecessary delays whilst they gain detailed knowledge of our file.

Your expedited response to this request would be appreciated.

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 25/03/2022 16:47

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

A new lead reviewer will not be assigned until a follow up submission is received. So there is currently not a primary contact unless there is an active submission under FDA review. All of our correspondence and the prior related review have been documented internally, so you can be assured that the history of the prior review and contact is available to the future lead reviewer.

Best,
Michele

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Friday, March 25, 2022 12:21 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

I've seen on the FDA customer collaboration portal that the time has automatically been added, but just thought it would be prudent to also inform you of the situation.

Could I ask who the primary contact is now? Will you be assisting or have any involvement with the review of our response?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 25/03/2022 15:59
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

I am sorry to hear about (b)(4). I hope all is able to be resolved soon.

Thank you for the update. I am actually working in a different division within FDA and no longer the primary contact for this submission. I believe that the 180 days is automatically granted for responses to AINN hold but you can also confirm with the 510(k) Program staff (510k_Program@fda.hhs.gov, telephone: 301-796-5640) to make sure.

Best,
Michele

Michele Lee, Ph.D.(she/her/hers)
Regulatory Science Program Manager
Partnerships to Advance Innovation and Regulatory Science (PAIRS)

Center for Devices and Radiological Health
Office of Strategic Partnerships and Technology Innovation
Division of All Hazards Response, Science, and Strategic Partnerships
U.S. Food and Drug Administration
michele.lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Friday, March 25, 2022 11:28 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: k211878@docs.fda.gov

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

I'd like to provide an update on our progress with responding to the deficiencies raised on K211878

We were on track to have a deficiency response submitted to the FDA by the 180 day hold period deadline of 2nd April 2022.

However, the organisation performing the (b)(4) (b)(4) (b)(4) As a result, they were unable to complete the testing by our targeted timeline.

Therefore, I just want to confirm that we are still intending to respond to the deficiencies, but we would need to use the second 180 day hold period granted to us through the COVID-19 situation.

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 08/11/2021 22:05
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thanks for your message. Iâ€™ll need some time to review the teleconference minutes with my team and also obtain some feedback from our consulting

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

toxicologist about the follow up questions. But I wanted to let you know I received your email and you may feel free to check in again next week.

I do have a clarification question about Follow Up (b)(4)

(b)(4)

Regarding the timeline clarification- I am also under the understanding that the COVID-19 guidance document you cited was still active and that would allow you an additional 180 days for the hold period. I have reached out to the 510(k) Staff multiple times to confirm and am still waiting on their response. Is there a customer service contact email for the customer collaboration portal specifically? You may try contacting them as well to have the date corrected on your end.

Thank you,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Friday, November 5, 2021 12:07 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

I hope you had a nice holiday!

Following on from the teleconference we had a few actions to complete and get back to you with.

1) Teleconference minutes

Please find a draft of the the teleconference minutes below. Could you review and confirm if you require any changes made?

2) Follow-up questions on the teleconference discussion

As suggested during the teleconference there was the opportunity for a followup email clarification on a few minor points.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

The supporting information which provides further clarity on the questions above has been attached if required.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3) Timeline clarification as per previous email

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Thank you again for your assistance

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>, "Liu, Lixin" <Lixin.Liu@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 20/10/2021 22:43
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Michele

Thank you for the prompt response to the clarifications! We'll take your points on board regarding future shelf life studies.

I do have a minor clarification question regarding our response timeline

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the

deficiencies?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 20/10/2021 14:55

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you to you and your team for attending the teleconference yesterday.

I wanted to follow up on two things I was discussing with my team:

(b)(4)

I will be on leave for the next two weeks and you may contact our team

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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management (Lixin.Liu@fda.hhs.gov) if you have questions during that time.

Best,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Lee, Michele

Sent: Friday, October 15, 2021 4:47 PM

To: Martin.Mitchell@admedsol.com

Cc: helen.topping@admedsol.com; k211878@docs.fda.gov

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you for providing your questions in advance of the meeting. We look forward to discussing our responses with you next week.

Have a good weekend,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

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Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Friday, October 15, 2021 12:00 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Please find the list of questions/clarifications attached below.

I hope you have a good weekend. I'm looking forwards to our discussion next week!

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 13/10/2021 22:35
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hello Martin,

I have scheduled the teleconference for next Tuesday October 19that 9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour but our biocompatibility consultant/ team management needs to drop off for another call at 9:30am. Please send me the questions for discussion in advance of the meeting so that we can plan to discuss biocompatibility/ regulatory questions first before the relevant parties need to drop off.

Join Zoom Meeting

One tap mobile:

(b)(4)

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(b)(4)

Thanks,

Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
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Michele.Lee@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 13, 2021 4:46 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Apologies Michele, one final thing I missed off my email... could you clarify how long the teleconference would be by default? Could we request 1 hour just incase some of the points end up taking longer to discuss?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 13/10/2021 20:35
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hi Michele

We're currently preparing our questions for the teleconference and will send these through in due course, however to assist with scheduling the relevant parties at FDA, I should let you know that we would definitely like to discuss the questions related to biocompatibility.

After discussion with the team we would like to request the teleconference on the Tuesday 19th October if that is possible? As we are based in the UK, we would also like to request that this is arranged between the hours of 2-5pm BST.

If this time slot is not available could you outline any alternative days/times which would be possible?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 08/10/2021 22:14
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hi Michele

Thank you for the offer. I think after today's meeting we may need a little more time to be better prepared for the teleconference.

We are reaching out to the (b)(4) for us as we feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible dates for you early next week.

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 06/10/2021 13:49
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference deadline up to October 19th. Let me know if you would like to select a date later than the 14thand I can check our management schedules.

Regarding review timelines, we are still on the 90 day review cycle and are planning to complete the review of your response with the 20 calendar days left on the clock. While we retain the right to add additional days,

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we are doing our best with the resources that we have to avoid delaying review timelines if possible.

Best,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

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Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>

Sent: Wednesday, October 6, 2021 6:00 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: helen.topping@admedsol.com

Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Thank you again for your review. Our team are busy discussing the questions and we would definitely like to have a teleconference with the FDA. We're currently consolidating our understanding of the deficiencies and are determining what our potential questions to you would be. I hope to get the questions to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we look to schedule a teleconference with the FDA on Wednesday 13th or Thursday 14th? As we're based in the UK we would appreciate a timeslot within our working hours which finish at 17:00 BST.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Additionally, I have a small question to allow us to predict timelines for this project.... regarding the FDA timeline I can see on the CCP tracker website that the FDA timeline is on day 70.

Will FDA be sticking to the 90 day target and as a result only have 20 days left on the clock?

Or, due to the current situation with the unprecedented resource limitations..... will you will assume 30 days to review the response as standard? Or perhaps stick to the 20 days but retain the right to add additional days?

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
To: <martin.mitchell@admedsol.com>, <helen.topping@admedsol.com>
Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
Date: 04/10/2021 21:44
Subject: K211878/S001 is on Hold Pending Your Response

October 4, 2021

We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Michele Lee.

*** This is a system-generated email notification ***[attachment "K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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storage mechanism.

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serif;font-size:16px;line-height:18px;color:#505050;padding:15px;text-align:center;">
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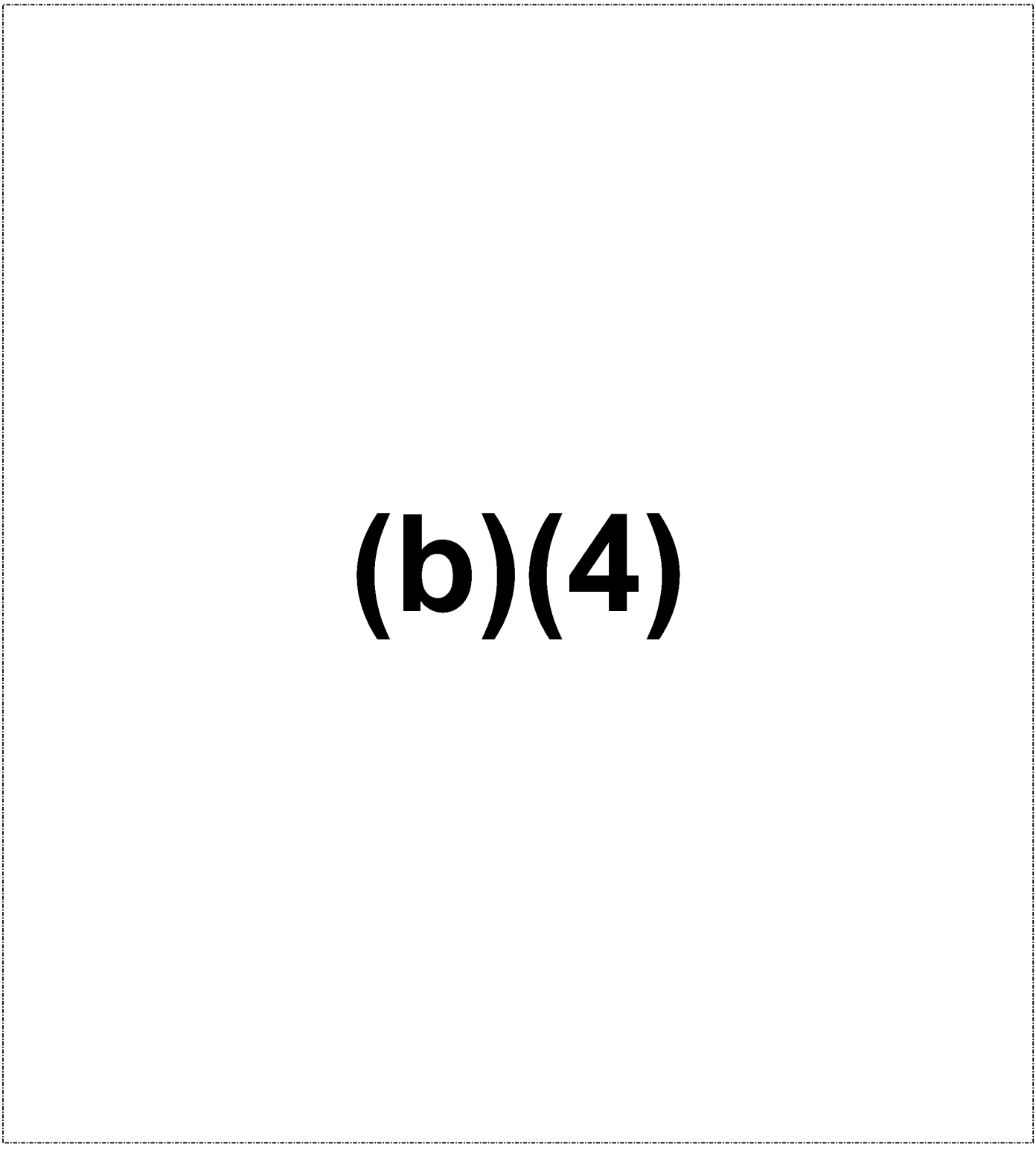

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Hi Michele

I'd like to provide an update on our progress with responding to the deficiencies raised on K211878

We were on track to have a deficiency response submitted to the FDA by the 180 day hold period deadline of 2nd April 2022.

However, the organisation performing the (b)(4) (b)(4) have been affected by (b)(4). As a result, they were unable to complete the testing by our targeted timeline.

Therefore, I just want to confirm that we are still intending to respond to the deficiencies, but we would need to use the second 180 day hold period granted to us through the COVID-19 situation.

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 08/11/2021 22:05
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thanks for your message. Iâ€™ll need some time to review the teleconference minutes with my team and also obtain some feedback from our consulting toxicologist about the follow up questions. But I wanted to let you know I received your email and you may feel free to check in again next week.

I do have a clarification question about Follow Up (b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

Regarding the timeline clarification- I am also under the understanding that the COVID-19 guidance document you cited was still active and that would allow you an additional 180 days for the hold period. I have reached out to the 510(k) Staff multiple times to confirm and am still waiting on their response. Is there a customer service contact email for the customer collaboration portal specifically? You may try contacting them as well to have the date corrected on your end.

Thank you,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Friday, November 5, 2021 12:07 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Cc: helen.topping@admedsol.com; k211878@docs.fda.gov

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

I hope you had a nice holiday!

Following on from the teleconference we had a few actions to complete and get back to you with.

1) Teleconference minutes

Please find a draft of the the teleconference minutes below. Could you review and confirm if you require any changes made?

2) Follow-up questions on the teleconference discussion

As suggested during the teleconference there was the opportunity for a followup email clarification on a few minor points.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

The supporting information which provides further clarity on the questions above has been attached if required.

3) Timeline clarification as per previous email

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Thank you again for your assistance

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>, "Liu, Lixin" <Lixin.Liu@fda.hhs.gov>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 20/10/2021 22:43

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Michele

Thank you for the prompt response to the clarifications! We'll take your points on board regarding future shelf life studies.

I do have a minor clarification question regarding our response timeline

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 20/10/2021 14:55

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you to you and your team for attending the teleconference yesterday. I wanted to follow up on two things I was discussing with my team:

(b)(4)

I will be on leave for the next two weeks and you may contact our team management (Lixin.Liu@fda.hhs.gov) if you have questions during that time.

Best,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov

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From: Lee, Michele

Sent: Friday, October 15, 2021 4:47 PM

To: Martin.Mitchell@admedsol.com

Cc: helen.topping@admedsol.com; k211878@docs.fda.gov

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you for providing your questions in advance of the meeting. We look forward to discussing our responses with you next week.

Have a good weekend,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>

Sent: Friday, October 15, 2021 12:00 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: helen.topping@admedsol.com; k211878@docs.fda.gov

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Please find the list of questions/clarifications attached below.

I hope you have a good weekend. I'm looking forwards to our discussion next week!

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 13/10/2021 22:35

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

I have scheduled the teleconference for next Tuesday October 19that 9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour but our biocompatibility consultant/ team management needs to drop off for another call at 9:30am. Please send me the questions for discussion in advance of the meeting so that we can plan to discuss biocompatibility/ regulatory

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
questions first before the relevant parties need to drop off.

Join Zoom Meeting

One tap mobile:

(b)(4)

Thanks,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 13, 2021 4:46 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Apologies Michele, one final thing I missed off my email... could you clarify how long the teleconference would be by default? Could we request 1 hour just incase some of the points end up taking longer to discuss?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 13/10/2021 20:35
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Response

Hi Michele

We're currently preparing our questions for the teleconference and will send these through in due course, however to assist with scheduling the relevant parties at FDA, I should let you know that we would definitely like to discuss the questions related to biocompatibility.

After discussion with the team we would like to request the teleconference on the Tuesday 19th October if that is possible? As we are based in the UK, we would also like to request that this is arranged between the hours of 2-5pm BST.

If this time slot is not available could you outline any alternative days/times which would be possible?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 08/10/2021 22:14
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hi Michele

Thank you for the offer. I think after today's meeting we may need a little more time to be better prepared for the teleconference.

We are reaching out to the (b)(4) for us as we feel that it may be beneficial to have them join us on the teleconference.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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As such we need to check their availability. I hope to have list of possible dates for you early next week.

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 06/10/2021 13:49
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference deadline up to October 19th. Let me know if you would like to select a date later than the 14thand I can check our management schedules.

Regarding review timelines, we are still on the 90 day review cycle and are planning to complete the review of your response with the 20 calendar days left on the clock. While we retain the right to add additional days, we are doing our best with the resources that we have to avoid delaying review timelines if possible.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>

Sent: Wednesday, October 6, 2021 6:00 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: helen.topping@admedsol.com

Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Thank you again for your review. Our team are busy discussing the questions and we would definitely like to have a teleconference with the FDA. We're currently consolidating our understanding of the deficiencies and are determining what our potential questions to you would be. I hope to get the questions to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we look to schedule a teleconference with the FDA on Wednesday 13th or Thursday 14th? As we're based in the UK we would appreciate a timeslot within our working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines for this project.... regarding the FDA timeline I can see on the CCP tracker website that the FDA timeline is on day 70.
Will FDA be sticking to the 90 day target and as a result only have 20 days left on the clock?
Or, due to the current situation with the unprecedented resource limitations..... will you will assume 30 days to review the response as standard? Or perhaps stick to the 20 days but retain the right to add additional days?

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
To: <martin.mitchell@admedsol.com>, <helen.topping@admedsol.com>
Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
Date: 04/10/2021 21:44
Subject: K211878/S001 is on Hold Pending Your Response

October 4, 2021
We have reviewed your submission. Please see attached.
If you have any questions, please contact the lead reviewer assigned to your submission, Michele Lee.

*** This is a system-generated email notification ***[attachment "K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hello Michele and Julie

Thank you Michele for providing further

clarification on the matter regarding maintenance of a lead reviewer. We

are sad to lose you as our lead reviewer and wish you the best in your

new role within the FDA.

During the initial review of the 510(k)

it was flagged that the FDA had resource challenges which resulted in the

review taking 70 days instead of the targeted 60 days....When we discussed

this previously it was stated that when we submit our deficiency response

the FDA would still target to complete the review within the remaining

20 days, however.... it was also flagged that if resource constraints still

existed this could take longer than 20 days.

To keep the FDA informed about our progress

we are planning to submit our response to the deficiency questions in around

3 weeks time. We would like to enquire about FDA's ability to complete

the review within 20 days?
Will there be any delays in assigning

a new reviewer? Are there still resource constraints

at the FDA?<li>Would a new reviewer who is not familiar

with the product/deficiencies require a longer period of time to perform

the review?
The timely completion of your review

would be massively appreciated as the large wound market is critical to

urgent patient demand, AMS and our partners who are very keen to provide

the improved product to hospitals across the United States.

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions

Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From:

 "Lee, Michele"

<Michele.Lee@fda.hhs.gov>
To:

 "Martin.Mitchell@admedsol.com"

<Martin.Mitchell@admedsol.com>
Cc:

 "k211878@docs.fda.gov"

<k211878@docs.fda.gov>, "Rose.Guang@admedsol.com" <Rose.Guang@admedsol.com>,

"Helen.Topping@admedsol.com" <Helen.Topping@admedsol.com>,

"Morabito, Julie" <Julie.Morabito@fda.hhs.gov>
Date:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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 05/04/2022 14:47
Subject:

   RE: [EXTERNAL]

Re: K211878/S001 is on Hold Pending Your Response
<hr noshade>

Hello Martin,

Unfortunately, it is not possible for me

to take on lead review of this submission. As previously mentioned, I am

currently working in another Office within FDA and do not conduct premarket

reviews of medical devices in my current role.

It is not uncommon for new lead reviewers

to be assigned to submissions returning from hold. The internal documentation

serves as a complete record of the previous interactions during prior review

of a submission. If you have further questions regarding the review process

for your submission, you may contact the Assistant Director for the Plastic

Surgery Skin & Wound Devices Team, Dr. Julie Morabito (<u>Julie.Morabito@fda.hhs.gov</u>).

Best,
Michele

Michele Lee, Ph.D.(she/her/hers)
Regulatory Science Program Manager
Partnerships to Advance Innovation

and Regulatory Science (PAIRS)

Center for Devices and Radiological

Health
Office of Strategic Partnerships and

Technology Innovation
Division of All Hazards Response, Science,

and Strategic Partnerships
U.S. Food and Drug Administration
<u>michele.lee@fda.hhs.gov</u>

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</u><img src=cid:_2_0C35BEAC0C34BAD8006B434F80258823 style="border:0px solid;"> <img src=cid:_2_0C35C2F80C34BAD8006B434F80258823 style="border:0px solid;"> <img src=cid:_2_0C35C7440C34BAD8006B434F80258823 style="border:0px solid;"> <img src=cid:_2_0C35CB900C34BAD8006B434F80258823 style="border:0px solid;"> <img src=cid:_2_0C35CFDC0C34BAD8006B434F80258823 style="border:0px solid;">

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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service you have received: <a
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UI"><u>https://www.research.net/s/cdrhcustomerservice?ID=7013&S=E</u><fo
nt size=1 face="Segoe UI">.

<font size=2
face="Calibri">

From: Martin.Mitchell@admedsol.com

<Martin.Mitchell@admedsol.com>
Sent: Tuesday, April 5, 2022 8:31
AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc:
k211878@docs.fda.gov; Rose.Guang@admedsol.com;
Helen.Topping@admedsol.com
Subject: RE: [EXTERNAL] Re: K211878/S001 is on
Hold Pending Your Response

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email originated from outside of the organization. Do not click links

or open attachments unless you recognize the sender and know the content

is safe.

<font size=2
face="Arial">Hello Michele,
<font size=2
face="Arial">
We have been pleased to have you as the lead reviewer for RTA review,
technical

review, and responses to deficiency discussions since July 2021, as well

as having you for the review for our previous 510(k) submission of the

same product.
<font size=2

(b)(4)

the (b)(4) k<li>Oct 2021
- Further deficiencies were raised

on the new K211878 submission
 We currently
have only 20 days of FDA review time left on our product

and have been advised that we will now be assigned a new reviewer. As

you can imagine this causing us a high level of concern given you have

 a detailed knowledge of our submissions and of the current outstanding

questions. Our concern being that a new reviewer will not have the same

detailed knowledge of our submission or of the outstanding questions and

hence this may cause unnecessary further delay.<font size=2
face="Calibri">

We have been very satisfied
with the support we have received from yourself

 and we would ask that you remain on our file for the final 20 days

if at all possible, or an explanation of why this is not possible with

some reassurances that a new assessor will not cause unnecessary delays

whilst they gain detailed knowledge of our file.<font size=2
face="Calibri">

Your expedited response to this
request would be appreciated.
<font size=2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

face="Arial">
Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>
To: "<u>Martin.Mitchell@admedsol.com</u>"

<<u>Martin.Mitchell@admedsol.com</u>>
Cc: "<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 25/03/2022

16:47
Subject: RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hello Martin,

A new lead reviewer will not be assigned until a follow up submission is

received. So there is currently not a primary contact unless there is an

active submission under FDA review. All of our correspondence and the prior

related review have been documented internally, so you can be assured that

the history of the prior review and contact is available to the future

lead reviewer.

Best,
Michele

From: <u>Martin.Mitchell@admedsol.com</u><<u>Martin.Mitchell@admedsol.com</u>>

Sent: Friday, March 25, 2022 12:21 PM
To: Lee, Michele <<u>Michele.Lee@fda.hhs.gov</u>>
Cc: <u>k211878@docs.fda.gov</u>
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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of the organization. Do not click links or open attachments unless you

recognize the sender and know the content is safe.

Hi Michele

I've seen on the FDA customer collaboration portal that the time has automatically

been added, but just thought it would be prudent to also inform you of

the situation.

Could I ask who the primary contact is now? Will you be assisting or have

any involvement with the review of our response?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>
To: "<u>Martin.Mitchell@admedsol.com</u>"

<<u>Martin.Mitchell@admedsol.com</u>>
Cc: "<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 25/03/2022

15:59
Subject: RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hello Martin,

I am sorry to hear about **(b)(4)** **(b)(4)**. I hope all is able to be resolved

soon.

Thank you for the update. I am actually working in a different division

within FDA and no longer the primary contact for this submission. I believe

that the 180 days is automatically granted for responses to AINN hold but

you can also confirm with the 510(k) Program staff (<u>510k_Program@fda.hhs.gov</u>,

telephone: 301-796-5640) to make sure.

Best,
Michele

Michele Lee, Ph.D.(she/her/hers)
Regulatory Science Program Manager
Partnerships to Advance Innovation and Regulatory Science (PAIRS)

Center for Devices and Radiological Health
Office of Strategic Partnerships and Technology Innovation
Division of All Hazards Response, Science, and Strategic Partnerships
U.S. Food and Drug Administration<u>
</u><u>michele.lee@fda.hhs.gov</u>
<u>
</u><u>
</u><img src=cid:_4_0D6293680D6286CC006B434F80258823 width=192 height=43 style="border:0px solid;"><u>
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</u><img src=cid:_2_0D6297F80D6286CC006B434F80258823 style="border:0px solid;"><img src=cid:_2_0D629C2C0D6286CC006B434F80258823 style="border:0px solid;"><img src=cid:_2_0D62A0780D6286CC006B434F80258823 style="border:0px solid;"><a

href=http://www.flickr.com/photos/fdaphotos/><img
src=cid:_2_0D62A4AC0D6286CC006B434F80258823 style="border:0px solid;"><font size=1
color=#4f4f4f face="Segoe UI"> <a
href=http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm><img
src=cid:_2_0D62A8F80D6286CC006B434F80258823 style="border:0px solid;"><font size=1
face="Segoe UI">

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moment to

provide feedback regarding the customer service you have received: <a
href="https://www.research.net/s/cdrhcustomerservice?ID=7013&S=E"><font size=1
color=blue face="Segoe
UI"><u>https://www.research.net/s/cdrhcustomerservice?ID=7013&S=E</u><fo
nt size=1 face="Segoe UI">.

From: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri"><<font size=2
color=blue face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri">>

Sent: Friday, March 25, 2022 11:28 AM
To: Lee, Michele
<<font size=2 color=blue
face="Calibri"><u>Michele.Lee@fda.hhs.gov</u><font size=2
face="Calibri">>
Cc: <u>k211878@docs.fda.gov</u><font size=2
face="Calibri">
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending
Your Response<font size=2 color=#806210
face="Calibri">

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from outside

of the organization. Do not click links or open attachments unless you

recognize the sender and know the content is safe.<font size=2
face="Arial">

Hi Michele

I'd like to provide an update on our progress
with responding to the deficiencies

raised on K211878

We were on track to have a deficiency response submitted to
the FDA by

the 180 day hold period deadline of 2nd April 2022.

However, the organisation
 performing the (b)(4)

(b)(4) have been affected (b)(4).

As a result, they were unable to complete the testing by our targeted
timeline.

Therefore, I just want to confirm that we are still intending to
respond

to the deficiencies, but we would need to use the second 180 day hold period

granted to us through the COVID-19 situation.

Best regards,<font size=2
color=#000080 face="Arial">

Martin Mitchell
Regulatory Affairs
Manager

Advanced Medical Solutions Ltd.
E-mail: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=2 color=#000080
face="Arial">
Tel: +44 (0) 1752 30 9360<font size=2
face="Calibri">

From:
       "Lee,

Michele" <<font size=1 color=blue
face="Arial"><u>Michele.Lee@fda.hhs.gov</u><font size=1
face="Arial">>
To:
   "<a
href=mailto:Martin.Mitchell@admedsol.com><font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">>
Cc:

   "<a
href=mailto:helen.topping@admedsol.com><font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">>,

"<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u>"

<<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u><font size=1
face="Arial">>
Date:
   08/11/2021

22:05
Subject:
 RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response<font size=2
face="Calibri"> <hr noshade>
<font size=2
face="Calibri">

Hello Martin,

Thanks for your message. Iâ€™ll
need some time to review the teleconference

minutes with my team and also obtain some feedback from our consulting

toxicologist about the follow up questions. But I wanted to let you know

I received your email and you may feel free to check in again next week.

I do have a clarification question about **(b)(4)**

(b)(4)

(b)(4)

br>
Regarding the timeline clarification- I am also under the
understanding

that the COVID-19 guidance document you cited was still active and that

would allow you an additional 180 days for the hold period. I have reached

out to the 510(k) Staff multiple times to confirm and am still waiting

on their response. Is there a customer service contact email for the customer

collaboration portal specifically? You may try contacting them as well

to have the date corrected on your end.

Thank you,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic

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Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993<u>
</u><u>Michele.Lee@fda.hhs.gov</u><u>
</u><u>
</u><img src=cid:_4_0D62E8200D62D894006B434F80258823 width=192 height=43 style="border:0px solid;"><u>
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Excellent customer service is important to us. Please take a moment

to provide feedback regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

From: <u>Martin.Mitchell@admedsol.com</u><<u>Martin.Mitchell@admedsol.com</u>>

Sent: Friday, November 5, 2021 12:07 PM
To: Lee, Michele <<u>Michele.Lee@fda.hhs.gov</u>>
Cc: <u>helen.topping@admedsol.com</u>;

<u>k211878@docs.fda.gov</u>
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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of the organization. Do not click links or open attachments unless you

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Hello Michele

I hope you had a nice holiday!

Following on from the teleconference we had a few actions to complete and

get back to you with.

1) Teleconference minutes

Please find a draft of the the teleconference minutes below. Could you

review and confirm if you require any changes made?

2) Follow-up questions on the teleconference discussion

As suggested during the teleconference there was the opportunity for a

followup email clarification on a few minor points.
1.   In alignment with FDA recommendation, the

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

(b)(4)

The supporting information which provides further clarity on the questions

above has been attached if required.

3) Timeline clarification as per previous email

I can see on the customer collaboration portal that we have a 180 day hold

period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below

was active which would provide us with an additional 180 day hold period?
<u>https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices</u>
Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Thank you again for your assistance

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: Martin

Mitchell/WIN/UK/AMS
To: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>,

"Liu, Lixin" <<u>Lixin.Liu@fda.hhs.gov</u>>
Cc: "<u>helen.topping@admedsol.com</u>"

<<u>helen.topping@admedsol.com</u>>,

"<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 20/10/2021

22:43
Subject: RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>
<font size=2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
face="Calibri">

Hello Michele

Thank you for the prompt response to the clarifications! We'll take your

points on board regarding future shelf life studies.

I do have a minor clarification question regarding our response timeline

I can see on the customer collaboration portal that we have a 180 day hold

period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below

was active which would provide us with an additional 180 day hold period?<u>
</u><u>
</u><u>https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices</u>

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>
To: "<u>Martin.Mitchell@admedsol.com</u>"

<<u>Martin.Mitchell@admedsol.com</u>>
Cc: "<u>helen.topping@admedsol.com</u>"

<<u>helen.topping@admedsol.com</u>>,

"<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 20/10/2021

14:55
Subject: RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hello Martin,

Thank you to you and your team for attending the teleconference yesterday.

I wanted to follow up on two things I was discussing with my team:
1.   Regarding

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

(b)(4)

I will be on leave for the next two weeks and you may contact our team

management (<u>Lixin.Liu@fda.hhs.gov</u>)

if you have questions during that time.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993<u>
</u><u>Michele.Lee@fda.hhs.gov</u><u>
</u><u>
</u><img src=cid:_4_0D6384A80D637570006B434F80258823 style="border:0px solid;"><u>
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</u><img src=cid:_2_0D6389380D637570006B434F80258823 style="border:0px solid;"><img src=cid:_2_0D638D6C0D637570006B434F80258823 style="border:0px solid;"><img src=cid:_2_0D6391A00D637570006B434F80258823 style="border:0px solid;"><img src=cid:_2_0D6395D40D637570006B434F80258823 style="border:0px solid;"><img src=cid:_2_0D639A080D637570006B434F80258823 style="border:0px solid;">
Excellent customer service is important to us. Please take a moment

to provide feedback regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

From: Lee, Michele
Sent: Friday, October 15, 2021 4:47 PM
To: <u>Martin.Mitchell@admedsol.com</u>
Cc: <u>helen.topping@admedsol.com</u>;

<u>k211878@docs.fda.gov</u>
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you for providing your questions in advance of the meeting. We look

forward to discussing our responses with you next week.

Have a good weekend,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993<u>
</u><u>Michele.Lee@fda.hhs.gov</u><u>
</u><u>
</u><img src=cid:_4_0D63AF900D637570006B434F80258823 style="border:0px solid;"><u>
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</u><img src=cid:_2_0D63B4200D637570006B434F80258823 style="border:0px solid;"><img src=cid:_2_0D63B8540D637570006B434F80258823 style="border:0px solid;"><img src=cid:_2_0D63BC880D637570006B434F80258823 style="border:0px solid;"><img src=cid:_2_0D63C0BC0D637570006B434F80258823 style="border:0px solid;"><img src=cid:_2_0D63C4F00D637570006B434F80258823 style="border:0px solid;">
Excellent customer service is important to us. Please take a moment

to provide feedback regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

From: <u>Martin.Mitchell@admedsol.com</u><<u>Martin.Mitchell@admedsol.com</u>>

Sent: Friday, October 15, 2021 12:00 PM
To: Lee, Michele <<u>Michele.Lee@fda.hhs.gov</u>>
Cc: <u>helen.topping@admedsol.com</u>;

<u>k211878@docs.fda.gov</u>
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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recognize the sender and know the content is safe.

Hi Michele

Please find the list of questions/clarifications attached below.

I hope you have a good weekend. I'm looking forwards to our discussion

next week!

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>
To: "<font size=1 color=blue

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">>
Cc:
   "<a
href=mailto:helen.topping@admedsol.com><font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">>,

"<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u>"

<<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u><font size=1
face="Arial">>
Date:
   13/10/2021

22:35
Subject:
 RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response<font size=2
face="Calibri"> <hr noshade>
<font size=2
face="Calibri">

Hello Martin,

I have scheduled the
teleconference for next Tuesday October 19that

9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour but

our biocompatibility consultant/ team management needs to drop off for

another call at 9:30am. Please send me the questions for discussion in

advance of the meeting so that we can plan to discuss biocompatibility/

regulatory questions first before the relevant parties need to drop off.

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color:#000000;border-width:0px 0px 0px 0px;padding:0px 0px;"><a
href="https://fda.zoomgov.com/j/1609831829?pwd=Mk16N1pXYnUrY2h2TFoyQTRaUCt5QT09"
target=_blank><u>Join

Zoom Meeting</u> <tr

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

size=2>

Thanks,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993<u>
</u><u>Michele.Lee@fda.hhs.gov</u><u>

</u><img src=cid:_4_0D5212800D63FF78006B434F80258823 style="border:0px solid;"><u>

</u><img src=cid:_2_0D5216CC0D63FF78006B434F80258823 style="border:0px solid;"><img src=cid:_2_0D521B000D63FF78006B434F80258823 style="border:0px solid;"><img src=cid:_2_0D521F340D63FF78006B434F80258823 style="border:0px solid;"><img src=cid:_2_0D5223680D63FF78006B434F80258823 style="border:0px solid;"><img src=cid:_2_0D52279C0D63FF78006B434F80258823 style="border:0px solid;">
Excellent customer service is important to us. Please take a moment

to provide feedback regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

From: <u>Martin.Mitchell@admedsol.com</u><<u>Martin.Mitchell@admedsol.com</u>>

Sent: Wednesday, October 13, 2021 4:46 PM
To: Lee, Michele <<u>Michele.Lee@fda.hhs.gov</u>>
Cc: <u>helen.topping@admedsol.com</u>;

<u>k211878@docs.fda.gov</u>
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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and know the content is safe.

Apologies Michele, one final thing I missed off my email... could you clarify

how long the teleconference would be by default? Could we request 1 hour

just incase some of the points end up taking longer to discuss?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360<font size=1 color=#5f5f5f

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

face="Arial">

From: <font size=1
face="Arial">Martin

Mitchell/WIN/UK/AMS
To:
   "Lee,

Michele" <<font size=1 color=blue
face="Arial"><u>Michele.Lee@fda.hhs.gov</u><font size=1
face="Arial">>
Cc:
   "<a
href=mailto:helen.topping@admedsol.com><font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">>,

"<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u>"

<<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u><font size=1
face="Arial">>
Date:
   13/10/2021

20:35
Subject:
 RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response<div
align=center><hr noshade>

<font size=2
face="Arial">

Hi Michele

We're currently preparing our
questions for the teleconference and will

send these through in due course, however to assist with scheduling the

relevant parties at FDA, I should let you know that we would definitely

like to discuss the questions related to biocompatibility.

After discussion with
the team we would like to request the teleconference

on the Tuesday 19th October

if that is possible? As we are based in

the UK, we would also like to request that this is arranged between the

hours of 2-5pm BST<font size=2
face="Arial">.

If this time slot is not available could you outline any alternative days/times

which would be possible?

Best regards,<font size=2 color=#000080
face="Arial">

Martin Mitchell
Regulatory Affairs
Manager

Advanced Medical Solutions Ltd.
E-mail: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=2 color=#000080
face="Arial">
Tel: +44 (0) 1752 30 9360<font size=1 color=#5f5f5f
face="Arial">

From: Martin

Mitchell/WIN/UK/AMS
To:
   "Lee,

Michele" <<font size=1 color=blue
face="Arial"><u>Michele.Lee@fda.hhs.gov</u><font size=1
face="Arial">>
Cc:
   "<a
href=mailto:helen.topping@admedsol.com><font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">"

<<u>helen.topping@admedsol.com</u>>,

"<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 08/10/2021

22:14
Subject: RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hi Michele

Thank you for the offer. I think after today's meeting we may need a little

more time to be better prepared for the teleconference.

We are reaching out to the toxicologist who wrote the TRA for us as we

feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible

dates for you early next week.

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>
To: "<u>Martin.Mitchell@admedsol.com</u>"

<<u>Martin.Mitchell@admedsol.com</u>>
Cc: "<u>helen.topping@admedsol.com</u>"

<<u>helen.topping@admedsol.com</u>>,

"<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 06/10/2021

13:49
Subject: RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hello Martin,

If it makes it

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easier for your team, we are able to extend the 10 day teleconference

deadline up to October 19th. Let me know if you would like to

select a date later than the 14thand I can check our management

schedules.

Regarding review timelines, we are still on the 90 day review cycle and

are planning to complete the review of your response with the 20 calendar

days left on the clock. While we retain the right to add additional days,

we are doing our best with the resources that we have to avoid delaying

review timelines if possible.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993<u>
</u><u>Michele.Lee@fda.hhs.gov</u><u>
</u><u>
</u><img src=cid:_4_0D5299F40D528E90006B434F80258823 style="border:0px solid;"><u>
</u><u>
</u><img src=cid:_2_0D529E840D528E90006B434F80258823 style="border:0px solid;"><img src=cid:_2_0D52A2B80D528E90006B434F80258823 style="border:0px solid;"><img src=cid:_2_0D52A6EC0D528E90006B434F80258823 style="border:0px solid;"><img src=cid:_2_0D52AB200D528E90006B434F80258823 style="border:0px solid;"><img src=cid:_2_0D52AF540D528E90006B434F80258823 style="border:0px solid;">
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to provide feedback regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

From: <u>Martin.Mitchell@admedsol.com</u><<u>Martin.Mitchell@admedsol.com</u>>

Sent: Wednesday, October 6, 2021 6:00 AM
To: Lee, Michele <<u>Michele.Lee@fda.hhs.gov</u>>
Cc: <u>helen.topping@admedsol.com</u>
Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Thank you again for your review. Our team are busy discussing the questions

and we would definitely like to have a teleconference with the FDA. We're

currently consolidating our understanding of the deficiencies and are determining

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

what our potential questions to you would be. I hope to get the questions

to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we

look to schedule a teleconference with the FDA on Wednesday 13th or Thursday

14th? As we're based in the UK we would appreciate a timeslot within our

working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines

for this project.... regarding the FDA timeline I can see on the CCP tracker

website that the FDA timeline is on day 70.
Will FDA be sticking to the 90 day target

and as a result only have 20 days left on the clock?<li>Or, due to the current situation with the

unprecedented resource limitations..... will you will assume 30 days to

review the response as standard? Or perhaps stick to the 20 days but retain

the right to add additional days?
Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Michele

Lee [MICHELE.LEE]" <<u>michele.lee@fda.hhs.gov</u>>
To: <<u>martin.mitchell@admedsol.com</u>>,

<<u>helen.topping@admedsol.com</u>>
Cc: "Michele

Lee [MICHELE.LEE]" <<u>michele.lee@fda.hhs.gov</u>>
Date: 04/10/2021

21:44
Subject: K211878/S001

is on Hold Pending Your Response <hr noshade>

October 4, 2021 <p>We have reviewed your submission. Please see attached.

<p>If you have any questions, please contact the lead reviewer

assigned to your submission, Michele Lee. <p> <p>*** This is a system-generated email notification ***[attachment

"K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin

Mitchell/WIN/UK/AMS] <p>

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color=blue><u>http://www.admedsol.com</u>.

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color=blue><u>http://www.admedsol.com</u>.

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Visit us at: http://www.admedsol.com. This e-mail, including any attached files, is confidential and intended for the exclusive use of the addressee(s) only. If you are not the intended recipient, please notify the sender immediately and delete it from your mailbox or any other storage mechanism.

Hello Martin,

Thank you for providing your questions in advance of the meeting. We look forward to discussing our responses with you next week.

Have a good weekend,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Friday, October 15, 2021 12:00 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Please find the list of questions/clarifications attached below.

I hope you have a good weekend. I'm looking forwards to our discussion next week!

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 13/10/2021 22:35
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

I have scheduled the teleconference for next Tuesday October 19th at 9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour but our biocompatibility consultant/ team management needs to drop off for another call at 9:30am. Please send me the questions for discussion in advance of the meeting so that we can plan to discuss biocompatibility/ regulatory questions first before the relevant parties need to drop off.

Join Zoom Meeting

One tap mobile:	**(b)(4)**
Meeting URL:	
Meeting ID:	
Passcode:	

Join by Telephone
For higher quality, dial a number based on your current location.
Dial:

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Meeting ID:
Passcode:
international numbers

(b)(4)

Join from an H.323/SIP room system
H.323:

Meeting ID:
Passcode:
SIP:
Passcode:

(b)(4)

Thanks,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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Michele.Lee@fda.hhs.gov



* * * * *

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 13, 2021 4:46 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

CAUTION:This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Apologies Michele, one final thing I missed off my email... could you clarify how long the teleconference would be by default? Could we request 1 hour just incase some of the points end up taking longer to discuss?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 13/10/2021 20:35
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hi Michele

We're currently preparing our questions for the teleconference and will send these through in due course, however to assist with scheduling the relevant parties at FDA, I should let you know that we would definitely like to discuss the questions related to biocompatibility.

After discussion with the team we would like to request the teleconference on the Tuesday 19th October if that is possible? As we are based in the UK, we would also like to request that this is arranged between the hours of 2-5pm BST.

If this time slot is not available could you outline any alternative days/times which would be possible?

Best regards,

Martin Mitchell

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Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 08/10/2021 22:14
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hi Michele

Thank you for the offer. I think after today's meeting we may need a little more time to be better prepared for the teleconference.

We are reaching out to the (b)(4) for us as we feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible dates for you early next week.

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 06/10/2021 13:49
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference deadline up to October 19th. Let me know if you would like to select a date later than the 14thand I can check our management schedules.

Regarding review timelines, we are still on the 90 day review cycle and are planning to complete the review of your response with the 20 calendar days left on the clock. While we retain the right to add additional days, we are doing our best with the resources that we have to avoid delaying review timelines if possible.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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Michele.Lee@fda.hhs.gov



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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 6, 2021 6:00 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com
Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hi Michele

Thank you again for your review. Our team are busy discussing the questions and we would definitely like to have a teleconference with the FDA. We're currently consolidating our understanding of the deficiencies and are determining what our potential questions to you would be. I hope to get the questions to you by Monday 11th at the latest.

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Additionally, I have a small question to allow us to predict timelines for this project.... regarding the FDA timeline I can see on the CCP tracker website that the FDA timeline is on day 70.

- Will FDA be sticking to the 90 day target and as a result only have 20 days left on the clock?
- Or, due to the current situation with the unprecedented resource limitations..... will you will assume 30 days to review the response as standard? Or perhaps stick to the 20 days but retain the right to add additional days?

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
To: <martin.mitchell@admedsol.com>, <helen.topping@admedsol.com>
Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
Date: 04/10/2021 21:44
Subject: K211878/S001 is on Hold Pending Your Response

October 4, 2021

We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Michele Lee.

*** This is a system-generated email notification ***[attachment "K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Advanced Medical Solutions Ltd

Advanced Medical Solutions Ltd
Western Wood Way, Langage Science Park,
Plympton, Plymouth, Devon, PL7 5BG UK
Tel: +44 (0) 1752 209955 Fax: +44 (0) 1752 209956
Web: www.admedsol.com
Registered in England 2666957 VAT No. GB 636 5551 27

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center (DCC) – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
USA

FDA/CDRH/DCC
JUL 26 2021
RECEIVED

K211878/S001

Dear Dr Michele Lee

In response to FDA's 510(k) acceptance review received 6th July 2021 for K211878 please find the reply from Advanced Medical Solutions Ltd to the missing elements listed.

This response is being submitted as the physical cover letter and an eCopy of the response on CD.

If you should you require any additional data, please do not hesitate to contact me at the contact information provided.

(b)(6)

Sincerely,

Martin Mitchell
Senior Regulatory Affairs Associate
Phone: +44 (0) 1752 30 9360
Email: Martin.Mitchell@admedsol.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Hello Martin,

Thank you for the additional clarification requests. If, (b)(4) (b)(4) then yes- this report would be sufficient to address the points raised in RTA Question B.12(a). Thank you for bringing this report to my attention.

Best Regards,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Wednesday, July 7, 2021 11:19 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Subject: [EXTERNAL] Re: K211878 is on Hold Pending Your Response

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Hi Michele

Nice to see we're working with you again.

I was a little surprised regarding the RTA decision as the level of information we've provided is the same as that which was provided in previous submissions, where we didn't receive an RTA from yourself. Therefore, I just wanted to reach out to you to ensure that I correctly answer the issue so as to avoid any further delays.

Regarding the RTA on question B.12(a)

In section 15.3 of the 510(k), (b)(4). I am wondering if this would be sufficient to address the point which you raised?

Regarding the RTA on question F.28 and F.29

We require no clarification on this point and can provide the documents as requested.

Thanks in advance for your assistance

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate
Advanced Medical Solutions Ltd.
Tel: +44 (0) 1752 30 9360
E-mail: Martin.Mitchell@admedsol.com

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
To: <martin.mitchell@admedsol.com>
Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
Date: 06/07/2021 20:49
Subject: K211878 is on Hold Pending Your Response

July 6, 2021**Acceptance Review Notification - Refuse To Accept (RTA)**

We have completed the administrative acceptance review of your submission K211878. Our review indicates that your submission does not meet the criteria

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit one eCopy of your response, referencing your submission K211878, addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Your submission will remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist by 01/02/2022, we will consider this submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your submission. We will contact you if we require any additional information during the course of our administrative review. FDA aims to apply the least burdensome principles when requesting additional information.

The lead reviewer assigned to your submission is me, Michele Lee. The file is being reviewed in Office of Health Technology 4, Division of Health Technology 4 B. The first line supervisor is the Assistant Director, Plastic Surgery Skin and Wound Devices. You may contact me at any point during the review if you have questions or concerns. You can provide valuable support for CDRH to continue to improve our programs by raising to the attention of management relevant issues that arise during the course of this review. If you feel there is an unresolved issue or a matter that requires additional attention, you should contact the Assistant Director. If your concern or issue is not addressed by the Assistant Director, you should contact the Division Director or OHT Director. The contact information for each management level can be found in the CDRH Management Directory.

For additional information about the Refuse to Accept Policy for for 510(k)s please refer to the guidance document available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf.

If you have general questions about the review process for your submission, you should contact OPEQSubmissionSupport@fda.hhs.gov.

*** This is a system-generated email notification ***[attachment "K211878.RTAChecklist.RTA1.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Hello Martin,

Thank you for your follow up email and your patience. It is an extremely busy time for the Agency this time of year.

I took a look at your comments and it seems your request on item #2 is for review of additional information in your response to our feedback rather than for clarification. In order to conduct review of the evidence provided in your response, we would need to issue a consult for a submission under active review. Currently, the Agency does not have resources to conduct informal review of submissions on hold. I recommend that you provide this justification and supporting evidence in your supplemental response for this submission and it will be reviewed when your submission is under active review.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Friday, December 17, 2021 4:58 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Good morning Michele

I was just emailing to ask if you picked up this email and forwarded this onto your **(b)(4)**?

If so do you think it may be possible to expect feedback before the end of this year?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 07/12/2021 17:08
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Michele

Thank you for your support on our questions below. Its been invaluable to our team to get this crucial feedback in such a short timeline.

After reading your response (provided in ~~red font~~below) we have provided a response on points 2 and 4 which have been provided in **blue font** to which we would like to get clarification on.

Supporting evidence is provided below if required.

[attachment "Supporting evidence.pdf" deleted by Martin Mitchell/WIN/UK/AMS] [attachment "**(b)(4)** pdf" deleted by Martin Mitchell/WIN/UK/AMS]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Additionally, please also find the finalised meeting minutes below

[attachment "K211878 - 19Oct2021 Meeting Minutes - Final.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

Thank you in advance for all your support.

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 24/11/2021 18:00
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Please find the responses to your questions below in red font and revised meeting minutes attached. Hope this is helpful!

Best,
Michele

(b)(4)

(b)(4) As requested, this clarification will also be provided

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

within the future supplement in addition to the rationale above.

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Friday, November 12, 2021 10:15 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

Regarding the timeline clarification i've taken a look on the customer collaboration portal but there was only an email to provide feedback on the portal. Nevertheless i've emailed as i'm a little concerned about what may happen if the portal shows that the 180 day hold periods has expired and we haven't yet submitted our response..... is there a risk that the 510(k) may be inadvertently withdrawn?

We have prepared our response to your question below which I hope you find helpful.

(b)(4)

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 08/11/2021 22:05
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thanks for your message. I'll need some time to review the teleconference minutes with my team and also obtain some feedback from our consulting (b)(4) about the follow up questions. But I wanted to let you know I received your email and you may feel free to check in again next week.

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I do have a clarification question about (b)(4)

(b)(4)

Regarding the timeline clarification- I am also under the understanding that the COVID-19 guidance document you cited was still active and that would allow you an additional 180 days for the hold period. I have reached out to the 510(k) Staff multiple times to confirm and am still waiting on their response. Is there a customer service contact email for the customer collaboration portal specifically? You may try contacting them as well to have the date corrected on your end.

Thank you,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Friday, November 5, 2021 12:07 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

I hope you had a nice holiday!

Following on from the teleconference we had a few actions to complete and get back to you with.

1) Teleconference minutes

Please find a draft of the the teleconference minutes below. Could you review and confirm if you require any changes made?

2) Follow-up questions on the teleconference discussion

As suggested during the teleconference there was the opportunity for a followup email clarification on a few minor points.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

3) Timeline clarification as per previous email

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Thank you again for your assistance

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>, "Liu, Lixin" <Lixin.Liu@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 20/10/2021 22:43
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Michele

Thank you for the prompt response to the clarifications! We'll take your points on board regarding future shelf life studies.

I do have a minor clarification question regarding our response timeline

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 20/10/2021 14:55
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you to you and your team for attending the teleconference yesterday. I wanted to follow up on two things I was discussing with my team:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

I will be on leave for the next two weeks and you may contact our team management (Lixin.Liu@fda.hhs.gov) if you have questions during that time.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov



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From: Lee, Michele
Sent: Friday, October 15, 2021 4:47 PM
To: Martin.Mitchell@admedsol.com
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you for providing your questions in advance of the meeting. We look forward to discussing our responses with you next week.

Have a good weekend,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov



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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Friday, October 15, 2021 12:00 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Please find the list of questions/clarifications attached below.

I hope you have a good weekend. I'm looking forwards to our discussion next week!

Best regards,

Martin Mitchell
Regulatory Affairs Manager

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Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 13/10/2021 22:35
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

I have scheduled the teleconference for next Tuesday October 19th at 9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour but our (b)(4) team management needs to drop off for another call at 9:30am. Please send me the questions for discussion in advance of the meeting so that we can plan to discuss (b)(4) (b)(4) questions first before the relevant parties need to drop off.

Join Zoom Meeting

(b)(4)

Thanks,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 13, 2021 4:46 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Apologies Michele, one final thing I missed off my email... could you clarify how long the teleconference would be by default? Could we request 1 hour just incase some of the points end up taking longer to discuss?

Best regards,

Martin Mitchell

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 13/10/2021 20:35
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hi Michele

We're currently preparing our questions for the teleconference and will send these through in due course, however to assist with scheduling the relevant parties at FDA, I should let you know that we would definitely like to discuss the questions related **(b)(4)**

After discussion with the team we would like to request the teleconference on the Tuesday 19th October if that is possible? As we are based in the UK, we would also like to request that this is arranged between the hours of 2-5pm BST.

If this time slot is not available could you outline any alternative days/times which would be possible?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 08/10/2021 22:14
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hi Michele

Thank you for the offer. I think after today's meeting we may need a little more time to be better prepared for the teleconference.

We are reaching out to the **(b)(4)** for us as we feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible dates for you early next week.

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 06/10/2021 13:49
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference deadline up to October 19th. Let me know if you would like to select a date later than the 14thand I can check our management schedules.

Regarding review timelines, we are still on the 90 day review cycle and are planning to complete the review of your response with the 20 calendar days left on the clock. While we retain the right to add additional days, we are doing our best with the resources that we have to avoid delaying review timelines if possible.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 6, 2021 6:00 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com
Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Thank you again for your review. Our team are busy discussing the questions and we would definitely like to have a teleconference with the FDA. We're currently consolidating our understanding of the deficiencies and are determining what our potential questions to you would be. I hope to get the questions to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we look to schedule a teleconference with the FDA on Wednesday 13th or Thursday 14th? As we're based in the UK we would appreciate a timeslot within our working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines for this project.... regarding the FDA timeline I can see on the CCP tracker website that the FDA timeline is on day 70.

- Will FDA be sticking to the 90 day target and as a result only have 20 days left on the clock?
- Or, due to the current situation with the unprecedented resource limitations..... will you will assume 30 days to review the response as standard? Or perhaps stick to the 20 days but retain the right to add additional days?

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
To: <martin.mitchell@admedsol.com>, <helen.topping@admedsol.com>
Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
Date: 04/10/2021 21:44
Subject: K211878/S001 is on Hold Pending Your Response

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October 4, 2021

We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Michele Lee.

*** This is a system-generated email notification ***[attachment "K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

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Advanced Medical Solutions Limited
Martin Mitchell
Senior Regulatory Affairs Associate
Western Wood Way , Langage Science Park
Plymouth, Devon PL7 5BG
United Kingdom

Re: K211878
Trade/Device Name: LiquiBand XL
Regulation Number: 21 CFR 878.4011
Regulation Name: Tissue Adhesive With Adjunct Wound Closure Device For Topical Approximation Of Skin
Regulatory Class: Class II
Product Code: OMD
Dated: May 4, 2022
Received: May 4, 2022

Dear Martin Mitchell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

LETTER SHOULD BE DATED BEFORE SIGNING, AND MUST BE SIGNED OUT OF CTS ON THE DATE INDICATED ON THE LETTER.

Julie Morabito
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Advanced Medical Solutions Ltd

Advanced Medical Solutions Limited
Western Wood Way,
Langage Science Park,
Plymouth,
Devon,
PL7 5BG,
United Kingdom
Tel: +44 (0) 1752 209955 **Fax:** +44 (0) 1752 209956
Web: www.admedsol.com
Registered in England 2666957 VAT No. GB 636 5551 27

510(k) Summary

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Advanced Medical Solutions Plymouth Ltd.

Design Verification Protocol

LIQUIBAND XL & COMPETITOR BENCH TESTING FOR ASTM 2458-05 WOUND CLOSURE	Doc No:	(b)(4)	
	Rev No:		

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

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Advanced Medical Solutions

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Design Verification Report

PROJECT YEALM LARGE WOUND ASTM F2458 WOUND CLOSURE STRENGTH SUBSTANTIAL EQUIVALENCE TESTING

Doc No:	(b)(4)
Rev No:	

Test facility: AMS - Plymouth
Test facility address: Western Wood Way
Langage Science Park
Plymouth
PL7 5BG, UK

REPORT APPROVAL			
Originated by:	**Title**	**Signature**	**Date**
(b)(4)	Project Scientist	(b)(4)	4th May 2021
Reviewed and Approved by:	**Title**	**Signature**	**Date**
(b)(4)	Development Manager	(b)(4)	05/05/21
Martin Mitchell	Senior Regulatory Affairs Associate		__/__/__
(b)(4)	Quality Manager		__/__/__
	Project Leader		__/__/__

Signing of the above confirms the signatories' agreement and approval of the contents of this document

CC	n/a	**Master Folder**	M110
Synopsis	(b)(4)		
Planned Start Date			
Key Words			

Product Name Covered	Product Code
LiquiBand XL	72014019
Chemence Fusion	EF70401

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Advanced Medical Solutions

Design Verification Report

PROJECT YEALM LARGE WOUND ASTM F2458 WOUND CLOSURE STRENGTH SUBSTANTIAL EQUIVALENCE TESTING	Doc No:	(b)(4)	
	Rev No:		

Test facility: AMS - Plymouth
Test facility address: Western Wood Way
Langage Science Park
Plymouth
PL7 5BG, UK

REPORT APPROVAL			
Originated by:	**Title**	**Signature**	**Date**
(b)(4)	Project Scientist		4th May 2021
Reviewed and Approved by:	**Title**	**Signature**	**Date**
(b)(4)	Development Manager		__/__/__
Martin Mitchell	Senior Regulatory Affairs Associate	(b)(4)	13/05/2021
(b)(4)	Quality Manager		__/__/__
	Project Leader		__/__/__

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Advanced Medical Solutions

Design Verification Report

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Plymouth
PL7 5BG, UK

REPORT APPROVAL			
Originated by:	**Title**	**Signature**	**Date**
(b)(4)	Project Scientist		4th May 2021
Reviewed and Approved by:	**Title**	**Signature**	**Date**
(b)(4)	Development Manager		__/__/__
Martin Mitchell	Senior Regulatory Affairs Associate		__/__/__
(b)(4)	Quality Manager	(b)(4)	14/05/2021
	Project Leader		__/__/__

Signing of the above confirms the signatories' agreement and approval of the contents of this document

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Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

TEST REPORT

Degradation Assessment of Cyanoacrylate Wound Care System (b)(4)

(b)(4)

CUSTOMER

(b)(4)

Advanced Medical Solutions
2 Western Wood Way
PL7 5BG
United Kingdom

REPORT NO.

(b)(4)

COMPILED BY

(b)(4)

Delivery Manager - Regulatory

(b)(4)

(b)(4)

DATE

17/04/2021

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

TEST REPORT

HPLC Analysis of (b)(4)

(b)(4)

CUSTOMER

(b)(4)

Advanced Medical Solutions
2 Western Wood Way
PL7 5BG
United Kingdom

REPORT NO.

(b)(4)

COMPILED BY

(b)(4)

Senior Analyst

(b)(4)

DATE

10/04/2021

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

TEST REPORT

Qualitative GC-MS Screen of (b)(4) Extracts

CUSTOMER

(b)(4)

Advanced Medical Solutions
2 Western Wood Way
PL7 5BG
United Kingdom

REPORT NO.

(b)(4)

COMPILED BY

(b)(4)

Senior Analyst

(b)(4)

DATE

09/04/2021

(b)(4)

Report No. (b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

TEST REPORT

Cyanoacrylate Degradation Screen by Liquid Chromatography with (b)(4)

CUSTOMER

(b)(4)

Advanced Medical Solutions
2 Western Wood Way
PL7 5BG
United Kingdom

REPORT NO.

(b)(4)

COMPILED BY

(b)(4)

Senior Research Scientist & Project Manager

(b)(4)

(b)(4)

DATE

28/04/2021

Report No. (b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

TEST REPORT

Qualitative Headspace GC-MS Screen of (b)(4) Saline Extracts

CUSTOMER

(b)(4)

Advanced Medical Solutions
2 Western Wood Way
PL7 5BG
United Kingdom

REPORT NO.

(b)(4)

COMPILED BY

(b)(4)

Senior Analyst

(b)(4)

(b)(4)

DATE

26/04/2021

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

TEST REPORT

Semi-quantitative GC-MS Analysis of Extracts

CUSTOMER
(b)(4)
Advanced Medical Solutions
2 Western Wood Way
PL7 5BG
United Kingdom

REPORT NO.
(b)(4)

COMPILED BY
(b)(4)
Senior Analyst

(b)(4)

DATE
10/06/2021

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Chemicals Analysis Team Study Plan

Labdat no: (b)(4)

Scientist:	(b)(4)	
Chit no:		
Originator:		**Advanced medical solutions**
Sample identifying marks:	(b)(4)	
Purpose/Information required:		
Procedure:		
Initial Storage of test samples:		
Safety procedures:		
Principal Scientist: **Supporting Staff:**		
Records to maintained:		
Report Template		
Quote reference		

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Scientist:	(b)(4)
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Records to maintained:	
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Hello Michele

Thank you for the prompt response to

the clarifications! We'll take your points on board regarding future shelf

life studies.

I do have a minor clarification question

regarding our response timeline

I can see on the customer collaboration

portal that we have a 180 day hold period which ends on the 2nd of April

2022.

However, I was under the understanding

that the guidance document below was active which would provide us with

an additional 180 day hold period?

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days

or 360 days to respond to the deficiencies?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions

Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From:

 "Lee, Michele"

<Michele.Lee@fda.hhs.gov>
To:

 "Martin.Mitchell@admedsol.com"

<Martin.Mitchell@admedsol.com>
Cc:

 "helen.topping@admedsol.com"

<helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date:

 20/10/2021 14:55
Subject:

   RE: [EXTERNAL]

Re: K211878/S001 is on Hold Pending Your Response
<hr noshade>

Hello Martin,

Thank you to you and your team for attending

the teleconference yesterday. I wanted to follow up on two things I was

discussing with my team:
1.   Regarding

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

face="Calibri">
I will be on leave for the next two weeks

and you may contact our team management (<u>Lixin.Liu@fda.hhs.gov</u>)

if you have questions during that time.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices

Team
DHT4B: Division of Infection Control and

Plastic Surgery Devices
OHT4: Office of Surgical and Infection

Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue

| Silver Spring, MD 20993
<u>Michele.Lee@fda.hhs.gov</u>

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</u><img src=cid:_2_0EF1CFD80EF1C7E80077561680258774 style="border:0px solid;"> <img src=cid:_2_0EF1D4240EF1C7E80077561680258774 style="border:0px solid;"> <img src=cid:_2_0EF1D8700EF1C7E80077561680258774 style="border:0px solid;"> <img src=cid:_2_0EF1DCBC0EF1C7E80077561680258774 style="border:0px solid;"> <img src=cid:_2_0EF1E1080EF1C7E80077561680258774 style="border:0px solid;">
Excellent customer

service is important to us. Please take a moment to provide feedback

regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

From: Lee, Michele
Sent: Friday, October 15, 2021 4:47 PM
To: Martin.Mitchell@admedsol.com
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold

Pending Your Response

Hello Martin,

Thank you for providing your questions

in advance of the meeting. We look forward to discussing our responses

with you next week.

Have a good weekend,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices

Team
DHT4B: Division of Infection Control and

Plastic Surgery Devices
OHT4: Office of Surgical and Infection

Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue

| Silver Spring, MD 20993
<u>Michele.Lee@fda.hhs.gov</u>

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Excellent customer

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From: <u>Martin.Mitchell@admedsol.com</u><<u>Martin.Mitchell@admedsol.com</u>>

Sent: Friday, October 15, 2021 12:00 PM
To: Lee, Michele <<u>Michele.Lee@fda.hhs.gov</u>>
Cc: <u>helen.topping@admedsol.com</u>;

<u>k211878@docs.fda.gov</u><font size=2

face="Calibri">
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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or open attachments unless you recognize the sender and know the content

is safe.

Hi Michele

Please find the list of questions/clarifications attached below.

I hope you have a good weekend. I'm looking forwards to our discussion

next week!

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>
To: "<u>Martin.Mitchell@admedsol.com</u>"

<<u>Martin.Mitchell@admedsol.com</u>>
Cc: "<u>helen.topping@admedsol.com</u>"

<<u>helen.topping@admedsol.com</u>>,

"<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 13/10/2021

22:35
Subject: RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hello Martin,

I have scheduled the teleconference for next Tuesday October 19that 9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour

but our biocompatibility consultant/ team management needs to drop off

for another call at 9:30am. Please send me the questions for discussion

in advance of the meeting so that we can plan to discuss biocompatibility/

regulatory questions first before the relevant parties need to drop off.

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Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

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href="https://fda.zoomgov.com/j/1609831829?pwd=Mk16N1pXYnUrY2h2TFoyQTRaUCt5QT09"
target=_blank><u>Join

Zoom Meeting</u> <tr

(b)(4)

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(b)(4)

face="Arial">429761</table><p>

Thanks,
Michele

Michele Lee,
Ph.D.
Lead Reviewer / Materials
Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of
Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and
Infection Control Devices
Office of Product Evaluation and Quality

CDRH |
Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver
Spring, MD 20993<u>
</u><a
href=mailto:Michele.Lee@fda.hhs.gov><font size=2 color=blue face="Segoe
UI"><u>Michele.Lee@fda.hhs.gov</u>
<u>
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color=#4f4f4f face="Arial"><img
src=cid:_2_10271A580EF6A9FC0077561680258774 style="border:0px solid;"><font size=1
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href=http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm><img
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color=#4f4f4f>
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take a moment

to provide feedback regarding the customer service you have received: <a
href="https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E"
target=_blank><font size=2 color=#0082bf
face="Helvetica"><u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u><

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

/font>

From: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2
color=blue><u>Martin.Mitchell@admedsol.com</u><<a
href=mailto:Martin.Mitchell@admedsol.com><font size=2
color=blue><u>Martin.Mitchell@admedsol.com</u>>

Sent: Wednesday, October 13, 2021 4:46 PM
To: Lee, Michele
<<font size=2
color=blue><u>Michele.Lee@fda.hhs.gov</u>>
Cc:
<font size=2
color=blue><u>helen.topping@admedsol.com</u>;

<font size=2
color=blue><u>k211878@docs.fda.gov</u>
Subject: RE:
[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response
 <font size=2
color=#806210>
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and know the content is safe.

Apologies
Michele, one final thing I missed off my email... could you clarify

how long the teleconference would be by default? Could we request 1 hour

just incase some of the points end up taking longer to discuss?

Best
regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-
mail: <font size=2 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=2 color=#000080
face="Arial">
Tel: +44 (0) 1752 30 9360

From: Martin

Mitchell/WIN/UK/AMS
To:
   "Lee,

Michele" <<font size=1 color=blue
face="Arial"><u>Michele.Lee@fda.hhs.gov</u><font size=1
face="Arial">>
Cc:
   "<a
href=mailto:helen.topping@admedsol.com><font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">>,

"<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u>"

<<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u><font size=1
face="Arial">>
Date:
   13/10/2021

20:35
Subject:
 RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response<div
align=center><hr noshade>

<font size=2
face="Arial">

Hi Michele

We're currently preparing our questions for the
teleconference and will

send these through in due course, however to assist with scheduling the

relevant parties at FDA, I should let you know that we would definitely

like to discuss the questions related to biocompatibility.

After discussion with
the team we would like to request the teleconference

on the Tuesday 19th October

if that is possible? As we are based in

the UK, we would also like to request that this is arranged between the

hours of 2-5pm BST<font size=2
face="Arial">.

If this time slot is not available could you outline any alternative days/times

which would be possible?

Best regards,<font size=2 color=#000080
face="Arial">

Martin Mitchell
Regulatory Affairs
Manager

Advanced Medical Solutions Ltd.
E-mail: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=2 color=#000080
face="Arial">
Tel: +44 (0) 1752 30 9360<font size=2
face="Calibri">

<font size=1 color=#5f5f5f
face="Arial">

From: <font size=1
face="Arial">Martin

Mitchell/WIN/UK/AMS
To:
   "Lee,

Michele" <<font size=1 color=blue
face="Arial"><u>Michele.Lee@fda.hhs.gov</u><font size=1
face="Arial">>
Cc:
   "<a
href=mailto:helen.topping@admedsol.com><font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">>,

"<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u>"

<<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u><font size=1
face="Arial">>
Date:
   08/10/2021

22:14
Subject:
 RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response<font size=2
face="Calibri"> <hr noshade>
<font size=2
face="Calibri">

Hi Michele

Thank you
for the offer. I think after today's meeting we may need a little

more time to be better prepared for the teleconference.

We are reaching out to
the toxicologist who wrote the TRA for us as we

feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible

dates for you early next week.

Best regards,<font size=2 color=#000080
face="Arial">

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=2 color=#000080
face="Arial">
Tel: +44 (0) 1752 30 9360<font size=2
face="Calibri">

<font size=1 color=#5f5f5f
face="Arial">

From: <font size=1
face="Arial">"Lee,

Michele" <<font size=1 color=blue
face="Arial"><u>Michele.Lee@fda.hhs.gov</u><font size=1
face="Arial">>
To:

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

   "<a
href=mailto:Martin.Mitchell@admedsol.com><font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">>
Cc:
   "<a
href=mailto:helen.topping@admedsol.com><font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">>,

"<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u>"

<<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u><font size=1
face="Arial">>
Date:
   06/10/2021

13:49
Subject:
 RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response<font size=2
face="Calibri"> <hr noshade>
<font size=2
face="Calibri">

Hello Martin,

If it makes it easier for your
team, we are able to extend the 10 day teleconference

deadline up to October 19th. Let me know if you would like to

select a date later than the 14thand I can check our management

schedules.

Regarding review timelines, we are still on the 90 day review cycle
and

are planning to complete the review of your response with the 20 calendar

days left on the clock. While we retain the right to add additional days,

we are doing our best with the resources that we have to avoid delaying

review timelines if possible.

Best,
Michele<font size=2 color=#0082bf
face="Segoe UI">

Michele Lee, Ph.D.<font size=2 face="Segoe
UI">
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound
Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices
Office of Product
Evaluation and Quality

CDRH | Food and Drug Administration
White Oak |
10903 New Hampshire Avenue | Silver Spring, MD 20993<font size=2 color=blue
face="Calibri"><u>
</u><font size=2
color=blue face="Segoe UI"><u>Michele.Lee@fda.hhs.gov</u><font size=2
color=blue face="Calibri"><u>
</u><font size=2 color=blue
face="Calibri"><u>
</u><img
src=cid:_4_0E6040E40E6035580077561680258774 style="border:0px solid;"><font size=2
color=blue face="Calibri"><u>
</u><font size=2 color=blue
face="Calibri"><u>
</u><img
src=cid:_2_0E6045740E6035580077561680258774 style="border:0px solid;"><a
href=https://twitter.com/US_FDA><img src=cid:_2_0E6049A80E6035580077561680258774
style="border:0px solid;"><a
href=http://www.youtube.com/user/USFoodandDrugAdmin><img
src=cid:_2_0E604DF40E6035580077561680258774 style="border:0px solid;"><a
href=http://www.flickr.com/photos/fdaphotos/><img
src=cid:_2_0E6052280E6035580077561680258774 style="border:0px solid;"><font size=1
color=#4f4f4f face="Arial"> <a
href=http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm><img
src=cid:_2_0E6056740E6035580077561680258774 style="border:0px solid;"><font size=2
color=#4f4f4f face="Calibri">
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

 Please take a moment

to provide feedback regarding the customer service you have received: </i><u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

From: <u>Martin.Mitchell@admedsol.com</u><<u>Martin.Mitchell@admedsol.com</u>>

Sent: Wednesday, October 6, 2021 6:00 AM
To: Lee, Michele <<u>Michele.Lee@fda.hhs.gov</u>>
Cc: <u>helen.topping@admedsol.com</u>
Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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of the organization. Do not click links or open attachments unless you

recognize the sender and know the content is safe.

Hi Michele

Thank you again for your review. Our team are busy discussing the questions

and we would definitely like to have a teleconference with the FDA. We're

currently consolidating our understanding of the deficiencies and are determining

what our potential questions to you would be. I hope to get the questions

to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we

look to schedule a teleconference with the FDA on Wednesday 13th or Thursday

14th? As we're based in the UK we would appreciate a timeslot within our

working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines

for this project.... regarding the FDA timeline I can see on the CCP tracker

website that the FDA timeline is on day 70.
Will FDA be sticking to the 90 day target

and as a result only have 20 days left on the clock?<li>Or, due to the current situation with the

unprecedented resource limitations..... will you will assume 30 days to

review the response as standard? Or perhaps stick to the 20 days but retain

the right to add additional days?
Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Michele

Lee [MICHELE.LEE]" <<u>michele.lee@fda.hhs.gov</u>>
To: <<font size=1 color=#0082bf

face="Arial"><u>martin.mitchell@admedsol.com</u><font size=1
face="Arial">>,

<<font size=1 color=#0082bf
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">>
Cc:
   "Michele

Lee [MICHELE.LEE]" <<font size=1
color=#0082bf face="Arial"><u>michele.lee@fda.hhs.gov</u><font size=1
face="Arial">>
Date:
   04/10/2021

21:44
Subject:
 K211878/S001

is on Hold Pending Your Response <div
align=center><hr noshade>

October 4, 2021
<p>We have reviewed your submission. Please see attached.

<p>If you have any questions, please contact the lead reviewer

assigned to your submission, Michele Lee. <p> <p>*** This is a system-generated email notification ***[attachment

"K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin

Mitchell/WIN/UK/AMS] <p>

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href=http://www.admedsol.com/><font size=3
color=#0082bf><u>http://www.admedsol.com</u>.

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color=blue><u>http://www.admedsol.com</u>.

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color=blue><u>http://www.admedsol.com</u>.

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Hi Sam

Firstly, thank you for staying late

to continue to work with us on in the final stages of this submission.

It is much appreciated.

Please find attached the IFU with updated

comments from ourselves

For most of the proposed updates we

will accept to make the changes. However there are two points we would

wish to clarify
Regarding the comment on

(b)(4)

serif">As discussed I'll call you tomorrow

to discuss your email below

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions

Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From:

 "Arepalli, Sambasiva"

<Sambasiva.Arepalli@fda.hhs.gov>
To:

 "Martin.Mitchell@admedsol.com"

<Martin.Mitchell@admedsol.com>
<font size=1 color=#5f5f5f face="sans-

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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serif">Cc:

 "Arepalli, Sambasiva"

<Sambasiva.Arepalli@fda.hhs.gov>, "K211878@docs.fda.gov"

<K211878@docs.fda.gov>
Date:

 18/05/2022 20:39
Subject:

   RE: [EXTERNAL]

Re: K211878-s002
<hr noshade>

Hi Mr. Mitchell:
Please see attached for the labeling and

510kSummary with FDA edits.

Please address these edits and send me

both the edited versions and clean copies of the labeling and the 510kSummary

by COB tomorrow (5-19-2022).

Please cc your response to K211878@docs.fda.gov.

Thx
Sam

Sam Arepalli, Ph.D.
FDA/CDRH/OPEQ/OHT4/PRSB2
Ph: 301 796 6434

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service is important to us. Please take a moment to provide feedback

regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u><u></u>

From: Martin.Mitchell@admedsol.com

<Martin.Mitchell@admedsol.com>
Sent: Tuesday, May 17, 2022 6:39 AM
To: Arepalli, Sambasiva <Sambasiva.Arepalli@fda.hhs.gov>
Subject: RE: [EXTERNAL] Re: K211878-s002

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or open attachments unless you recognize the sender and know the content

is safe.

Hi Sam

Just to be safe for the email trail.... so that your email has a response

The email with this information was send yesterday; however it is also

provided again below:

Please find a response to the two points we discussed over the phone

FDA deficiency 13

(b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

<<u>Martin.Mitchell@admedsol.com</u>>
Date: 17/05/2022

10:32
Subject: RE:

[EXTERNAL] Re: K211878-s002 <hr noshade>

Hi Mr. Mitchell:
Can you please give an update on the revised labeling request? Could you

please send the information cob today? Please give me a call when you have

a minute.
Thx
Sam

Sam Arepalli, Ph.D.
FDA/CDRH/OPEQ/OHT4/PRSB2
Ph: 301 796 6434

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to provide feedback regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

From: <u>Martin.Mitchell@admedsol.com</u><<u>Martin.Mitchell@admedsol.com</u>>

Sent: Monday, May 16, 2022 12:06 PM
To: Arepalli, Sambasiva <<u>Sambasiva.Arepalli@fda.hhs.gov</u>>
Subject: [EXTERNAL] Re: K211878-s002

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of the organization. Do not click links or open attachments unless you

recognize the sender and know the content is safe.

Hi Sam

Just so you're aware it's 17:00 now so i'll be heading home; however i'll

try to make myself available outside of hours so please don't hesitate

to get in touch if you have any further questions.

Additionally i'll be working from home the next few days so I won't pick

up calls from my office number you used previously.

If you have any further questions please email me or call me on my personal

mobile number (b)(6)

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: Martin

Mitchell/WIN/UK/AMS
To: "Arepalli,

Sambasiva" <<u>Sambasiva.Arepalli@fda.hhs.gov</u>>
Cc: "<font size=1 color=blue

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

face="Arial"><u>K211878@docs.fda.gov</u>"

<<u>K211878@docs.fda.gov</u>>,

Rose Guang/WIN/UK/AMS@ams, Helen Topping/WIN/UK/AMS@ams
Date: 16/05/2022

16:28
Subject: Re:

K211878-s002 <hr noshade>

Hi Sam

Please find a response to the two points we discussed over the phone

FDA deficiency 13

(b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Arepalli,

Sambasiva" <<u>Sambasiva.Arepalli@fda.hhs.gov</u>>
To: "<u>Martin.Mitchell@admedsol.com</u>"

<<u>Martin.Mitchell@admedsol.com</u>>
Cc: "Arepalli,

Sambasiva" <<u>Sambasiva.Arepalli@fda.hhs.gov</u>>,

"<u>K211878@docs.fda.gov</u>"

<<u>K211878@docs.fda.gov</u>>
Date: 16/05/2022

14:39
Subject: K211878-s002 <hr noshade>

Hi Mr. Martin:
Please address the following:

(b)(4)

(b)(4)

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Visit us at: <a href=http://secure-web.cisco.com/1Yi27zECe4ODh1_O-Awak5BuDz-bhudej5-

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
NEnj4Rx_sEZZuGCqcO98DlC4LCZvtxk5p6Bxdkfcxu3-8SLdt2B92O2XAfCM7xDRu9XDjd-eLkxtjw0r12Uie0dfU5vyh4vhBBvkxCsrNppko7UF3f4IDv2ekgN0nX6lY8PF-ILdbmZ2ZBrjufc0AM_C3ivdFe/http%3A%2F%2Fwww.admedsol.com%2F>
<u>http://www.admedsol.com</u>.

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Revised labeling received on 5-16-2022.jam.pdf" deleted by Martin

Mitchell/WIN/UK/AMS] [attachment "K211878.510kSummary(Final).jam.pdf"

deleted by Martin Mitchell/WIN/UK/AMS]

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Hello all,

Thank you, Martin, for the connection.

(b)(4)

Best Regards,

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Thursday, November 4, 2021 11:29 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>; k211878@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

Regarding the recent deficiency question on our medical device submission which is currently under review with the FDA:

(b)(4)

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Hello Helen,

I understand your position and can assure you that we intend to meet the Monday time frame for completion of the substantive review.

Best regards,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov



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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Helen.Topping@admedsol.com <Helen.Topping@admedsol.com>
Sent: Tuesday, September 28, 2021 2:48 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: k211878@docs.fda.gov; Martin.Mitchell@admedsol.com; Rose.Guang@admedsol.com
Subject: RE: [EXTERNAL] Re: K211878/S001 Review Status

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Hi Michelle,

I realise we're in unprecedented times and I do want to be respectful to FDA's challenges. As this project is business critical for us, could you reassure me that Monday's timeframe will not move again?

Best regards
Helen

Helen Topping
Senior Regulatory Affairs Manager
Advanced Medical Solutions
Tel: +44 (0) 7721261214
Email: **helen.topping@admedsol.com**

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>, "Helen.Topping@admedsol.com" <Helen.Topping@admedsol.com>, "Rose.Guang@admedsol.com" <Rose.Guang@admedsol.com>
Cc: "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 28/09/2021 16:45
Subject: RE: [EXTERNAL] Re: K211878/S001 Review Status

Hello Martin, Helen, & Rose:

I am writing to inform you of a revision to the review timeline for your 510(k) Submission K211878/S001. Unfortunately, we are unable to complete the substantive review by the previously revised timeline of September 29th. We now anticipate completion of the substantive review by next Monday, October 4th. We apologize for any inconveniences caused because of the multiple extensions of review timeline and appreciate your understanding as the Agency works through resource limitations during this time.

Best Regards,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov



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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Tuesday, September 21, 2021 10:03 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: k211878@docs.fda.gov; Helen.Topping@admedsol.com; Rose.Guang@admedsol.com
Subject: [EXTERNAL] Re: K211878/S001 Review Status

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Hello Michele

Thank you for your email to keep us updated with progress.

Please note that next week i'll be out on annual leave... therefore, could you also place Helen and Rose (on this email) on copy with any further communication you send over.

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 20/09/2021 22:31
Subject: K211878/S001 Review Status

Hello Martin:

I want to inform you of a slightly revised review timeline for your 510(k) submission K211878/S001. Due to a limitation of Agency resources, we are unable to complete the substantive review by September 24th. We want to inform you that we expect to complete the review by next Wednesday, September 29th. We apologize for any inconveniences because of the extension of timeline.

Best Regards,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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Michele.Lee@fda.hhs.gov



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Hello Martin,

Please find the responses to your questions below in red font and revised meeting minutes attached. Hope this is helpful!

Best,
Michele

(b)(4)

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Friday, November 12, 2021 10:15 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

Regarding the timeline clarification i've taken a look on the customer collaboration portal but there was only an email to provide feedback on the portal. Nevertheless i've emailed as i'm a little concerned about what may happen if the portal shows that the 180 day hold periods has expired and we haven't yet submitted our response..... is there a risk that the 510(k) may be inadvertently withdrawn?

We have prepared our response to your question below which I hope you find helpful.

(b)(4)

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 08/11/2021 22:05
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thanks for your message. I'll need some time to review the teleconference minutes with my team and also obtain some feedback from our consulting toxicologist about the follow up questions. But I wanted to let you know I received your email and you may feel free to check in again next week.

I do have a clarification question about (b)(4)

(b)(4)

Regarding the timeline clarification- I am also under the understanding that the COVID-19 guidance document you cited was still active and that would allow you an additional 180 days for the hold period. I have reached out to the 510(k) Staff multiple times to confirm and am still waiting on their response. Is there a customer service contact email for the customer collaboration portal specifically? You may try contacting them as well to have the date corrected on your end.

Thank you,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Friday, November 5, 2021 12:07 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

I hope you had a nice holiday!

Following on from the teleconference we had a few actions to complete and get back to you with.

1) Teleconference minutes

Please find a draft of the the teleconference minutes below. Could you review and confirm if you require any changes made?

2) Follow-up questions on the teleconference discussion

As suggested during the teleconference there was the opportunity for a followup email clarification on a few minor points.

(b)(4)

The supporting information which provides further clarity on the questions above has been attached if required.

3) Timeline clarification as per previous email

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Thank you again for your assistance

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

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From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>, "Liu, Lixin" <Lixin.Liu@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 20/10/2021 22:43
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Michele

Thank you for the prompt response to the clarifications! We'll take your points on board regarding future shelf life studies.

I do have a minor clarification question regarding our response timeline

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 20/10/2021 14:55
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you to you and your team for attending the teleconference yesterday. I wanted to follow up on two things I was discussing with my team:

(b)(4)

I will be on leave for the next two weeks and you may contact our team management (Lixin.Liu@fda.hhs.gov) if you have questions during that time.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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Michele.Lee@fda.hhs.gov

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From: Lee, Michele
Sent: Friday, October 15, 2021 4:47 PM

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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To: Martin.Mitchell@admedsol.com
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you for providing your questions in advance of the meeting. We look forward to discussing our responses with you next week.

Have a good weekend,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/odhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Friday, October 15, 2021 12:00 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Please find the list of questions/clarifications attached below.

I hope you have a good weekend. I'm looking forwards to our discussion next week!

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 13/10/2021 22:35
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

I have scheduled the teleconference for next Tuesday October 19th at 9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour but our biocompatibility consultant/ team management needs to drop off for another call at 9:30am. Please send me the questions for discussion in advance of the meeting so that we can plan to discuss biocompatibility/ regulatory questions first before the relevant parties need to drop off.

Join Zoom Meeting
One tap mobile:
Meeting URL:
Meeting ID:
Passcode:
(b)(4)

Join by Telephone
For higher quality, dial a number based on your current location.
Dial:

Meeting ID:
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Passcode: (b)(4)
International numbers
Join from an H.323/SIP room system
H.323:

Meeting ID:
Passcode:
SIP:
Passcode:

(b)(4)

Thanks,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
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Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 13, 2021 4:46 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Apologies Michele, one final thing I missed off my email... could you clarify how long the teleconference would be by default? Could we request 1 hour just incase some of the points end up taking longer to discuss?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 13/10/2021 20:35
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hi Michele

We're currently preparing our questions for the teleconference and will send these through in due course, however to assist with scheduling the relevant parties at FDA, I should let you know that we would definitely like to discuss the questions related to biocompatibility.

After discussion with the team we would like to request the teleconference on the Tuesday 19th October if that is possible? As we are based in the UK, we would also like to request that this is arranged between the hours of 2-5pm BST.

If this time slot is not available could you outline any alternative days/times which would be possible?

Best regards,

Martin Mitchell

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 08/10/2021 22:14
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hi Michele

Thank you for the offer. I think after today's meeting we may need a little more time to be better prepared for the teleconference.

We are reaching out to the (b)(4) for us as we feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible dates for you early next week.

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 06/10/2021 13:49
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference deadline up to October 19th. Let me know if you would like to select a date later than the 14th and I can check our management schedules.

Regarding review timelines, we are still on the 90 day review cycle and are planning to complete the review of your response with the 20 calendar days left on the clock. While we retain the right to add additional days, we are doing our best with the resources that we have to avoid delaying review timelines if possible.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov



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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Sent: Wednesday, October 6, 2021 6:00 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com
Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Thank you again for your review. Our team are busy discussing the questions and we would definitely like to have a teleconference with the FDA. We're currently consolidating our understanding of the deficiencies and are determining what our potential questions to you would be. I hope to get the questions to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we look to schedule a teleconference with the FDA on Wednesday 13th or Thursday 14th? As we're based in the UK we would appreciate a timeslot within our working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines for this project.... regarding the FDA timeline I can see on the CCP tracker website that the FDA timeline is on day 70.

- Will FDA be sticking to the 90 day target and as a result only have 20 days left on the clock?
- Or, due to the current situation with the unprecedented resource limitations..... will you will assume 30 days to review the response as standard? Or perhaps stick to the 20 days but retain the right to add additional days?

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
To: <martin.mitchell@admedsol.com>, <helen.topping@admedsol.com>
Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
Date: 04/10/2021 21:44
Subject: K211878/S001 is on Hold Pending Your Response

October 4, 2021

We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Michele Lee.

*** This is a system-generated email notification ***[attachment "K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

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Hi Martin,

(b)(4)

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Friday, November 26, 2021 6:41 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

(b)(4)

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Cc: (b)(4)
Date: 05/11/2021 13:34
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello all,

Thank you, Martin, for the connection.

(b)(4)

Best Regards,

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices

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Office of Product Evaluation and Quality

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov



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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Thursday, November 4, 2021 11:29 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>; k211878@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

Regarding the recent deficiency question on our medical device submission which is currently under review with the FDA:

(b)(4)

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

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Good morning Michele

I was just emailing to ask if you picked

up this email and forwarded this onto your consulting toxicologist?

If so do you think it may be possible

to expect feedback before the end of this year?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions

Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From:

 Martin Mitchell/WIN/UK/AMS
To:

 "Lee, Michele"

<Michele.Lee@fda.hhs.gov>
Cc:

 "helen.topping@admedsol.com"

<helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date:

 07/12/2021 17:08
Subject:

   RE: [EXTERNAL]

Re: K211878/S001 is on Hold Pending Your Response
<hr noshade>

Hello Michele

Thank you for your support on our questions

below. Its been invaluable to our team to get this crucial feedback in

such a short timeline.

After reading your response (provided

in red fontbelow) we have provided a response on points 2 and 4 which have been

provided in blue font

to which we would like to get

clarification on.

Supporting evidence is provided below

if required.

[attachment "Supporting evidence.pdf"

deleted by Martin Mitchell/WIN/UK/AMS] [attachment "JECFA review on

food flavourings.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

Additionally, please also find the finalised

meeting minutes below

[attachment "K211878 - 19Oct2021

Meeting Minutes - Final.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

Thank you in advance for all your support.

Best regards,

<font size=2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

color=#000080 face="sans-serif">Martin Mitchell
<font size=2
color=#000080 face="sans-serif">Regulatory Affairs Manager

<font size=2
color=#000080 face="sans-serif">Advanced Medical Solutions

Ltd.
E-mail:
Martin.Mitchell@admedsol.com
<font size=2 color=#000080 face="sans-
serif">Tel: +44 (0) 1752 30 9360

<font size=1
color=#5f5f5f face="sans-serif">From:

 "Lee, Michele"

<Michele.Lee@fda.hhs.gov>
<font size=1 color=#5f5f5f face="sans-
serif">To:

 "Martin.Mitchell@admedsol.com"

<Martin.Mitchell@admedsol.com>
<font size=1 color=#5f5f5f face="sans-
serif">Cc:

 "helen.topping@admedsol.com"

<helen.topping@admedsol.com>, "k211878@docs.fda.gov"
<k211878@docs.fda.gov>
<font size=1 color=#5f5f5f face="sans-
serif">Date:

 24/11/2021 18:00
<font size=1
color=#5f5f5f face="sans-serif">Subject:

   RE: [EXTERNAL]

Re: K211878/S001 is on Hold Pending Your Response
<hr
noshade>

Hello Martin,
<font size=2
face="Calibri">
Please find the responses
to your questions

below in red font and

revised meeting minutes attached. Hope this is helpful!
<font size=2
face="Calibri">
Best,
Michele
<font size=2
face="Calibri">
1.
 (b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

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(b)(4)

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(b)(4)

As requested, this clarification will also be provided within the future

supplement in addition to the rationale above.

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices

Team
DHT4B: Division of Infection Control and

Plastic Surgery Devices
OHT4: Office of Surgical and Infection

Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue

| Silver Spring, MD 20993
<u>Michele.Lee@fda.hhs.gov</u>

<img src=cid:_4_0FAC92180FAC8EB80036C65E802587AE width=192 height=43 style="border:0px solid;">
<u>
</u><img src=cid:_2_0FAC96A80FAC8EB80036C65E802587AE style="border:0px solid;"> <img src=cid:_2_0FAC9AF40FAC8EB80036C65E802587AE style="border:0px solid;"> <img src=cid:_2_0FAC9F400FAC8EB80036C65E802587AE style="border:0px solid;"> <img src=cid:_2_0FACA38C0FAC8EB80036C65E802587AE style="border:0px solid;"> <img src=cid:_2_0FACA7D80FAC8EB80036C65E802587AE style="border:0px solid;">
Excellent customer

service is important to us. Please take a moment to provide feedback

regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

From: Martin.Mitchell@admedsol.com

<Martin.Mitchell@admedsol.com>
Sent: Friday, November 12, 2021 10:15 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

CAUTION:This email originated from outside of the organization. Do not click links

or open attachments unless you recognize the sender and know the content

is safe.

Hello Michele

Regarding the timeline clarification i've taken a look on the customer

collaboration portal but there was only an email to provide feedback on

the portal. Nevertheless i've emailed as i'm a little concerned about what

may happen if the portal shows that the 180 day hold periods has expired

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
and we haven't yet submitted our response..... is there a risk that the

510(k) may be inadvertently withdrawn?<font size=2
face="Calibri">

We have prepared our response
to your question below which I hope you find

helpful.<p><table width=100% style="border-collapse:collapse;"><tr height=8><td
width=18% style="border-style:none solid solid none;border-color:#000000;border-
width:0px 1px 1px 0px;padding:0px 0px;"><td colspan=3 style="border-style:none solid
solid none;border-color:#000000;border-width:0px 1px 1px 0px;padding:0px 0px;"><div
align=center>(b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

face="Arial">50Â°C <td style="border-style:solid solid solid solid;border-color:#000000;border-width:1px 1px 1px 1px;padding:0px 0px;"> 50Â°C <td style="border-style:solid solid solid solid;border-color:#000000;border-width:1px 1px 1px 1px;padding:0px 0px;"> 50Â°C <td style="border-style:solid solid solid solid;border-color:#000000;border-width:1px 1px 1px 1px;padding:0px 0px;"> 50Â°C <td style="border-style:solid solid solid solid;border-color:#000000;border-width:1px 1px 1px 1px;padding:0px 0px;"> 50Â°C <td style="border-style:solid none solid solid;border-color:#000000;border-width:1px 0px 1px 1px;padding:0px 0px;"> 50Â°C <tr height=8><td style="border-style:solid solid solid none;border-color:#000000;border-width:1px 1px 1px 0px;padding:0px 0px;"> Sampling time point <td style="border-style:solid solid solid solid;border-color:#000000;border-width:1px 1px 1px 1px;padding:0px 0px;"> 0.5 hours <td style="border-style:solid solid solid solid;border-color:#000000;border-width:1px 1px 1px 1px;padding:0px 0px;"> 168 hours <td style="border-style:solid solid solid solid;border-color:#000000;border-width:1px 1px 1px 1px;padding:0px 0px;"> 360 hours <td style="border-style:solid solid solid solid;border-color:#000000;border-width:1px 1px 1px 1px;padding:0px 0px;"> 96 hours <td style="border-style:solid solid solid solid;border-color:#000000;border-width:1px 1px 1px 1px;padding:0px 0px;"> 96 hours <td style="border-style:solid none solid solid;border-color:#000000;border-width:1px 0px 1px 1px;padding:0px 0px;"> 72 hours <tr height=8><td style="border-style:solid solid none none;border-color:#000000;border-width:1px 1px 0px 0px;padding:0px 0px;"> Representing <td style="border-style:solid solid none solid;border-color:#000000;border-width:1px 1px 0px 1px;padding:0px 0px;"> Normal product <td style="border-style:solid solid none solid;border-color:#000000;border-width:1px 1px 0px 1px;padding:0px 0px;"> (b)(4)

(b)(4)

conditions <td style="border-style:solid solid none solid;border-color:#000000;border-width:1px 1px 0px 1px;padding:0px 0px;"> (b)(4)

(b)(4) nt> <td style="border-style:solid solid none solid;border-color:#000000;border-width:1px 1px 0px 1px;padding:0px 0px;"> Normal product <td style="border-style:solid solid none solid;border-color:#000000;border-width:1px 1px 0px 1px;padding:0px 0px;"> Normal product <td style="border-style:solid none none solid;border-color:#000000;border-width:1px 0px 0px 1px;padding:0px 0px;"> Normal product </table>

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

       "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>
To: "<u>Martin.Mitchell@admedsol.com</u>"

<<u>Martin.Mitchell@admedsol.com</u>>
Cc: "<u>helen.topping@admedsol.com</u>"

<<u>helen.topping@admedsol.com</u>>,

"<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 08/11/2021

22:05
Subject: RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hello Martin,

Thanks for your message. Iâ€™ll need some time to review the teleconference

minutes with my team and also obtain some feedback from our consulting

toxicologist about the follow up questions. But I wanted to let you know

I received your email and you may feel free to check in again next week.

I do have a clarification question about (b)(4)

(b)(4)

(b)(4)

Regarding the timeline clarification- I am also under the understanding

that the COVID-19 guidance document you cited was still active and that

would allow you an additional 180 days for the hold period. I have reached

out to the 510(k) Staff multiple times to confirm and am still waiting

on their response. Is there a customer service contact email for the customer

collaboration portal specifically? You may try contacting them as well

to have the date corrected on your end.

Thank you,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993<u>
</u><u>Michele.Lee@fda.hhs.gov</u>
 <u>
</u><img src=cid:_4_0FADE3C00FADD3D80036C65E802587AE width=192 height=43 style="border:0px solid;"><u>
</u><u>
</u><img src=cid:_2_0FADE8500FADD3D80036C65E802587AE style="border:0px solid;"><img src=cid:_2_0FADEC9C0FADD3D80036C65E802587AE style="border:0px solid;"> <img src=cid:_2_0FADF0E80FADD3D80036C65E802587AE style="border:0px solid;"><img src=cid:_2_0FADF5340FADD3D80036C65E802587AE style="border:0px solid;"> <img src=cid:_2_0FADF9800FADD3D80036C65E802587AE style="border:0px solid;">
Excellent customer service is important to us. Please take a moment

to provide feedback regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

From: <u>Martin.Mitchell@admedsol.com</u><<u>Martin.Mitchell@admedsol.com</u>>

Sent: Friday, November 5, 2021 12:07 PM
To: Lee, Michele <<u>Michele.Lee@fda.hhs.gov</u>>
Cc: <u>helen.topping@admedsol.com</u>;

<u>k211878@docs.fda.gov</u>
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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of the organization. Do not click links or open attachments unless you

recognize the sender and know the content is safe.

Hello Michele

I hope you had a nice holiday!

Following on from the teleconference we had a few actions to complete and

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get back to you with.

1) Teleconference minutes

Please find a draft of the the teleconference minutes below. Could you

review and confirm if you require any changes made?

2) Follow-up questions on the teleconference discussion

As suggested during the teleconference there was the opportunity for a

followup email clarification on a few minor points.

(b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

(b)(4)

The supporting information which provides further clarity on the questions

above has been attached if required.

3) Timeline clarification as per previous email

I can see on the customer collaboration portal that we have a 180 day hold

period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below

was active which would provide us with an additional 180 day hold period?
<u>https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices</u>
Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Thank you again for your assistance

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: Martin

Mitchell/WIN/UK/AMS
To: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>,

"Liu, Lixin" <<u>Lixin.Liu@fda.hhs.gov</u>>
Cc: "<u>helen.topping@admedsol.com</u>"

<<u>helen.topping@admedsol.com</u>>,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

"<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 20/10/2021

22:43
Subject: RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hello Michele

Thank you for the prompt response to the clarifications! We'll take your

points on board regarding future shelf life studies.

I do have a minor clarification question regarding our response timeline

I can see on the customer collaboration portal that we have a 180 day hold

period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below

was active which would provide us with an additional 180 day hold period?<u>
</u><u>
</u><u>https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices</u>

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>
To: "<u>Martin.Mitchell@admedsol.com</u>"

<<u>Martin.Mitchell@admedsol.com</u>>
Cc: "<u>helen.topping@admedsol.com</u>"

<<u>helen.topping@admedsol.com</u>>,

"<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 20/10/2021

14:55
Subject:

 RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hello Martin,

Thank you to you and your team for attending the teleconference yesterday.

I wanted to follow up on two things I was discussing with my team:
1.   Regarding

(b)(4)

(b)(4)

I will be on leave for the next two weeks and you may contact our team

management (<u>Lixin.Liu@fda.hhs.gov</u>)

if you have questions during that time.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993<u>
</u><u>Michele.Lee@fda.hhs.gov</u><u>
</u><u>
</u><img src=cid:_4_0FAE99540FAE8A580036C65E802587AE style="border:0px solid;"><u>
</u><u>
</u><img src=cid:_2_0FAE9DE40FAE8A580036C65E802587AE style="border:0px solid;"><img src=cid:_2_0FAEA2180FAE8A580036C65E802587AE style="border:0px solid;"><img src=cid:_2_0FAEA6640FAE8A580036C65E802587AE style="border:0px solid;"><img src=cid:_2_0FAEAA980FAE8A580036C65E802587AE style="border:0px solid;"> <img src=cid:_2_0FAEAEE40FAE8A580036C65E802587AE style="border:0px solid;">
Excellent customer service is important to us. Please take a moment

to provide feedback regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

From: Lee, Michele
Sent: Friday, October 15, 2021 4:47 PM
To: <u>Martin.Mitchell@admedsol.com</u><font size=2

face="Calibri">
Cc: <u>helen.topping@admedsol.com</u>;

<u>k211878@docs.fda.gov</u>
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you for providing your questions in advance of the meeting. We look

forward to discussing our responses with you next week.

Have a good weekend,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993<u>
</u><u>Michele.Lee@fda.hhs.gov</u><u>
</u><u>
</u><img src=cid:_4_0FAEC3300FAE8A580036C65E802587AE style="border:0px solid;"><u>
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</u><img src=cid:_2_0FAEC7C00FAE8A580036C65E802587AE style="border:0px solid;"><img src=cid:_2_0FAECBF40FAE8A580036C65E802587AE style="border:0px solid;"><img src=cid:_2_0FAED0400FAE8A580036C65E802587AE style="border:0px solid;"><img src=cid:_2_0FAED4740FAE8A580036C65E802587AE style="border:0px solid;"> <img src=cid:_2_0FAED8C00FAE8A580036C65E802587AE style="border:0px solid;">
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to provide feedback regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

From: <u>Martin.Mitchell@admedsol.com</u><<u>Martin.Mitchell@admedsol.com</u>>

Sent: Friday, October 15, 2021 12:00 PM
To: Lee, Michele <<u>Michele.Lee@fda.hhs.gov</u>>
Cc: <u>helen.topping@admedsol.com</u>;

<u>k211878@docs.fda.gov</u>
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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of the organization. Do not click links or open attachments unless you

recognize the sender and know the content is safe.<font size=2 face="Arial">

Hi Michele

Please find the list of questions/clarifications attached below.

I hope you have a good weekend. I'm looking forwards to our

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```
discussion

next week! </font><font size=2 face="Calibri"><br></font><font size=2
face="Arial"><br><br><br>Best regards,</font><font size=2 color=#000080
face="Arial"><b><br><br>Martin Mitchell </b><br>Regulatory Affairs
Manager<b><br><br>Advanced Medical Solutions Ltd. </b><br>E-mail: </font><a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u></font></a><font size=2 color=#000080
face="Arial"><br>Tel: +44 (0) 1752 30 9360</font><font size=2
face="Calibri"><br><br></font><font size=1 color=#5f5f5f face="Arial"><br><br><br>From:
       </font><font size=1 face="Arial">&amp;quot;Lee,

Michele&amp;quot; &amp;lt;</font><a href=mailto:Michele.Lee@fda.hhs.gov><font size=1 color=blue
face="Arial"><u>Michele.Lee@fda.hhs.gov</u></font></a><font size=1
face="Arial">&amp;gt;</font><font size=1 color=#5f5f5f face="Arial"><br>To:    
   </font><font size=1 face="Arial">&amp;quot;</font><a
href=mailto:Martin.Mitchell@admedsol.com><font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u></font></a><font size=1
face="Arial">&amp;quot;

&amp;lt;</font><a href=mailto:Martin.Mitchell@admedsol.com><font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u></font></a><font size=1
face="Arial">&amp;gt;</font><font size=1 color=#5f5f5f face="Arial"><br>Cc:    
   </font><font size=1 face="Arial">&amp;quot;</font><a
href=mailto:helen.topping@admedsol.com><font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u></font></a><font size=1
face="Arial">&amp;quot;

&amp;lt;</font><a href=mailto:helen.topping@admedsol.com><font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u></font></a><font size=1
face="Arial">&amp;gt;,

&amp;quot;</font><a href=mailto:k211878@docs.fda.gov><font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u></font></a><font size=1 face="Arial">&amp;quot;

&amp;lt;</font><a href=mailto:k211878@docs.fda.gov><font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u></font></a><font size=1
face="Arial">&amp;gt;</font><font size=1 color=#5f5f5f face="Arial"><br>Date:    
   </font><font size=1 face="Arial">13/10/2021

22:35</font><font size=1 color=#5f5f5f face="Arial"><br>Subject:      
 </font><font size=1 face="Arial">RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response</font><font size=2
face="Calibri"></font><div align=center><hr noshade></div><br><font size=2
face="Calibri"><br><br><br><br><br>Hello Martin,<br><br>I have scheduled the
teleconference for next Tuesday October 19<sup>th</sup>at

9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour but

our biocompatibility consultant/ team management needs to drop off for

another call at 9:30am. Please send me the questions for discussion in

advance of the meeting so that we can plan to discuss biocompatibility/

regulatory questions first before the relevant parties need to drop off.

</font><p><table width=100% style="border-collapse:collapse;"><tr height=8><td
colspan=2 bgcolor=white style="border-style:none none none none;border-
color:#000000;border-width:0px 0px 0px 0px;padding:0px 0px;"><a
href="https://fda.zoomgov.com/j/1609831829?pwd=Mk16N1pXYnUrY2h2TFoyQTRaUCt5QT09"
target=_blank><font size=5 color=#2181ff face="Arial"><u>Join
```

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

size=2>

Thanks,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993<u>
</u><u>Michele.Lee@fda.hhs.gov</u><u>

</u><img src=cid:_4_0FAFBF940FAF12E00036C65E802587AE style="border:0px solid;"><u>

</u><img src=cid:_2_0FAFC3E00FAF12E00036C65E802587AE style="border:0px solid;"><img src=cid:_2_0FAFC8140FAF12E00036C65E802587AE style="border:0px solid;"><img src=cid:_2_0FAFCC480FAF12E00036C65E802587AE style="border:0px solid;"><img src=cid:_2_0FAFD07C0FAF12E00036C65E802587AE style="border:0px solid;"><img src=cid:_2_0FAFD4C80FAF12E00036C65E802587AE style="border:0px solid;">
Excellent customer service is important to us. Please take a moment

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From: <u>Martin.Mitchell@admedsol.com</u><<u>Martin.Mitchell@admedsol.com</u>>

Sent: Wednesday, October 13, 2021 4:46 PM
To: Lee, Michele <<u>Michele.Lee@fda.hhs.gov</u>>
Cc: <u>helen.topping@admedsol.com</u>;

<font size=2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
color=blue><u>k211878@docs.fda.gov</u>
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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and know the content is safe.

Apologies Michele, one final thing I missed off my email... could you clarify

how long the teleconference would be by default? Could we request 1 hour

just incase some of the points end up taking longer to discuss?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: Martin

Mitchell/WIN/UK/AMS
To: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>
Cc: "<u>helen.topping@admedsol.com</u>"

<<u>helen.topping@admedsol.com</u>>,

"<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 13/10/2021

20:35
Subject: RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hi Michele

We're currently preparing our questions for the teleconference and will

send these through in due course, however to assist with scheduling the

relevant parties at FDA, I should let you know that we would definitely

like to discuss the questions related to biocompatibility.

After discussion with the team we would like to request the teleconference

on the Tuesday 19th October

if that is possible? As we are based in

the UK, we would also like to request that this is arranged between the

hours of 2-5pm BST.

If this time slot is not available could you outline any alternative days/times

which would be possible?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <a
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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href=mailto:Martin.Mitchell@admedsol.com><u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: Martin

Mitchell/WIN/UK/AMS
To: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>
Cc: "<u>helen.topping@admedsol.com</u>"

<<u>helen.topping@admedsol.com</u>>,

"<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 08/10/2021

22:14
Subject: RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hi Michele

Thank you for the offer. I think after today's meeting we may need a little

more time to be better prepared for the teleconference.

We are reaching out to the (b)(4) for us as we

feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible

dates for you early next week.

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>
To: "<u>Martin.Mitchell@admedsol.com</u>"

<<u>Martin.Mitchell@admedsol.com</u>>
Cc: "<u>helen.topping@admedsol.com</u>"
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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<<u>helen.topping@admedsol.com</u>>,

"<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 06/10/2021

13:49
Subject: RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference

deadline up to October 19th. Let me know if you would like to

select a date later than the 14thand I can check our management

schedules.

Regarding review timelines, we are still on the 90 day review cycle and

are planning to complete the review of your response with the 20 calendar

days left on the clock. While we retain the right to add additional days,

we are doing our best with the resources that we have to avoid delaying

review timelines if possible.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993<u>
</u><u>Michele.Lee@fda.hhs.gov</u><u>
</u><u>
</u><img src=cid:_4_0FDF6C040FDF60AC0036C65E802587AE style="border:0px solid;"><u>
</u><u>
</u><img src=cid:_2_0FDF70940FDF60AC0036C65E802587AE style="border:0px solid;"><img src=cid:_2_0FDF74C80FDF60AC0036C65E802587AE style="border:0px solid;"><img src=cid:_2_0FDF78FC0FDF60AC0036C65E802587AE style="border:0px solid;"><img src=cid:_2_0FDF7F040FDF60AC0036C65E802587AE style="border:0px solid;"><img src=cid:_2_0FDF826C0FDF60AC0036C65E802587AE style="border:0px solid;">
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to provide feedback regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

From: <u>Martin.Mitchell@admedsol.com</u><<u>Martin.Mitchell@admedsol.com</u>>

Sent: Wednesday, October 6, 2021 6:00 AM
To: Lee, Michele
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

<<u>Michele.Lee@fda.hhs.gov</u>>
Cc: <u>helen.topping@admedsol.com</u>
Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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recognize the sender and know the content is safe.

Hi Michele

Thank you again for your review. Our team are busy discussing the questions

and we would definitely like to have a teleconference with the FDA. We're

currently consolidating our understanding of the deficiencies and are determining

what our potential questions to you would be. I hope to get the questions

to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we

look to schedule a teleconference with the FDA on Wednesday 13th or Thursday

14th? As we're based in the UK we would appreciate a timeslot within our

working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines

for this project.... regarding the FDA timeline I can see on the CCP tracker

website that the FDA timeline is on day 70.
Will FDA be sticking to the 90 day target

and as a result only have 20 days left on the clock?<li>Or, due to the current situation with the

unprecedented resource limitations..... will you will assume 30 days to

review the response as standard? Or perhaps stick to the 20 days but retain

the right to add additional days?
Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Michele

Lee [MICHELE.LEE]" <<u>michele.lee@fda.hhs.gov</u>>
To: <<u>martin.mitchell@admedsol.com</u>>,

<<u>helen.topping@admedsol.com</u>>
Cc: "Michele

Lee [MICHELE.LEE]" <<u>michele.lee@fda.hhs.gov</u>>
Date: 04/10/2021

21:44
Subject:

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 K211878/S001

is on Hold Pending Your Response <div
align=center><hr noshade>

October 4, 2021<font size=2
face="Calibri"> <p>We have reviewed your submission. Please see
attached.

<p>If you have any questions, please contact the lead reviewer

assigned to your submission, Michele Lee. <p> <p>*** This is a system-generated email notification ***[attachment

"K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin

Mitchell/WIN/UK/AMS] <p>

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href=http://www.admedsol.com/><font size=3
color=#0082bf><u>http://www.admedsol.com</u>.

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recipient, please notify the sender immediately and delete it from your

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Meeting Minutes.FDAEdit.docx" deleted by Martin Mitchell/WIN/UK/AMS]

<p><p><p>

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U.S. FOOD & DRUG ADMINISTRATION

K211878
Advanced Medical Solutions Limited
Trade/Device Name: LiquiBand XL
Contact Name: Martin Mitchell

This document is being communicated via e-mail as an attachment. The date on which FDA sent this e-mail is the official date of this correspondence.

We have reviewed your submission K211878 and have determined that additional information is required. Your file is being placed on hold pending a complete response to the attached deficiencies.

Please submit your response, referencing the submission number K211878 to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Please refer to the eCopy guidance at https://www.fda.gov/media/83522/download for current information on eCopy requirements.

Your response is due within 180 days from the date of this request, which is the hold date plus 180 days. If a complete response is not received in CDRH's Document Control Center by this date, we will consider this submission to be withdrawn, and we will delete it from our review system.

You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without FDA clearance, you will be in violation of the Federal Food, Drug, and Cosmetic Act.

If you would like a meeting or teleconference with the review team and management to discuss your planned approach for responding to the attached deficiencies, please submit your request for feedback as a Submission Issue Q-Submission (Q-Sub). Please note that a Submission Issue Q-Sub does not take the place of a formal response to this email notification. As noted above, FDA will consider this submission to be withdrawn if FDA does not receive, in a submission to the Document Control Center, a complete response to all of the attached deficiencies within 180 calendar days of the date of this request.

This request for additional information has undergone supervisory review to ensure that the deficiencies cited are least burdensome and relevant to the marketing decision. Please see the revised guidance "Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions" issued on September 29, 2017 (https://www.fda.gov/media/71735/download) for clarification regarding major and minor deficiencies.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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MAJOR DEFICIENCY LIST

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

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(b)(4)

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(b)(4)

MINOR DEFICIENCY LIST

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

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(b)(4)

FDA is offering a teleconference within 10 calendar days from the date on this letter to address any clarification questions you may have pertaining to the deficiencies. If you are interested in a teleconference, please provide (1) proposed dates and (2) a list of your clarification questions via email at least 48 hours before the teleconference to the lead reviewer assigned to your submission. We would like to emphasize that the purpose of the meeting is to address specific clarification questions. Please note that if the specific clarification questions are not received at least 48 hours before the teleconference, the review team might not be able to provide feedback. The teleconference is not intended for review of new information, test methods or data; these types of questions could be better addressed via a Submission Issue Q-Submission (Q-Sub). For additional information regarding Q-Subs, please refer to the Guidance for Industry and FDA Staff on Medical Devices: Requests for Feedback and Meetings for Medical Device Submissions at https://www.fda.gov/media/114034/download.

Least Burdensome (LB) Flag

The LB flag is an approach to allow submitters the opportunity for the informal review by or on behalf of Division management of an issue raised in an FDA request for additional information (i.e., a deficiency letter). The goal of the LB flag is to quickly address FDA requests that submitters do not believe are least burdensome or when submitters believe they are being held to a different standard than their legally marketed predicate device. The LB flag is not intended to clarify deficiencies, is not an appeal under 21 CFR 10.75, and is not intended to provide a review of a proposed response to deficiencies.

If you would like to throw the LB flag, FDA has several criteria that should be met before you submit your request:

- You should have tried to address your concern by discussing it with Division management before attempting to throw the LB flag. This discussion with Division management may take place as part of a teleconference (such as the voluntary teleconference held within 10 days following transmission of an Additional Information letter to clarify deficiencies), email, or a Q-Submission Submission Issue Request.
- Your flag should generally be limited to two topic areas. Topic areas are common premarket review deficiency categories that apply to many device types across multiple reviewing Divisions. Examples of topic areas include biocompatibility, sterility, reprocessing, software, electromagnetic compatibility, wireless, electrical safety, clinical, and non-clinical performance testing.
- If you would like to discuss issues pertaining to more than two topic areas, you should contact OPEQSubmissionSupport@fda.hhs.gov for more information.
- You should throw the LB flag within 60 calendar days of the date that FDA sent the deficiency letter.

Upon meeting the criteria, you should send a short email (e.g., 1-2 page) that includes: 1) a summary of the deficiencies under disagreement, 2) a summary of relevant communications with Division management, and 3) a proposed path forward. The LB flag should be sent to the lead reviewer and their Assistant Director. You should also copy OPEQSubmissionSupport@fda.hhs.gov on your LB flag email request. Within two

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business days of your email, your request will be acknowledged by the reviewing Division. If you do not meet the criteria for the LB flag, you will be notified in this acknowledgement email.

Your LB flag should contain sufficient information to determine whether the deficiency letter was not least burdensome, or you are being held to a different standard than your predicate device. FDA may request a phone call with you to discuss your concern further and intends to communicate feedback from Division management on LB flags through email no later than 21 calendar days of their receipt. Please note that the LB flag does not change the deadline for your response to the Document Control Center. If you have any questions, please contact OPEQSubmissionSupport@fda.hhs.gov.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hello Michele

Thank you for your email to keep us updated with progress.

Please note that next week i'll be out on annual leave... therefore, could you also place Helen and Rose (on this email) on copy with any further communication you send over.

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 20/09/2021 22:31
Subject: K211878/S001 Review Status

Hello Martin:

I want to inform you of a slightly revised review timeline for your 510(k) submission K211878/S001. Due to a limitation of Agency resources, we are unable to complete the substantive review by September 24th. We want to inform you that we expect to complete the review by next Wednesday, September 29th. We apologize for any inconveniences because of the extension of timeline.

Best Regards,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

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Advanced Medical Solutions

General Report

LIQUIBAND XL ADHESIVE (b)(4) EXTRACTION COLOUR CHANGE ASSESSMENT

Doc No:	(b)(4)
Rev No:	

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

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(b)(4)

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Advanced Medical Solutions (Plymouth) Ltd.

Design Verification Protocol

LIQUIBAND XL AND COMPETITOR BENCH TESTING FOR MESH SAMPLES	Doc No:	(b)(4)
	Rev No:	

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Advanced Medical Solutions

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Design Verification Report

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	Rev No:	

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Design Verification Report

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Design Verification Protocol

ASTM 2255-05 LAP SHEAR BENCH TESTING OF LIQUIBAND XL AND CHEMENCE EXOFIN	Doc No:	(b)(4)
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Design Verification Report

PROJECT YEALM LARGE WOUND ASTM F2255 LAP SHEAR STRENGTH SUBSTANTIAL EQUIVALENCE TESTING	Doc No:	(b)(4)
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Design Verification Protocol

LIQUIBAND XL & COMPETITOR BENCH TESTING FOR ASTM F2256 T-PEEL	Doc No:	(b)(4)
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Design Verification Protocol

LIQUIBAND XL & COMPETITOR BENCH TESTING FOR ASTM F2258 TENSION LOADING	Doc No:	(b)(4)
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PROJECT YEALM LARGE WOUND ASTM F2258 TENSION LOADING SUBSTANTIAL EQUIVALENCE TESTING	Doc No:	(b)(4)
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Advanced Medical Solutions Ltd

Advanced Medical Solutions Limited
Western Wood Way,
Langage Science Park,
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Tel: +44 (0) 1752 209955 **Fax:** +44 (0) 1752 209956
Web: www.admedsol.com
Registered in England 2666957 VAT No. GB 636 5551 27

510(k) Summary

(b)(4)

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October 4, 2021</br></br> We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Michele Lee.

 *** This is a system-generated email notification ***

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Advanced Medical Solutions

Design Validation Protocol

PROTOCOL TO EVALUATE THE STABILITY PROFILE OF LIQUIBAND XL FINAL FINISHED DEVICE WITH (b)(4)

Doc No

Rev No (b)(4)

(b)(4)

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Contains Nonbinding Recommendations

Print Form

510(k) Acceptance Checklist

Not for use with Third Party 510(k)s

Choose Submission Type: ☒ **Traditional** ☐ **Abbreviated** ☐ **Special**

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K211878 Date Received by DCC: Jun 21, 2021

Lead Reviewer: Michele Lee

Center: CDRH Office: OHT 4 Division: DHT4B

Decision:

○ Accept. If Accept, notify submitter.

◉ Refuse to Accept. If Refuse to Accept, notify submitter electronically and include a copy of this checklist.

Is an Addendum attached?: ○ Yes ◉ No Click paperclip icon on the left panel if Addendum is attached.

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

Preliminary Questions

Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDA's preliminary assessment of these questions at the time of administrative review.)	Yes	No	N/A
1 Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product (per 21 CFR 3.2(e)), or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action, and inform management. *Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If the product does not appear to be a device or such a combination product, mark "No."	☒	☐	
Comments:			
2 Is the submission with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If submission should not be reviewed by your Center mark "No."	☒	☐	
Comments:			

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3 If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: **a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?** **b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide a summary of Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."	☐	☐	☒
Comments:			
4 Is the submission for a combination product that contains as a constituent part a drug that has the same active moiety as an approved drug with exclusivity as described in 21 USC 503(g)(5)(C)(ii)-(v) (section 503(g)(5)(C)(ii)-(v) of the FD&C Act)? If "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide the summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below*.	☐	☐	☒
Comments:			
5 Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), consult with the appropriate CDRH or CBER staff during the acceptance review, provide a summary of the discussion with them, and indicate their recommendation/action in the comment section below. If 510(k) is not the appropriate regulatory submission, mark "No."	☒	☐	
Comments:			
6 Is there a pending PMA for the same device with the same indications for use? If "Yes," consult your management and CDRH Office of Product Evaluation and Quality/Office of Regulatory Programs/Division of Regulatory Programs 1 (Submission Support) (OPEQ/ORP/DRP1) or appropriate CBER staff to determine the appropriate action.	☐	☒	
Comments:			
7 If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If "Yes," consult with the CDRH Office of Product Evaluation and Quality/ Office of Clinical Evidence and Analysis/Division of Clinical Science and Quality (OPEQ/OCEA/DCEA1) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action, provide a summary of the discussion with them, and indicate their recommendation/action. If no clinical studies have been submitted, mark "N/A." Check on the AIP list at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/application-integrity-policy/application-integrity-policy-list.	☐	☐	☒
Comments:			

- If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.
- If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.
- If the answer to 4 is "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer, provide a summary of the discussion with them, and indicate their recommendation/action.
- If the answer to 5 is "No," the lead reviewer should consult management and other Center resources to determine the appropriate action.
- If the answer to 6 is "Yes," then stop review of the 510(k), contact the CDRH/OPEQ/ORP/DRP1, or appropriate CBER staff.
- If the answer to 7 is "Yes," then contact CDRH/OPEQ/OCEA/DCEA1 or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DCEA1 or BMB Staff, and indicate their recommendation/action.

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Organizational Elements

Failure to include these items should not result in an RTA designation.

*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	*Page #
1) Submission contains a Table of Contents	☒	☐	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	☒	☐	
3) All pages of the submission are numbered. *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2…).*	☒	☐	
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special). *If type of 510(k) is not designated, review as a Traditional 510(k).*	☒	☐	
Comments:			

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

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A. Administrative					
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	☒	☐		☐	
2) Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form (Form 3514, available at https://www.fda.gov/media/72421/download)):				☐	
a) Device trade/proprietary name	☒	☐			
b) Device class and panel OR Classification regulation OR Statement that device has not been classified with rationale for that conclusion	☒	☐			
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/alternative-certain-prescription-device-labeling-requirements.) *See recommended* format (https://www.fda.gov/media/86323/download).	☒	☐		☐	
4) Submission contains a 510(k) Summary or 510(k) Statement.	☒	☐		☐	
5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(l) *See recommended format (https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-truthful-and-accurate-statement).*	☒	☐		☐	
6) Submission is a Class III 510(k) device.	☐		☒	☐	
7) Submission contains clinical data	☐		☒	☐	
8) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Q-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device.	☒	☐		☐	
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed.	☒	☐	☐		
9) The submission utilizes voluntary consensus standard(s) (See section 514(c) of the FD&C Act). *This includes both FDA-recognized and non-recognized consensus standards.*	☒		☐	☐	
a) The submission cites FDA-recognized voluntary consensus standard(s).	☒		☐		
i) The submission includes a Declaration of Conformity (DOC) as outlined in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices. **OR** If citing general use of a standard as noted in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," the basis of such use is included along with the underlying information or data that supports how the standard was used.	☒	☐			

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b) The submission cites non-FDA-recognized voluntary consensus standard(s).	☐		☒		
Combination Product Provisions - Per 503(g) of the FD&C Act. Select "N/A" if the product is not a combination product. 21 CFR 3.2(e). The remaining criteria in this section will be omitted from the checklist if "N/A" is selected. If you are unsure if the product is a combination product, consult with the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.			☒		
B. Device Description					
12) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding the device description that is applicable to the subject device.	☒		☐	☒	
a) The submission addresses device description recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	☐	☒	☐		
b) The submission includes device description information that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	☒	☐	☐		
Comments:	(b)(4)				
13) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).	☒	☐		☐	
14) The submission includes descriptive information for the device, including the following:				☐	
a) A description of the principle of operation or mechanism of action for achieving the intended effect.	☒	☐			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	☒	☐	☐		
c) A list and description of each device for which clearance is requested.	☒	☐	☐		

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d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).	☒	☐			
15) Device is intended to be marketed with accessories and/or as part of a system.	☐		☒	☐	
C. Substantial Equivalence Discussion					
16) Submitter has identified a predicate device(s), including the following information:				☐	
a) Predicate device identifier provided (e.g., 510(k) number, De Novo number, reclassified PMA number, classification regulation reference, if exempt (e.g., 21 CFR 872.3710), or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online (https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/preamendment-status).*	☒	☐			
b) The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).	☒	☐			
17) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See the FDA guidance document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k for more information on comparing intended use and technological characteristics.*				☐	
a) Indications for Use	☒	☐			
b) Technology, including technical specifications, features, materials, and principles of operation	☒	☐			
D. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)					
18) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	☒	☐		☐	
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	☒	☐			
b) Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) **AND** - Includes adequate directions for use (see 21 CFR 801.5) **OR** - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D	☒	☐			

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19) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	☒	☐		☐	
20) Labeling includes the prescription statement [see 21 CFR 801.109(b)(1)] or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's guidance "Alternative to Certain Prescription Device Labeling Requirements," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/alternative-certain-prescription-device-labeling-requirements.	☒	☐	☐	☐	
21) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding labeling that is applicable to the subject device.	☒		☐		
a) The submission addresses labeling recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	☒	☐	☐		
b) The submission includes labeling information that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	☒	☐	☐		
22) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.	☐	☐	☒	☐	
E. Sterilization					
If an *in vitro* diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.			☐		
☒ Provided sterile, intended to be single-use					
☐ Requires processing during its use-life					
☐ Non-sterile when used (and no processing required)					
☐ Information regarding the sterility status of the device is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Sterility status not needed for this device (e.g., software-only device)					
☐ Sterility status needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *Please refer to the FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling, for additional information.*					
23) Assessment of the need for cleaning and subsequent disinfection or sterilization information				☐	

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
a) Identification of device and/or accessories, if applicable, that are provided sterile.	☒	☐	☐		
b) Identification of device and/or accessories, if applicable, that are end user sterilized or disinfected.	☐	☐	☒		
c) Identification of device, and/or accessories, if applicable, that are reusable.	☐	☐	☒		
24) If the device and/or accessories, if applicable, are provided sterile:			☐	☐	
a) Sterilization method is stated for each device (including dose for radiation sterilization).	☒	☐			
b) A description of method to validate the sterilization parameters is provided for each proposed sterilization method (e.g., half-cycle method and full citation of FDA-recognized standard, including date).	☒	☐			
c) For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.	☒	☐	☐		
d) Sterility Assurance Level (SAL) is stated.	☒	☐			
e) Submission includes description of packaging.	☒	☐			
f) For products labeled "non-pyrogenic," a description of the method used to make the determination stated (e.g., limulus amebocyte lysate [LAL]).	☐	☐	☒		
25) If the device and/or accessory, if applicable, is reusable or end user sterilized or disinfected:			☒	☐	
a) Cleaning method is provided in labeling for each device and/or accessory, if applicable.	☐	☐	☒		
b) Disinfection method is provided in labeling for each device and/or accessory, if applicable.	☐	☐	☒		
c) Sterilization method is provided in labeling for each device and/or accessory, if applicable.	☐	☐	☒		
d) Device types in this submission are listed in the Federal Register (FR) Notice entitled "Validated Instructions for Use and Validation Data Requirements for Certain Reusable Medical Devices in Premarket Notifications" (Reprocessing FR Notice, available at https://www.federalregister.gov / documents/2017/06/09/2017-12007/medical-devices-validated-instructions-for-use-and-validation-data-requirements-for-certain-reusable).	☐		☒		
26) The device has a device-specific guidance document, special controls, and/or requirement in a device-specific regulation regarding sterility and/or reprocessing that is applicable to the subject device.	☒		☐	☐	
a) The submission addresses sterility and/or reprocessing recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	☒	☐	☐		

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b) The submission includes sterility and/or reprocessing information that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	☒	☐	☐		
F. Shelf Life					
27) Proposed shelf life/expiration date stated **OR** Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation	☒	☐	☐	☐	
28) For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf life.	☐	☒	☐	☒	
Comments:	(b)(4)				
29) Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). **OR** Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	☐	☒		☒	
Comments:	(b)(4)				
G. Biocompatibility					
If an vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.			☐		
Submission states that there: (one of the below must be checked)		☐		☐	
☒ Are direct or indirect tissue-contacting components.					
☐ Are no direct or indirect tissue-contacting components.					
☐ Information regarding tissue contact status of the device is not provided (if this box checked, please also check one of the two boxes below).					
☐ Tissue contact information not needed for this device (e.g., software-only device)					
☐ Tissue contact information needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					

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30) Submission includes a list identifying each of tissue-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.	☒	☐		☐	
31) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration) for each tissue-contacting device component (e.g., implant, delivery catheter)	☒	☐		☐	
32) For a biocompatibility assessment of tissue-contacting components, submission includes: – Each relevant endpoint for the device (as identified in device-specific guidance, or Attachment A of the FDA guidance document entitled "Use of International Standard ISO 10993-1, `Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and), has been addressed. - For any testing performed, test protocol (including identification and description of test article including whether the test article is the device in its final finished form using the recommended approach in Attachment F of "Use of International Standard ISO 10993-1, `Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" methods, and pass/fail criteria), and analysis of results (including tables with data points and statistical analyses, where appropriate), as described in Attachment E of the guidance document entitled "Use of International Standard ISO 10993-1, `Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" provided for each completed test. **OR** A statement that biocompatibility testing is not needed with a rationale that considers all relevant endpoints (e.g., materials and manufacturing/processing are identical to the predicate).	☒	☐		☐	
H. Software					
Submission states that the device: (one of the below must be checked)		☐		☐	
☐ Does contain software/firmware					
☒ Does not contain software/firmware					
☐ Information on whether device contains software/firmware is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Software/firmware information not needed for this device (e.g., surgical suture, condom)					
☐ Software/firmware information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
I. Cybersecurity					
Submission states that the device: *(one of the below must be checked)*		☐		☐	
☐ Does contain any external wired and/or wireless communication interfaces (Wired: USB, ethernet, SD, CD, RGA, etc. or Wireless: Wi-Fi, Bluetooth, RF, inductive, Cloud, etc.)					
☒ Does not contain external interfaces as described above					
☐ Information on whether device has external interfaces is not provided. (If this box is checked, please also check one of the two boxes below.)					

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☐ Cybersecurity information not needed for this device (e.g., surgical suture, condom)					
☐ Cybersecurity information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
J. Electrical Safety and EMC					
Electrical Safety Submission states that the device: *(one of the below must be checked)*		☐		☐	
☐ Does require electrical safety evaluation					
☒ Does not require electrical safety evaluation					
☐ Information on whether device requires electrical safety evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Electrical safety information not needed for this device (e.g., surgical suture, condom)					
☐ Electrical safety information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
EMC Submission states that the device: (one of the below must be checked)		☐		☐	
☐ Does require EMC evaluation					
☒ Does not require EMC evaluation					
☐ Information on whether device requires EMC evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ EMC information not needed for this device (e.g., surgical suture, condom)					
☐ EMC information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
K. Performance Data - General					
If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.			☐		

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38) Summaries of the non-clinical laboratory studies and full test reports* are provided. *Summary and full test report content recommendations can be found in FDA's guidance "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket. If a submitter chooses to declare conformity to a voluntary consensus standard that FDA has recognized, submission of a full test report may not be necessary. Refer to 9a. See FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.	☒	☐	☐	☐	
a) Submission includes an explanation of how the data generated from each test supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.).	☒	☐			
39) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding performance data that is applicable to the subject device.	☒		☐	☐	
a) The submission addresses performance data recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	☒	☐	☐		
b) The submission includes performance data that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	☒	☐	☐		
40) If literature is referenced in the submission, submission includes:			☒		
41) For each completed animal study, the submission provides the following:			☐	☐	
a) Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120.	☒	☐			
b) Submission includes final study report which includes all elements outlined in 21 CFR 58.185.	☒	☐			
c) Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.	☒	☐			
L. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**					
Submission states that the device: (one of the below must be checked)				☐	
☐ is an in vitro diagnostic device					

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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☒ is not an in vitro diagnostic device.					
If "is not" is selected, the performance data-related criteria below are omitted from the checklist.					

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Digital Signature Concurrence Table

Reviewer Sign-Off	Michele Lee -S	Digitally signed by Michele Lee -S Date: 2021.07.06 15:04:54 -04'00'
Management Sign-Off (digital signature optional)*	Yu-chieh Chiu -S	Digitally signed by Yu-chieh Chiu -S Date: 2021.07.06 15:44:23 -04'00'

* Management review of checklist and concurrence with with decision required.

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

FINAL GLP REPORT: (b)(4)
AMENDED

RABBIT PYROGEN TEST (MATERIAL MEDIATED) – ISO

Test Article
LIQUIBAND XL (Adhesive Mesh Component Only)

21 CFR Part 58 Compliance
Good Laboratory Practice for Nonclinical Laboratory Studies

Final Report Date
1/20/2021

Amended Final Report Date
2/26/2021

Study Director
(b)(4)

Sponsor
Advanced Medical Solutions Limited
2 Western Wood Way, Langage Science Park
Plymouth, PL7 5BG
UK

(b)(4)

Questions? Contact FDA/CDRH/OC/ODE/DIDSR at CDRH-FOIA-DIDSR@fda.hhs.gov or 301-796-8118

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(b)(4)

(b)(4) TEST PROTOCOL
FDA GLP REGULATIONS
FILE COPY/CONFIDENTIAL PROPERTY (b)(4)

RABBIT PYROGEN TEST (MATERIAL MEDIATED) - ISO

(b)(4) PROTOCOL NUMBER: (b)(4)

21 CFR Part 58 Compliance
Good Laboratory Practice for Nonclinical Laboratory Studies

MANAGEMENT OF THE STUDY

Test Facility
(b)(4)

Sponsor
Advanced Medical Solutions Limited
2 Western Wood Way,
Langage Science Park
Plymouth, PL7 5BG
United Kingdom

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

FINAL GLP REPORT: (b)(4)

SYSTEMIC INJECTION TEST – ISO

Test Article
LIQUIBAND XL (Adhesive Mesh Component Only)

21 CFR Part 58 Compliance
Good Laboratory Practice for Nonclinical Laboratory Studies

Final Report Date
2/5/2021

Study Director
(b)(4)

Sponsor
Advanced Medical Solutions Limited
2 Western Wood Way, Langage Science Park
Plymouth, PL7 5BG
United Kingdom

Questions? Contact FDA/CDRH/OCE/DIDSI CDRH-FOIASTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) TEST PROTOCOL
FDA GLP REGULATIONS
FILE COPY/CONFIDENTIAL PROPERTY (b)(4)

SYSTEMIC INJECTION TEST - ISO

(b)(4) PROTOCOL NUMBER: (b)(4)

21 CFR Part 58 Compliance
Good Laboratory Practice for Nonclinical Laboratory Studies

MANAGEMENT OF THE STUDY

Test Facility
(b)(4)

Sponsor
Advanced Medical Solutions Limited
2 Western Wood Way,
Langage Science Park
Plymouth, PL7 5BG
United Kingdom

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(b)(4)

FINAL GLP REPORT: (b)(4)
AMENDED

L929 NEUTRAL RED UPTAKE TEST (1 CONCENTRATION) – ISO

Test Article
LIQUIBAND XL (Complete Device)

21 CFR Part 58 Compliance
Good Laboratory Practice for Nonclinical Laboratory Studies

Report Date
1/21/2021

Amended Final Report Date
2/18/2021

Study Director
(b)(4)

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(b)(4) TEST PROTOCOL
FDA GLP REGULATIONS
FILE COPY/CONFIDENTIAL PROPERTY (b)(4)

L929 NEUTRAL RED UPTAKE TEST (4 CONCENTRATIONS) - ISO

(b)(4) PROTOCOL NUMBER: (b)(4)

21 CFR Part 58 Compliance
Good Laboratory Practice for Nonclinical Laboratory Studies

MANAGEMENT OF THE STUDY

Test Facility
(b)(4)

Sponsor
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Langage Science Park
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United Kingdom

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(b)(4)

FINAL GLP REPORT: (b)(4)

KLIGMAN MAXIMIZATION TEST – ISO

Test Article
LIQUIBAND XL (Complete Device)

21 CFR Part 58 Compliance
Good Laboratory Practice for Nonclinical Laboratory Studies

Final Report Date
3/26/2021

Study Director
(b)(4)

Sponsor
Advanced Medical Solutions Limited
2 Western Wood Way,
Langage Science Park
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Questions? Contact FDA/CDRH/OCE/DCD at CDRH-OIDATA-USer@fda.hhs.gov or 301-796-8118

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ATTACHMENT A:
Test Article Photographs

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(b)(4) TEST PROTOCOL
FDA GLP REGULATIONS
FILE COPY/CONFIDENTIAL PROPERTY OF (b)(4)

KLIGMAN MAXIMIZATION TEST - ISO

(b)(4) PROTOCOL NUMBER: (b)(4)

21 CFR Part 58 Compliance
Good Laboratory Practice for Nonclinical Laboratory Studies

MANAGEMENT OF THE STUDY

Test Facility
(b)(4)

Sponsor
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2 Western Wood Way,
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FINAL GLP REPORT: (b)(4)

INTRACUTANEOUS INJECTION TEST - ISO

Test Article
LIQUIBAND XL (Complete Device)

21 CFR Part 58 Compliance
Good Laboratory Practice for Nonclinical Laboratory Studies

Final Report Date
3/2/2021

Study Director
(b)(4)

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Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

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(b)(4)

(b)(4) TEST PROTOCOL
FDA GLP REGULATIONS
FILE COPY/CONFIDENTIAL PROPERTY (b)(4)

INTRACUTANEOUS INJECTION TEST - ISO

(b)(4) PROTOCOL NUMBER: (b)(4)

21 CFR Part 58 Compliance
Good Laboratory Practice for Nonclinical Laboratory Studies

MANAGEMENT OF THE STUDY

Test Facility
(b)(4)

Sponsor
Advanced Medical Solutions Limited
2 Western Wood Way,
Langage Science Park
Plymouth, PL7 5BG
United Kingdom

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-OISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Hello Martin,

Thanks for your message. I'll need some time to review the teleconference minutes with my team and also obtain some feedback from our consulting toxicologist about the follow up questions. But I wanted to let you know I received your email and you may feel free to check in again next week.

I do have a clarification question about Follow Up (b)(4)

(b)(4)

Regarding the timeline clarification- I am also under the understanding that the COVID-19 guidance document you cited was still active and that would allow you an additional 180 days for the hold period. I have reached out to the 510(k) Staff multiple times to confirm and am still waiting on their response. Is there a customer service contact email for the customer collaboration portal specifically? You may try contacting them as well to have the date corrected on your end.

Thank you,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Friday, November 5, 2021 12:07 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

I hope you had a nice holiday!

Following on from the teleconference we had a few actions to complete and get back to you with.

1) Teleconference minutes

Please find a draft of the the teleconference minutes below. Could you review and confirm if you require any changes made?

2) Follow-up questions on the teleconference discussion

As suggested during the teleconference there was the opportunity for a followup email clarification on a few minor points.

(b)(4)

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(b)(4)

The supporting information which provides further clarity on the questions above has been attached if required.

3) Timeline clarification as per previous email

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Thank you again for your assistance

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>, "Liu, Lixin" <Lixin.Liu@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 20/10/2021 22:43
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Michele

Thank you for the prompt response to the clarifications! We'll take your points on board regarding future shelf life studies.

I do have a minor clarification question regarding our response timeline

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 20/10/2021 14:55
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you to you and your team for attending the teleconference yesterday. I wanted to follow up on two things I was discussing with my team:

(b)(4)

I will be on leave for the next two weeks and you may contact our team management (Lixin.Liu@fda.hhs.gov) if you have questions during that time.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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From: Lee, Michele
Sent: Friday, October 15, 2021 4:47 PM
To: Martin.Mitchell@admedsol.com
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you for providing your questions in advance of the meeting. We look forward to discussing our responses with you next week.

Have a good weekend,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Friday, October 15, 2021 12:00 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Please find the list of questions/clarifications attached below.

I hope you have a good weekend. I'm looking forwards to our discussion next week!

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 13/10/2021 22:35
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

I have scheduled the teleconference for next Tuesday October 19th at 9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour but our biocompatibility consultant/ team management needs to drop off for another call at 9:30am. Please send me the questions for discussion in advance of the meeting so that we can plan to discuss biocompatibility/ regulatory questions first before the relevant parties need to drop off.

Join Zoom Meeting
One tap mobile:
Meeting URL:
Meeting ID:
Passcode:
(b)(4)

Join by Telephone
For higher quality, dial a number based on your current location.
Dial:

Meeting ID:
Passcode:
(b)(4)
International numbers

Join from an H.323/SIP room system
H.323:

Meeting ID:
Passcode:
SIP:
Passcode:
(b)(4)

Thanks,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Michele.Lee@fda.hhs.gov



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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 13, 2021 4:46 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Apologies Michele, one final thing I missed off my email... could you clarify how long the teleconference would be by default? Could we request 1 hour just incase some of the points end up taking longer to discuss?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 13/10/2021 20:35
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hi Michele

We're currently preparing our questions for the teleconference and will send these through in due course, however to assist with scheduling the relevant parties at FDA, I should let you know that we would definitely like to discuss the questions related to biocompatibility.

After discussion with the team we would like to request the teleconference on the Tuesday 19th October if that is possible? As we are based in the UK, we would also like to request that this is arranged between the hours of 2-5pm BST.

If this time slot is not available could you outline any alternative days/times which would be possible?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 08/10/2021 22:14
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Thank you for the offer. I think after today's meeting we may need a little more time to be better prepared for the teleconference.

We are reaching out to the **(b)(4)** for us as we feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible dates for you early next week.

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 06/10/2021 13:49
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference deadline up to October 19th. Let me know if you would like to select a date later than the 14thand I can check our management schedules.

Regarding review timelines, we are still on the 90 day review cycle and are planning to complete the review of your response with the 20 calendar days left on the clock. While we retain the right to add additional days, we are doing our best with the resources that we have to avoid delaying review timelines if possible.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 6, 2021 6:00 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com
Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Thank you again for your review. Our team are busy discussing the questions and we would definitely like to have a teleconference with the FDA. We're currently consolidating our understanding of the deficiencies and are determining what our potential questions to you would be. I hope to get the questions to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we look to schedule a teleconference with the FDA on Wednesday 13th or Thursday 14th? As we're based in the UK we would appreciate a timeslot within our working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines for this project.... regarding the FDA timeline I can see on the CCP tracker website that the FDA timeline is on day 70.

- Will FDA be sticking to the 90 day target and as a result only have 20 days left on the clock?
- Or, due to the current situation with the unprecedented resource limitations..... will you will assume 30 days to review the response as standard? Or perhaps stick to the 20 days but retain the right to add additional days?

Best regards,

Martin Mitchell

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Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
To: <martin.mitchell@admedsol.com>, <helen.topping@admedsol.com>
Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
Date: 04/10/2021 21:44
Subject: K211878/S001 is on Hold Pending Your Response

October 4, 2021

We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Michele Lee.

*** This is a system-generated email notification ***[attachment "K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

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Hello Martin,

Sure, I will also put Helen and Rose on future communication for this submission.

Take care,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D7AEDA.42686380]<http://www.fda.gov/>

[cid:image002.jpg@01D7AEDA.42686380]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D7AEDA.42686380] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7AEDA.42686380] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7AEDA.42686380] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D7AEDA.42686380]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Tuesday, September 21, 2021 10:03 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: k211878@docs.fda.gov; Helen.Topping@admedsol.com; Rose.Guang@admedsol.com

Subject: [EXTERNAL] Re: K211878/S001 Review Status

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Hello Michele

Thank you for your email to keep us updated with progress.

Please note that next week i'll be out on annual leave... therefore, could you also place Helen and Rose (on this email) on copy with any further communication you send over.

Best regards,

Martin Mitchell

Senior Regulatory Affairs Associate

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 20/09/2021 22:31

Subject: K211878/S001 Review Status

Hello Martin:

I want to inform you of a slightly revised review timeline for your 510(k) submission K211878/S001. Due to a limitation of Agency resources, we are unable to complete the substantive review by September 24th. We want to inform you that we expect to complete the review by next Wednesday, September 29th. We apologize for any inconveniences because of the extension of timeline.

Best Regards,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

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[cid:image004.jpg@01D7AEDA.42686380] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7AEDA.42686380] <http://www.flickr.com/photos/fdaphotos/>
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From: Martin.Mitchell@admedsol.com [Martin.Mitchell@admedsol.com]
Sent: 5/18/2022 9:37:48 PM
To: Arepalli, Sambasiva [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d64e0490c9cf498eba4dc7db4813db4b-sra_39e5703]
CC: K211878@docs.fda.gov; Rose.Guang@admedsol.com
Subject: RE: [EXTERNAL] Re: K211878-s002
Attachments: K211878-S002 (b)(4)

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Hi Sam

Firstly, thank you for staying late to continue to work with us on in the final stages of this submission. It is much appreciated.

(b)(4)

For most of the proposed updates we will accept to make the changes. However there are two points we would wish to clarify

- (b)(4)

As discussed I'll call you tomorrow to discuss your email below

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
Cc: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>, "K211878@docs.fda.gov" <K211878@docs.fda.gov>
Date: 18/05/2022 20:39
Subject: RE: [EXTERNAL] Re: K211878-s002

Hi Mr. Mitchell:

(b)(4)

Please cc your response to K211878@docs.fda.gov.

Thx
Sam

Sam Arepalli, Ph.D.
FDA/CDRH/OPEQ/OHT4/PRSB2
Ph: 301 796 6434

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Tuesday, May 17, 2022 6:39 AM
To: Arepalli, Sambasiva <Sambasiva.Arepalli@fda.hhs.gov>
Subject: RE: [EXTERNAL] Re: K211878-s002

CAUTION:This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Sam

Just to be safe for the email trail.... so that your email has a response

The email with this information was send yesterday; however it is also provided again below:

Please find a response to the two points we discussed over the phone

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

As requested, the IFU has been revised with the updated warning

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Date: 17/05/2022 10:32
Subject: RE: [EXTERNAL] Re: K211878-s002

Hi Mr. Mitchell:
Can you please give an update on the revised labeling request? Could you please send the information cob today? Please give me a call when you have a minute.
Thx
Sam

Sam Arepalli, Ph.D.
FDA/CDRH/OPEQ/OHT4/PRSB2
Ph: 301 796 6434

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Monday, May 16, 2022 12:06 PM
To: Arepalli, Sambasiva <Sambasiva.Arepalli@fda.hhs.gov>
Subject: [EXTERNAL] Re: K211878-s002

CAUTION:This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Sam

Just so you're aware it's 17:00 now so i'll be heading home; however i'll try to make myself available outside of hours so please don't hesitate to get in touch if you have any further questions.

Additionally i'll be working from home the next few days so I won't pick up calls from my office number you used previously.

If you have any further questions please email me or call me on my personal mobile number (b)(6)

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>
Cc: "K211878@docs.fda.gov" <K211878@docs.fda.gov>, Rose Guang/WIN/UK/AMS@ams, Helen Topping/WIN/UK/AMS@ams
Date: 16/05/2022 16:28
Subject: Re: K211878-s002

Hi Sam

Please find a response to the two points we discussed over the phone

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

As requested, the IFU has been revised with the updated warning

[attachment "IFU.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>, "K211878@docs.fda.gov" <K211878@docs.fda.gov>
Date: 16/05/2022 14:39
Subject: K211878-s002

Hi Mr. Martin:
Please address the following:

(b)(4)

Thx
Sam

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Sam Arepalli, Ph.D.
FDA/CDRH/OPEQ/OHT4/PRSB2
Ph: 301 796 6434

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Hello Helen,

I understand your position and can assure you that we intend to meet the Monday time frame for completion of the substantive review.

Best regards,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

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Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D7B47B.AAE720D0]<http://www.fda.gov/>

[cid:image002.jpg@01D7B47B.AAE720D0]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D7B47B.AAE720D0] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7B47B.AAE720D0] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7B47B.AAE720D0] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D7B47B.AAE720D0]
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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Helen.Topping@admedsol.com <Helen.Topping@admedsol.com>

Sent: Tuesday, September 28, 2021 2:48 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: k211878@docs.fda.gov; Martin.Mitchell@admedsol.com; Rose.Guang@admedsol.com

Subject: RE: [EXTERNAL] Re: K211878/S001 Review Status

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Hi Michelle,

I realise we're in unprecedented times and I do want to be respectful to FDA's challenges. As this project is business critical for us, could you reassure me that Monday's timeframe will not move again?

Best regards

Helen

Helen Topping

Senior Regulatory Affairs Manager

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Advanced Medical Solutions

Tel: +44 (0) 7721261214

Email: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>, "Helen.Topping@admedsol.com<mailto:Helen.Topping@admedsol.com>" <Helen.Topping@admedsol.com<mailto:Helen.Topping@admedsol.com>>, "Rose.Guang@admedsol.com<mailto:Rose.Guang@admedsol.com>" <Rose.Guang@admedsol.com<mailto:Rose.Guang@admedsol.com>>

Cc: "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 28/09/2021 16:45

Subject: RE: [EXTERNAL] Re: K211878/S001 Review Status

Hello Martin, Helen, & Rose:

I am writing to inform you of a revision to the review timeline for your 510(k) Submission K211878/S001. Unfortunately, we are unable to complete the substantive review by the previously revised timeline of September 29th. We now anticipate completion of the substantive review by next Monday, October 4th. We apologize for any inconveniences caused because of the multiple extensions of review timeline and appreciate your understanding as the Agency works through resource limitations during this time.

Best Regards,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

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Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

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[cid:image003.jpg@01D7B47B.AAE720D0] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7B47B.AAE720D0] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7B47B.AAE720D0] <http://www.flickr.com/photos/fdaphotos/>
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From:Martin.Mitchell@admedsol.com
<Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Tuesday, September 21, 2021 10:03 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>;
Helen.Topping@admedsol.com<mailto:Helen.Topping@admedsol.com>;
Rose.Guang@admedsol.com<mailto:Rose.Guang@admedsol.com>

Subject: [EXTERNAL] Re: K211878/S001 Review Status

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Hello Michele

Thank you for your email to keep us updated with progress.

Please note that next week i'll be out on annual leave... therefore, could you also place Helen and Rose (on this email) on copy with any further communication you send over.

Best regards,

Martin Mitchell

Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>"

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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<Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>"
<k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 20/09/2021 22:31

Subject: K211878/S001 Review Status

Hello Martin:

I want to inform you of a slightly revised review timeline for your 510(k) submission K211878/S001. Due to a limitation of Agency resources, we are unable to complete the substantive review by September 24th. We want to inform you that we expect to complete the review by next Wednesday, September 29th. We apologize for any inconveniences because of the extension of timeline.

Best Regards,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

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Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

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[cid:image002.jpg@01D7B47B.AAE720D0]<https://www.facebook.com/FDA>[cid:image003.jpg@01D7B47B.AAE720D0]<https://twitter.com/US_FDA> [cid:image004.jpg@01D7B47B.AAE720D0]<http://www.youtube.com/user/USFoodandDrugAdmin> [cid:image005.jpg@01D7B47B.AAE720D0]<http://www.flickr.com/photos/fdaphotos/> [cid:image006.jpg@01D7B47B.AAE720D0]<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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Apologies Michele, one final thing I missed off my email... could you clarify how long the teleconference would be by default? Could we request 1 hour just incase some of the points end up taking longer to discuss?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 13/10/2021 20:35
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hi Michele

We're currently preparing our questions for the teleconference and will send these through in due course, however to assist with scheduling the relevant parties at FDA, I should let you know that we would definitely like to discuss the questions related to biocompatibility.

After discussion with the team we would like to request the teleconference on the Tuesday 19th October if that is possible? As we are based in the UK, we would also like to request that this is arranged between the hours of 2-5pm BST.

If this time slot is not available could you outline any alternative days/times which would be possible?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 08/10/2021 22:14

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hi Michele

Thank you for the offer. I think after today's meeting we may need a little more time to be better prepared for the teleconference.

We are reaching out to the (b)(4) for us as we feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible dates for you early next week.

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 06/10/2021 13:49

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference deadline up to October 19th. Let me know if you would like

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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to select a date later than the 14th and I can check our management schedules.

Regarding review timelines, we are still on the 90 day review cycle and are planning to complete the review of your response with the 20 calendar days left on the clock. While we retain the right to add additional days, we are doing our best with the resources that we have to avoid delaying review timelines if possible.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 6, 2021 6:00 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com
Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Thank you again for your review. Our team are busy discussing the questions and we would definitely like to have a teleconference with the FDA. We're currently consolidating our understanding of the deficiencies and are determining what our potential questions to you would be. I hope

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Therefore, with the 10 day teleconference deadline in mind.... could we look to schedule a teleconference with the FDA on Wednesday 13th or Thursday 14th? As we're based in the UK we would appreciate a timeslot within our working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines for this project.... regarding the FDA timeline I can see on the CCP tracker website that the FDA timeline is on day 70.
Will FDA be sticking to the 90 day target and as a result only have 20 days left on the clock?
Or, due to the current situation with the unprecedented resource limitations..... will you will assume 30 days to review the response as standard? Or perhaps stick to the 20 days but retain the right to add additional days?

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
To: <martin.mitchell@admedsol.com>, <helen.topping@admedsol.com>
Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
Date: 04/10/2021 21:44
Subject: K211878/S001 is on Hold Pending Your Response

October 4, 2021
We have reviewed your submission. Please see attached.
If you have any questions, please contact the lead reviewer assigned to your submission, Michele Lee.

*** This is a system-generated email notification ***[attachment "K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Hello Martin,

Thank you to you and your team for attending the teleconference yesterday. I wanted to follow up on two things I was discussing with my team:

(b)(4)

I will be on leave for the next two weeks and you may contact our team management (Lixin.Liu@fda.hhs.gov<mailto:Lixin.Liu@fda.hhs.gov>) if you have questions during that time.

Best,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D7C598.846AEDA0]<http://www.fda.gov/>

[cid:image002.jpg@01D7C598.846AEDA0]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D7C598.846AEDA0] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7C598.846AEDA0] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7C598.846AEDA0] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D7C598.846AEDA0]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: Lee, Michele

Sent: Friday, October 15, 2021 4:47 PM

To: Martin.Mitchell@admedsol.com

Cc: helen.topping@admedsol.com; k211878@docs.fda.gov

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Thank you for providing your questions in advance of the meeting. We look forward to discussing our responses with you next week.

Have a good weekend,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D7C598.846AEDA0]<http://www.fda.gov/>

[cid:image002.jpg@01D7C598.846AEDA0]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D7C598.846AEDA0] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7C598.846AEDA0] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7C598.846AEDA0] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D7C598.846AEDA0]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>
<Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Friday, October 15, 2021 12:00 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>;
k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Please find the list of questions/clarifications attached below.

I hope you have a good weekend. I'm looking forwards to our discussion next week!

Best regards,

Martin Mitchell

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 13/10/2021 22:35

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

I have scheduled the teleconference for next Tuesday October 19th at 9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour but our biocompatibility consultant/ team management needs to drop off for another call at 9:30am. Please send me the questions for discussion in advance of the meeting so that we can plan to discuss biocompatibility/ regulatory questions first before the relevant parties need to drop off.

Join Zoom

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Thanks,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

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[cid:image004.jpg@01D7C598.846AEDA0] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7C598.846AEDA0] <http://www.flickr.com/photos/fdaphotos/>
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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>
<Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Wednesday, October 13, 2021 4:46 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>;
k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Apologies Michele, one final thing I missed off my email... could you clarify how long the teleconference would be by default? Could we request 1 hour just incase some of the points end up taking longer to discuss?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

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Date: 13/10/2021 20:35

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hi Michele

We're currently preparing our questions for the teleconference and will send these through in due course, however to assist with scheduling the relevant parties at FDA, I should let you know that we would definitely like to discuss the questions related to biocompatibility.

After discussion with the team we would like to request the teleconference on the Tuesday 19th October if that is possible? As we are based in the UK, we would also like to request that this is arranged between the hours of 2-5pm BST.

If this time slot is not available could you outline any alternative days/times which would be possible?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

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From: Martin Mitchell/WIN/UK/AMS

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Date: 08/10/2021 22:14

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hi Michele

Thank you for the offer. I think after today's meeting we may need a little more time to be better prepared for the teleconference.

We are reaching out to the (b)(4) for us as we feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible dates for you early next week.

Best regards,

Martin Mitchell

Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

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Date: 06/10/2021 13:49

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Lead Reviewer / Materials Engineer

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From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Wednesday, October 6, 2021 6:00 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>

Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Thank you again for your review. Our team are busy discussing the questions and we would definitely like to have a teleconference with the FDA. We're currently consolidating our understanding of the deficiencies and are determining what our

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* Will FDA be sticking to the 90 day target and as a result only have 20 days left on the clock?

* Or, due to the current situation with the unprecedented resource limitations..... will you will assume 30 days to review the response as standard? Or perhaps stick to the 20 days but retain the right to add additional days?

Best regards,

Martin Mitchell

Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov<mailto:michele.lee@fda.hhs.gov>>

To: <martin.mitchell@admedsol.com<mailto:martin.mitchell@admedsol.com>>, <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>

Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov<mailto:michele.lee@fda.hhs.gov>>

Date: 04/10/2021 21:44

Subject: K211878/S001 is on Hold Pending Your Response

October 4, 2021

We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Michele Lee.

*** This is a system-generated email notification ***[attachment "K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

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Hello Michele

Thank you for your clarification; we have reviewed your feedback in line

(b)(4)

Could you provide a small clarification regarding the FDA timeline with regards the RTA issued

I've read a statement in a MDFUA performance goals document which states "FDA Days begin on the date of receipt of the submission or of the amendment to the submission that enables the submission to be accepted 510(k)"

Once the RTA is closed and the 510(k) is accepted.... would Day 1 of the FDA clock remain as the "acknowledgment" notification date (21st June 2021) or would now change to be the date of the 510(k) "acceptance" notification?

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 09/07/2021 20:12
Subject: RE: [EXTERNAL] Re: K211878 is on Hold Pending Your Response

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hello Martin,

Thank you for the additional (b)(4)

(b)(4)

(b)(4). Thank you for bringing this report to my attention.

Best Regards,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Wednesday, July 7, 2021 11:19 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Subject: [EXTERNAL] Re: K211878 is on Hold Pending Your Response

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Hi Michele

Nice to see we're working with you again.

I was a little surprised regarding the RTA decision as the level of

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information we've provided is the same as that which was provided in previous submissions, where we didn't receive an RTA from yourself. Therefore, I just wanted to reach out to you to ensure that I correctly answer the issue so as to avoid any further delays.

(b)(4)

Thanks in advance for your assistance

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate
Advanced Medical Solutions Ltd.
Tel: +44 (0) 1752 30 9360
E-mail: Martin.Mitchell@admedsol.com

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
To: <martin.mitchell@admedsol.com>
Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
Date: 06/07/2021 20:49
Subject: K211878 is on Hold Pending Your Response

July 6, 2021Acceptance Review Notification - Refuse To Accept (RTA)
We have completed the administrative acceptance review of your submission K211878. Our review indicates that your submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.
Please submit one eCopy of your response, referencing your submission K211878, addressing the elements identified as missing or inconsistent in the attached checklist to:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

U.S. Food and Drug Administration

Center for Devices and Radiological Health

Document Control Center - WO66-G609

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

Your submission will remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist by 01/02/2022, we will consider this submission to be withdrawn, and we will delete it from our review system. Upon receipt of the requested information, FDA will conduct another administrative review of your submission. We will contact you if we require any additional information during the course of our administrative review. FDA aims to apply the least burdensome principles when requesting additional information.

The lead reviewer assigned to your submission is me, Michele Lee. The file is being reviewed in Office of Health Technology 4, Division of Health Technology 4 B. The first line supervisor is the Assistant Director, Plastic Surgery Skin and Wound Devices. You may contact me at any point during the review if you have questions or concerns. You can provide valuable support for CDRH to continue to improve our programs by raising to the attention of management relevant issues that arise during the course of this review. If you feel there is an unresolved issue or a matter that requires additional attention, you should contact the Assistant Director. If your concern or issue is not addressed by the Assistant Director, you should contact the Division Director or OHT Director. The contact information for each management level can be found in the CDRH Management Directory.

For additional information about the Refuse to Accept Policy for for 510(k)s please refer to the guidance document available at

http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf

.

If you have general questions about the review process for your submission, you should contact OPEQSubmissionSupport@fda.hhs.gov.

*** This is a system-generated email notification ***[attachment "K211878.RTAChecklist.RTA1.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

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Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Hello Martin,

I have scheduled the teleconference for next Tuesday October 19th at 9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour but our biocompatibility consultant/ team management needs to drop off for another call at 9:30am. Please send me the questions for discussion in advance of the meeting so that we can plan to discuss biocompatibility/ regulatory questions first before the relevant parties need to drop off.

Join Zoom Meeting

One tap mobile:

Meeting URL:
Meeting ID:
Passcode:

(b)(4)

Join by Telephone

For higher quality, dial a number based on your current location.
Dial:

Meeting ID:

Passcode:

(b)(4)

International numbers

Join from an H.323/SIP room system

H.323:

Meeting ID:

Passcode:

SIP:

Passcode:

(b)(4)

Thanks,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/odrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 13, 2021 4:46 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Apologies Michele, one final thing I missed off my email... could you clarify how long the teleconference would be by default? Could we request 1 hour just incase some of the points end up taking longer to discuss?

Best regards,

Martin Mitchell

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 13/10/2021 20:35
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

We're currently preparing our questions for the teleconference and will send these through in due course, however to assist with scheduling the relevant parties at FDA, I should let you know that we would definitely like to discuss the questions related to biocompatibility.

After discussion with the team we would like to request the teleconference on the Tuesday 19th October if that is possible? As we are based in the UK, we would also like to request that this is arranged between the hours of 2-5pm BST.

If this time slot is not available could you outline any alternative days/times which would be possible?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 08/10/2021 22:14
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Thank you for the offer. I think after today's meeting we may need a little more time to be better prepared for the teleconference.

We are reaching out to the (b)(4) for us as we feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible dates for you early next week.

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 06/10/2021 13:49
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference deadline up to October 19th. Let me know if you would like to select a date later than the 14th and I can check our management schedules.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Regarding review timelines, we are still on the 90 day review cycle and are planning to complete the review of your response with the 20 calendar days left on the clock. While we retain the right to add additional days, we are doing our best with the resources that we have to avoid delaying review timelines if possible.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 6, 2021 6:00 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com
Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Thank you again for your review. Our team are busy discussing the questions and we would definitely like to have a teleconference with the FDA. We're currently consolidating our understanding of the deficiencies and are determining what our potential questions to you would be. I hope to get the questions to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we look to schedule a teleconference with the FDA on Wednesday 13th or Thursday 14th? As we're based in the UK we would appreciate a timeslot within our working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines for this project.... regarding the FDA timeline I can see on the CCP tracker website that the FDA timeline is on day 70.

- Will FDA be sticking to the 90 day target and as a result only have 20 days left on the clock?
- Or, due to the current situation with the unprecedented resource limitations..... will you will assume 30 days to review the response as standard? Or perhaps stick to the 20 days but retain the right to add additional days?

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
To: <martin.mitchell@admedsol.com>, <helen.topping@admedsol.com>
Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
Date: 04/10/2021 21:44
Subject: K211878/S001 is on Hold Pending Your Response

October 4, 2021

We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Michele Lee.

*** This is a system-generated email notification ***[attachment "K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hello Michele

Regarding the timeline clarification i've taken a look on the customer collaboration portal but there was only an email to provide feedback on the portal. Nevertheless i've emailed as i'm a little concerned about what may happen if the portal shows that the 180 day hold periods has expired and we haven't yet submitted our response..... is there a risk that the 510(k) may be inadvertently withdrawn?

We have prepared our response to your question below which I hope you find helpful.

(b)(4)

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(b)(4)

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 08/11/2021 22:05
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thanks for your message. Iâ€™ll need some time to review the teleconference minutes with my team and also obtain some feedback from our consulting toxicologist about the follow up questions. But I wanted to let you know I

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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received your email and you may feel free to check in again next week.

I do have a clarification question about Follow Up (b)(4)

(b)(4)

Regarding the timeline clarification- I am also under the understanding that the COVID-19 guidance document you cited was still active and that would allow you an additional 180 days for the hold period. I have reached out to the 510(k) Staff multiple times to confirm and am still waiting on their response. Is there a customer service contact email for the customer collaboration portal specifically? You may try contacting them as well to have the date corrected on your end.

Thank you,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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provide feedback regarding the customer service you have received:

https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Friday, November 5, 2021 12:07 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: helen.topping@admedsol.com; k211878@docs.fda.gov

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

I hope you had a nice holiday!

Following on from the teleconference we had a few actions to complete and get back to you with.

1) Teleconference minutes

Please find a draft of the the teleconference minutes below. Could you review and confirm if you require any changes made?

2) Follow-up questions on the teleconference discussion

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

The supporting information which provides further clarity on the questions above has been attached if required.

3) Timeline clarification as per previous email

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Thank you again for your assistance

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>, "Liu, Lixin" <Lixin.Liu@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 20/10/2021 22:43
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Michele

Thank you for the prompt response to the clarifications! We'll take your points on board regarding future shelf life studies.

I do have a minor clarification question regarding our response timeline

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 20/10/2021 14:55

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you to you and your team for attending the teleconference yesterday.

I wanted to follow up on two things I was discussing with my team:

(b)(4)

I will be on leave for the next two weeks and you may contact our team management (Lixin.Liu@fda.hhs.gov) if you have questions during that time.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Best,

Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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Michele.Lee@fda.hhs.gov

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From: Lee, Michele
Sent: Friday, October 15, 2021 4:47 PM
To: Martin.Mitchell@admedsol.com
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you for providing your questions in advance of the meeting. We look forward to discussing our responses with you next week.

Have a good weekend,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Friday, October 15, 2021 12:00 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Please find the list of questions/clarifications attached below.

I hope you have a good weekend. I'm looking forwards to our discussion next week!

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 13/10/2021 22:35
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

I have scheduled the teleconference for next Tuesday October 19that 9am

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

EST/ 2pm BST. Per your request, I can be on the call for 1 hour but our biocompatibility consultant/ team management needs to drop off for another call at 9:30am. Please send me the questions for discussion in advance of the meeting so that we can plan to discuss biocompatibility/ regulatory questions first before the relevant parties need to drop off.

Join Zoom Meeting

One tap mobile:

(b)(4)

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Thanks,

Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

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DHT4B: Division of Infection Control and Plastic Surgery Devices
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Sent: Wednesday, October 13, 2021 4:46 PM
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Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
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Martin Mitchell
Regulatory Affairs Manager

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E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

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To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 13/10/2021 20:35

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hi Michele

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After discussion with the team we would like to request the teleconference on the Tuesday 19th October if that is possible? As we are based in the UK, we would also like to request that this is arranged between the hours of 2-5pm BST.

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Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 08/10/2021 22:14

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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We are reaching out to the (b)(4) for us as we feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible dates for you early next week.

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 06/10/2021 13:49
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference deadline up to October 19th. Let me know if you would like to select a date later than the 14thand I can check our management schedules.

Regarding review timelines, we are still on the 90 day review cycle and are planning to complete the review of your response with the 20 calendar days left on the clock. While we retain the right to add additional days, we are doing our best with the resources that we have to avoid delaying review timelines if possible.

Best,
Michele

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 6, 2021 6:00 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com
Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Thank you again for your review. Our team are busy discussing the questions and we would definitely like to have a teleconference with the FDA. We're currently consolidating our understanding of the deficiencies and are determining what our potential questions to you would be. I hope to get the questions to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we look to schedule a teleconference with the FDA on Wednesday 13th or Thursday 14th? As we're based in the UK we would appreciate a timeslot within our working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines for this project.... regarding the FDA timeline I can see on the CCP tracker website that the FDA timeline is on day 70.
Will FDA be sticking to the 90 day target and as a result only have 20

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days left on the clock?

Or, due to the current situation with the unprecedented resource limitations..... will you will assume 30 days to review the response as standard? Or perhaps stick to the 20 days but retain the right to add additional days?

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
To: <martin.mitchell@admedsol.com>, <helen.topping@admedsol.com>
Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
Date: 04/10/2021 21:44
Subject: K211878/S001 is on Hold Pending Your Response

October 4, 2021
We have reviewed your submission. Please see attached.
If you have any questions, please contact the lead reviewer assigned to your submission, Michele Lee.

*** This is a system-generated email notification ***[attachment "K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Hello Martin, Helen, & Rose:

I am writing to inform you of a revision to the review timeline for your 510(k) Submission K211878/S001. Unfortunately, we are unable to complete the substantive review by the previously revised timeline of September 29th. We now anticipate completion of the substantive review by next Monday, October 4th. We apologize for any inconveniences caused because of the multiple extensions of review timeline and appreciate your understanding as the Agency works through resource limitations during this time.

Best Regards,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Tuesday, September 21, 2021 10:03 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: k211878@docs.fda.gov; Helen.Topping@admedsol.com; Rose.Guang@admedsol.com
Subject: [EXTERNAL] Re: K211878/S001 Review Status

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Hello Michele

Thank you for your email to keep us updated with progress.

Please note that next week i'll be out on annual leave... therefore, could you also place Helen and Rose (on this email) on copy with any further communication you send over.

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 20/09/2021 22:31
Subject: K211878/S001 Review Status

Hello Martin:

I want to inform you of a slightly revised review timeline for your 510(k) submission K211878/S001. Due to a limitation of Agency resources, we are unable to complete the substantive review by September 24th. We want to inform you that we expect to complete the review by next Wednesday, September 29th. We apologize for any inconveniences because of the extension of timeline.

Best Regards,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
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Michele.Lee@fda.hhs.gov



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Advanced Medical Solutions (Plymouth) Ltd.

General Report

MICROBIAL BARRIER SUMMARY REPORT FOR LIQUIBAND XL – (b)(4)	Doc No:	(b)(4)
	Rev No:	

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

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(b)(4)

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(b)(4)

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Michele:

Just confirming you are looking at 1:30 pm Eastern time.

(b)(4) That time would work for me; please confirm your availability.

(b)(4)

(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov>
Sent: Friday, November 5, 2021 11:08 AM
To: (b)(4) k211878@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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---

Hello (b)(4)

I have another meeting before that scheduled time. I can do a half hour earlier (6:30pm UTC+1) on Wednesday or a different time on another day next week?

Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov



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From: (b)(4)
Sent: Friday, November 5, 2021 11:02 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>; k211878@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Dear Michele,

many thanks for sending the invite.

I fear, I´ve made a mistake, when communicating the time.
Could we schedule one hour earlier?

Kind regards.

(b)(4)

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(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov>
Sent: Freitag, 5. November 2021 15:59
To: (b)(4) k211878@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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---

Hello (b)(4)

Sure, we can discuss via teleconference on 10 Nov 2021 at 7pm UTC+1/ 2pm EDT. I sent a ZoomGov invite via email and also copied the call-in information below.

Image removed

Hi there,

Michele.Lee@fda.hhs.gov is inviting you to a scheduled ZoomGov meeting.

Join Zoom Meeting

One tap mobile:

Meeting URL:

Meeting ID:
Passcode:

(b)(4)

Join by Telephone

For higher quality, dial a number based on your current location.
Dial:

Meeting ID:

Passcode:

(b)(4)

International numbers

Join from an H.323/SIP room system

H.323:

Meeting ID:
Passcode:
SIP:
Passcode:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Best Regards,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov



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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: (b)(4)
Sent: Friday, November 5, 2021 10:10 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>; k211878@docs.fda.gov
Cc: (b)(4); Martin.Mitchell@admedsol.com
Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Dear Michele,

Many thanks for your message.
Martin, thank you for the connection.

Michele, would you be available next Wednesday, 10 November 2021, at 7 pm (UTC+1)?
Then I would send an invitation.

Kind regards.

(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov>
Sent: Freitag, 5. November 2021 14:33
To: Martin.Mitchell@admedsol.com; k211878@docs.fda.gov
Cc: (b)(4)
Subject: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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---

Hello all,

Thank you, Martin, for the connection.

(b)(4)

Best Regards,

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Michele.Lee@fda.hhs.gov



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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Thursday, November 4, 2021 11:29 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>; k211878@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

Regarding the recent deficiency question on our medical device submission which is currently under review with the FDA:

(b)(4)

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

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Hello Michele

I hope you had a nice holiday!

Following on from the teleconference

we had a few actions to complete and get back to you with.

1) Teleconference minutes

Please find a draft of the the teleconference

minutes below. Could you review and confirm if you require any changes

made?

2) Follow-up questions on the teleconference

discussion

As suggested during the teleconference

there was the opportunity for a followup email clarification on a few minor

points.
<li value=1>

(b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

serif">The supporting information which provides

further clarity on the questions above has been attached if required.

3) Timeline clarification as per

previous email

I can see on the customer collaboration

portal that we have a 180 day hold period which ends on the 2nd of April

2022.

However, I was under the understanding

that the guidance document below was active which would provide us with

an additional 180 day hold period?
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices
Could you clarify if we have 180 days

or 360 days to respond to the deficiencies?

Thank you again for your assistance

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions

Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From:

 Martin Mitchell/WIN/UK/AMS
To:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

 "Lee, Michele"

<Michele.Lee@fda.hhs.gov>, "Liu, Lixin"
<Lixin.Liu@fda.hhs.gov>
Cc:

 "helen.topping@admedsol.com"

<helen.topping@admedsol.com>, "k211878@docs.fda.gov"
<k211878@docs.fda.gov>
Date:

 20/10/2021 22:43
Subject:

   RE: [EXTERNAL]

Re: K211878/S001 is on Hold Pending Your Response
<hr noshade>

Hello Michele

Thank you for the prompt response to

the clarifications! We'll take your points on board regarding future shelf

life studies.

I do have a minor clarification question

regarding our response timeline

I can see on the customer collaboration

portal that we have a 180 day hold period which ends on the 2nd of April

2022.

However, I was under the understanding

that the guidance document below was active which would provide us with

an additional 180 day hold period?

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days

or 360 days to respond to the deficiencies?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions

Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From:

 "Lee, Michele"

<Michele.Lee@fda.hhs.gov>
To:

 "Martin.Mitchell@admedsol.com"

<Martin.Mitchell@admedsol.com>
Cc:

 "helen.topping@admedsol.com"

<helen.topping@admedsol.com>, "k211878@docs.fda.gov"
<k211878@docs.fda.gov>
Date:

 20/10/2021 14:55
Subject:

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

   RE: [EXTERNAL]

Re: K211878/S001 is on Hold Pending Your Response
<hr noshade>

Hello Martin,

Thank you to you and your team for attending

the teleconference yesterday. I wanted to follow up on two things I was

discussing with my team:
1.   Regarding

(b)(4)

face="Calibri">
I will be on leave for the next two weeks

and you may contact our team management (<u>Lixin.Liu@fda.hhs.gov</u>)

if you have questions during that time.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices

Team
DHT4B: Division of Infection Control and

Plastic Surgery Devices
OHT4: Office of Surgical and Infection

Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue

| Silver Spring, MD 20993
<u>Michele.Lee@fda.hhs.gov</u>

<img src=cid:_4_0DBCF7B40DBCF438005880C180258784 style="border:0px solid;">
<u>
</u><img src=cid:_2_0DBCFC440DBCF438005880C180258784 style="border:0px solid;"> <img src=cid:_2_0DBD00900DBCF438005880C180258784 style="border:0px solid;"> <img src=cid:_2_0DBD04DC0DBCF438005880C180258784 style="border:0px solid;"> <img

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

src=cid:_2_0DBD09280DBCF438005880C180258784 style="border:0px solid;"> <img src=cid:_2_0DBD0D740DBCF438005880C180258784 style="border:0px solid;">
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regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

From: Lee, Michele
Sent: Friday, October 15, 2021 4:47 PM
To: Martin.Mitchell@admedsol.com
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you for providing your questions

in advance of the meeting. We look forward to discussing our responses

with you next week.

Have a good weekend,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices

Team
DHT4B: Division of Infection Control and

Plastic Surgery Devices
OHT4: Office of Surgical and Infection

Control Devices
Office of Product Evaluation and Quality

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| Silver Spring, MD 20993
<u>Michele.Lee@fda.hhs.gov</u>

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</u><img src=cid:_2_0DBD5CB80DBD54C8005880C180258784 style="border:0px solid;"> <img src=cid:_2_0DBD61040DBD54C8005880C180258784 style="border:0px solid;"> <img src=cid:_2_0DBD65500DBD54C8005880C180258784 style="border:0px solid;"> <img src=cid:_2_0DBD699C0DBD54C8005880C180258784 style="border:0px solid;"> <img src=cid:_2_0A05912C0DBD54C8005880C180258784 style="border:0px solid;">
Excellent customer

service is important to us. Please take a moment to provide feedback

regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

<font size=2

face="Calibri">From: <u>Martin.Mitchell@admedsol.com</u><<u>Martin.Mitchell@admedsol.com</u>>

Sent: Friday, October 15, 2021 12:00 PM
To: Lee, Michele <<u>Michele.Lee@fda.hhs.gov</u>>
Cc: <u>helen.topping@admedsol.com</u>;

<u>k211878@docs.fda.gov</u>
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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or open attachments unless you recognize the sender and know the content

is safe.

Hi Michele

Please find the list of questions/clarifications attached below.

I hope you have a good weekend. I'm looking forwards to our discussion

next week!

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>
To: "<u>Martin.Mitchell@admedsol.com</u>"

<<u>Martin.Mitchell@admedsol.com</u>>
Cc: "<u>helen.topping@admedsol.com</u>"

<<u>helen.topping@admedsol.com</u>>,

"<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 13/10/2021

22:35
Subject: RE:

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hello Martin,

I have scheduled the teleconference for next Tuesday October 19that 9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour

but our biocompatibility consultant/ team management needs to drop off

for another call at 9:30am. Please send me the questions for discussion

in advance of the meeting so that we can plan to discuss biocompatibility/

regulatory questions first before the relevant parties need to drop off.

<p><table width=100% style="border-collapse:collapse;"><tr height=8><td colspan=2 bgcolor=white style="border-style:none none none none;border-color:#000000;border-width:0px 0px 0px 0px;padding:0px 0px;"><u>Join

Zoom Meeting (b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

face="Arial">429761</table><p>

Thanks,
Michele

Michele Lee,
Ph.D.
Lead Reviewer / Materials
Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of
Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and
Infection Control Devices
Office of Product Evaluation and Quality

CDRH |
Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver
Spring, MD 20993<u>
</u><a
href=mailto:Michele.Lee@fda.hhs.gov><font size=2 color=blue face="Segoe
UI"><u>Michele.Lee@fda.hhs.gov</u>
<u>
</u><img
src=cid:_4_0DBDD42C0A05DFB8005880C180258784 style="border:0px solid;"><font size=2
color=blue><u>
</u><u>
</u><a
href=https://www.facebook.com/FDA><img src=cid:_2_0DBDD8BC0A05DFB8005880C180258784
style="border:0px solid;"><a
href=https://twitter.com/US_FDA><img src=cid:_2_0DBDDD080A05DFB8005880C180258784

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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href=http://www.youtube.com/user/USFoodandDrugAdmin><img
src=cid:_2_0DBDE1540A05DFB8005880C180258784 style="border:0px solid;"><font size=1
color=#4f4f4f face="Arial"><img
src=cid:_2_0DBDE5A00A05DFB8005880C180258784 style="border:0px solid;"><font size=1
color=#4f4f4f face="Arial"> <a
href=http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm><img
src=cid:_2_0DBDEA900A05DFB8005880C180258784 style="border:0px solid;"><font size=2
color=#4f4f4f>
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take a moment

to provide feedback regarding the customer service you have received: <a
href="https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E"
target=_blank><font size=2 color=#0082bf
face="Helvetica"><u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u><
/font>

From: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2
color=blue><u>Martin.Mitchell@admedsol.com</u><<a
href=mailto:Martin.Mitchell@admedsol.com><font size=2
color=blue><u>Martin.Mitchell@admedsol.com</u>>

Sent: Wednesday, October 13, 2021 4:46 PM
To: Lee, Michele
<<font size=2
color=blue><u>Michele.Lee@fda.hhs.gov</u>>
Cc:
<font size=2
color=blue><u>helen.topping@admedsol.com</u>;

<font size=2
color=blue><u>k211878@docs.fda.gov</u>
Subject: RE:
[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response
 <font size=2
color=#806210>
CAUTION:This email originated from outside of the
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and know the content is safe.

Apologies
Michele, one final thing I missed off my email... could you clarify

how long the teleconference would be by default? Could we request 1 hour

just incase some of the points end up taking longer to discuss?

Best
regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-
mail: <font size=2 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=2 color=#000080
face="Arial">
Tel: +44 (0) 1752 30 9360

From: Martin

Mitchell/WIN/UK/AMS
To:
   "Lee,

Michele" <<font size=1 color=blue
face="Arial"><u>Michele.Lee@fda.hhs.gov</u><font size=1
face="Arial">>
Cc:
   "<a
href=mailto:helen.topping@admedsol.com><font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">>,

"<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u>"

<<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u><font size=1
face="Arial">>
Date:

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

   13/10/2021

20:35
Subject:
 RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response<div
align=center><hr noshade>

<font size=2
face="Arial">

Hi Michele

We're currently preparing our questions for the
teleconference and will

send these through in due course, however to assist with scheduling the

relevant parties at FDA, I should let you know that we would definitely

like to discuss the questions related to biocompatibility.

After discussion with
the team we would like to request the teleconference

on the Tuesday 19th October

if that is possible? As we are based in

the UK, we would also like to request that this is arranged between the

hours of 2-5pm BST<font size=2
face="Arial">.

If this time slot is not available could you outline any alternative days/times

which would be possible?

Best regards,<font size=2 color=#000080
face="Arial">

Martin Mitchell
Regulatory Affairs
Manager

Advanced Medical Solutions Ltd.
E-mail: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=2 color=#000080
face="Arial">
Tel: +44 (0) 1752 30 9360<font size=2
face="Calibri">

<font size=1 color=#5f5f5f
face="Arial">

From: <font size=1
face="Arial">Martin

Mitchell/WIN/UK/AMS
To:
   "Lee,

Michele" <<font size=1 color=blue
face="Arial"><u>Michele.Lee@fda.hhs.gov</u><font size=1
face="Arial">>
Cc:
   "<a
href=mailto:helen.topping@admedsol.com><font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">>,

"<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u>"

<<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u><font size=1
face="Arial">>
Date:
   08/10/2021

22:14
Subject:
 RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response<font size=2
face="Calibri"> <hr noshade>
<font size=2
face="Calibri">

Hi Michele

Thank you
for the offer. I think after today's meeting we may need a little

more time to be better prepared for the teleconference.

We are reaching out to
the (b)(4) for us as we

feel that it may be beneficial to have them join us on the teleconference.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

As such we need to check their availability. I hope to have list of possible

dates for you early next week.

Best regards,<font size=2 color=#000080
face="Arial">

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=2 color=#000080
face="Arial">
Tel: +44 (0) 1752 30 9360<font size=2
face="Calibri">

<font size=1 color=#5f5f5f
face="Arial">

From: <font size=1
face="Arial">"Lee,

Michele" <<font size=1 color=blue
face="Arial"><u>Michele.Lee@fda.hhs.gov</u><font size=1
face="Arial">>
To:
   "<a
href=mailto:Martin.Mitchell@admedsol.com><font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">>
Cc:
   "<a
href=mailto:helen.topping@admedsol.com><font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">"

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face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">>,

"<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u>"

<<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u><font size=1
face="Arial">>
Date:
   06/10/2021

13:49
Subject:
 RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response<font size=2
face="Calibri"> <hr noshade>
<font size=2
face="Calibri">

Hello Martin,

If it makes it easier for your
team, we are able to extend the 10 day teleconference

deadline up to October 19th. Let me know if you would like to

select a date later than the 14thand I can check our management

schedules.

Regarding review timelines, we are still on the 90 day review cycle
and

are planning to complete the review of your response with the 20 calendar

days left on the clock. While we retain the right to add additional days,

we are doing our best with the resources that we have to avoid delaying

review timelines if possible.

Best,
Michele<font size=2 color=#0082bf
face="Segoe UI">

Michele Lee, Ph.D.<font size=2 face="Segoe
UI">
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound
Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices
Office of Product
Evaluation and Quality

CDRH | Food and Drug Administration
White Oak |
10903 New Hampshire Avenue | Silver Spring, MD 20993<font size=2 color=blue
face="Calibri"><u>
</u><font size=2
color=blue face="Segoe UI"><u>Michele.Lee@fda.hhs.gov</u><font size=2
color=blue face="Calibri"><u>
</u><font size=2 color=blue

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
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src=cid:_2_0DBE5FE00DBE4FFC005880C180258784 style="border:0px solid;"><a
href=https://twitter.com/US_FDA><img src=cid:_2_0DBE64140DBE4FFC005880C180258784
style="border:0px solid;"><a
href=http://www.youtube.com/user/USFoodandDrugAdmin><img
src=cid:_2_0DBE68B40DBE4FFC005880C180258784 style="border:0px solid;"><a
href=http://www.flickr.com/photos/fdaphotos/><img
src=cid:_2_0DBE6CE80DBE4FFC005880C180258784 style="border:0px solid;"><font size=1
color=#4f4f4f face="Arial"> <a
href=http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm><img
src=cid:_2_0DBE71340DBE4FFC005880C180258784 style="border:0px solid;"><font size=2
color=#4f4f4f face="Calibri">
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 Please take a moment

to provide feedback regarding the customer service you have received: <a
href="https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E"
target=_blank><font size=2 color=#0082bf
face="Arial"><u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u></fon
t>

From: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri"><<font size=2
color=blue face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri">>

Sent: Wednesday, October 6, 2021 6:00 AM
To: Lee, Michele
<<font size=2 color=blue
face="Calibri"><u>Michele.Lee@fda.hhs.gov</u><font size=2
face="Calibri">>
Cc: <a
href=mailto:helen.topping@admedsol.com><font size=2 color=blue
face="Calibri"><u>helen.topping@admedsol.com</u><font size=2
face="Calibri">
Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your
Response

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of the organization. Do not click links or open attachments unless you

recognize the sender and know the content is safe.<font size=2
face="Arial">

Hi Michele

Thank you again for your review. Our team are
busy discussing the questions

and we would definitely like to have a teleconference with the FDA. We're

currently consolidating our understanding of the deficiencies and are determining

what our potential questions to you would be. I hope to get the questions

to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference
deadline in mind.... could we

look to schedule a teleconference with the FDA on Wednesday 13th or Thursday

14th? As we're based in the UK we would appreciate a timeslot within our

working hours which finish at 17:00 BST.

Additionally, I have a small question
to allow us to predict timelines

for this project.... regarding the FDA timeline I can see on the CCP tracker

website that the FDA timeline is on day 70.<font size=2
face="Calibri">
Will FDA be sticking to the 90
day target

and as a result only have 20 days left on the clock?
<font size=2
face="Arial">Or, due to the current situation with the

unprecedented resource limitations..... will you will assume 30 days to

review the response as standard? Or perhaps stick to the 20 days but retain
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

the right to add additional days?
Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Michele

Lee [MICHELE.LEE]" <<u>michele.lee@fda.hhs.gov</u>>
To: <<u>martin.mitchell@admedsol.com</u>>,

<<u>helen.topping@admedsol.com</u>>
Cc: "Michele

Lee [MICHELE.LEE]" <<u>michele.lee@fda.hhs.gov</u>>
Date: 04/10/2021

21:44
Subject: K211878/S001

is on Hold Pending Your Response <hr noshade>

October 4, 2021 <p>We have reviewed your submission. Please see attached.

<p>If you have any questions, please contact the lead reviewer

assigned to your submission, Michele Lee. <p> <p>*** This is a system-generated email notification ***[attachment

"K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin

Mitchell/WIN/UK/AMS] <p>

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hello (b)(4)

Sure, we can discuss via teleconference on 10 Nov 2021 at 7pm UTC+1/ 2pm EDT. I sent a ZoomGov invite via email and also copied the call-in information below.

[https://www.zoomgov.com/static/5.2.1818/image/new/ZoomLogo_110_25.png]<https://zoom.us/>

Hi there,

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov> is inviting you to a scheduled ZoomGov meeting.

Join Zoom

(b)(4)

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

Best Regards,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D7D234.156A4F60]<http://www.fda.gov/>

[cid:image002.jpg@01D7D234.156A4F60]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D7D234.156A4F60] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7D234.156A4F60] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7D234.156A4F60] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D7D234.156A4F60]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: (b)(4)

Sent: Friday, November 5, 2021 10:10 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>; k211878@docs.fda.gov

Cc: (b)(4)
(b)(4) Martin.Mitchell@admedsol.com

Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Michele,

Many thanks for your message.

Martin, thank you for the connection.

Michele, would you be available next Wednesday, 10 November 2021, at 7 pm (UTC+1)?

Then I would send an invitation.

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Kind regards.

(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Sent: Freitag, 5. November 2021 14:33

To: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Cc: (b)(4)

(b)(4)

Subject: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

This message is from an EXTERNAL SENDER â€" be CAUTIOUS, particularly with links and attachments

---

Hello all,

Thank you, Martin, for the connection.

(b)(4)

Best Regards,

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D7D234.156A4F60]<http://www.fda.gov/>

[cid:image002.jpg@01D7D234.156A4F60]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D7D234.156A4F60] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7D234.156A4F60] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7D234.156A4F60] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D7D234.156A4F60]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>
<Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Thursday, November 4, 2021 11:29 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>;
k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Cc: (b)(4)
(b)(4)

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

Regarding the recent deficiency question on our medical device submission which is currently under review with the FDA:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hello Julie

I've seen on the customer collaboration

portal that our response has been acknowledged by the FDA and the clock

has started moving.

Can we assume that a new reviewer has

been successfully assigned?

<img src=cid:_1_0E5E88D80E5E4AB4003569FA80258839 style="border:0px solid;">

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions

Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From:

 "Morabito, Julie"

<Julie.Morabito@fda.hhs.gov>
To:

 "Martin.Mitchell@admedsol.com"

<Martin.Mitchell@admedsol.com>
Cc:

 "Helen.Topping@admedsol.com"

<Helen.Topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>,

"Rose.Guang@admedsol.com" <Rose.Guang@admedsol.com>, "Lee,

Michele" <Michele.Lee@fda.hhs.gov>
Date:

 14/04/2022 01:01
Subject:

   RE: [EXTERNAL]

Re: K211878/S001 is on Hold Pending Your Response
<hr noshade>

Hello Martin,

Thanks for reaching out.

Iâ€™ll be glad to assist in answering your questions.
Will there be any delays in assigning a new

reviewer?
We do not anticipate a delay

in assigning a new reviewer.<li>Are there still resource constraints at the

FDA?
Speaking regarding our team,

we are still working through resource constraints and doing our best to

meet deadlines.<li>Would a new reviewer who is not familiar

with the product/deficiencies require a longer period of time to perform

the review?
We will do our best to align

the new reviewer that is familiar and experienced with the review product,

to limit delay to the extent possible.
<font size=2 color=#0082bf

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

face="Calibri">I

hope this is helpful, but please let me know if youâ€™d like to discuss

further.

Best,
Julie

Julie Morabito, PhD,

RAC (she/her/hers)
Assistant Director

Plastic Surgery Skin and

Wound Devices Team
DHT4B: Division of Infection

Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection

Control Devices
Office of Product Evaluation

and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm.

4668 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (240) 402-3839 | Cell:

(b)(6) /font>
<u>julie.morabito@fda.hhs.gov</u>

Formerly:
Assistant Director, Outreach

and Partnerships Team 2 (MedSun)
DCEA1: Division of Clinical

Science and Quality | OCEA: Office of Clinical Evidence and Analysis
Office of Product Evaluation

and Quality

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</u><img src=cid:_2_0A7AA4A00A7A9CB0003569FA80258839 style="border:0px solid;"> <img src=cid:_2_0A7AA8EC0A7A9CB0003569FA80258839 style="border:0px solid;"> <img src=cid:_2_0A7AAD380A7A9CB0003569FA80258839 style="border:0px solid;"> <img src=cid:_2_0A7AB1840A7A9CB0003569FA80258839 style="border:0px solid;"> <img src=cid:_2_0A7AB5D00A7A9CB0003569FA80258839 style="border:0px solid;">

Excellent customer

service is important to us. Please take a moment to provide feedback

regarding the customer service you have received <u>here.</u>

From:

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
Martin.Mitchell@admedsol.com

<Martin.Mitchell@admedsol.com>
Sent: Wednesday, April 13, 2022 3:32 PM
To: Morabito, Julie <Julie.Morabito@fda.hhs.gov>
Cc: Helen.Topping@admedsol.com; k211878@docs.fda.gov; Rose.Guang@admedsol.com;

Lee, Michele <Michele.Lee@fda.hhs.gov>
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

CAUTION:This email originated from outside of the organization. Do not click links

or open attachments unless you recognize the sender and know the content

is safe.

Hello Michele and Julie

Thank you Michele for providing further clarification on the matter regarding

maintenance of a lead reviewer. We are sad to lose you as our lead reviewer

and wish you the best in your new role within the FDA.

During the initial review of the 510(k) it was flagged that the FDA had

resource challenges which resulted in the review taking 70 days instead

of the targeted 60 days....When we discussed this previously it was stated

that when we submit our deficiency response the FDA would still target

to complete the review within the remaining 20 days, however.... it was

also flagged that if resource constraints still existed this could take

longer than 20 days.

To keep the FDA informed about our progress we are planning to submit our

response to the deficiency questions in around 3 weeks time. We would like

to enquire about FDA's ability to complete the review within 20 days?
Will there be any delays in assigning a new

reviewer? Are there still resource constraints at the

FDA?<li>Would a new reviewer who is not familiar

with the product/deficiencies require a longer period of time to perform

the review?
The timely completion of your review would be massively appreciated as

the large wound market is critical to urgent patient demand, AMS and our

partners who are very keen to provide the improved product to hospitals

across the United States.

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>
To:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

   "<a
href=mailto:Martin.Mitchell@admedsol.com><font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">>
Cc:
   "<a
href=mailto:k211878@docs.fda.gov><font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u>"

<<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u>>,

"<font size=1 color=blue
face="Arial"><u>Rose.Guang@admedsol.com</u>"

<<font size=1 color=blue
face="Arial"><u>Rose.Guang@admedsol.com</u>>,

"<font size=1 color=blue
face="Arial"><u>Helen.Topping@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>Helen.Topping@admedsol.com</u><font size=1
face="Arial">>,

"Morabito, Julie" <<u>Julie.Morabito@fda.hhs.gov</u><font size=1
face="Arial">>
Date:
   05/04/2022

14:47
Subject:
 RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response<div
align=center><hr noshade>

Hello Martin,

Unfortunately, it is not possible for
me to take on lead review of this

submission. As previously mentioned, I am currently working in another

Office within FDA and do not conduct premarket reviews of medical devices

in my current role.

It is not uncommon for new lead reviewers to be assigned
to submissions

returning from hold. The internal documentation serves as a complete record

of the previous interactions during prior review of a submission. If you

have further questions regarding the review process for your submission,

you may contact the Assistant Director for the Plastic Surgery Skin &

Wound Devices Team, Dr. Julie Morabito (<a
href=mailto:Julie.Morabito@fda.hhs.gov><font size=2 color=blue
face="Calibri"><u>Julie.Morabito@fda.hhs.gov</u><font size=2
face="Calibri">).

Best,
Michele
 <font size=2 color=#424282 face="Segoe
UI">
Michele Lee, Ph.D.(she/her/hers)<font size=1 face="Segoe
UI">
Regulatory Science Program Manager
Partnerships to Advance Innovation and
Regulatory Science (PAIRS)

Center for Devices and Radiological
Health
Office of Strategic Partnerships and Technology Innovation
Division of All
Hazards Response, Science, and Strategic Partnerships
U.S. Food and Drug
Administration<u>
</u><a
href=mailto:michele.lee@fda.hhs.gov><font size=1 color=#0082bf face="Segoe
UI"><u>michele.lee@fda.hhs.gov</u>

<u>
</u><a

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

href=http://www.fda.gov/><img src=cid:_4_0F152EF00F152144003569FA80258839 width=192
height=43 style="border:0px solid;"><font size=2 color=blue
face="Calibri"><u>
</u><font size=2 color=blue
face="Calibri"><u>
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src=cid:_2_0F1533800F152144003569FA80258839 style="border:0px solid;"><font size=1
color=#4f4f4f face="Segoe UI"><img
src=cid:_2_0F1537CC0F152144003569FA80258839 style="border:0px solid;"><font size=1
color=#4f4f4f face="Segoe UI"> <a
href=http://www.youtube.com/user/USFoodandDrugAdmin><img
src=cid:_2_0F153C180F152144003569FA80258839 style="border:0px solid;"><font size=1
color=#4f4f4f face="Segoe UI"><a
href=http://www.flickr.com/photos/fdaphotos/><img
src=cid:_2_0F1540640F152144003569FA80258839 style="border:0px solid;"><font size=1
color=#4f4f4f face="Segoe UI"> <a
href=http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm><img
src=cid:_2_0F1544B00F152144003569FA80258839 style="border:0px solid;"><font size=1
face="Segoe UI">

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moment to

provide feedback regarding the customer service you have received: <a
href="https://www.research.net/s/cdrhcustomerservice?ID=7013&S=E"><font size=1
color=blue face="Segoe
UI"><u>https://www.research.net/s/cdrhcustomerservice?ID=7013&S=E</u><fo
nt size=1 face="Segoe UI">.

From: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri"><<font size=2
color=blue face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri">>

Sent: Tuesday, April 5, 2022 8:31 AM
To: Lee, Michele
<<font size=2 color=blue
face="Calibri"><u>Michele.Lee@fda.hhs.gov</u><font size=2
face="Calibri">>
Cc: <u>k211878@docs.fda.gov</u><font size=2
face="Calibri">;

<font size=2 color=blue
face="Calibri"><u>Rose.Guang@admedsol.com</u>;

<font size=2 color=blue
face="Calibri"><u>Helen.Topping@admedsol.com</u><font size=2
face="Calibri">
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending
Your Response
 <font size=2 color=#806210
face="Calibri">
CAUTION:This email originated
from outside

of the organization. Do not click links or open attachments unless you

recognize the sender and know the content is safe.
 <font size=2
face="Arial">
Hello Michele,

We have been pleased to have you as the lead
reviewer for RTA review, technical

review, and responses to deficiency discussions since July 2021, as well

as having you for the review for our previous 510(k) submission of the

same product.

(b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

size=2 face="Arial">Jun 2021 - We submitted K211878 in response

the (b)(4) k/font>
Oct 2021 - Further deficiencies were raised

on the new K211878 submission
We currently have only 20 days of FDA review time left on our product and

have been advised that we will now be assigned a new reviewer. As

you can imagine this causing us a high level of concern given you have

 a detailed knowledge of our submissions and of the current outstanding

questions. Our concern being that a new reviewer will not have the same

detailed knowledge of our submission or of the outstanding questions and

hence this may cause unnecessary further delay.

We have been very satisfied with the support we have received from yourself

 and we would ask that you remain on our file for the final 20 days

if at all possible, or an explanation of why this is not possible with

some reassurances that a new assessor will not cause unnecessary delays

whilst they gain detailed knowledge of our file.

Your expedited response to this request would be appreciated.

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>
To: "<u>Martin.Mitchell@admedsol.com</u>"

<<u>Martin.Mitchell@admedsol.com</u>>
Cc: "<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 25/03/2022

16:47
Subject: RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hello Martin,

A new lead reviewer will not be assigned until a follow up submission is

received. So there is currently not a primary contact unless there is an

active submission under FDA review. All of our correspondence and the prior

related review have been documented internally, so you can be assured that

the history of the prior review and contact is available to the future

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

lead reviewer.

Best,
Michele

From: <u>Martin.Mitchell@admedsol.com</u><<u>Martin.Mitchell@admedsol.com</u>>

Sent: Friday, March 25, 2022 12:21 PM
To: Lee, Michele <<u>Michele.Lee@fda.hhs.gov</u>>
Cc: <u>k211878@docs.fda.gov</u>
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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of the organization. Do not click links or open attachments unless you

recognize the sender and know the content is safe.

Hi Michele

I've seen on the FDA customer collaboration portal that the time has automatically

been added, but just thought it would be prudent to also inform you of

the situation.

Could I ask who the primary contact is now? Will you be assisting or have

any involvement with the review of our response?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>
To: "<u>Martin.Mitchell@admedsol.com</u>"

<<u>Martin.Mitchell@admedsol.com</u>>
Cc: "<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 25/03/2022

15:59
Subject: RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hello Martin,

I am sorry to hear about the **(b)(4)**. I hope all is able to be resolved

soon.

Thank you for the update. I am actually working in a different division

within FDA and no longer the primary contact for this submission. I believe

that the 180 days is automatically granted for responses to AINN hold but

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you can also confirm with the 510(k) Program staff (<a
href=mailto:510k_Program@fda.hhs.gov><font size=2 color=blue
face="Calibri"><u>510k_Program@fda.hhs.gov</u>,

telephone: 301-796-5640) to make sure.

Best,
Michele<font size=2
color=#424282 face="Segoe UI">

Michele Lee,
Ph.D.(she/her/hers)
Regulatory
Science Program Manager
Partnerships to Advance Innovation and Regulatory Science
(PAIRS)

Center for Devices and Radiological Health
Office of Strategic
Partnerships and Technology Innovation
Division of All Hazards Response, Science,
and Strategic Partnerships
U.S. Food and Drug Administration<font size=2
color=blue face="Calibri"><u>
</u><a
href=mailto:michele.lee@fda.hhs.gov><font size=1 color=#0082bf face="Segoe
UI"><u>michele.lee@fda.hhs.gov</u><font size=2 color=blue
face="Calibri"><u>

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face="Calibri"><u>
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href=https://twitter.com/US_FDA><img src=cid:_2_0F15C2340F15AD30003569FA80258839
style="border:0px solid;"><a
href=http://www.youtube.com/user/USFoodandDrugAdmin><img
src=cid:_2_0F15C6680F15AD30003569FA80258839 style="border:0px solid;"><a
href=http://www.flickr.com/photos/fdaphotos/><img
src=cid:_2_0F15CA9C0F15AD30003569FA80258839 style="border:0px solid;"><font size=1
color=#4f4f4f face="Segoe UI"><a
href=http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm><img
src=cid:_2_0F15CEE80F15AD30003569FA80258839 style="border:0px solid;"><font size=1
face="Segoe UI">

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href="https://www.research.net/s/cdrhcustomerservice?ID=7013&S=E"><font size=1
color=blue face="Segoe
UI"><u>https://www.research.net/s/cdrhcustomerservice?ID=7013&S=E</u><fo
nt size=1 face="Segoe UI">.

From: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri"><<font size=2
color=blue face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri">>

Sent: Friday, March 25, 2022 11:28 AM
To: Lee, Michele
<<font size=2 color=blue
face="Calibri"><u>Michele.Lee@fda.hhs.gov</u><font size=2
face="Calibri">>
Cc: <u>k211878@docs.fda.gov</u><font size=2
face="Calibri">
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending
Your Response<font size=2 color=#806210
face="Calibri">

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of the organization. Do not click links or open attachments unless you

recognize the sender and know the content is safe.<font size=2
face="Arial">

Hi Michele

I'd like to provide an update on our progress
with responding to the deficiencies

raised on K211878

We were on track to have a deficiency response submitted to
the FDA by

the 180 day hold period deadline of 2nd April 2022.

However, the organisation
 performing the (b)(4)
(b)(4) have been affected by (b)(4).

As a result, they were unable to complete the testing by our targeted

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
timeline.

Therefore, I just want to confirm that we are still intending to respond

to the deficiencies, but we would need to use the second 180 day hold period

granted to us through the COVID-19 situation.

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>
To: "<u>Martin.Mitchell@admedsol.com</u>"

<<u>Martin.Mitchell@admedsol.com</u>>
Cc: "<u>helen.topping@admedsol.com</u>"

<<u>helen.topping@admedsol.com</u>>,

"<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 08/11/2021

22:05
Subject: RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hello Martin,

Thanks for your message. Iâ€™ll need some time to review the teleconference

minutes with my team and also obtain some feedback from our consulting

toxicologist about the follow up questions. But I wanted to let you know

I received your email and you may feel free to check in again next week.

I do have a clarification question about Follow Up (b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

(b)(4).

Regarding the timeline clarification- I am also under the understanding

that the COVID-19 guidance document you cited was still active and that

would allow you an additional 180 days for the hold period. I have reached

out to the 510(k) Staff multiple times to confirm and am still waiting

on their response. Is there a customer service contact email for the customer

collaboration portal specifically? You may try contacting them as well

to have the date corrected on your end.

Thank you,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993<u>
</u><u>Michele.Lee@fda.hhs.gov</u><u>
</u><u>
</u><img src=cid:_4_0F170B880F16FBCC003569FA80258839 width=192 height=43 style="border:0px solid;"><u>
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Excellent customer service is important to us. Please take a moment

to provide feedback regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

From: <u>Martin.Mitchell@admedsol.com</u><<u>Martin.Mitchell@admedsol.com</u>>

Sent: Friday, November 5, 2021 12:07 PM
To: Lee, Michele <<u>Michele.Lee@fda.hhs.gov</u>>
Cc: <u>helen.topping@admedsol.com</u>;

<u>k211878@docs.fda.gov</u><font size=2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

face="Calibri">
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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of the organization. Do not click links or open attachments unless you

recognize the sender and know the content is safe.

Hello Michele

I hope you had a nice holiday!

Following on from the teleconference we had a few actions to complete and

get back to you with.

1) Teleconference minutes

Please find a draft of the the teleconference minutes below. Could you

review and confirm if you require any changes made?

2) Follow-up questions on the teleconference discussion

As suggested during the teleconference there was the opportunity for a

followup email clarification on a few minor points.
1.   In alignment with FDA recommendation, **(b)(4)**

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

(b)(4)

The supporting information which provides further clarity on the questions

above has been attached if required.

3) Timeline clarification as per previous email

I can see on the customer collaboration portal that we have a 180 day hold

period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below

was active which would provide us with an additional 180 day hold period?
<u>https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices</u>
Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Thank you again for your assistance

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: Martin

Mitchell/WIN/UK/AMS
To: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>,

"Liu, Lixin" <<u>Lixin.Liu@fda.hhs.gov</u>>
Cc:

   "<a
href=mailto:helen.topping@admedsol.com><font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">>,

"<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u>"

<<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u><font size=1
face="Arial">>
Date:
   20/10/2021

22:43
Subject:
 RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response<font size=2
face="Calibri"> <hr noshade>
<font size=2
face="Calibri">

Hello
Michele

Thank you for the prompt response to the clarifications! We'll take your

points on board regarding future shelf life studies.

I do have a minor
clarification question regarding our response timeline

I can see on the customer
collaboration portal that we have a 180 day hold

period which ends on the 2nd of April 2022.

However, I was under the
understanding that the guidance document below

was active which would provide us with an additional 180 day hold period?<u>
</u><font size=2 color=blue
face="Calibri"><u>
</u><a href="https://www.fda.gov/regulatory-
information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-
formal-meetings-and-user-fee-applications-medical-devices"><font size=2 color=blue
face="Arial"><u>https://www.fda.gov/regulatory-information/search-fda-guidance-
documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-
applications-medical-devices</u>

Could you
clarify if we have 180 days or 360 days to respond to the deficiencies?

Best
regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-
mail: <font size=2 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=2 color=#000080
face="Arial">
Tel: +44 (0) 1752 30 9360<font size=2
face="Calibri">
<font size=1 color=#5f5f5f
face="Arial">

From: <font size=1
face="Arial">"Lee,

Michele" <<font size=1 color=blue
face="Arial"><u>Michele.Lee@fda.hhs.gov</u><font size=1
face="Arial">>
To:
   "<a
href=mailto:Martin.Mitchell@admedsol.com><font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">>
Cc:
   "<a
href=mailto:helen.topping@admedsol.com><font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">>,

"<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 20/10/2021

14:55
Subject: RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hello Martin,

Thank you to you and your team for attending the teleconference yesterday.

I wanted to follow up on two things I was discussing with my team:
1.   Regarding

(b)(4)

(b)(4)

I will be on leave for the next two weeks and you may contact our team

management (<u>Lixin.Liu@fda.hhs.gov</u>)

if you have questions during that time.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993<u>
</u><u>Michele.Lee@fda.hhs.gov</u><u>
</u><u>
</u><img src=cid:_4_0A7B3B100A7B2BD8003569FA80258839 style="border:0px solid;"><u>
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</u><img src=cid:_2_0A7B3FA00A7B2BD8003569FA80258839 style="border:0px solid;"><img src=cid:_2_0A7B43D40A7B2BD8003569FA80258839 style="border:0px solid;"><img src=cid:_2_0A7B48080A7B2BD8003569FA80258839 style="border:0px solid;"><img src=cid:_2_0A7B4C3C0A7B2BD8003569FA80258839 style="border:0px solid;"><img src=cid:_2_0A7B50700A7B2BD8003569FA80258839 style="border:0px solid;">
Excellent customer service is important to us. Please take a moment

to provide feedback regarding the customer service you have received: <a

href="https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E"
target=_blank><font size=2 color=#0082bf
face="Arial"><u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u></fon
t>

From: Lee, Michele
Sent:
Friday, October 15, 2021 4:47 PM
To: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri">
Cc: <u>helen.topping@admedsol.com</u>;

<font size=2 color=blue
face="Calibri"><u>k211878@docs.fda.gov</u><font size=2
face="Calibri">
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending
Your Response

Hello Martin,

Thank you for providing your questions in
advance of the meeting. We look

forward to discussing our responses with you next week.

Have a good
weekend,
Michele

Michele
Lee, Ph.D.
Lead Reviewer / Materials
Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of
Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and
Infection Control Devices
Office of Product Evaluation and Quality

CDRH |
Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver
Spring, MD 20993<u>
</u><a
href=mailto:Michele.Lee@fda.hhs.gov><font size=2 color=blue face="Segoe
UI"><u>Michele.Lee@fda.hhs.gov</u><font size=2 color=blue
face="Calibri"><u>
</u><font size=2 color=blue
face="Calibri"><u>
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</u><img
src=cid:_2_0A7B6A880A7B2BD8003569FA80258839 style="border:0px solid;"><a
href=https://twitter.com/US_FDA><img src=cid:_2_0A7B6EBC0A7B2BD8003569FA80258839
style="border:0px solid;"><a
href=http://www.youtube.com/user/USFoodandDrugAdmin><img
src=cid:_2_0A7B72F00A7B2BD8003569FA80258839 style="border:0px solid;"><a
href=http://www.flickr.com/photos/fdaphotos/><img
src=cid:_2_0A7B77240A7B2BD8003569FA80258839 style="border:0px solid;"><a
href=http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm><img
src=cid:_2_0A7B7B580A7B2BD8003569FA80258839 style="border:0px solid;"><font size=2
color=#4f4f4f face="Calibri">
Excellent customer service is important to us.
 Please take a moment

to provide feedback regarding the customer service you have received: <a
href="https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E"
target=_blank><font size=2 color=#0082bf
face="Arial"><u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u></fon
t>

From: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri"><<font size=2
color=blue face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri">>

Sent: Friday, October 15, 2021 12:00 PM
To: Lee, Michele
<<font size=2 color=blue
face="Calibri"><u>Michele.Lee@fda.hhs.gov</u><font size=2
face="Calibri">>
Cc: <a
href=mailto:helen.topping@admedsol.com><font size=2 color=blue
face="Calibri"><u>helen.topping@admedsol.com</u><font size=2
face="Calibri">;

<font size=2 color=blue
face="Calibri"><u>k211878@docs.fda.gov</u><font size=2
face="Calibri">
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending
Your Response<font size=2 color=#806210
face="Calibri">

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from outside

of the organization. Do not click links or open attachments unless you

recognize the sender and know the content is safe.<font size=2
face="Arial">

Hi Michele

Please find the list of questions/clarifications
attached below.

I hope you have a good weekend. I'm looking forwards to our
discussion

next week!

Best regards,<font size=2 color=#000080
face="Arial">

Martin Mitchell
Regulatory Affairs
Manager

Advanced Medical Solutions Ltd.
E-mail: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=2 color=#000080
face="Arial">
Tel: +44 (0) 1752 30 9360<font size=1 color=#5f5f5f
face="Arial">

From: <font size=1
face="Arial">"Lee,

Michele" <<font size=1 color=blue
face="Arial"><u>Michele.Lee@fda.hhs.gov</u><font size=1
face="Arial">>
To:
   "<a
href=mailto:Martin.Mitchell@admedsol.com><font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">>
Cc:
   "<a
href=mailto:helen.topping@admedsol.com><font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">>,

"<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u>"

<<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u><font size=1
face="Arial">>
Date:
   13/10/2021

22:35
Subject:
 RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response<font size=2
face="Calibri"> <hr noshade>
<font size=2
face="Calibri">

Hello Martin,

I have scheduled
the teleconference for next Tuesday October 19that

9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour but

our biocompatibility consultant/ team management needs to drop off for

another call at 9:30am. Please send me the questions for discussion in

advance of the meeting so that we can plan to discuss biocompatibility/

regulatory questions first before the relevant parties need to drop off.

<p><table width=100% style="border-collapse:collapse;"><tr height=8><td
colspan=2 bgcolor=white style="border-style:none none none none;border-
color:#000000;border-width:0px 0px 0px 0px;padding:0px 0px;"><a
href="https://fda.zoomgov.com/j/1609831829?pwd=Mk16N1pXYnUrY2h2TFoyQTRaUCt5QT09"
target=_blank><u>Join

Zoom Meeting</u> <tr

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

size=2>

Thanks,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993<u>
</u><u>Michele.Lee@fda.hhs.gov</u><u>

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Excellent customer service is important to us. Please take a moment

to provide feedback regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

From: <u>Martin.Mitchell@admedsol.com</u><<u>Martin.Mitchell@admedsol.com</u>>

Sent: Wednesday, October 13, 2021 4:46 PM
To: Lee, Michele

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

<<u>Michele.Lee@fda.hhs.gov</u>>
Cc: <u>helen.topping@admedsol.com</u>;

<u>k211878@docs.fda.gov</u>
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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and know the content is safe.

Apologies Michele, one final thing I missed off my email... could you clarify

how long the teleconference would be by default? Could we request 1 hour

just incase some of the points end up taking longer to discuss?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: Martin

Mitchell/WIN/UK/AMS
To: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>
Cc: "<u>helen.topping@admedsol.com</u>"

<<u>helen.topping@admedsol.com</u>>,

"<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 13/10/2021

20:35
Subject: RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hi Michele

We're currently preparing our questions for the teleconference and will

send these through in due course, however to assist with scheduling the

relevant parties at FDA, I should let you know that we would definitely

like to discuss the questions related to biocompatibility.

After discussion with the team we would like to request the teleconference

on the Tuesday 19th October

if that is possible? As we are based in

the UK, we would also like to request that this is arranged between the

hours of 2-5pm BST<font size=2

face="Arial">.

If this time slot is not available could you outline any alternative days/times

which would be possible?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: Martin

Mitchell/WIN/UK/AMS
To: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>
Cc: "<u>helen.topping@admedsol.com</u>"

<<u>helen.topping@admedsol.com</u>>,

"<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 08/10/2021

22:14
Subject: RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hi Michele

Thank you for the offer. I think after today's meeting we may need a little

more time to be better prepared for the teleconference.

We are reaching out to the (b)(4) for us as we

feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible

dates for you early next week.

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>
To: "<u>Martin.Mitchell@admedsol.com</u>"

<<u>Martin.Mitchell@admedsol.com</u><font size=1

face="Arial">>
Cc:
   "<a
href=mailto:helen.topping@admedsol.com><font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">>,

"<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u>"

<<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u><font size=1
face="Arial">>
Date:
   06/10/2021

13:49
Subject:
 RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response<font size=2
face="Calibri"> <hr noshade>
<font size=2
face="Calibri">

Hello Martin,

If it makes it
easier for your team, we are able to extend the 10 day teleconference

deadline up to October 19th. Let me know if you would like to

select a date later than the 14thand I can check our management

schedules.

Regarding review timelines, we are still on the 90 day review cycle
and

are planning to complete the review of your response with the 20 calendar

days left on the clock. While we retain the right to add additional days,

we are doing our best with the resources that we have to avoid delaying

review timelines if possible.

Best,
Michele<font size=2 color=#0082bf
face="Segoe UI">

Michele Lee, Ph.D.<font size=2 face="Segoe
UI">
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound
Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices
Office of Product
Evaluation and Quality

CDRH | Food and Drug Administration
White Oak |
10903 New Hampshire Avenue | Silver Spring, MD 20993<font size=2 color=blue
face="Calibri"><u>
</u><font size=2
color=blue face="Segoe UI"><u>Michele.Lee@fda.hhs.gov</u><font size=2
color=blue face="Calibri"><u>
</u><font size=2 color=blue
face="Calibri"><u>
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color=blue face="Calibri"><u>
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src=cid:_2_0F19478C0F193798003569FA80258839 style="border:0px solid;"><a
href=https://twitter.com/US_FDA><img src=cid:_2_0F194BC00F193798003569FA80258839
style="border:0px solid;"><a
href=http://www.youtube.com/user/USFoodandDrugAdmin><img
src=cid:_2_0F194FF40F193798003569FA80258839 style="border:0px solid;"><a
href=http://www.flickr.com/photos/fdaphotos/><img
src=cid:_2_0F1954280F193798003569FA80258839 style="border:0px solid;"><a
href=http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm><img
src=cid:_2_0F19585C0F193798003569FA80258839 style="border:0px solid;"><font size=2
color=#4f4f4f face="Calibri">
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 Please take a moment

to provide feedback regarding the customer service you have received: <a
href="https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E"
target=_blank><font size=2 color=#0082bf
face="Arial"><u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u></fon
t>

From: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri"><<font size=2
color=blue face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri">>

Sent: Wednesday, October 6, 2021 6:00 AM
To: Lee, Michele
<<font size=2 color=blue
face="Calibri"><u>Michele.Lee@fda.hhs.gov</u><font size=2
face="Calibri">>
Cc: <a
href=mailto:helen.topping@admedsol.com><font size=2 color=blue
face="Calibri"><u>helen.topping@admedsol.com</u><font size=2
face="Calibri">
Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your
Response

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face="Arial">

Hi Michele

Thank you again for your review. Our team are
busy discussing the questions

and we would definitely like to have a teleconference with the FDA. We're

currently consolidating our understanding of the deficiencies and are determining

what our potential questions to you would be. I hope to get the questions

to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference
deadline in mind.... could we

look to schedule a teleconference with the FDA on Wednesday 13th or Thursday

14th? As we're based in the UK we would appreciate a timeslot within our

working hours which finish at 17:00 BST.

Additionally, I have a small question
to allow us to predict timelines

for this project.... regarding the FDA timeline I can see on the CCP tracker

website that the FDA timeline is on day 70.<font size=2
face="Calibri">
Will FDA be sticking to the 90
day target

and as a result only have 20 days left on the clock?
<font size=2
face="Arial">Or, due to the current situation with the

unprecedented resource limitations..... will you will assume 30 days to

review the response as standard? Or perhaps stick to the 20 days but retain

the right to add additional days?
Best
regards,

Martin Mitchell

Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.

E-mail: <font size=2
color=#0082bf face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=2
color=#000080 face="Arial">
Tel: +44 (0) 1752 30 9360<font size=1
color=#5f5f5f face="Arial">

From:
 "Michele

Lee [MICHELE.LEE]" <<font size=1
color=#0082bf face="Arial"><u>michele.lee@fda.hhs.gov</u><font size=1
face="Arial">>
To:
   <<a
href=mailto:martin.mitchell@admedsol.com><font size=1 color=#0082bf
face="Arial"><u>martin.mitchell@admedsol.com</u><font size=1
face="Arial">>,

<<font size=1 color=#0082bf
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">>
Cc:
   "Michele

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Lee [MICHELE.LEE]" <<u>michele.lee@fda.hhs.gov</u>>
Date: 04/10/2021

21:44
Subject: K211878/S001

is on Hold Pending Your Response <hr noshade>

October 4, 2021 <p>We have reviewed your submission. Please see attached.

<p>If you have any questions, please contact the lead reviewer

assigned to your submission, Michele Lee. <p> <p>*** This is a system-generated email notification ***[attachment

"K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin

Mitchell/WIN/UK/AMS] <p>

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From: Martin.Mitchell@admedsol.com [Martin.Mitchell@admedsol.com]
Sent: 5/19/2022 9:17:27 AM
To: Arepalli, Sambasiva [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d64e0490c9cf498eba4dc7db4813db4b-sra_39e5703]
CC: K211878@docs.fda.gov; Rose.Guang@admedsol.com
Subject: RE: [EXTERNAL] Re: K211878-s002
Attachments: IFU - LiquiBand XL.pdf; IFU - LiquiBand XL - Tracked.pdf; 510K Summary.pdf

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Hi Sam

I'll call you today at 6am (11am UK time); we thought it would be better to send you the updated documents to help aid the discussion during the call.

The IFU has been updated with your comments (and as per our modifications we suggest below). I've provided a redlined and clean copy of this:

The 510(k) summary has been updated with your comments

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>
Cc: "K211878@docs.fda.gov" <K211878@docs.fda.gov>, Rose Guang/WIN/UK/AMS@ams
Date: 18/05/2022 22:37
Subject: RE: [EXTERNAL] Re: K211878-s002

Hi Sam

Firstly, thank you for staying late to continue to work with us on in the final stages of this submission. It is much appreciated.

Please find attached the IFU with updated comments from ourselves

[attachment "K211878-S002 - Revised labeling received on 5-16-2022.jam.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

For most of the proposed updates we will accept to make the changes. However there are two points we would wish to clarify

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(b)(4)

As discussed I'll call you tomorrow to discuss your email below

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>, "K211878@docs.fda.gov" <K211878@docs.fda.gov>
Date: 18/05/2022 20:39
Subject: RE: [EXTERNAL] Re: K211878-s002

Hi Mr. Mitchell:
Please see attached for the labeling and 510kSummary with FDA edits.

Please address these edits and send me both the edited versions and clean copies of the labeling and the 510kSummary by COB tomorrow (5-19-2022).

Please cc your response to K211878@docs.fda.gov.

Thx
Sam

Sam Arepalli, Ph.D.
FDA/CDRH/OPEQ/OHT4/PRSB2
Ph: 301 796 6434

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Tuesday, May 17, 2022 6:39 AM
To: Arepalli, Sambasiva <Sambasiva.Arepalli@fda.hhs.gov>
Subject: RE: [EXTERNAL] Re: K211878-s002

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Hi Sam

Just to be safe for the email trail.... so that your email has a response

The email with this information was send yesterday; however it is also provided again below:

Please find a response to the two points we discussed over the phone

(b)(4)

As requested, the IFU has been revised with the updated warning

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Date: 17/05/2022 10:32
Subject: RE: [EXTERNAL] Re: K211878-s002

Hi Mr. Mitchell:
Can you please give an update on the revised labeling request? Could you please send the information cob today? Please give me a call when you have a minute.
Thx
Sam

Sam Arepalli, Ph.D.
FDA/CDRH/OPEQ/OHT4/PRSB2
Ph: 301 796 6434

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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Monday, May 16, 2022 12:06 PM
To: Arepalli, Sambasiva <Sambasiva.Arepalli@fda.hhs.gov>
Subject: [EXTERNAL] Re: K211878-s002

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Hi Sam

Just so you're aware it's 17:00 now so i'll be heading home; however i'll try to make myself available outside of hours so please don't hesitate to get in touch if you have any further questions.

Additionally i'll be working from home the next few days so I won't pick up calls from my office number you used previously.

If you have any further questions please email me or call me on my personal mobile number (b)(6)

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

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E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>
Cc: "K211878@docs.fda.gov" <K211878@docs.fda.gov>, Rose Guang/WIN/UK/AMS@ams, Helen Topping/WIN/UK/AMS@ams
Date: 16/05/2022 16:28
Subject: Re: K211878-s002

Hi Sam

Please find a response to the two points we discussed over the phone

(b)(4)

As requested, the IFU has been revised with the updated warning

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

[attachment "IFU.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>, "K211878@docs.fda.gov" <K211878@docs.fda.gov>
Date: 16/05/2022 14:39
Subject: K211878-s002

Hi Mr. Martin:
Please address the following:

(b)(4)

Thx
Sam

Sam Arepalli, Ph.D.
FDA/CDRH/OPEQ/OHT4/PRSB2
Ph: 301 796 6434

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Use by

Do not re-use

Do not re-sterilize

Consult instruction for use

Coution

REF Catalogue number

LOT Botch code

Do not use if packaging is damaged

STERILE EO Sterilized using ethylene oxide

STERILE Sterilized using dry heat

store between 4°C (+5°C) and 77°F (+25°C) Temperature limitation

℞ Only Caution, federal (USA) law restricts this device to sale by or on the order of a physician

Manufacturer

LIQUIBAND® XL

SKIN CLOSURE SYSTEM

INSTRUCTIONS FOR USE

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

CAUTION: Federal (USA) law restricts this device to sale and use by, or on the order of, a physician.

IMPORTANT! This insert is designed to assist in using LiquiBand® XL Skin Closure System. It is not a reference to surgical techniques.

DESCRIPTION

LiquiBand® XL Skin Closure System is a sterile, liquid adhesive containing a monomeric (2-octyl cyanoacrylate) formulation and the colorant D & C Violet No. 2. It is provided in a single-use applicator packaged in a pouch. As applied to skin, the liquid adhesive is slightly more viscous than water and polymerizes within minutes. In vitro studies have shown that LiquiBand® XL acts as a barrier to microbial penetration as long as the adhesive film remains intact. Clinical studies were not conducted to demonstrate microbial barrier properties.

LiquiBand® XL also incorporates a self-adhering mesh that is applied to the approximated skin edges to provide temporary skin edge alignment to an incision up to 20 cm until the liquid adhesive is applied to achieve skin closure.

INDICATIONS

LiquiBand® XL is intended for topical application only to hold closed easily approximated skin edges of wounds from surgical incisions, including incisions from minimally invasive surgery, and simple thoroughly cleansed, trauma-induced lacerations.

LiquiBand® XL should be used in conjunction with, but not in place of, deep dermal stitches. Additionally, the adjunct wound closure device component maintains temporary skin edge alignment along the length of the wound during application of the liquid adhesive.

CONTRAINDICATIONS

- Do not use on any wounds with evidence of infection, gangrene, or on wounds of decubitus etiology.
- Do not use on mucosal surfaces or across mucocutaneous junctions (e.g., oral cavity, lips), or on skin that may be regularly exposed to body fluids or with dense natural hair (e.g., scalp).
- Do not use on patients with a known hypersensitivity to cyanoacrylate, formaldehyde, benzyltributyl ammonium bromide, or pressure-sensitive adhesive.

WARNINGS

- LiquiBand® XL incorporates a fast-setting liquid adhesive capable of adhering to most body tissue and to many other materials, such as surgical gloves and stainless steel. Inadvertent contact with any body tissue, and any surfaces or equipment that are not disposable or that cannot be readily cleaned with a solvent such as acetone, should be avoided.
- Polymerization of the liquid adhesive component may be accelerated by water or fluids containing alcohol. LiquiBand® XL should not be applied to wet wounds.
- LiquiBand® XL should not be applied to the eye. If contact of the liquid adhesive with the eye occurs, flush the eye copiously with saline or water. If residual liquid adhesive remains, apply topical ophthalmic ointment to help loosen the bond and contact an ophthalmologist.
- When closing facial wounds near the eye with LiquiBand® XL position the patient so that any run-off of the liquid adhesive is away from the eye. The eye should be closed and protected with gauze. Prophylactic placement of petroleum jelly around the eye to act as a mechanical barrier or dam can be effective in preventing inadvertent flow of liquid adhesive into the eye. LiquiBand® XL will not adhere to skin pre-coated with petroleum jelly. Therefore, avoid using petroleum jelly on any skin area where LiquiBand® XL is intended to adhere. Use of liquid adhesive near the eye has inadvertently caused some patients' eyelids to be sealed shut. In some of these cases, general anesthesia and surgical removal has been required to open the eyelid.
- LiquiBand® XL should not be used below the skin because the polymerized material is not absorbed by tissue and can elicit a foreign body reaction.
- LiquiBand® XL should not be used in high skin tension areas or across areas of increased skin tension, such as joints, unless the area will be immobilized during the skin healing period or unless skin tension has been removed by application of another wound closure device (e.g. sutures or skin staples) prior to application of LiquiBand® XL.
- LiquiBand® XL treated wounds should be monitored for signs of infection. Wounds with signs of infection, such as erythema, edema, warmth, pain, and pus, should be evaluated and treated according to standard practice for infection.
- LiquiBand® XL should not be used on wound sites that will be subjected to repeated or prolonged moisture or friction.
- LiquiBand® XL should only be used after wounds have been cleaned, debrided, and are otherwise closed in accordance with standard surgical practice. Local anesthetic should be used when necessary to ensure adequate cleansing and debridement.
- Excessive pressure of the applicator tip against the wound edges or surrounding skin can force the wound edges apart and allow liquid adhesive into the wound. Liquid adhesive within the wound could delay wound healing or result in adverse cosmetic outcome, or both. Therefore, LiquiBand® XL liquid component should be applied with a very light brushing motion of the applicator tip over the mesh and surrounding skin area.
- LiquiBand® XL liquid adhesive polymerizes through an exothermic reaction in which a small amount of heat is released. With the proper technique of applying LiquiBand® XL liquid adhesive in a single layer onto a dry wound, heat is released slowly and the sensation of heat or pain experienced by the patient is minimized. However, if LiquiBand® XL liquid adhesive is applied so that large droplets of liquid are allowed to remain unspread, the patient may experience a sensation of heat or discomfort.
- LiquiBand® XL is packaged for single patient use. Discard remaining opened material after each wound closure procedure.
- Do not resterilize LiquiBand® XL. Reuse of this device (or portions of this device) may create a risk of product degradation and/or cross-contamination, which may lead to product failure or infection or transmission of bloodborne pathogens to patients and users.
- Do not place LiquiBand® XL in a procedure pack/tray that is to be sterilized prior to use without prior written authorization from manufacturer. Exposure of LiquiBand® XL after its final manufacture to excessive heat (as in autoclaves or ethylene oxide sterilization) or radiation (such as gamma or electron beam), is known to increase its viscosity and may render the product unusable.
- Do not use on children. Only for use on adults on wound(s) up to a combined length of 20cm on a single patient.

PRECAUTIONS

- Do not apply liquid or ointment medications or other substances to the wound after closure with LiquiBand® XL, as these substances can weaken the polymerized film and allow for wound dehiscence. LiquiBand® XL permeability by topical medications has not been studied. Prior to application, cleanse the application site thoroughly to remove any remaining blood, fluids or topical medications/

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Tel: +44(0)8444 125754 Fax +44(0)1752 209956 e-mail:
enquiries@admedsol.com
www.admedsol.com

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Advanced Medical Solutions

DRM 06 0835 x01 YYYY-MM-DD

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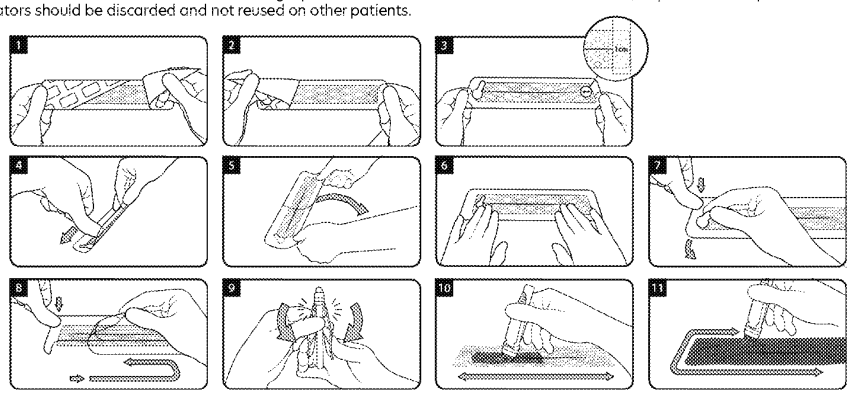
anesthetics.
- LiquiBand® XL permeability by fluids is not known and has not been studied.
- LiquiBand® XL liquid adhesive, as a liquid, is slightly more viscous than water. To prevent inadvertent flow of liquid adhesive to unintended areas, the wound should be held in a horizontal position, with LiquiBand® XL liquid adhesive applied from above. Any excess liquid adhesive can be quickly wiped off with sterile gauze.
- If unintended bonding of intact skin with the adhesive should occur, removal may be accomplished by using either acetone or petroleum jelly. Typical cleansers such as soap and other agents such as water, saline, Betadine® or chlorhexidine gluconate are not expected to loosen the bond. Peel, do not pull skin apart.
- Safety and effectiveness of LiquiBand® XL on wounds of patients with peripheral vascular disease, insulin-dependent diabetes mellitus, blood clotting disorders, personal or family history of keloid formation or hypertrophy, or burst stellate lacerations, have not been studied.
- Safety and effectiveness of LiquiBand® XL on the following wounds have not been studied: animal or human bites, puncture, or stab wounds.
- Safety and effectiveness on wounds that have been treated with LiquiBand® XL and then exposed for prolonged periods to direct sunlight or tanning lamps have not been studied.
- Safety and effectiveness of LiquiBand® XL liquid adhesive on wounds in vermilion surfaces have not been studied
- LiquiBand® XL should be used immediately after crushing the glass ampoule as the liquid adhesive will not flow freely from the applicator tip after a few minutes
- Hold applicator away from yourself and the patient and break ampoule using the wings. Do not crush the contents of the applicator tube repeatedly as excessive manipulation of the applicator may cause glass shard penetration.

ADVERSE REACTIONS
Clinical use of Cyanoacrylate with adjunct wound closure devices has suggested that the following adverse events may occur.

- Infection (redness more than 3 to 5 mm from the wound margin, swelling, purulent discharge, pain, increased skin temperature, fever)
- Acute inflammation (erythema, edema, drainage, pain, warmth)
- Dehiscence
- Bleeding
- Skin edge necrosis
- Excessive itching
- Skin blistering
- Seroma
- Hematoma
- Bonding to unintended tissues such as the eye
- Thermal discomfort during polymerisation
- Allergic reaction
- Foreign body reaction
- Chronic non-healing of a wound

DIRECTIONS FOR USE
LiquiBand® XL is intended for single patient use. The mesh patch or patches and liquid adhesive applicators should only be used for wound closure of a maximum of 20 cm on a single patient. After wound closure has been achieved, any excess mesh patch and adhesive applicators should be discarded and not reused on other patients.



1. The application of LiquiBand® XL system requires thorough wound cleansing. Follow standard surgical practice for wound preparation before application of LiquiBand® XL (i.e., cleanse, irrigate, debride, obtain hemostasis, and close deep layers such that there is no tension on the skin). The skin edges must be closely approximated prior to application of the mesh, such that significant manual approximation is not required during mesh application.
2. Pat the wound dry with a sterile gauze to assure direct tissue contact for adherence of the mesh and the liquid skin adhesive to the skin.
3. Open the packaging to access the device components.
4. LiquiBand® XL is applied in a 2-step process with 1 mesh patch and 1 applicator for dispensing the liquid skin adhesive. Steps for application of LiquiBand® XL are illustrated below.
5. Remove both sections of the white release liner from the mesh, peeling from the centre towards the outer edge. (Fig. 1 & 2). Hold the mesh by the clear release liner refraining from touching the mesh.
6. With the mesh facing the wound, position so the incision is central to the mesh (**without making contact**), ensuring that at least 1 cm of mesh extends from each end of the incision (Fig. 3).
7. Press gently to ensure intimate contact of the mesh to one side of the incision.
8. Gently pull the mesh perpendicularly over the incision while adjusting with fingers or forceps to achieve skin edge approximation and affix the remainder of the mesh to the other side of the incision (Fig. 4 & 5). Ensure the mesh is placed at least 1 cm from each of the ends of the incision. Use sterile scissors to trim any excess mesh, if necessary.
9. Pat the clear release liner down so that the mesh has fully adhered to the skin (Fig. 6)
10. Remove the clear release liner by maintaining pressure on the clear release liner whilst pulling the release tab from the mesh in the opposing direction (Fig. 7), **tearing** the clear release liner and removing in a circular direction.(Fig. 8)
11. Ensure that the mesh is in intimate contact with the skin prior to application of the liquid adhesive. If there are areas where the mesh is loose, gently pass a gloved finger or instrument over the affected area to ensure complete adherence of the mesh to the skin. If the mesh is still not adhered to the skin, carefully cut any affected segments of the mesh and remove them from the skin. Ensure the skin edges are clean and dry and reapply new mesh.
12. For the continuation of the skin edge approximation, overlap the end of the existing mesh by approximately 1 cm.
13. Pat the deployed mesh dry gently with dry sterile gauze in the event of bodily fluid seepage without disturbing skin edge approximation prior to spreading the adhesive over the mesh. Once complete, proceed immediately to the next step.
14. Activate the liquid adhesive applicator by holding the applicator with finger and thumb by the wings with the tip pointed upwards and away from the patient to avoid unintentional placement of the liquid adhesive into the wound or on the patient. Squeeze the applicator wings to apply sufficient pressure to fully crush the inner glass ampoule.(Fig. 9)
15. Invert the applicator and firmly squeeze the wings to express the liquid adhesive and **IMMEDIATELY** apply to the mesh (Fig. 10).
16. Spread the liquid adhesive smoothly and evenly over the entire length of the mesh using the foam tip making sure that the entire mesh is covered. The liquid adhesive should also be applied slightly over the edge of the mesh, covering a small margin of surrounding skin (Fig. 11). Any excess liquid adhesive can be wiped off quickly with sterile gauze.
17. If the adhesive has not fully polymerized within 60 seconds, wait an additional 60-90 seconds before testing the adhesive again. Do not apply any dressing or covering of any kind (including gown or sheet) until the adhesive has fully polymerized into a solid.

NOTE: A single device contains sufficient adhesive to coat a single mesh. Device is only recommended to have one coat of adhesive.

Once complete coverage is achieved, do not touch any part of the mesh or surrounding skin for approximately 60 seconds. After 60 seconds has past, lightly touch the surface with a clean gloved finger to ensure the adhesive has fully polymerized.

Inspect the incision for any blood or fluid accumulation under the mesh, including areas where fluid may be seeping through the mesh. If such areas exist, carefully cut any affected segments of the mesh and remove them from the skin and reapply new mesh and liquid adhesive according to the directions for use.

A protective, dry wound dressing such as gauze may be applied only after the liquid adhesive has completely polymerized and LiquiBand® XL is no longer tacky to the touch. If the liquid adhesive is not allowed to fully polymerize prior to application of a dressing, LiquiBand® XL may adhere to the dressing, causing it to become loose or be pulled away from the skin when the dressing is removed, which can result in dehiscence (skin edge separation).

Mesh should remain in place on the patient up to 14 days after application with proper aftercare.

PATIENT INSTRUCTIONS
Patients should be advised that LiquiBand® XL will need to remain in place until the wound/incision is properly healed (typically 7 to 14 days). During this time, LiquiBand® XL should be kept dry. The wound should not be soaked or scrubbed. Patients should not swim or otherwise immerse the wound in water for prolonged periods. If a protective wound dressing is being used over LiquiBand® XL, it should be replaced with a dry dressing after showering or bathing.

Patients should also be instructed not to scratch, rub or pick at LiquiBand® XL and reminded not to apply topical ointments, lotions, or liquids to the wound while LiquiBand® XL is in place. This may loosen LiquiBand® XL, causing it to peel away from the skin before the wound has fully healed. Patients should be instructed not to engage in strenuous physical activity that may cause tension on the wound or cause perspiration to wet LiquiBand® XL.

Report any discomfort or other concerns regarding your wound to your doctor.

REMOVAL INSTRUCTIONS
LiquiBand® XL is designed to gradually slough off or it can be removed by following removal instructions below, if indicated by the health care provider:

1. Gently grasp the edge of the LiquiBand® XL mesh patch at one end of the wound. If the edge of the device is still adhered to the skin, gently pick at the edge until it begins to peel away from the skin.
2. Slowly peel the LiquiBand® XL mesh away from the skin along the line of the wound. Do not pull the mesh straight up from the skin. LiquiBand® XL mesh should be pulled back along the line of the wound close to the skin. Use the other hand to stabilize the wound as the mesh is peeled away.
3. Once the entire length of LiquiBand® XL mesh has been removed, discard the device in an appropriate medical waste container.
4. Any residual adhesive and/or dried wound exudate can be cleaned from the skin, according to institutional standard of care for skin cleansing.

HOW SUPPLIED
LiquiBand® XL system is supplied sterile, in single patient use components: mesh patch and liquid adhesive applicator. The components are packaged in a pouch to maintain the sterility of the device until opened or damaged. LiquiBand® XL is supplied in boxes of 2 systems.

STORAGE
Recommended storage conditions: between 41°F (5°C) and 77°F (25°C), away from moisture, direct heat, and direct light. Avoid prolonged exposure to elevated temperatures. LiquiBand® XL should always be stored in its original packaging. Do not use after expiry date expiration date shown on the packaging.

STERILITY
LiquiBand® XL is terminally sterilized by dry heat and ethylene oxide gas. LiquiBand® XL is packaged for single patient use. Do not resterilize. Do not use if package is opened or damaged. Discard any unused materials following completion of medical procedure.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(k) Summary

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Food and Drug Administration

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PL Study Report

Status: Final Histopathological Report

(b)(4) Study Number

(b)(4)

(b)(4) Study Number

(b)(4)

Study Title

Pre-Clinical Evaluation of the Safety and Performance of the Advanced Medical Solutions Device LiquiBand XL in a (b)(4)

Test Facility

Pre-clinical Research and Development Unit

(b)(4)

Study director

(b)(4)

Test Site I

(b)(4)

Principal Investigator Test Site I

(b)(4)

Sponsor

Advanced Medical Solutions Ltd

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Pre Clinical Evaluation of the Safety and Performance of the Advanced Medical Solutions Device LiquiBand XL in a (b)(4)

STUDY REPORT- SUPPLEMENT I

STUDY NO.

(b)(4)

Study Sponsor:

Advanced Medical Solutions Ltd

2 Western Wood Way | Langage Science Park | Plymouth | PL7 5BG | UK

Testing Facility:

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Issue date: May 31, 2021

Total No. of Pages: 76

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Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hello Sam

Regarding your deadline where you planned to have completed versions of the IFU and 510(k) Summary by COB today.

Have you managed to discuss the issue in your department?

I'm wondering if there is any further clarification we can provide to assist in the discussion; or perhaps a call could be scheduled quickly to resolve the matter?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>
Cc: "K211878@docs.fda.gov" <K211878@docs.fda.gov>, Rose Guang/WIN/UK/AMS@ams
Date: 19/05/2022 11:28
Subject: RE: [EXTERNAL] Re: K211878-s002

Hi Sam

For your ease of reference, please find our response to (b)(4)

(b)(4)

[attachment "AMS deficiency response.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

As requested I've highlighted the teleconference meeting minutes showing the FDA agreement to use the (b)(4)

(b)(4)

[attachment "K211878 - 19Oct2021 Meeting Minutes - Final.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

I've also highlighted and provided the pertinent pages from (b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

[attachment (b)(4) deleted by Martin Mitchell/WIN/UK/AMS]

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>

Cc: "K211878@docs.fda.gov" <K211878@docs.fda.gov>, Rose Guang/WIN/UK/AMS@ams

Date: 19/05/2022 10:17

Subject: RE: [EXTERNAL] Re: K211878-s002

Hi Sam

I'll call you today at 6am (11am UK time); we thought it would be better to send you the updated documents to help aid the discussion during the call.

The IFU has been updated with your comments (and as per our modifications we suggest below). I've provided a redlined and clean copy of this: [attachment "IFU - LiquiBand XL.pdf" deleted by Martin Mitchell/WIN/UK/AMS] [attachment "IFU - LiquiBand XL - Tracked.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

The 510(k) summary has been updated with your comments [attachment "510K Summary.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

From: Martin Mitchell/WIN/UK/AMS

To: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>

Cc: "K211878@docs.fda.gov" <K211878@docs.fda.gov>, Rose Guang/WIN/UK/AMS@ams

Date: 18/05/2022 22:37

Subject: RE: [EXTERNAL] Re: K211878-s002

Hi Sam

Firstly, thank you for staying late to continue to work with us on in the final stages of this submission. It is much appreciated.

Please find attached the IFU with updated comments from ourselves

[attachment "K211878-S002 - Revised labeling received on 5-16-2022.jam.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

For most of the proposed updates we will accept to make the changes. However there are two points we would wish to clarify

(b)(4)

As discussed I'll call you tomorrow to discuss your email below

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>,

"K211878@docs.fda.gov" <K211878@docs.fda.gov>

Date: 18/05/2022 20:39

Subject: RE: [EXTERNAL] Re: K211878-s002

Hi Mr. Mitchell:

Please see attached for the labeling and 510kSummary with FDA edits.

Please address these edits and send me both the edited versions and clean copies of the labeling and the 510kSummary by COB tomorrow (5-19-2022).

Please cc your response to K211878@docs.fda.gov.

Thx

Sam

Sam Arepalli, Ph.D.

FDA/CDRH/OPEQ/OHT4/PRSB2

Ph: 301 796 6434

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https://secure-web.cisco.com/1Ylc6HR_lIp_i1xH8NVlquCCBCMtnevdc1wnb6xsCCg59WhGXIpMStG5EwBH7NPAFcipnnOIKknWTbTLIIdxrv0az8s_Msy88mAbylPuOV7-dtc756LMZSkAPorkEkmih2cGZiaUQsCvPaNxef8fKwGm80W3waEzylCuS-P2HbDcc3Y6B4yVesckuV7cpyiINEWzickjMV2xPjZ3cEN6rhg/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1624%26S%3DE

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Tuesday, May 17, 2022 6:39 AM

To: Arepalli, Sambasiva <Sambasiva.Arepalli@fda.hhs.gov>

Subject: RE: [EXTERNAL] Re: K211878-s002

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

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Hi Sam

Just to be safe for the email trail.... so that your email has a response

The email with this information was send yesterday; however it is also provided again below:

Please find a response to the two points we discussed over the phone

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

As requested, the IFU has been revised with the updated warning

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Date: 17/05/2022 10:32

Subject: RE: [EXTERNAL] Re: K211878-s002

Hi Mr. Mitchell:

Can you please give an update on the revised labeling request? Could you please send the information cob today? Please give me a call when you have a minute.

Thx

Sam

Sam Arepalli, Ph.D.

FDA/CDRH/OPEQ/OHT4/PRSB2

Ph: 301 796 6434

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Monday, May 16, 2022 12:06 PM

To: Arepalli, Sambasiva <Sambasiva.Arepalli@fda.hhs.gov>

Subject: [EXTERNAL] Re: K211878-s002

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Hi Sam

Just so you're aware it's 17:00 now so i'll be heading home; however i'll try to make myself available outside of hours so please don't hesitate to get in touch if you have any further questions.

Additionally i'll be working from home the next few days so I won't pick up calls from my office number you used previously.

If you have any further questions please email me or call me on my personal mobile number (b)(6)

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>

Cc: "K211878@docs.fda.gov" <K211878@docs.fda.gov>, Rose Guang/WIN/UK/AMS@ams, Helen Topping/WIN/UK/AMS@ams

Date: 16/05/2022 16:28

Subject: Re: K211878-s002

Hi Sam

Please find a response to the two points we discussed over the phone

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342, Released by CDRH on 04-11-2024

(b)(4)

As requested, the IFU has been revised with the updated warning

[attachment "IFU.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>, "K211878@docs.fda.gov" <K211878@docs.fda.gov>

Date: 16/05/2022 14:39

Subject: K211878-s002

Hi Mr. Martin:

Please address the following:

(b)(4)

Thx

Sam

Sam Arepalli, Ph.D.

FDA/CDRH/OPEQ/OHT4/PRSB2

Ph: 301 796 6434

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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August 10, 2021</br></br>

Acceptance Review Notification - Accepted

An administrative acceptance review was conducted on your submission K211878/S001, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review.

The lead reviewer assigned to your submission is me, John Azeke. The file is being reviewed in Office of Health Technology 4, Division of Health Technology 4 B. The first line supervisor is the Assistant Director, Plastic Surgery Skin and Wound Devices. You may contact me at any point during the review if you have questions or concerns. You can provide valuable support for CDRH to continue to improve our programs by raising to the attention of management relevant issues that arise during the course of this review. If you feel there is an unresolved issue or a matter that requires additional attention, you should contact the Assistant Director. If your concern or issue is not addressed by the Assistant Director, you should contact the Division Director or OHT Director. The contact information for each management level can be found in the CDRH Management Directory.

We will contact you should we require any additional information during the course of the substantive review. FDA aims to apply the least burdensome principles when requesting additional information.

If you have general questions about the review process for your submission, you should contact OPEQSubmissionSupport@fda.hhs.gov.

 *** This is a system-generated email notification ***

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Hello Martin,

Thanks for checking in. I'll reply to you in the other email chain we have going with the clarification questions- just so everything is in one email chain.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov



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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Wednesday, November 24, 2021 11:58 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: k211878@docs.fda.gov
Subject: RE: [EXTERNAL] K211878 timeline - COVID-19

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hello Michele

Hope you have a nice thanksgiving tomorrow!

Just checking how things are going with your (b)(4) Are we still on track to get an update this week to our questions?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 16/11/2021 19:03
Subject: RE: [EXTERNAL] K211878 timeline - COVID-19

Hello Martin,

Thanks for the update and good to know this information. I also received your previous email with additional information about the (b)(4) (b)(4) I am still waiting on feedback from our consulting (b)(4) but hope to have more information to provide you mid next week.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov



* * * * *

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Monday, November 15, 2021 3:54 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Subject: Fw: [EXTERNAL] K211878 timeline - COVID-19

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Hi Michele

I got an update regarding timeline from the CCP email address.

FYI we are exploring a number of backup strategies to resolve **(b)(4)** .. and some of these take us past the 180 day hold period.

As per the request below, I'll let you know closer to the time if we end up needing to request the additional 180 days.

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

---- Forwarded by Martin Mitchell/WIN/UK/AMS on 15/11/2021 08:31 ----

From: "CCP" <CCP@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Date: 12/11/2021 21:08
Subject: RE: [EXTERNAL] K211878 timeline - COVID-19

Good day to you Martin,

The extra 180 days for response are added as needed, and then only shortly before the original 180 days expires.

--
Happy trails,
~N els A nder son
Regulatory Systems & Data Management Staff
Center for Devices and Radiological Health | Office of Product Evaluation and Quality| Office of Regulatory Programs

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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Friday, November 12, 2021 09:49
To: CCP <CCP@fda.hhs.gov>
Subject: [EXTERNAL] K211878 timeline - COVID-19

CAUTION:This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hello

Regarding the timeline showing for K211878 I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I (and the lead reviewer Michele Lee) were under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify that the 180 timeline in the customer collaboration portal won't trigger premature closure of the 510(k) before the actual 360 day timeline expires?

Best regards,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Hello Martin,

Thanks for checking in. I'll reply to you in the other email chain we have going with the clarification questions- just so everything is in one email chain.

Best,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D7E130.3933E0E0]<http://www.fda.gov/>

[cid:image002.jpg@01D7E130.3933E0E0]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D7E130.3933E0E0] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7E130.3933E0E0] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7E130.3933E0E0] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D7E130.3933E0E0]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Wednesday, November 24, 2021 11:58 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: k211878@docs.fda.gov

Subject: RE: [EXTERNAL] K211878 timeline - COVID-19

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hello Michele

Hope you have a nice thanksgiving tomorrow!

Just checking how things are going with your toxicologist. Are we still on track to get an update this week to our questions?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 16/11/2021 19:03

Subject: RE: [EXTERNAL] K211878 timeline - COVID-19

Hello Martin,

Thanks for the update and good to know this information. I also received your previous email with additional information about the test parameters of the degradation & extraction studies. I am still waiting on feedback from our consulting toxicologist but hope to have more information to provide you mid next week.

Best,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D7E130.3933E0E0]<http://www.fda.gov/>

[cid:image002.jpg@01D7E130.3933E0E0]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D7E130.3933E0E0] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7E130.3933E0E0] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7E130.3933E0E0] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D7E130.3933E0E0]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
<Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Monday, November 15, 2021 3:54 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Subject: Fw: [EXTERNAL] K211878 timeline - COVID-19

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Hi Michele

I got an update regarding timeline from the CCP email address.

FYI we are exploring a number of backup strategies to resolve the 510(k) deficiencies.... and some of these take us past the 180 day hold period.

As per the request below, I'll let you know closer to the time if we end up needing to request the additional 180 days.

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

----- Forwarded by Martin Mitchell/WIN/UK/AMS on 15/11/2021 08:31 -----

From: "CCP" <CCP@fda.hhs.gov<mailto:CCP@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Date: 12/11/2021 21:08

Subject: RE: [EXTERNAL] K211878 timeline - COVID-19

Good day to you Martin,

The extra 180 days for response are added as needed, and then only shortly before the original 180 days expires.

--

Happy trails,

~Nels Anderson

Regulatory Systems & Data Management Staff

Center for Devices and Radiological Health | Office of Product Evaluation and Quality| Office of Regulatory Programs

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Friday, November 12, 2021 09:49

To: CCP <CCP@fda.hhs.gov<mailto:CCP@fda.hhs.gov>>

Subject: [EXTERNAL] K211878 timeline - COVID-19

CAUTION:This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hello

Regarding the timeline showing for K211878 I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I (and the lead reviewer Michele Lee) were under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify that the 180 timeline in the customer collaboration portal won't trigger premature closure of the 510(k) before the actual 360 day timeline expires?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Hello all,

Thank you, Martin, for the connection.

(b)(4)

Best Regards,

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D7D228.2450D140]<http://www.fda.gov/>

[cid:image002.jpg@01D7D228.2450D140]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D7D228.2450D140] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7D228.2450D140] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7D228.2450D140] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D7D228.2450D140]
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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Thursday, November 4, 2021 11:29 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>; k211878@docs.fda.gov

Cc: (b)(4)

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

Regarding the recent deficiency question on our medical device submission which is currently under review with the FDA:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

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AMS Reference: (b)(4)

(b)(4)

FINAL NON-GLP REPORT: (b)(4)

CHEMICAL CHARACTERIZATION OF THE EXTRACTABLE AMOUNT OF CHEMICAL COMPOUNDS FROM LIQUIBAND XL (TIP COMPONENT)

Reference Standard
LIQUIBAND XL (TIP COMPONENT)

Final Report Date
4/28/2022

Study Director
(b)(4)

Sponsor
Advanced Medical Solutions Limited
2 Western Wood Way, Langage Science Park
Plymouth PL7 5BG
United Kingdom

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

(b)(4) NON-GLP TEST PROTOCOL
CONFIDENTIAL PROPERTY (b)(4)

CHEMICAL CHARACTERIZATION OF THE EXTRACTABLE AMOUNT OF CHEMICAL COMPOUNDS FROM LIQUIBAND XL DEVICE

(b)(4) PROTOCOL NUMBER: (b)(4)

MANAGEMENT OF THE STUDY

Performing Laboratory

(b)(4)

Sponsor
Advanced Medical Solutions Limited
2 Western Wood Way,
Langage Science Park
Plymouth, PL7 5BG
United Kingdom

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hello (b)(4)

(b)(4)

Best Regards,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

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[cid:image002.jpg@01D7DAF2.49F91380]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D7DAF2.49F91380] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7DAF2.49F91380] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7DAF2.49F91380] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D7DAF2.49F91380]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: (b)(4)>

Sent: Friday, November 12, 2021 4:39 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>; k211878@docs.fda.gov

Cc: (b)(4)

(b)(4)

Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hello Michele

Regarding the timeline clarification

i've taken a look on the customer collaboration portal but there was only

an email to provide feedback on the portal. Nevertheless i've emailed as

i'm a little concerned about what may happen if the portal shows that the

180 day hold periods has expired and we haven't yet submitted our response.....

is there a risk that the 510(k) may be inadvertently withdrawn?

We have prepared our response to your

question below which I hope you find helpful.
<table width=100% style="border-collapse:collapse;"><tr height=8><td width=16% style="border-style:none solid solid none;border-color:#000000;border-width:0px 1px 1px 0px;padding:0px 7px;"> <td colspan=3 style="border-style:none solid solid solid;border-color:#000000;border-width:0px 1px 1px 1px;padding:0px 7px;"> (b)(4)

(b)(4) <td colspan=3 style="border-style:none none solid solid;border-color:#000000;border-width:0px 0px 1px 1px;padding:0px 7px;"> (b)(4)

(b)(4) <tr height=8><td style="border-style:solid solid solid none;border-color:#000000;border-width:1px 1px 1px 0px;padding:0px 7px;"> In alignment with <td colspan=3 style="border-style:solid solid solid solid;border-color:#000000;border-width:1px 1px 1px 1px;padding:0px 7px;"> (b)(4)

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(b)(4)

face="sans-serif">Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions

Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From:

 "Lee, Michele"

<Michele.Lee@fda.hhs.gov>
To:

 "Martin.Mitchell@admedsol.com"

<Martin.Mitchell@admedsol.com>
Cc:

 "helen.topping@admedsol.com"

<helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date:

 08/11/2021 22:05
Subject:

   RE: [EXTERNAL]

Re: K211878/S001 is on Hold Pending Your Response
<hr noshade>

Hello Martin,

Thanks for your message. Iâ€™ll need some

time to review the teleconference minutes with my team and also obtain

some feedback from our consulting toxicologist about the follow up questions.

But I wanted to let you know I received your email and you may feel free

to check in again next week.

I do have a clarification question about

Follow Up (b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Regarding the timeline clarification- I

am also under the understanding that the COVID-19 guidance document you

cited was still active and that would allow you an additional 180 days

for the hold period. I have reached out to the 510(k) Staff multiple times

to confirm and am still waiting on their response. Is there a customer

service contact email for the customer collaboration portal specifically?

You may try contacting them as well to have the date corrected on your

end.

Thank you,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices

Team
DHT4B: Division of Infection Control and

Plastic Surgery Devices
OHT4: Office of Surgical and Infection

Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue

| Silver Spring, MD 20993
<u>Michele.Lee@fda.hhs.gov</u>

<img src=cid:_4_0BE487980BE484380053BC6A8025878B width=192 height=43 style="border:0px solid;">
<u>
</u><img src=cid:_2_0BE48C280BE484380053BC6A8025878B style="border:0px solid;"> <img src=cid:_2_0BE490740BE484380053BC6A8025878B style="border:0px solid;"> <img src=cid:_2_0BE494C00BE484380053BC6A8025878B style="border:0px solid;"> <img src=cid:_2_0BE4990C0BE484380053BC6A8025878B style="border:0px solid;"> <img src=cid:_2_0BE49D580BE484380053BC6A8025878B style="border:0px solid;">
Excellent customer

service is important to us. Please take a moment to provide feedback

regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

From: Martin.Mitchell@admedsol.com

<Martin.Mitchell@admedsol.com>
Sent: Friday, November 5, 2021 12:07 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

CAUTION:This email originated from outside of the organization. Do not click links

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

or open attachments unless you recognize the sender and know the content

is safe.

Hello Michele

I hope you had a nice holiday!

Following on from the teleconference we had a few actions to complete and

get back to you with.

1) Teleconference minutes

Please find a draft of the the teleconference minutes below. Could you

review and confirm if you require any changes made?

2) Follow-up questions on the teleconference discussion

As suggested during the teleconference there was the opportunity for a

followup email clarification on a few minor points.
1.   In

alignment with FDA recommendation, (b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

face="Arial">
The supporting information which provides further clarity on the questions

above has been attached if required.

3) Timeline clarification as per previous email

I can see on the customer collaboration portal that we have a 180 day hold

period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below

was active which would provide us with an additional 180 day hold period?
<u>https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices</u>
Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Thank you again for your assistance

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360<font size=2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

face="Calibri">

From:
       Martin

Mitchell/WIN/UK/AMS
To:
   "Lee,

Michele" <<font size=1 color=blue
face="Arial"><u>Michele.Lee@fda.hhs.gov</u>>,

"Liu, Lixin" <<font size=1
color=blue face="Arial"><u>Lixin.Liu@fda.hhs.gov</u><font size=1
face="Arial">>
Cc:
   "<a
href=mailto:helen.topping@admedsol.com><font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">>,

"<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u>"

<<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u><font size=1
face="Arial">>
Date:
   20/10/2021

22:43
Subject:
 RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response<div
align=center><hr noshade>

<font size=2
face="Arial">
Hello Michele

Thank you for the prompt response to the clarifications! We'll
take your

points on board regarding future shelf life studies.<font size=2
face="Calibri">

I do have a minor clarification
question regarding our response timeline<font size=2
face="Calibri">

I can see on the customer
collaboration portal that we have a 180 day hold

period which ends on the 2nd of April 2022.<font size=2
face="Calibri">

However, I was under the
understanding that the guidance document below

was active which would provide us with an additional 180 day hold period?
<font size=2 color=blue
face="Calibri"><u>
</u><a href="https://www.fda.gov/regulatory-
information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-
formal-meetings-and-user-fee-applications-medical-devices"><font size=2 color=blue
face="Arial"><u>https://www.fda.gov/regulatory-information/search-fda-guidance-
documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-
applications-medical-devices</u>

Could you clarify if we have 180 days or 360 days to respond to
the deficiencies?
<font size=2
face="Arial">
Best regards,

Martin Mitchell
Regulatory Affairs
Manager
<font size=2 color=#000080
face="Arial">
Advanced Medical Solutions Ltd.
E-mail: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=2 color=#000080
face="Arial">
Tel: +44 (0) 1752 30 9360<font size=2
face="Calibri">

<font size=1 color=#5f5f5f
face="Arial">
From: <font size=1
face="Arial">"Lee,

Michele" <<font size=1 color=blue

face="Arial"><u>Michele.Lee@fda.hhs.gov</u><font size=1
face="Arial">>
To:
   "<a
href=mailto:Martin.Mitchell@admedsol.com><font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">>
Cc:
   "<a
href=mailto:helen.topping@admedsol.com><font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">"

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face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">>,

"<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u>"

<<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u><font size=1
face="Arial">>
Date:
   20/10/2021

14:55
Subject:
 RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response<div
align=center><hr noshade>

Hello Martin,

Thank you to you and your team for
attending the teleconference yesterday.

I wanted to follow up on two things I was discussing with my team: <font size=2
face="Arial">
1.   <font size=2
face="Calibri">Regarding

(b)(4)

(b)(4).

I will be on leave for the next
two weeks and you may contact our team

management (<font size=2 color=blue
face="Calibri"><u>Lixin.Liu@fda.hhs.gov</u>)

if you have questions during that time.

Best,
Michele

Michele Lee, Ph.D.<font size=2
face="Segoe UI">
Lead Reviewer / Materials Engineer

Plastic Surgery
Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery
Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product
Evaluation and Quality

CDRH | Food and Drug Administration
White Oak |
10903 New Hampshire Avenue | Silver Spring, MD 20993<font size=2 color=blue
face="Calibri"><u>
</u><font size=2

color=blue face="Segoe UI"><u>Michele.Lee@fda.hhs.gov</u><font size=3
face="Segoe UI">
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</u><a
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href=http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm><img
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color=#4f4f4f face="Calibri">
Excellent customer service is important to us.
 Please take a moment

to provide feedback regarding the customer service you have received: <a
href="https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E"
target=_blank><font size=2 color=#0082bf face="sans-
serif"><u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

From: Lee, Michele
Sent: Friday,
October 15, 2021 4:47 PM
To: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri">
Cc: <u>helen.topping@admedsol.com</u>;

<font size=2 color=blue
face="Calibri"><u>k211878@docs.fda.gov</u><font size=2
face="Calibri">
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending
Your Response

Hello Martin,

Thank you for providing your questions in
advance of the meeting. We look

forward to discussing our responses with you next week.

Have a good
weekend,
Michele
 <font size=2 color=#0082bf face="Segoe
UI">
Michele Lee, Ph.D.
Lead
Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices
Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4:
Office of Surgical and Infection Control Devices
Office of Product Evaluation and
Quality

CDRH | Food and Drug Administration
White Oak | 10903 New
Hampshire Avenue | Silver Spring, MD 20993<font size=2 color=blue
face="Calibri"><u>
</u><font size=2
color=blue face="Segoe UI"><u>Michele.Lee@fda.hhs.gov</u><font size=3
face="Segoe UI">
 <u>
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</u><font size=2 color=blue
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color=#4f4f4f face="Arial"> <a
href=http://www.youtube.com/user/USFoodandDrugAdmin><img
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color=#4f4f4f face="Arial"><img
src=cid:_2_0C16F25C0BE537E80053BC6A8025878B style="border:0px solid;"><font size=1
color=#4f4f4f face="Arial"> <a
href=http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm><img
src=cid:_2_0C16F6A80BE537E80053BC6A8025878B style="border:0px solid;"><font size=2
color=#4f4f4f face="Calibri">
Excellent customer service is important to us.
 Please take a moment

to provide feedback regarding the customer service you have received: <a

href="https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E"
target=_blank><font size=2 color=#0082bf face="sans-
serif"><u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

From: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri"><<font size=2
color=blue face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri">>

Sent: Friday, October 15, 2021 12:00 PM
To: Lee, Michele
<<font size=2 color=blue
face="Calibri"><u>Michele.Lee@fda.hhs.gov</u><font size=2
face="Calibri">>
Cc: <a
href=mailto:helen.topping@admedsol.com><font size=2 color=blue
face="Calibri"><u>helen.topping@admedsol.com</u><font size=2
face="Calibri">;

<font size=2 color=blue
face="Calibri"><u>k211878@docs.fda.gov</u><font size=2
face="Calibri">
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending
Your Response
 <font size=2 color=#806210
face="Calibri">
CAUTION:This email originated
from outside

of the organization. Do not click links or open attachments unless you

recognize the sender and know the content is safe.
 <font size=2
face="Arial">
Hi Michele

Please find the list of questions/clarifications
attached below.

I hope you have a good weekend. I'm looking forwards to our
discussion

next week!

<font size=2
face="Arial">

Best regards,<font size=2 color=#000080
face="Arial">

Martin Mitchell
Regulatory Affairs
Manager

Advanced Medical Solutions Ltd.
E-mail: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=2 color=#000080
face="Arial">
Tel: +44 (0) 1752 30 9360<font size=2
face="Calibri">

From:
       "Lee,

Michele" <<font size=1 color=blue
face="Arial"><u>Michele.Lee@fda.hhs.gov</u><font size=1
face="Arial">>
To:
   "<a
href=mailto:Martin.Mitchell@admedsol.com><font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">>
Cc:
   "<a
href=mailto:helen.topping@admedsol.com><font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">>,

"<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u>"

<<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u><font size=1
face="Arial">>
Date:
   13/10/2021

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

22:35
Subject: RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hello Martin,

I have scheduled the teleconference for next Tuesday October 19that

9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour but

our biocompatibility consultant/ team management needs to drop off for

another call at 9:30am. Please send me the questions for discussion in

advance of the meeting so that we can plan to discuss biocompatibility/

regulatory questions first before the relevant parties need to drop off.

<p><table width=100% style="border-collapse:collapse;"><tr height=8><td colspan=2 bgcolor=white style="border-style:none none none none;border-color:#000000;border-width:0px 0px 0px 0px;padding:0px 0px;"><u>Join

Zoom Meeting</u> <tr

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

size=2>

Thanks,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993<u>
</u><u>Michele.Lee@fda.hhs.gov</u><u>

</u><img src=cid:_4_0BF1A33C0C1731240053BC6A8025878B style="border:0px solid;"><u>

</u><img

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

src=cid:_2_0E14D3BC0C1731240053BC6A8025878B style="border:0px solid;"><a
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href=http://www.youtube.com/user/USFoodandDrugAdmin><img
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color=#4f4f4f>
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target=_blank><font size=2 color=#0082bf face="sans-
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From: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2
color=blue><u>Martin.Mitchell@admedsol.com</u><<a
href=mailto:Martin.Mitchell@admedsol.com><font size=2
color=blue><u>Martin.Mitchell@admedsol.com</u>>

Sent: Wednesday, October 13, 2021 4:46 PM
To: Lee, Michele
<<font size=2
color=blue><u>Michele.Lee@fda.hhs.gov</u>>
Cc:
<font size=2
color=blue><u>helen.topping@admedsol.com</u>;

<font size=2
color=blue><u>k211878@docs.fda.gov</u>
Subject: RE:
[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response<font size=2
color=#806210>

CAUTION:This email originated from outside of
the organization.

Do not click links or open attachments unless you recognize the sender

and know the content is safe.

Apologies
Michele, one final thing I missed off my email... could you clarify

how long the teleconference would be by default? Could we request 1 hour

just incase some of the points end up taking longer to discuss?

Best
regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-
mail: <font size=2 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=2 color=#000080
face="Arial">
Tel: +44 (0) 1752 30 9360

From:
 Martin

Mitchell/WIN/UK/AMS
To:
   "Lee,

Michele" <<font size=1 color=blue
face="Arial"><u>Michele.Lee@fda.hhs.gov</u><font size=1
face="Arial">>
Cc:
   "<a
href=mailto:helen.topping@admedsol.com><font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">"

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face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">>,

"<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u>"

<<font size=1 color=blue

face="Arial"><u>k211878@docs.fda.gov</u><font size=1
face="Arial">>
Date:
   13/10/2021

20:35
Subject:
 RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response<div
align=center><hr noshade>

<font size=2
face="Arial">

Hi Michele

We're currently preparing our questions for
the teleconference and will

send these through in due course, however to assist with scheduling the

relevant parties at FDA, I should let you know that we would definitely

like to discuss the questions related to biocompatibility.

After discussion with
the team we would like to request the teleconference

on the Tuesday 19th October

if that is possible? As we are based in

the UK, we would also like to request that this is arranged between the

hours of 2-5pm BST<font size=2
face="Arial">.

If this time slot is not available could you outline any alternative days/times

which would be possible?

Best regards,<font size=2 color=#000080
face="Arial">

Martin Mitchell
Regulatory Affairs
Manager

Advanced Medical Solutions Ltd.
E-mail: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=2 color=#000080
face="Arial">
Tel: +44 (0) 1752 30 9360<font size=2
face="Calibri">

<font size=1 color=#5f5f5f
face="Arial">

From: <font size=1
face="Arial">Martin

Mitchell/WIN/UK/AMS
To:
   "Lee,

Michele" <<font size=1 color=blue
face="Arial"><u>Michele.Lee@fda.hhs.gov</u><font size=1
face="Arial">>
Cc:
   "<a
href=mailto:helen.topping@admedsol.com><font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">>,

"<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u>"

<<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u><font size=1
face="Arial">>
Date:
   08/10/2021

22:14
Subject:
 RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response<font size=2
face="Calibri"> <hr noshade>
<font size=2
face="Calibri">

Hi Michele

Thank
you for the offer. I think after today's meeting we may need a little

more time to be better prepared for the teleconference.

We are reaching out to

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
the (b)(4) for us as we

feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible

dates for you early next week.

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>
To: "<u>Martin.Mitchell@admedsol.com</u>"

<<u>Martin.Mitchell@admedsol.com</u>>
Cc: "<u>helen.topping@admedsol.com</u>"

<<u>helen.topping@admedsol.com</u>>,

"<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 06/10/2021

13:49
Subject: RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference

deadline up to October 19th. Let me know if you would like to

select a date later than the 14thand I can check our management

schedules.

Regarding review timelines, we are still on the 90 day review cycle and

are planning to complete the review of your response with the 20 calendar

days left on the clock. While we retain the right to add additional days,

we are doing our best with the resources that we have to avoid delaying

review timelines if possible.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993<font size=2 color=blue

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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color=blue face="Segoe UI"><u>Michele.Lee@fda.hhs.gov</u><font size=2
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From: <a
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face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri"><<font size=2
color=blue face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri">>

Sent: Wednesday, October 6, 2021 6:00 AM
To: Lee, Michele
<<font size=2 color=blue
face="Calibri"><u>Michele.Lee@fda.hhs.gov</u><font size=2
face="Calibri">>
Cc: <a
href=mailto:helen.topping@admedsol.com><font size=2 color=blue
face="Calibri"><u>helen.topping@admedsol.com</u><font size=2
face="Calibri">
Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your
Response

CAUTION:This email originated from outside

of the organization. Do not click links or open attachments unless you

recognize the sender and know the content is safe.<font size=2
face="Arial">

Hi Michele

Thank you again for your review. Our team are
busy discussing the questions

and we would definitely like to have a teleconference with the FDA. We're

currently consolidating our understanding of the deficiencies and are determining

what our potential questions to you would be. I hope to get the questions

to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference
deadline in mind.... could we

look to schedule a teleconference with the FDA on Wednesday 13th or Thursday

14th? As we're based in the UK we would appreciate a timeslot within our

working hours which finish at 17:00 BST.

Additionally, I have a small question
to allow us to predict timelines

for this project.... regarding the FDA timeline I can see on the CCP tracker

website that the FDA timeline is on day 70.<font size=2
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Will FDA be sticking to the 90
day target

and as a result only have 20 days left on the clock?
<font size=2
face="Arial">Or, due to the current situation with the

unprecedented resource limitations..... will you will assume 30 days to

review the response as standard? Or perhaps stick to the 20 days but retain

the right to add additional days?
Best
regards,

Martin Mitchell

Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.

E-mail: <font size=2
color=#0082bf face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=2
color=#000080 face="Arial">
Tel: +44 (0) 1752 30 9360<font size=2
face="Calibri">

From:
       "Michele

Lee [MICHELE.LEE]" <<font size=1
color=#0082bf face="Arial"><u>michele.lee@fda.hhs.gov</u><font size=1
face="Arial">>
To:
   <<a
href=mailto:martin.mitchell@admedsol.com><font size=1 color=#0082bf
face="Arial"><u>martin.mitchell@admedsol.com</u><font size=1
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<<font size=1 color=#0082bf
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">>
Cc:
   "Michele

Lee [MICHELE.LEE]" <<font size=1
color=#0082bf face="Arial"><u>michele.lee@fda.hhs.gov</u><font size=1
face="Arial">>
Date:
   04/10/2021

21:44
Subject:
 K211878/S001

is on Hold Pending Your Response <div
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October 4, 2021<font size=2
face="Calibri"> <p>We have reviewed your submission. Please see
attached.

<p>If you have any questions, please contact the lead reviewer

assigned to your submission, Michele Lee. <p> <p>*** This is a system-generated email notification ***[attachment

"K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin

Mitchell/WIN/UK/AMS] <p>

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color=#0082bf><u>http://www.admedsol.com</u>.

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Registered in England 2666957 VAT No. GB 636 5551 27

510(k) Summary

Submitted by: Advanced Medical Solutions Limited
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United Kingdom
Tel: +44 (0)1752 209955
Fax: +44 (0) 1752 209956

Contact Person: Martin Mitchell
Regulatory Affairs Manager

Date of Summary: 19th May 2022

Device Name: LiquiBand® XL

Common Name: Cutaneous Tissue Adhesive With Mesh

Classification Name: Tissue adhesive with adjunct wound closure device for topical approximation of skin

Regulatory Number: 21 CFR 878.4011

Device Class: Class II

Product Code: OMD

Predicate Device
Device Name: Exofin Fusion Skin Closure System
510(k) Clearance: K191461

Reference Device
Device Name: LiquiBand® Plus
510(k) Clearance: K183570

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Device Description

LiquiBand® XL is a sterile, liquid topical skin adhesive containing a monomeric (2-octyl cyanoacrylate) formulation and the colorant D & C Violet No. 2. It is provided in a single-use applicator. As applied to skin, the liquid topical skin adhesive is slightly more viscous than water and polymerizes within minutes.

In vitro studies have shown that LiquiBand® XL acts as a barrier to microbial penetration as long as the adhesive film remains intact. Clinical studies were not conducted to demonstrate microbial barrier properties.

LiquiBand® XL also incorporates a self-adhering mesh that is applied to the approximated skin edges to provide temporary skin edge alignment to an incision until the liquid adhesive is applied to achieve skin closure.

Indications for Use

LiquiBand® XL is intended for topical application only to hold closed easily approximated skin edges of wounds from surgical incisions, including incisions from minimally invasive surgery, and simple, thoroughly cleansed, trauma-induced lacerations. LiquiBand® XL should be used in conjunction with, but not in place of, deep dermal stitches. Additionally, the adjunct wound closure device component maintains temporary skin edge alignment along the length of the wound during application of the liquid adhesive.

Comparison of Technological Characteristics with the Predicate Device

The technological characteristics of the LiquiBand® XL and the predicate device are similar, in that they both contain the same technological characteristics:

Device	Subject device: LiquiBand® XL	Predicate device: Exofin Fusion Skin Closure System	Comparison
Adhesive	2-octyl cyanoacrylate adhesive with D&C Violet #2 colorant	2-octyl cyanoacrylate adhesive with D&C Violet #2 colorant	Same
Accelerant	Quaternary ammonium salt	Quaternary ammonium salt	Same
Applicator	Sterile single use applicator; comprising of a glass ampoule (containing the adhesive) within a plastic applicator body with a porous block (containing the accelerant) with a foam applicator tip	Sterile single use applicator; comprised of an aluminum tube (containing the adhesive) with a porous disk (containing the accelerant) with an applicator tip	Equivalent
Mesh	Polyester mesh with pressure sensitive adhesive	Polyester mesh with pressure sensitive adhesive	Same

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Performance Data

Testing was performed in accordance with the FDA special controls guidance document for "Tissue Adhesive with Adjunct Wound Closure Device Intended for the Topical Approximation of Skin"

Performance Testing

The following tests were performed on the LiquiBand® XL to demonstrate substantial equivalence to the predicate device:

- Peel Adhesion of Pressure-Sensitive Tape (ASTM D3330/D3330M-04)
- Shear Adhesion of Pressure-Sensitive Tapes (ASTM D3654/D3654M-06)
- Tensile Properties of Thin Plastic Sheeting (ASTM D882-12)
- Lap-shear strength (ASTM F2255-05)
- T-peel adhesion strength (ASTM F2256-05)
- Adhesive strength in tension (ASTM F2258-05)
- Wound closure strength (ASTM F2458-05)
- Adhesive degradation study
- Heat of polymerization
- Force to actuate and express
- Viscosity
- Polymerization set time
- Microbial barrier testing
- Quality of adhesive film on mesh
- Accelerant degradation study
- Animal wound healing study

Biocompatibility

The biological evaluation of the LiquiBand® XL was performed in accordance with FDA guidance on the use of ISO 10993-1. The following test reports were provided in this submission:

- Cytotoxicity
- Sensitization
- Irritation
- Material mediated pyrogenicity
- Acute systemic toxicity
- Chemical characterization and toxicological risk assessment

Clinical Testing

- No clinical testing has been submitted, referenced, or relied upon for determining substantial equivalence.

Conclusions

Based on the intended use, technological characteristics, safety and performance testing, LiquiBand® XL has been demonstrated to be substantially equivalent to the predicate device, Exofin Fusion Skin Closure System.

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Design Verification Protocol

LIQUIBAND XL & COMPETITOR BENCH TESTING FOR HEAT OF POLYMERISATION AND FORCE TO ACTUATE	Doc No:	(b)(4)	
	Rev No:		

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Design Verification Report

LIQUIBAND XL & COMPETITOR BENCH TESTING FOR HEAT OF POLYMERISATION AND FORCE TO ACTUATE	Doc No:	(b)(4)
	Rev No:	

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Process Work Instruction

MICROBIAL BARRIER TESTING	**Doc No.**	**(b)(4)**
	Rev No.	

(b)(4)

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Advanced Medical Solutions (Plymouth) Ltd

General Report

MICROBIAL BARRIER SUMMARY REPORT FOR STABILITY PROFILE OF LIQUIBAND XL AT (b)(4)	Doc No:	(b)(4)
	Rev No:	

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General Report

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Advanced Medical Solutions (Plymouth) Ltd.

Design Verification Protocol

LIQUIBAND XL QUALITY OF POLYMERISED FILM VERIFICATION PROTOCOL	Doc No:	(b)(4)
	Rev No:	

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Advanced Medical Solutions (Plymouth) Ltd.

Validation Report

QUALITY OF FILM REPORT FOR PROJECT YEALM	Doc No:	(b)(4)	
	Rev No:		

(b)(4)

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(b)(4)

FINAL NON-GLP REPORT: (b)(4)

CHEMICAL CHARACTERIZATION OF THE EXTRACTABLE AMOUNT OF CHEMICAL COMPOUNDS FROM (b)(4)

Test Article
Project Walkham Device (b)(4)

Final Report Date
8/8/2019

Study Director
(b)(4)

Sponsor
Advanced Medical Solutions Limited
2 Western Wood Way, Language Science Park
Plymouth PL7 5BG
United Kingdom

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ATTACHMENT B:
Protocol and Protocol Amendments/Deviations

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(b)(4)

(b)(4) NON-GLP TEST PROTOCOL
CONFIDENTIAL PROPERTY (b)(4)

CHEMICAL CHARACTERIZATION OF THE EXTRACTABLE AMOUNT OF CHEMICAL COMPOUNDS FROM (b)(4)

(b)(4) PROTOCOL NUMBER: (b)(4)

MANAGEMENT OF THE STUDY

Test Facility

(b)(4)

Sponsor
Advanced Medical Solutions Limited
2 Western Wood Way
Language Science Park
Plymouth PL7 5BG
United Kingdom

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Technical Memorandum

December 4, 2019

To: Martin Mitchell
Advanced Medical Solutions Limited
2 Western Wood Way
Language Science Park
Plymouth, PL7 5BG
United Kingdom

From: (b)(4) 12/4/2019

Subject: (b)(4)
RE: LiquiBand Plus

Overview

The objective of this memo is to respond to FDA comments (b)(4)
(b)(4)

(b)(4)

(b)(4)

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(b)(4) (b)(4) (b)(4)

CONFIDENTIAL

Pre Clinical Evaluation of the Safety and Performance of the Advanced Medical Solutions Device LiquiBand XL in a (b)(4)

STUDY PROTOCOL

STUDY NO.

(b)(4)

ETHICAL APPROVAL NO.

(b)(4)

Study Sponsor:

Advanced Medical Solutions Ltd

2 Western Wood Way | Langage Science Park | Plymouth | PL7 5BG | UK

Testing Facility:

(b)(4)

Issue date: January 06, 2020

Total No. of Pages: 41

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Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

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(b)(4)

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(b)(4)

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(b)(4)

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(b)(4)

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Hello Martin,

Thank you for the additional response- you may include it in your supplement response to RTA Checklist. Regarding the timeline, the clock resets to Day 1 being the day of the 510(k) acceptance notification for your supplement S001.

Best,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D77E50.CB020670]<http://www.fda.gov/>

[cid:image002.jpg@01D77E50.CB020670]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D77E50.CB020670] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D77E50.CB020670] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D77E50.CB020670] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D77E50.CB020670]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Thursday, July 15, 2021 10:37 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: k211878@docs.fda.gov; Helen.Topping@admedsol.com; Rose.Guang@admedsol.com

Subject: RE: [EXTERNAL] Re: K211878 is on Hold Pending Your Response

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Hello Michele

Thank you for your clarification; we have reviewed your feedback in line with the (b)(4) and we believe that this addresses your request:

(b)(4)

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

Could you provide a small clarification regarding the FDA timeline with regards the RTA issued

* I've read a statement in a MDFUA performance goals document which states "FDA Days begin on the date of receipt of the submission or of the amendment to the submission that enables the submission to be accepted 510(k)"

* Once the RTA is closed and the 510(k) is accepted.... would Day 1 of the FDA clock remain as the "acknowledgment" notification date (21st June 2021) or would now change to be the date of the 510(k) "acceptance" notification?

Best regards,

Martin Mitchell

Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 09/07/2021 20:12

Subject: RE: [EXTERNAL] Re: K211878 is on Hold Pending Your Response

---

Hello Martin,

Thank you for the additional clarification requests. (b)(4)

(b)(4)

(b)(4), then yes- this report would be sufficient to address the points raised in RTA Question B.12(a). Thank you for bringing this report to my attention.

Best Regards,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D77E50.CB020670]<http://www.fda.gov/>

[cid:image002.jpg@01D77E50.CB020670]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D77E50.CB020670] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D77E50.CB020670] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D77E50.CB020670] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D77E50.CB020670]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>
<Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Wednesday, July 7, 2021 11:19 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Subject: [EXTERNAL] Re: K211878 is on Hold Pending Your Response

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Hi Michele

Nice to see we're working with you again.

I was a little surprised regarding the RTA decision as the level of information we've provided is the same as that which was provided in previous submissions, where we didn't receive an RTA from yourself. Therefore, I just wanted to reach out to you to ensure that I correctly answer the issue so as to avoid any further delays.

Regarding the RTA on question B.12(a)

(b)(4)

Regarding the RTA on question F.28 and F.29

We require no clarification on this point and can provide the documents as requested.

Thanks in advance for your assistance

Best regards,

Martin Mitchell

Senior Regulatory Affairs Associate

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Advanced Medical Solutions Ltd.

Tel: +44 (0) 1752 30 9360

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

From: "Michele Lee [MICHELE.LEE]"
<michele.lee@fda.hhs.gov<mailto:michele.lee@fda.hhs.gov>>

To: <martin.mitchell@admedsol.com<mailto:martin.mitchell@admedsol.com>>

Cc: "Michele Lee [MICHELE.LEE]"
<michele.lee@fda.hhs.gov<mailto:michele.lee@fda.hhs.gov>>

Date: 06/07/2021 20:49

Subject: K211878 is on Hold Pending Your Response

July 6, 2021Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your submission K211878. Our review indicates that your submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit one eCopy of your response, referencing your submission K211878, addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration

Center for Devices and Radiological Health

Document Control Center - WO66-G609

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

Your submission will remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist by 01/02/2022, we will consider this submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your submission. We will contact you if we require any additional information during the course of our administrative review. FDA aims to apply the least burdensome principles<https://www.fda.gov/media/73188/download> when requesting additional information.

The lead reviewer assigned to your submission is me, Michele Lee. The file is being reviewed in Office of Health Technology 4, Division of Health Technology 4 B. The first line supervisor is the Assistant Director, Plastic Surgery Skin and Wound Devices. You may contact me at any point during the review if you have questions or concerns. You can provide valuable support for CDRH to continue to improve our programs by raising to the attention of management relevant issues that arise during the course of this review. If you feel there is an unresolved issue or a matter that requires additional attention, you should contact the Assistant Director. If your concern or issue is not addressed by the Assistant Director, you should contact the Division Director or OHT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Director. The contact information for each management level can be found in the CDRH Management Directory<https://www.fda.gov/about-fda/cdrh-offices/cdrh-management-directory-organization>.

For additional information about the Refuse to Accept Policy for for 510(k)s please refer to the guidance document available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf.

If you have general questions about the review process for your submission, you should contact OPEQSubmissionSupport@fda.hhs.gov<mailto:OPEQSubmissionSupport@fda.hhs.gov>.

*** This is a system-generated email notification ***[attachment "K211878.RTAChecklist.RTA1.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

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Hello Michele

Hope you have a nice thanksgiving tomorrow!

Just checking how things are going with your (b)(4). Are we still on track to get an update this week to our questions?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 16/11/2021 19:03
Subject: RE: [EXTERNAL] K211878 timeline - COVID-19

Hello Martin,

Thanks for the update and good to know this information. I also received your previous email with additional information about the (b)(4) (b)(4). I am still waiting on feedback from our (b)(4) but hope to have more information to provide you mid next week.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Monday, November 15, 2021 3:54 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Subject: Fw: [EXTERNAL] K211878 timeline - COVID-19

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Hi Michele

I got an update regarding timeline from the CCP email address.

FYI we are exploring a number of backup strategies to resolve (b)(4) deficiencies.... and some of these take us past the 180 day hold period.

As per the request below, I'll let you know closer to the time if we end up needing to request the additional 180 days.

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

----- Forwarded by Martin Mitchell/WIN/UK/AMS on 15/11/2021 08:31 -----

From: "CCP" <CCP@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Date: 12/11/2021 21:08
Subject: RE: [EXTERNAL] K211878 timeline - COVID-19

Good day to you Martin,

The extra 180 days for response are added as needed, and then only shortly before the original 180 days expires.

--

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Happy trails,

~Nels Anderson

Regulatory Systems & Data Management Staff

Center for Devices and Radiological Health | Office of Product Evaluation and Quality| Office of Regulatory Programs

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Friday, November 12, 2021 09:49

To: CCP <CCP@fda.hhs.gov>

Subject: [EXTERNAL] K211878 timeline - COVID-19

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Hello

Regarding the timeline showing for K211878 I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I (and the lead reviewer Michele Lee) were under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify that the 180 timeline in the customer collaboration portal won't trigger premature closure of the 510(k) before the actual 360 day timeline expires?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

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Plympton, Plymouth,
Devon, PL7 5BG, UK
Tel : +44 (0)1752 209955 **Fax :** +44 (0)1752 209956
Web : www.admedsol.com

Meeting Minutes

Submission Number:	K211878 / S001
Submission Type:	510(k)
Product Name:	LiquiBand XL
Submitter:	Martin Mitchell
Meeting Date / Time:	14:00 BST on the 19th of October 2021
Meeting Format:	Teleconference via Zoom
Date FDA feedback was Sent:	4th October 2021

FDA attendees:

- Dr. Michele Lee, Lead Reviewer
- Lixin Liu, TBC
- Diego Rua, TBC

Advanced Medical Solutions attendees:

- Martin Mitchell, RA Manager

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Morning Sam

I hope you've had a nice weekend.

I'm just following up on my previous email from last Friday....we believe that the information we provided satisfied your request; however we would like to check on the feedback from management.

Please feel free to contact me if you require further assistance. As there is now only 1 day left of the review (completing on the 24th May) myself and the project team are fully available to provide you with any assistance to support you in the review.

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>
Date: 20/05/2022 11:07
Subject: RE: [EXTERNAL] Re: K211878-s002

Good morning Sam!

Do you think we can expect feedback from management today?

If we don't get feedback; as the FDA review is performed on calendar days.... should we be prepared to deal with any further requests during the weekend?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

From: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Date: 19/05/2022 16:44

Subject: RE: [EXTERNAL] Re: K211878-s002

Being reviewed by mgt

Sam Arepalli, Ph.D.

FDA/CDRH/OPEQ/OHT4/PRSB2

Ph: 301 796 6434

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Thursday, May 19, 2022 11:37 AM

To: Arepalli, Sambasiva <Sambasiva.Arepalli@fda.hhs.gov>

Subject: RE: [EXTERNAL] Re: K211878-s002

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Hi Sam

Sorry, i'm not following your response... Was it implying that
Its been discussed and the issue is resolved?
Or you need more clarification and want a teleconference?

It's almost 5pm here so I just wanted to make sure I can offer the most support I can before I go home and try to juggle family and checking my emails

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

From: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Date: 19/05/2022 16:32

Subject: RE: [EXTERNAL] Re: K211878-s002

yes

Sam Arepalli, Ph.D.

FDA/CDRH/OPEQ/OHT4/PRSB2

Ph: 301 796 6434

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Thursday, May 19, 2022 11:30 AM

To: Arepalli, Sambasiva <Sambasiva.Arepalli@fda.hhs.gov>

Cc: K211878@docs.fda.gov; Rose.Guang@admedsol.com

Subject: RE: [EXTERNAL] Re: K211878-s002

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Hello Sam

Regarding your deadline where you planned to have completed versions of the IFU and 510(k) Summary by COB today.

Have you managed to discuss the issue in your department?

I'm wondering if there is any further clarification we can provide to assist in the discussion; or perhaps a call could be scheduled quickly to resolve the matter?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>

Cc: "K211878@docs.fda.gov" <K211878@docs.fda.gov>, Rose Guang/WIN/UK/AMS@ams

Date: 19/05/2022 11:28

Subject: RE: [EXTERNAL] Re: K211878-s002

Hi Sam

For your ease of reference, please find our response to deficiency 11 below where we discuss the teleconference minutes and the data from the (b)(4)

[attachment "AMS deficiency response.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

As requested I've highlighted the teleconference meeting minutes showing the FDA agreement (b)(4) (b)(4)

[attachment "K211878 - 19Oct2021 Meeting Minutes - Final.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

I've also highlighted and provided the pertinent pages from (b)(4) (b)(4) (b)(4)" deleted by Martin Mitchell/WIN/UK/AMS]

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

From: Martin Mitchell/WIN/UK/AMS

To: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>

Cc: "K211878@docs.fda.gov" <K211878@docs.fda.gov>, Rose Guang/WIN/UK/AMS@ams

Date: 19/05/2022 10:17

Subject: RE: [EXTERNAL] Re: K211878-s002

Hi Sam

I'll call you today at 6am (11am UK time); we thought it would be better to send you the updated documents to help aid the discussion during the call.

The IFU has been updated with your comments (and as per our modifications we suggest below). I've provided a redlined and clean copy of this: [attachment "IFU - LiquiBand XL.pdf" deleted by Martin Mitchell/WIN/UK/AMS] [attachment "IFU - LiquiBand XL - Tracked.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

The 510(k) summary has been updated with your comments [attachment "510K Summary.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>

Cc: "K211878@docs.fda.gov" <K211878@docs.fda.gov>, Rose Guang/WIN/UK/AMS@ams

Date: 18/05/2022 22:37

Subject: RE: [EXTERNAL] Re: K211878-s002

Hi Sam

Firstly, thank you for staying late to continue to work with us on in the

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final stages of this submission. It is much appreciated.

Please find attached the IFU with updated comments from ourselves

[attachment "K211878-S002 - Revised labeling received on 5-16-2022.jam.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

For most of the proposed updates we will accept to make the changes.

However there are two points we would wish to clarify

Regarding the comment (b)(4)

(b)(4)

As discussed I'll call you tomorrow to discuss your email below

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

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From: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>, "K211878@docs.fda.gov" <K211878@docs.fda.gov>

Date: 18/05/2022 20:39

Subject: RE: [EXTERNAL] Re: K211878-s002

Hi Mr. Mitchell:

Please see attached for the labeling and 510kSummary with FDA edits.

Please address these edits and send me both the edited versions and clean copies of the labeling and the 510kSummary by COB tomorrow (5-19-2022).

Please cc your response to K211878@docs.fda.gov.

Thx

Sam

Sam Arepalli, Ph.D.

FDA/CDRH/OPEQ/OHT4/PRSB2

Ph: 301 796 6434

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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>

Sent: Tuesday, May 17, 2022 6:39 AM

To: Arepalli, Sambasiva <Sambasiva.Arepalli@fda.hhs.gov>

Subject: RE: [EXTERNAL] Re: K211878-s002

CAUTION:This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Sam

Just to be safe for the email trail.... so that your email has a response

The email with this information was send yesterday; however it is also provided again below:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Please find a response to the two points we discussed over the phone

(b)(4)

As requested, the IFU has been revised with the updated warning

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Date: 17/05/2022 10:32

Subject: RE: [EXTERNAL] Re: K211878-s002

Hi Mr. Mitchell:

Can you please give an update on the revised labeling request? Could you please send the information cob today? Please give me a call when you have a minute.

Thx

Sam

Sam Arepalli, Ph.D.

FDA/CDRH/OPEQ/OHT4/PRSB2

Ph: 301 796 6434

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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>

Sent: Monday, May 16, 2022 12:06 PM

To: Arepalli, Sambasiva <Sambasiva.Arepalli@fda.hhs.gov>

Subject: [EXTERNAL] Re: K211878-s002

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Hi Sam

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Just so you're aware it's 17:00 now so i'll be heading home; however i'll try to make myself available outside of hours so please don't hesitate to get in touch if you have any further questions.

Additionally i'll be working from home the next few days so I won't pick up calls from my office number you used previously.

If you have any further questions please email me or call me on my personal mobile number (b)(6)

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

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To: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>
Cc: "K211878@docs.fda.gov" <K211878@docs.fda.gov>, Rose Guang/WIN/UK/AMS@ams, Helen Topping/WIN/UK/AMS@ams
Date: 16/05/2022 16:28
Subject: Re: K211878-s002

Hi Sam

Please find a response to the two points we discussed over the phone

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

As requested, the IFU has been revised with the updated warning

[attachment "IFU.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

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To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>, "

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K211878@docs.fda.gov" <K211878@docs.fda.gov>

Date: 16/05/2022 14:39

Subject: K211878-s002

Hi Mr. Martin:

Please address the following:

(b)(4)

Thx

Sam

Sam Arepalli, Ph.D.

FDA/CDRH/OPEQ/OHT4/PRSB2

Ph: 301 796 6434

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Advanced Medical Solutions Ltd

Advanced Medical Solutions Ltd
Western Wood Way, Langage Science Park,
Plympton, Plymouth, Devon, PL7 5BG UK
Tel: +44 (0) 1752 209955 Fax: +44 (0) 1752 209956
Web: www.admedsol.com
Registered in England 2666957 VAT No. GB 636 5551 27

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center (DCC) – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
USA

Dear Dr Michele Lee

In response to FDA's 510(k) acceptance review received 6th July 2021 for K211878 please find the reply from Advanced Medical Solutions Ltd to the missing elements listed.

This response is being submitted as the physical cover letter and an eCopy of the response on CD.

If you should you require any additional data, please do not hesitate to contact me at the contact information provided.

(b)(6)

Sincerely,

Martin Mitchell
Senior Regulatory Affairs Associate
Phone: +44 (0) 1752 30 9360
Email: Martin.Mitchell@admedsol.com

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Advanced Medical Solutions (Plymouth) Ltd.

Design Validation Protocol

PROTOCOL TO EVALUATE THE STABILITY PROFILE OF LIQUIBAND XL FINAL FINISHED DEVICE WITH (b)(4)	Doc No:	(b)(4)
	Rev No:	

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Supporting information for Question 1

(b)(4)

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Supporting information for Question 2

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Supporting information for Question 4

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hi Michelle,

I realise we're in unprecedented times and I do want to be respectful to FDA's challenges. As this project is business critical for us, could you reassure me that Monday's timeframe will not move again?

Best regards

Helen

Helen Topping
Senior Regulatory Affairs Manager
Advanced Medical Solutions
Tel: +44 (0) 7721261214
Email: helen.topping@admedsol.com

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>, "Helen.Topping@admedsol.com" <Helen.Topping@admedsol.com>, "Rose.Guang@admedsol.com" <Rose.Guang@admedsol.com>
Cc: "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 28/09/2021 16:45
Subject: RE: [EXTERNAL] Re: K211878/S001 Review Status

Hello Martin, Helen, & Rose:

I am writing to inform you of a revision to the review timeline for your 510(k) Submission K211878/S001. Unfortunately, we are unable to complete the substantive review by the previously revised timeline of September 29 th. We now anticipate completion of the substantive review by next Monday, October 4th. We apologize for any inconveniences caused because of the multiple extensions of review timeline and appreciate your understanding as the Agency works through resource limitations during this time.

Best Regards,

Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices

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Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

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Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Tuesday, September 21, 2021 10:03 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: k211878@docs.fda.gov; Helen.Topping@admedsol.com; Rose.Guang@admedsol.com

Subject: [EXTERNAL] Re: K211878/S001 Review Status

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Hello Michele

Thank you for your email to keep us updated with progress.

Please note that next week i'll be out on annual leave... therefore, could you also place Helen and Rose (on this email) on copy with any further communication you send over.

Best regards,

Martin Mitchell

Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 20/09/2021 22:31

Subject: K211878/S001 Review Status

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Hello Martin:

I want to inform you of a slightly revised review timeline for your 510(k) submission K211878/S001. Due to a limitation of Agency resources, we are unable to complete the substantive review by September 24th. We want to inform you that we expect to complete the review by next Wednesday, September 29th. We apologize for any inconveniences because of the extension of timeline.

Best Regards,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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Hello Martin,

I have scheduled the teleconference for next Tuesday October 19th at 9am EST/ 2pm BST. Per your request, (b)(4) team management needs to drop off for another call at 9:30am. Please send me the questions for discussion in advance of the meeting so that we can plan to discuss (b)(4) questions first before the relevant parties need to drop off.

Join Zoom

(b)(4)

Thanks,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

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Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D7C058.A817DC30]<http://www.fda.gov/>

[cid:image002.jpg@01D7C058.A817DC30]<https://www.facebook.com/FDA>
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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Wednesday, October 13, 2021 4:46 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: helen.topping@admedsol.com; k211878@docs.fda.gov

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Apologies Michele, one final thing I missed off my email... could you clarify how long the teleconference would be by default? Could we request 1 hour just incase some of the points end up taking longer to discuss?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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To: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 13/10/2021 20:35

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hi Michele

We're currently preparing our questions for the teleconference and will send these through in due course, however to assist with scheduling the relevant parties at FDA, I should let you know that we would definitely like to discuss the questions (b)(4) (b)(4).

After discussion with the team we would like to request the teleconference on the Tuesday 19th October if that is possible? As we are based in the UK, we would also like to request that this is arranged between the hours of 2-5pm BST.

If this time slot is not available could you outline any alternative days/times which would be possible?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 08/10/2021 22:14

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hi Michele

Thank you for the offer. I think after today's meeting we may need a little more time to be better prepared for the teleconference.

We are reaching out to the (b)(4) for us as we feel that it may be beneficial to have them join us on the teleconference.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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As such we need to check their availability. I hope to have list of possible dates for you early next week.

Best regards,

Martin Mitchell

Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 06/10/2021 13:49

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference deadline up to October 19th. Let me know if you would like to select a date later than the 14thand I can check our management schedules.

Regarding review timelines, we are still on the 90 day review cycle and are planning to complete the review of your response with the 20 calendar days left on the clock. While we retain the right to add additional days, we are doing our best with the resources that we have to avoid delaying review timelines if possible.

Best,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

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[cid:image003.jpg@01D7C058.A817DC30] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7C058.A817DC30] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7C058.A817DC30] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D7C058.A817DC30]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com> <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Wednesday, October 6, 2021 6:00 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>

Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Thank you again for your review. Our team are busy discussing the questions and we would definitely like to have a teleconference with the FDA. We're currently consolidating our understanding of the deficiencies and are determining what our potential questions to you would be. I hope to get the questions to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we look to schedule a teleconference with the FDA on Wednesday 13th or Thursday 14th? As we're based in the UK we would appreciate a timeslot within our working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines for this project.... regarding the FDA timeline I can see on the CCP tracker website that the FDA timeline is on day 70.

* Will FDA be sticking to the 90 day target and as a result only have 20 days left on the clock?

* Or, due to the current situation with the unprecedented resource limitations..... will you will assume 30 days to review the response as standard? Or perhaps stick to the 20 days but retain the right to add additional days?

Best regards,

Martin Mitchell

Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov<mailto:michele.lee@fda.hhs.gov>>

To: <martin.mitchell@admedsol.com<mailto:martin.mitchell@admedsol.com>>, <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>

Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov<mailto:michele.lee@fda.hhs.gov>>

Date: 04/10/2021 21:44

Subject: K211878/S001 is on Hold Pending Your Response

October 4, 2021

We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Michele Lee.

*** This is a system-generated email notification ***[attachment "K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Hi Michele

We're currently preparing our questions for the teleconference and will send these through in due course, however to assist with scheduling the relevant parties at FDA, I should let you know that we would definitely like to discuss the questions related to biocompatibility.

After discussion with the team we would like to request the teleconference on the Tuesday 19th October if that is possible? As we are based in the UK, we would also like to request that this is arranged between the hours of 2-5pm BST.

If this time slot is not available could you outline any alternative days/times which would be possible?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 08/10/2021 22:14
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hi Michele

Thank you for the offer. I think after today's meeting we may need a little more time to be better prepared for the teleconference.

We are reaching out to the (b)(4) for us as we feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible dates for you early next week.

Best regards,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Martin Mitchell

Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 06/10/2021 13:49

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference deadline up to October 19th. Let me know if you would like to select a date later than the 14th and I can check our management schedules.

Regarding review timelines, we are still on the 90 day review cycle and are planning to complete the review of your response with the 20 calendar days left on the clock. While we retain the right to add additional days, we are doing our best with the resources that we have to avoid delaying review timelines if possible.

Best,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 6, 2021 6:00 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com
Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Thank you again for your review. Our team are busy discussing the questions and we would definitely like to have a teleconference with the FDA. We're currently consolidating our understanding of the deficiencies and are determining what our potential questions to you would be. I hope to get the questions to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we look to schedule a teleconference with the FDA on Wednesday 13th or Thursday 14th? As we're based in the UK we would appreciate a timeslot within our working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines for this project.... regarding the FDA timeline I can see on the CCP tracker website that the FDA timeline is on day 70.
Will FDA be sticking to the 90 day target and as a result only have 20 days left on the clock?
Or, due to the current situation with the unprecedented resource limitations..... will you will assume 30 days to review the response as standard? Or perhaps stick to the 20 days but retain the right to add additional days?

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>

To: <martin.mitchell@admedsol.com>, <helen.topping@admedsol.com>

Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>

Date: 04/10/2021 21:44

Subject: K211878/S001 is on Hold Pending Your Response

October 4, 2021

We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Michele Lee.

*** This is a system-generated email notification ***[attachment "K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Dear Michele,

Many thanks for your message.
Martin, thank you for the connection.

Michele, would you be available next Wednesday, 10 November 2021, at 7 pm (UTC+1)?
Then I would send an invitation.

Kind regards.

(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov>
Sent: Freitag, 5. November 2021 14:33
To: Martin.Mitchell@admedsol.com; k211878@docs.fda.gov
Cc: (b)(4)
Subject: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

This message is from an EXTERNAL SENDER -- be CAUTIOUS, particularly with links and attachments

---

Hello all,

Thank you, Martin, for the connection.

(b)(4)

(b)(4)

Best Regards,

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Thursday, November 4, 2021 11:29 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>; k211878@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Regarding the recent deficiency question on our medical device submission which is currently under review with the FDA:

(b)(4)

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

Visit us at: http://www.admedsol.com. This e-mail, including any attached files, is confidential and intended for the exclusive use of the addressee(s) only. If you are not the intended recipient, please notify the sender immediately and delete it from your mailbox or any other storage mechanism.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Supporting evidence:

(b)(4)

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

May 23, 2022</br></br> We have completed our review. Please refer to the attached letter for details.

If you have any questions, please contact the lead reviewer assigned to your submission, Sam Arepalli.

 *** This is a system-generated email notification ***

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

K211878
Advanced Medical Solutions Limited
Trade/Device Name: LiquiBand XL
Contact Name: Martin Mitchell

This document is being communicated via e-mail as an attachment. The date on which FDA sent this e-mail is the official date of this correspondence.

We have reviewed your submission K211878 and have determined that additional information is required. Your file is being placed on hold pending a complete response to the attached deficiencies.

Please submit your response, referencing the submission number K211878 to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Please refer to the eCopy guidance at https://www.fda.gov/media/83522/download for current information on eCopy requirements.

Your response is due within 180 days from the date of this request, which is the hold date plus 180 days. If a complete response is not received in CDRH's Document Control Center by this date, we will consider this submission to be withdrawn, and we will delete it from our review system.

You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without FDA clearance, you will be in violation of the Federal Food, Drug, and Cosmetic Act.

If you would like a meeting or teleconference with the review team and management to discuss your planned approach for responding to the attached deficiencies, please submit your request for feedback as a Submission Issue Q-Submission (Q-Sub). Please note that a Submission Issue Q-Sub does not take the place of a formal response to this email notification. As noted above, FDA will consider this submission to be withdrawn if FDA does not receive, in a submission to the Document Control Center, a complete response to all of the attached deficiencies within 180 calendar days of the date of this request.

This request for additional information has undergone supervisory review to ensure that the deficiencies cited are least burdensome and relevant to the marketing decision. Please see the revised guidance "Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions" issued on September 29, 2017 (https://www.fda.gov/media/71735/download) for clarification regarding major and minor deficiencies.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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MAJOR DEFICIENCY LIST

The Agency has identified major deficiencies that if not adequately resolved, may preclude a favorable decision on the marketing application.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

MINOR DEFICIENCY LIST

The Agency has identified minor deficiencies that can be resolved in a straightforward manner, but that need to be addressed to meet regulatory requirements or to prevent potential misbranding or adulteration.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

FDA is offering a teleconference within 10 calendar days from the date on this letter to address any clarification questions you may have pertaining to the deficiencies. If you are interested in a teleconference, please provide (1) proposed dates and (2) a list of your clarification questions via email at least 48 hours before the teleconference to the lead reviewer assigned to your submission. We would like to emphasize that the purpose of the meeting is to address specific clarification questions. Please note that if the specific clarification questions are not received at least 48 hours before the teleconference, the review team might not be able to provide feedback. The teleconference is not intended for review of new information, test methods or data; these types of questions could be better addressed via a Submission Issue Q-Submission (Q-Sub). For additional information regarding Q-Subs, please refer to the Guidance for Industry and FDA Staff on Medical Devices: Requests for Feedback and Meetings for Medical Device Submissions at https://www.fda.gov/media/114034/download.

Least Burdensome (LB) Flag

The LB flag is an approach to allow submitters the opportunity for the informal review by or on behalf of Division management of an issue raised in an FDA request for additional information (i.e., a deficiency letter). The goal of the LB flag is to quickly address FDA requests that submitters do not believe are least burdensome or when submitters believe they are being held to a different standard than their legally marketed predicate device. The LB flag is not intended to clarify deficiencies, is not an appeal under 21 CFR 10.75, and is not intended to provide a review of a proposed response to deficiencies.

If you would like to throw the LB flag, FDA has several criteria that should be met before you submit your request:

- You should have tried to address your concern by discussing it with Division management before attempting to throw the LB flag. This discussion with Division management may take place as part of a teleconference (such as the voluntary teleconference held within 10 days following transmission of an Additional Information letter to clarify deficiencies), email, or a Q-Submission Submission Issue Request.
- Your flag should generally be limited to two topic areas. Topic areas are common premarket review deficiency categories that apply to many device types across multiple reviewing Divisions. Examples of topic areas include biocompatibility, sterility, reprocessing, software, electromagnetic compatibility, wireless, electrical safety, clinical, and non-clinical performance testing.
- If you would like to discuss issues pertaining to more than two topic areas, you should contact OPEQSubmissionSupport@fda.hhs.gov for more information.
- You should throw the LB flag within 60 calendar days of the date that FDA sent the deficiency letter.

Upon meeting the criteria, you should send a short email (e.g., 1-2 page) that includes: 1) a summary of the deficiencies under disagreement, 2) a summary of relevant communications with Division management, and 3) a proposed path forward. The LB flag should be sent to the lead reviewer and their Assistant Director. You should also copy OPEQSubmissionSupport@fda.hhs.gov on your LB flag email request. Within two

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business days of your email, your request will be acknowledged by the reviewing Division. If you do not meet the criteria for the LB flag, you will be notified in this acknowledgement email.

Your LB flag should contain sufficient information to determine whether the deficiency letter was not least burdensome, or you are being held to a different standard than your predicate device. FDA may request a phone call with you to discuss your concern further and intends to communicate feedback from Division management on LB flags through email no later than 21 calendar days of their receipt. Please note that the LB flag does not change the deadline for your response to the Document Control Center. If you have any questions, please contact OPEQSubmissionSupport@fda.hhs.gov.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

K211878 / S002

Advanced Medical Solutions Ltd

Advanced Medical Solutions Limited
Western Wood Way,
Langage Science Park,
Plymouth,
Devon,
PL7 5BG,
United Kingdom
Tel: +44 (0) 1752 209955 Fax: +44 (0) 1752 209956
Web: www.admedsol.com
Registered in England 2666957 VAT No. GB 886 5551 27

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center (DCC) – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
USA

FDA/CDRH/DCC
MAY 04 2022
RECEIVED

Dear FDA

In response to FDA's request for additional information letter (AI) received 4th October 2021, for K211878 please find the reply from Advanced Medical Solutions Ltd (AMS) to the deficiencies listed which support the subject device, LiquiBand® XL. FDA's deficiencies are in bold and are immediately followed by AMS' answers.

To address the deficiencies **(b)(4)** in line with FDA request.

This response is being submitted as the physical cover letter and an eCopy of the response on CD.

Should you require any additional data or clarification on the response provided, please do not hesitate to contact me using the details below.

(b)(6)

Sincerely,

Martin Mitchell
Regulatory Affairs Manager
Phone: +44 (0) 1752 30 9360
Email: Martin.Mitchell@admedsol.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

7LL

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Hello Julie

I've seen on the customer collaboration portal that our response has been acknowledged by the FDA and the clock has started moving.

Can we assume that a new reviewer has been successfully assigned?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Morabito, Julie" <Julie.Morabito@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "Helen.Topping@admedsol.com" <Helen.Topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>, "Rose.Guang@admedsol.com" <Rose.Guang@admedsol.com>, "Lee, Michele" <Michele.Lee@fda.hhs.gov>
Date: 14/04/2022 01:01
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thanks for reaching out. Iâ€™ll be glad to assist in answering your questions.
Will there be any delays in assigning a new reviewer?
We do not anticipate a delay in assigning a new reviewer.
Are there still resource constraints at the FDA?
Speaking regarding our team, we are still working through resource constraints and doing our best to meet deadlines.
Would a new reviewer who is not familiar with the product/deficiencies require a longer period of time to perform the review?
We will do our best to align the new reviewer that is familiar and experienced with the review product, to limit delay to the extent possible.
I hope this is helpful, but please let me know if youâ€™d like to discuss further.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Best,

Julie

Julie Morabito, PhD, RAC (she/her/hers)
Assistant Director

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4668 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (240) 402-3839 | Cell: (b)(6)
julie.morabito@fda.hhs.gov

Formerly:
Assistant Director, Outreach and Partnerships Team 2 (MedSun)
DCEA1: Division of Clinical Science and Quality | OCEA: Office of Clinical Evidence and Analysis
Office of Product Evaluation and Quality

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Wednesday, April 13, 2022 3:32 PM
To: Morabito, Julie <Julie.Morabito@fda.hhs.gov>
Cc: Helen.Topping@admedsol.com; k211878@docs.fda.gov; Rose.Guang@admedsol.com; Lee, Michele <Michele.Lee@fda.hhs.gov>
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele and Julie

Thank you Michele for providing further clarification on the matter regarding maintenance of a lead reviewer. We are sad to lose you as our lead reviewer and wish you the best in your new role within the FDA.

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

During the initial review of the 510(k) it was flagged that the FDA had resource challenges which resulted in the review taking 70 days instead of the targeted 60 days....When we discussed this previously it was stated that when we submit our deficiency response the FDA would still target to complete the review within the remaining 20 days, however.... it was also flagged that if resource constraints still existed this could take longer than 20 days.

To keep the FDA informed about our progress we are planning to submit our response to the deficiency questions in around 3 weeks time. We would like to enquire about FDA's ability to complete the review within 20 days?
Will there be any delays in assigning a new reviewer?
Are there still resource constraints at the FDA?
Would a new reviewer who is not familiar with the product/deficiencies require a longer period of time to perform the review?

The timely completion of your review would be massively appreciated as the large wound market is critical to urgent patient demand, AMS and our partners who are very keen to provide the improved product to hospitals across the United States.

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "k211878@docs.fda.gov" <k211878@docs.fda.gov>, "Rose.Guang@admedsol.com" <Rose.Guang@admedsol.com>, "Helen.Topping@admedsol.com" <Helen.Topping@admedsol.com>, "Morabito, Julie" <Julie.Morabito@fda.hhs.gov>
Date: 05/04/2022 14:47
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Unfortunately, it is not possible for me to take on lead review of this submission. As previously mentioned, I am currently working in another Office within FDA and do not conduct premarket reviews of medical devices in my current role.

It is not uncommon for new lead reviewers to be assigned to submissions returning from hold. The internal documentation serves as a complete record of the previous interactions during prior review of a submission. If you have further questions regarding the review process for your submission, you may contact the Assistant Director for the Plastic Surgery Skin & Wound Devices Team, Dr. Julie Morabito (Julie.Morabito@fda.hhs.gov).

Best,
Michele

Michele Lee, Ph.D.(she/her/hers)
Regulatory Science Program Manager
Partnerships to Advance Innovation and Regulatory Science (PAIRS)

Center for Devices and Radiological Health
Office of Strategic Partnerships and Technology Innovation
Division of All Hazards Response, Science, and Strategic Partnerships
U.S. Food and Drug Administration
michele.lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Tuesday, April 5, 2022 8:31 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: k211878@docs.fda.gov; Rose.Guang@admedsol.com; Helen.Topping@admedsol.com
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

CAUTION:This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Hello Michele,

We have been pleased to have you as the lead reviewer for RTA review, technical review, and responses to deficiency discussions since July 2021, as well as having you for the review for our previous 510(k) submission of the same product.

(b)(4)

Jun 2021 - We submitted K211878 in response the (b)(4)

(b)(4)

Oct 2021 - Further deficiencies were raised on the new K211878 submission

We currently have only 20 days of FDA review time left on our product and have been advised that we will now be assigned a new reviewer. As you can imagine this causing us a high level of concern given you have a detailed knowledge of our submissions and of the current outstanding questions. Our concern being that a new reviewer will not have the same detailed knowledge of our submission or of the outstanding questions and hence this may cause unnecessary further delay.

We have been very satisfied with the support we have received from yourself and we would ask that you remain on our file for the final 20 days if at all possible, or an explanation of why this is not possible with some reassurances that a new assessor will not cause unnecessary delays whilst they gain detailed knowledge of our file.

Your expedited response to this request would be appreciated.

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 25/03/2022 16:47

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

A new lead reviewer will not be assigned until a follow up submission is received. So there is currently not a primary contact unless there is an active submission under FDA review. All of our correspondence and the prior related review have been documented internally, so you can be assured that the history of the prior review and contact is available to the future lead reviewer.

Best,

Michele

From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>

Sent: Friday, March 25, 2022 12:21 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: k211878@docs.fda.gov

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

I've seen on the FDA customer collaboration portal that the time has automatically been added, but just thought it would be prudent to also inform you of the situation.

Could I ask who the primary contact is now? Will you be assisting or have any involvement with the review of our response?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 25/03/2022 15:59
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

I am sorry to hear about the (b)(4). I hope all is able to be resolved soon.

Thank you for the update. I am actually working in a different division within FDA and no longer the primary contact for this submission. I believe that the 180 days is automatically granted for responses to AINN hold but you can also confirm with the 510(k) Program staff (510k_Program@fda.hhs.gov, telephone: 301-796-5640) to make sure.

Best,
Michele

Michele Lee, Ph.D.(she/her/hers)
Regulatory Science Program Manager
Partnerships to Advance Innovation and Regulatory Science (PAIRS)

Center for Devices and Radiological Health
Office of Strategic Partnerships and Technology Innovation
Division of All Hazards Response, Science, and Strategic Partnerships
U.S. Food and Drug Administration
michele.lee@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?ID=7013&S=E.

From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Sent: Friday, March 25, 2022 11:28 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: k211878@docs.fda.gov

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

I'd like to provide an update on our progress with responding to the deficiencies raised on K211878

We were on track to have a deficiency response submitted to the FDA by the 180 day hold period deadline of 2nd April 2022.

However, the organisation performing the (b)(4) (b)(4) have been affected by (b)(4). As a result, they were unable to complete the testing by our targeted timeline.

Therefore, I just want to confirm that we are still intending to respond to the deficiencies, but we would need to use the second 180 day hold period granted to us through the COVID-19 situation.

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 08/11/2021 22:05

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Hello Martin,

Thanks for your message. Iâ€™ll need some time to review the teleconference minutes with my team and also obtain some feedback from our consulting toxicologist about the follow up questions. But I wanted to let you know I received your email and you may feel free to check in again next week.

I do have a clarification question about Follow Up (b)(4)

(b)(4)

Regarding the timeline clarification- I am also under the understanding that the COVID-19 guidance document you cited was still active and that would allow you an additional 180 days for the hold period. I have reached out to the 510(k) Staff multiple times to confirm and am still waiting on their response. Is there a customer service contact email for the customer collaboration portal specifically? You may try contacting them as well to have the date corrected on your end.

Thank you,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>

Sent: Friday, November 5, 2021 12:07 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: helen.topping@admedsol.com; k211878@docs.fda.gov

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

I hope you had a nice holiday!

Following on from the teleconference we had a few actions to complete and get back to you with.

1) Teleconference minutes

Please find a draft of the the teleconference minutes below. Could you review and confirm if you require any changes made?

2) Follow-up questions on the teleconference discussion

As suggested during the teleconference there was the opportunity for a followup email clarification on a few minor points.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The supporting information which provides further clarity on the questions above has been attached if required.

3) Timeline clarification as per previous email

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Thank you again for your assistance

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>, "Liu, Lixin" <Lixin.Liu@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 20/10/2021 22:43
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Michele

Thank you for the prompt response to the clarifications! We'll take your points on board regarding future shelf life studies.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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I do have a minor clarification question regarding our response timeline

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 20/10/2021 14:55

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you to you and your team for attending the teleconference yesterday.

I wanted to follow up on two things I was discussing with my team:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

I will be on leave for the next two weeks and you may contact our team management (Lixin.Liu@fda.hhs.gov) if you have questions during that time.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Lee, Michele
Sent: Friday, October 15, 2021 4:47 PM
To: Martin.Mitchell@admedsol.com
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you for providing your questions in advance of the meeting. We look forward to discussing our responses with you next week.

Have a good weekend,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>

Sent: Friday, October 15, 2021 12:00 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: helen.topping@admedsol.com; k211878@docs.fda.gov

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Please find the list of questions/clarifications attached below.

I hope you have a good weekend. I'm looking forwards to our discussion next week!

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

k211878@docs.fda.gov" <k211878@docs.fda.gov>

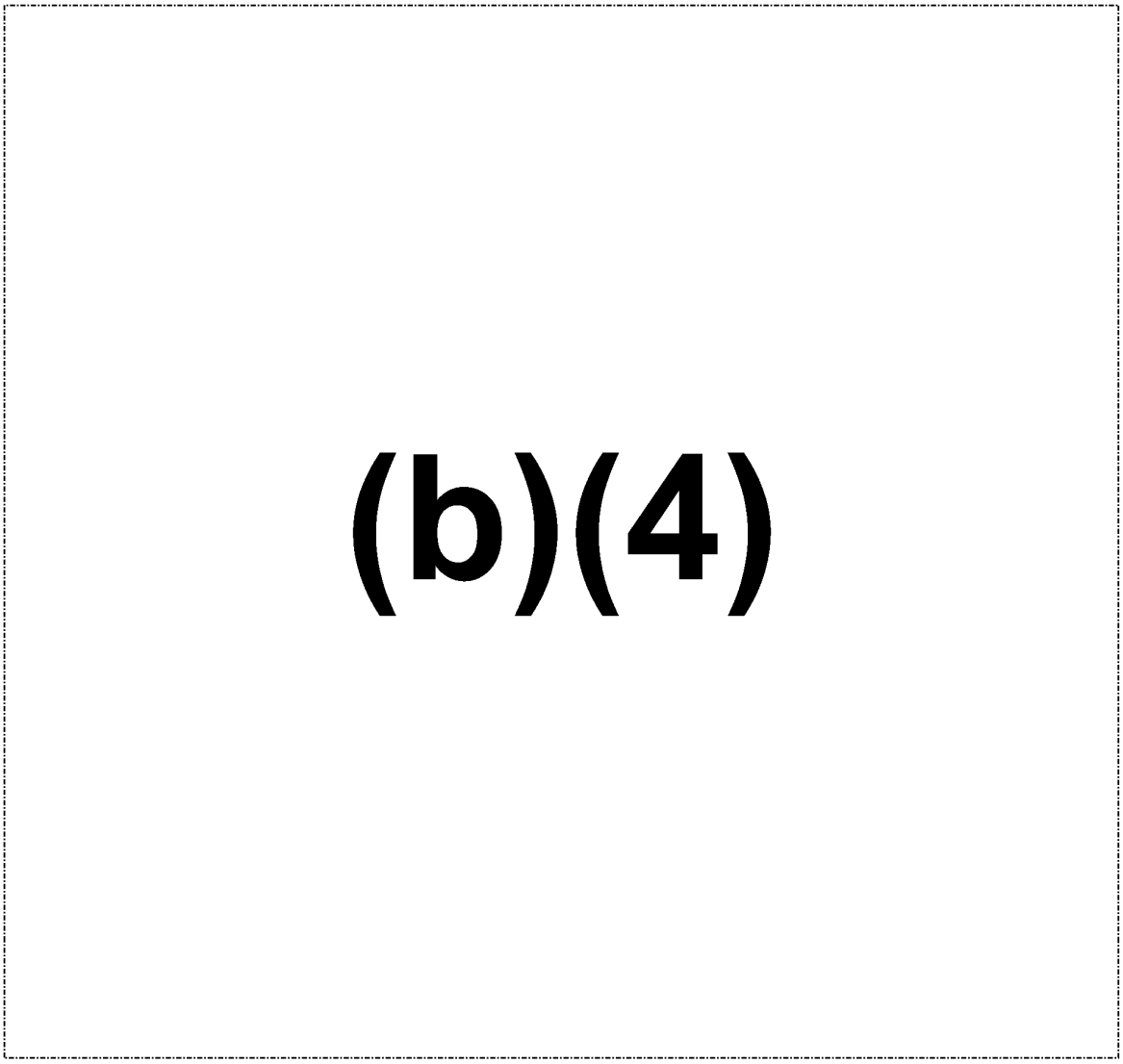
Date: 13/10/2021 22:35

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

I have scheduled the teleconference for next Tuesday October 19that 9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour but our biocompatibility consultant/ team management needs to drop off for another call at 9:30am. Please send me the questions for discussion in advance of the meeting so that we can plan to discuss biocompatibility/ regulatory questions first before the relevant parties need to drop off.

Join Zoom Meeting



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Thanks,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

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Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>

Sent: Wednesday, October 13, 2021 4:46 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: helen.topping@admedsol.com; k211878@docs.fda.gov

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Apologies Michele, one final thing I missed off my email... could you clarify how long the teleconference would be by default? Could we request 1 hour just incase some of the points end up taking longer to discuss?

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 13/10/2021 20:35

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hi Michele

We're currently preparing our questions for the teleconference and will send these through in due course, however to assist with scheduling the relevant parties at FDA, I should let you know that we would definitely like to discuss the questions related to biocompatibility.

After discussion with the team we would like to request the teleconference on the Tuesday 19th October if that is possible? As we are based in the UK, we would also like to request that this is arranged between the hours of 2-5pm BST.

If this time slot is not available could you outline any alternative days/times which would be possible?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 08/10/2021 22:14
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hi Michele

Thank you for the offer. I think after today's meeting we may need a little more time to be better prepared for the teleconference.

We are reaching out to the (b)(4) for us as we feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible dates for you early next week.

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 06/10/2021 13:49
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference deadline up to October 19th. Let me know if you would like to select a date later than the 14thand I can check our management schedules.

Regarding review timelines, we are still on the 90 day review cycle and are planning to complete the review of your response with the 20 calendar days left on the clock. While we retain the right to add additional days, we are doing our best with the resources that we have to avoid delaying review timelines if possible.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 6, 2021 6:00 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com
Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

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Thank you again for your review. Our team are busy discussing the questions and we would definitely like to have a teleconference with the FDA. We're currently consolidating our understanding of the deficiencies and are determining what our potential questions to you would be. I hope to get the questions to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we look to schedule a teleconference with the FDA on Wednesday 13th or Thursday 14th? As we're based in the UK we would appreciate a timeslot within our working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines for this project.... regarding the FDA timeline I can see on the CCP tracker website that the FDA timeline is on day 70.
Will FDA be sticking to the 90 day target and as a result only have 20 days left on the clock?
Or, due to the current situation with the unprecedented resource limitations..... will you will assume 30 days to review the response as standard? Or perhaps stick to the 20 days but retain the right to add additional days?

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
To: <martin.mitchell@admedsol.com>, <helen.topping@admedsol.com>
Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
Date: 04/10/2021 21:44
Subject: K211878/S001 is on Hold Pending Your Response

October 4, 2021

We have reviewed your submission. Please see attached.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
If you have any questions, please contact the lead reviewer assigned to your submission, Michele Lee.

*** This is a system-generated email notification ***[attachment "K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

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Hello Michele and Julie

Thank you Michele for providing further clarification on the matter regarding maintenance of a lead reviewer. We are sad to lose you as our lead reviewer and wish you the best in your new role within the FDA.

During the initial review of the 510(k) it was flagged that the FDA had resource challenges which resulted in the review taking 70 days instead of the targeted 60 days....When we discussed this previously it was stated that when we submit our deficiency response the FDA would still target to complete the review within the remaining 20 days, however.... it was also flagged that if resource constraints still existed this could take longer than 20 days.

To keep the FDA informed about our progress we are planning to submit our response to the deficiency questions in around 3 weeks time. We would like to enquire about FDA's ability to complete the review within 20 days?
Will there be any delays in assigning a new reviewer?
Are there still resource constraints at the FDA?
Would a new reviewer who is not familiar with the product/deficiencies require a longer period of time to perform the review?

The timely completion of your review would be massively appreciated as the large wound market is critical to urgent patient demand, AMS and our partners who are very keen to provide the improved product to hospitals across the United States.

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "k211878@docs.fda.gov" <k211878@docs.fda.gov>, "Rose.Guang@admedsol.com" <Rose.Guang@admedsol.com>, "Helen.Topping@admedsol.com" <Helen.Topping@admedsol.com>, "Morabito, Julie" <Julie.Morabito@fda.hhs.gov>
Date: 05/04/2022 14:47

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Unfortunately, it is not possible for me to take on lead review of this submission. As previously mentioned, I am currently working in another Office within FDA and do not conduct premarket reviews of medical devices in my current role.

It is not uncommon for new lead reviewers to be assigned to submissions returning from hold. The internal documentation serves as a complete record of the previous interactions during prior review of a submission. If you have further questions regarding the review process for your submission, you may contact the Assistant Director for the Plastic Surgery Skin & Wound Devices Team, Dr. Julie Morabito (Julie.Morabito@fda.hhs.gov).

Best,
Michele

Michele Lee, Ph.D. (she/her/hers)
Regulatory Science Program Manager
Partnerships to Advance Innovation and Regulatory Science (PAIRS)

Center for Devices and Radiological Health
Office of Strategic Partnerships and Technology Innovation
Division of All Hazards Response, Science, and Strategic Partnerships
U.S. Food and Drug Administration
michele.lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Tuesday, April 5, 2022 8:31 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: k211878@docs.fda.gov; Rose.Guang@admedsol.com; Helen.Topping@admedsol.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele,

We have been pleased to have you as the lead reviewer for RTA review, technical review, and responses to deficiency discussions since July 2021, as well as having you for the review for our previous 510(k) submission of the same product.

(b)(4)

Jun 2021 - We submitted K211878 in response (b)(4)

(b)(4)

Oct 2021 - Further deficiencies were raised on the new K211878 submission

We currently have only 20 days of FDA review time left on our product and have been advised that we will now be assigned a new reviewer. As you can imagine this causing us a high level of concern given you have a detailed knowledge of our submissions and of the current outstanding questions. Our concern being that a new reviewer will not have the same detailed knowledge of our submission or of the outstanding questions and hence this may cause unnecessary further delay.

We have been very satisfied with the support we have received from yourself and we would ask that you remain on our file for the final 20 days if at all possible, or an explanation of why this is not possible with some reassurances that a new assessor will not cause unnecessary delays whilst they gain detailed knowledge of our file.

Your expedited response to this request would be appreciated.

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 25/03/2022 16:47

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

A new lead reviewer will not be assigned until a follow up submission is received. So there is currently not a primary contact unless there is an active submission under FDA review. All of our correspondence and the prior related review have been documented internally, so you can be assured that the history of the prior review and contact is available to the future lead reviewer.

Best,

Michele

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Friday, March 25, 2022 12:21 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: k211878@docs.fda.gov

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

I've seen on the FDA customer collaboration portal that the time has automatically been added, but just thought it would be prudent to also inform you of the situation.

Could I ask who the primary contact is now? Will you be assisting or have any involvement with the review of our response?

Best regards,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 25/03/2022 15:59

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

I am sorry to hear about the (b)(4). I hope all is able to be resolved soon.

Thank you for the update. I am actually working in a different division within FDA and no longer the primary contact for this submission. I believe that the 180 days is automatically granted for responses to AINN hold but you can also confirm with the 510(k) Program staff (510k_Program@fda.hhs.gov, telephone: 301-796-5640) to make sure.

Best,

Michele

Michele Lee, Ph.D.(she/her/hers)

Regulatory Science Program Manager

Partnerships to Advance Innovation and Regulatory Science (PAIRS)

Center for Devices and Radiological Health

Office of Strategic Partnerships and Technology Innovation

Division of All Hazards Response, Science, and Strategic Partnerships

U.S. Food and Drug Administration

michele.lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=7013&S=E.

From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>

Sent: Friday, March 25, 2022 11:28 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: k211878@docs.fda.gov

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

I'd like to provide an update on our progress with responding to the deficiencies raised on K211878

We were on track to have a deficiency response submitted to the FDA by the 180 day hold period deadline of 2nd April 2022.

However, the organisation performing the (b)(4) (b)(4) have been affected by (b)(4) As a result, they were unable to complete the testing by our targeted timeline.

Therefore, I just want to confirm that we are still intending to respond to the deficiencies, but we would need to use the second 180 day hold period granted to us through the COVID-19 situation.

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 08/11/2021 22:05

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hello Martin,

Thanks for your message. Iâ€™ll need some time to review the teleconference minutes with my team and also obtain some feedback from our consulting toxicologist about the follow up questions. But I wanted to let you know I received your email and you may feel free to check in again next week.

I do have a clarification question about Follow Up Question (b)(4)

(b)(4)

Regarding the timeline clarification- I am also under the understanding that the COVID-19 guidance document you cited was still active and that would allow you an additional 180 days for the hold period. I have reached out to the 510(k) Staff multiple times to confirm and am still waiting on their response. Is there a customer service contact email for the customer collaboration portal specifically? You may try contacting them as well to have the date corrected on your end.

Thank you,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Office of Product Evaluation and Quality

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>

Sent: Friday, November 5, 2021 12:07 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: helen.topping@admedsol.com; k211878@docs.fda.gov

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

I hope you had a nice holiday!

Following on from the teleconference we had a few actions to complete and get back to you with.

1) Teleconference minutes

Please find a draft of the the teleconference minutes below. Could you review and confirm if you require any changes made?

2) Follow-up questions on the teleconference discussion

As suggested during the teleconference there was the opportunity for a followup email clarification on a few minor points.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

3) Timeline clarification as per previous email

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Thank you again for your assistance

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>, "Liu, Lixin" <Lixin.Liu@fda.hhs.gov>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 20/10/2021 22:43

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Michele

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Thank you for the prompt response to the clarifications! We'll take your points on board regarding future shelf life studies.

I do have a minor clarification question regarding our response timeline

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 20/10/2021 14:55

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you to you and your team for attending the teleconference yesterday.

I wanted to follow up on two things I was discussing with my team:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

I will be on leave for the next two weeks and you may contact our team management (Lixin.Liu@fda.hhs.gov) if you have questions during that time.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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From: Lee, Michele
Sent: Friday, October 15, 2021 4:47 PM
To: Martin.Mitchell@admedsol.com
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you for providing your questions in advance of the meeting. We look forward to discussing our responses with you next week.

Have a good weekend,
Michele

Michele Lee, Ph.D.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>

Sent: Friday, October 15, 2021 12:00 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: helen.topping@admedsol.com; k211878@docs.fda.gov

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Please find the list of questions/clarifications attached below.

I hope you have a good weekend. I'm looking forwards to our discussion next week!

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 13/10/2021 22:35

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

I have scheduled the teleconference for next Tuesday October 19that 9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour but our biocompatibility consultant/ team management needs to drop off for another call at 9:30am. Please send me the questions for discussion in advance of the meeting so that we can plan to discuss biocompatibility/ regulatory questions first before the relevant parties need to drop off.

Join Zoom Meeting

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Thanks,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

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Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>

Sent: Wednesday, October 13, 2021 4:46 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: helen.topping@admedsol.com; k211878@docs.fda.gov

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Apologies Michele, one final thing I missed off my email... could you clarify how long the teleconference would be by default? Could we request 1 hour just incase some of the points end up taking longer to discuss?

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 13/10/2021 20:35

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hi Michele

We're currently preparing our questions for the teleconference and will send these through in due course, however to assist with scheduling the relevant parties at FDA, I should let you know that we would definitely like to discuss the questions related to biocompatibility.

After discussion with the team we would like to request the teleconference on the Tuesday 19th October if that is possible? As we are based in the UK, we would also like to request that this is arranged between the hours of 2-5pm BST.

If this time slot is not available could you outline any alternative days/times which would be possible?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 08/10/2021 22:14

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hi Michele

Thank you for the offer. I think after today's meeting we may need a little more time to be better prepared for the teleconference.

We are reaching out to the (b)(4) for us as we feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible dates for you early next week.

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 06/10/2021 13:49

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference deadline up to October 19th. Let me know if you would like to select a date later than the 14thand I can check our management schedules.

Regarding review timelines, we are still on the 90 day review cycle and are planning to complete the review of your response with the 20 calendar days left on the clock. While we retain the right to add additional days, we are doing our best with the resources that we have to avoid delaying review timelines if possible.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 6, 2021 6:00 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com
Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Thank you again for your review. Our team are busy discussing the

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questions and we would definitely like to have a teleconference with the FDA. We're currently consolidating our understanding of the deficiencies and are determining what our potential questions to you would be. I hope to get the questions to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we look to schedule a teleconference with the FDA on Wednesday 13th or Thursday 14th? As we're based in the UK we would appreciate a timeslot within our working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines for this project.... regarding the FDA timeline I can see on the CCP tracker website that the FDA timeline is on day 70.
Will FDA be sticking to the 90 day target and as a result only have 20 days left on the clock?
Or, due to the current situation with the unprecedented resource limitations..... will you will assume 30 days to review the response as standard? Or perhaps stick to the 20 days but retain the right to add additional days?

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
To: <martin.mitchell@admedsol.com>, <helen.topping@admedsol.com>
Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
Date: 04/10/2021 21:44
Subject: K211878/S001 is on Hold Pending Your Response

October 4, 2021
We have reviewed your submission. Please see attached.
If you have any questions, please contact the lead reviewer assigned to

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

your submission, Michele Lee.

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(b)(4)

size=2 face="sans-serif">Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions

Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From:

 "Lee, Michele"

<Michele.Lee@fda.hhs.gov>
To:

 "Martin.Mitchell@admedsol.com"

<Martin.Mitchell@admedsol.com>, "k211878@docs.fda.gov"

<k211878@docs.fda.gov>
Cc:

 "(b)(4)com"

<(b)(4)com>, "(b)(4).com"

<(b)(4)>, "(b)(4)com"

<(b)(4)>
Date:

 05/11/2021 13:34
Subject:

   RE: [EXTERNAL]

Re: K211878/S001 is on Hold Pending Your Response
<hr noshade>

Hello all,

Thank you, Martin, for the connection.

To the (b)(4)

(b)(4)

Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices

Team
DHT4B: Division of Infection Control and

Plastic Surgery Devices
OHT4: Office of Surgical and Infection

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue

| Silver Spring, MD 20993
<u>Michele.Lee@fda.hhs.gov</u>

<img src=cid:_4_0B61A1F00B619E900040359980258799 width=192 height=43 style="border:0px solid;">
<u>
</u><img src=cid:_2_0B61A6800B619E900040359980258799 style="border:0px solid;"> <img src=cid:_2_0B61AACC0B619E900040359980258799 style="border:0px solid;"> <img src=cid:_2_0B61AF180B619E900040359980258799 style="border:0px solid;"> <img src=cid:_2_0B61B3640B619E900040359980258799 style="border:0px solid;"> <img src=cid:_2_0B61B7B00B619E900040359980258799 style="border:0px solid;">
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regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

From: Martin.Mitchell@admedsol.com

<Martin.Mitchell@admedsol.com>
Sent: Thursday, November 4, 2021 11:29 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>;
k211878@docs.fda.gov
Cc: (b)(4); (b)(4)
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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or open attachments unless you recognize the sender and know the content

is safe.

Hello Michele

Regarding the recent deficiency question on our medical device submission

which is currently under review with the FDA:

8. In Section 10 Device Description, (b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

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Hello Martin,

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Best,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

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Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D7BA8A.D3065620]<http://www.fda.gov/>

[cid:image002.jpg@01D7BA8A.D3065620]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D7BA8A.D3065620] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7BA8A.D3065620] <http://www.youtube.com/user/USFoodandDrugAdmin>
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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Wednesday, October 6, 2021 6:00 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: helen.topping@admedsol.com

Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Thank you again for your review. Our team are busy discussing the questions and we would definitely like to have a teleconference with the FDA. We're currently consolidating our understanding of the deficiencies and are determining what our potential questions to you would be. I hope to get the questions to you by Monday 11th

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at the latest.

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Additionally, I have a small question to allow us to predict timelines for this project.... regarding the FDA timeline I can see on the CCP tracker website that the FDA timeline is on day 70.

* Will FDA be sticking to the 90 day target and as a result only have 20 days left on the clock?

* Or, due to the current situation with the unprecedented resource limitations..... will you will assume 30 days to review the response as standard? Or perhaps stick to the 20 days but retain the right to add additional days?

Best regards,

Martin Mitchell

Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov<mailto:michele.lee@fda.hhs.gov>>

To: <martin.mitchell@admedsol.com<mailto:martin.mitchell@admedsol.com>>, <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>

Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov<mailto:michele.lee@fda.hhs.gov>>

Date: 04/10/2021 21:44

Subject: K211878/S001 is on Hold Pending Your Response

October 4, 2021

We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Michele Lee.

*** This is a system-generated email notification ***[attachment "K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

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Hello Martin,

Thanks for the update and good to know this information. I also received your previous email with additional information about the (b)(4) (b)(4). I am still waiting on feedback from our (b)(4) but hope to have more information to provide you mid next week.

Best,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

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[cid:image002.jpg@01D7DAF2.B871DE50]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D7DAF2.B871DE50] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7DAF2.B871DE50] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7DAF2.B871DE50] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D7DAF2.B871DE50]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Monday, November 15, 2021 3:54 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Subject: Fw: [EXTERNAL] K211878 timeline - COVID-19

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Hi Michele

I got an update regarding timeline from the CCP email address.

FYI we are exploring a number of backup strategies to resolve (b)(4) deficiencies.... and some of these take us past the 180 day hold period.

As per the request below, I'll let you know closer to the time if we end up needing to request the additional 180 days.

Best regards,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

----- Forwarded by Martin Mitchell/WIN/UK/AMS on 15/11/2021 08:31 -----

From: "CCP" <CCP@fda.hhs.gov<mailto:CCP@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Date: 12/11/2021 21:08

Subject: RE: [EXTERNAL] K211878 timeline - COVID-19

Good day to you Martin,

The extra 180 days for response are added as needed, and then only shortly before the original 180 days expires.

--

Happy trails,

~Nels Anderson

Regulatory Systems & Data Management Staff

Center for Devices and Radiological Health | Office of Product Evaluation and Quality| Office of Regulatory Programs

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From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com> <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Friday, November 12, 2021 09:49

To: CCP <CCP@fda.hhs.gov<mailto:CCP@fda.hhs.gov>>

Subject: [EXTERNAL] K211878 timeline - COVID-19

CAUTION:This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hello

Regarding the timeline showing for K211878 I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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However, I (and the lead reviewer Michele Lee) were under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify that the 180 timeline in the customer collaboration portal won't trigger premature closure of the 510(k) before the actual 360 day timeline expires?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

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Hi Mr. Martin:
Please address the following:

(b)(4)

Thx
Sam

Sam Arepalli, Ph.D.
FDA/CDRH/OPEQ/OHT4/PRSB2
Ph: 301 796 6434

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Hello (b)(4)

I have another meeting before that scheduled time. I can do a half hour earlier (6:30pm UTC+1) on Wednesday or a different time on another day next week?

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

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[cid:image002.jpg@01D7D235.67F10F70]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D7D235.67F10F70] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7D235.67F10F70] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7D235.67F10F70] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D7D235.67F10F70]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: (b)(4)>

Sent: Friday, November 5, 2021 11:02 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>; k211878@docs.fda.gov

Cc: (b)(4)

(b)(4)

Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Dear Michele,

many thanks for sending the invite.

I fear, IÂ´ve made a mistake, when communicating the time.

Could we schedule one hour earlier?

Kind regards.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Sent: Freitag, 5. November 2021 15:59

To: (b)(4); k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Cc: (b)(4)
(b)(4)

Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

This message is from an EXTERNAL SENDER â€" be CAUTIOUS, particularly with links and attachments

---

Hello (b)(4)

Sure, we can discuss via teleconference on 10 Nov 2021 at 7pm UTC+1/ 2pm EDT. I sent a ZoomGov invite via email and also copied the call-in information below.

[Image removed by sender.]<https://zoom.us/>

Hi there,

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov> is inviting you to a scheduled ZoomGov meeting.

Join Zoom

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Best Regards,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D7D235.67F10F70]<http://www.fda.gov/>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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[cid:image004.jpg@01D7D235.67F10F70] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7D235.67F10F70] <http://www.flickr.com/photos/fdaphotos/>
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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: (b)(4)

Sent: Friday, November 5, 2021 10:10 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Cc: (b)(4)
(b)(4);
Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Michele,

Many thanks for your message.

Martin, thank you for the connection.

Michele, would you be available next Wednesday, 10 November 2021, at 7 pm (UTC+1)?

Then I would send an invitation.

Kind regards.

(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Sent: Freitag, 5. November 2021 14:33

To: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Cc: (b)(4)

(b)(4)

(b)(4)

Subject: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

This message is from an EXTERNAL SENDER â€" be CAUTIOUS, particularly with links and attachments

---

Hello all,

Thank you, Martin, for the connection.

(b)(4)

Best Regards,

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D7D235.67F10F70]<http://www.fda.gov/>

[cid:image002.jpg@01D7D235.67F10F70]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D7D235.67F10F70] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7D235.67F10F70] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7D235.67F10F70] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D7D235.67F10F70]
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From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com> <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Thursday, November 4, 2021 11:29 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Cc: (b)(4)

(b)(4)

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

Regarding the recent deficiency question on our medical device submission which is currently under review with the FDA:

(b)(4)

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

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Hi Michele

Thank you for the offer. I think after today's meeting we may need a little more time to be better prepared for the teleconference.

We are reaching out to the (b)(4) for us as we feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible dates for you early next week.

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 06/10/2021 13:49
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference deadline up to October 19th. Let me know if you would like to select a date later than the 14th and I can check our management schedules.

Regarding review timelines, we are still on the 90 day review cycle and are planning to complete the review of your response with the 20 calendar days left on the clock. While we retain the right to add additional days, we are doing our best with the resources that we have to avoid delaying review timelines if possible.

Best,
Michele

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 6, 2021 6:00 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com
Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Thank you again for your review. Our team are busy discussing the questions and we would definitely like to have a teleconference with the FDA. We're currently consolidating our understanding of the deficiencies and are determining what our potential questions to you would be. I hope to get the questions to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we look to schedule a teleconference with the FDA on Wednesday 13th or Thursday 14th? As we're based in the UK we would appreciate a timeslot within our working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines for this project.... regarding the FDA timeline I can see on the CCP tracker website that the FDA timeline is on day 70.
Will FDA be sticking to the 90 day target and as a result only have 20

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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days left on the clock?

Or, due to the current situation with the unprecedented resource limitations..... will you will assume 30 days to review the response as standard? Or perhaps stick to the 20 days but retain the right to add additional days?

Best regards,

Martin Mitchell

Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>

To: <martin.mitchell@admedsol.com>, <helen.topping@admedsol.com>

Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>

Date: 04/10/2021 21:44

Subject: K211878/S001 is on Hold Pending Your Response

October 4, 2021

We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Michele Lee.

*** This is a system-generated email notification ***[attachment "K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

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Hi Sam

Firstly, thank you for staying late to continue to work with us on in the final stages of this submission. It is much appreciated.

Please find attached the IFU with updated comments from ourselves

For most of the proposed updates we will accept to make the changes.

However there are two points we would wish to clarify

Regarding the comment on using a (b)(4)

(b)(4)

As discussed I'll call you tomorrow to discuss your email below

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>,

"K211878@docs.fda.gov" <K211878@docs.fda.gov>

Date: 18/05/2022 20:39

Subject: RE: [EXTERNAL] Re: K211878-s002

Hi Mr. Mitchell:

Please see attached for the labeling and 510kSummary with FDA edits.

Please address these edits and send me both the edited versions and clean copies of the labeling and the 510kSummary by COB tomorrow (5-19-2022).

Please cc your response to K211878@docs.fda.gov.

Thx

Sam

Sam Arepalli, Ph.D.

FDA/CDRH/OPEQ/OHT4/PRSB2

Ph: 301 796 6434

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Tuesday, May 17, 2022 6:39 AM

To: Arepalli, Sambasiva <Sambasiva.Arepalli@fda.hhs.gov>

Subject: RE: [EXTERNAL] Re: K211878-s002

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Hi Sam

Just to be safe for the email trail.... so that your email has a response

The email with this information was send yesterday; however it is also provided again below:

Please find a response to the two points we discussed over the phone

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(b)(4)

Best regards,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Date: 17/05/2022 10:32

Subject: RE: [EXTERNAL] Re: K211878-s002

Hi Mr. Mitchell:

Can you please give an update on the revised labeling request? Could you please send the information cob today? Please give me a call when you have a minute.

Thx

Sam

Sam Arepalli, Ph.D.

FDA/CDRH/OPEQ/OHT4/PRSB2

Ph: 301 796 6434

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Monday, May 16, 2022 12:06 PM

To: Arepalli, Sambasiva <Sambasiva.Arepalli@fda.hhs.gov>

Subject: [EXTERNAL] Re: K211878-s002

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Hi Sam

Just so you're aware it's 17:00 now so i'll be heading home; however i'll

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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try to make myself available outside of hours so please don't hesitate to get in touch if you have any further questions.

Additionally i'll be working from home the next few days so I won't pick up calls from my office number you used previously.

If you have any further questions please email me or call me on my personal mobile number (b)(6)

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>

Cc: "K211878@docs.fda.gov" <K211878@docs.fda.gov>, Rose Guang/WIN/UK/AMS@ams, Helen Topping/WIN/UK/AMS@ams

Date: 16/05/2022 16:28

Subject: Re: K211878-s002

Hi Sam

Please find a response to the two points we discussed over the phone

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

As requested, the IFU has been revised with the updated warning

[attachment "IFU.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>, "K211878@docs.fda.gov" <K211878@docs.fda.gov>

Date: 16/05/2022 14:39

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Subject: K211878-s002

Hi Mr. Martin:

Please address the following:

(b)(4)

Thx

Sam

Sam Arepalli, Ph.D.

FDA/CDRH/OPEQ/OHT4/PRSB2

Ph: 301 796 6434

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Mitchell/WIN/UK/AMS]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

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Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Hello Martin,

Unfortunately, it is not possible for me to take on lead review of this submission. As previously mentioned, I am currently working in another Office within FDA and do not conduct premarket reviews of medical devices in my current role.

It is not uncommon for new lead reviewers to be assigned to submissions returning from hold. The internal documentation serves as a complete record of the previous interactions during prior review of a submission. If you have further questions regarding the review process for your submission, you may contact the Assistant Director for the Plastic Surgery Skin & Wound Devices Team, Dr. Julie Morabito (Julie.Morabito@fda.hhs.gov).

Best,
Michele

Michele Lee, Ph.D. *(she/her/hers)*
Regulatory Science Program Manager
Partnerships to Advance Innovation and Regulatory Science (PAIRS)

Center for Devices and Radiological Health
Office of Strategic Partnerships and Technology Innovation
Division of All Hazards Response, Science, and Strategic Partnerships
U.S. Food and Drug Administration
michele.lee@fda.hhs.gov



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https://www.research.net/s/cdrhcustomerservice?ID=7013&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Tuesday, April 5, 2022 8:31 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: k211878@docs.fda.gov; Rose.Guang@admedsol.com; Helen.Topping@admedsol.com
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele,

We have been pleased to have you as the lead reviewer for RTA review, technical review, and responses to deficiency discussions since July 2021, as well as having you for the review for our previous 510(k) submission of the same product.

(b)(4)

- Jun 2021 - We submitted K211878 in response the **(b)(4)**
- Oct 2021 - Further deficiencies were raised on the new K211878 submission

We currently have only 20 days of FDA review time left on our product and have been advised that we will now be assigned a new reviewer. As you can imagine this causing us a high level of concern given you have a detailed knowledge of our submissions and of the current outstanding questions. Our concern being that a new reviewer will not have the same detailed knowledge of our submission or of the outstanding questions and hence this may cause unnecessary further delay.

We have been very satisfied with the support we have received from yourself and we would ask that you remain on our file for the final 20 days if at all possible, or an explanation of why this is not possible with some reassurances that a new assessor will not cause unnecessary delays whilst they gain detailed knowledge of our file.

Your expedited response to this request would be appreciated.

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Cc: "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 25/03/2022 16:47
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

A new lead reviewer will not be assigned until a follow up submission is received. So there is currently not a primary contact unless there is an active submission under FDA review. All of our correspondence and the prior related review have been documented internally, so you can be assured that the history of the prior review and contact is available to the future lead reviewer.

Best,
Michele

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Friday, March 25, 2022 12:21 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

I've seen on the FDA customer collaboration portal that the time has automatically been added, but just thought it would be prudent to also inform you of the situation.

Could I ask who the primary contact is now? Will you be assisting or have any involvement with the review of our response?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 25/03/2022 15:59
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

I am sorry to hear about the cyber attack. I hope all is able to be resolved soon.

Thank you for the update. I am actually working in a different division within FDA and no longer the primary contact for this submission. I believe that the 180 days is automatically granted for responses to AINN hold but you can also confirm with the 510(k) Program staff (510k_Program@fda.hhs.gov, telephone: 301-796-5640) to make sure.

Best,
Michele

Michele Lee, Ph.D.*(she/her/hers)*
Regulatory Science Program Manager
Partnerships to Advance Innovation and Regulatory Science (PAIRS)

Center for Devices and Radiological Health
Office of Strategic Partnerships and Technology Innovation
Division of All Hazards Response, Science, and Strategic Partnerships
U.S. Food and Drug Administration
michele.lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Friday, March 25, 2022 11:28 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Hi Michele

I'd like to provide an update on our progress with responding to the deficiencies raised on K211878

We were on track to have a deficiency response submitted to the FDA by the 180 day hold period deadline of 2nd April 2022.

However, the organisation performing the (b)(4) have been affected by a (b)(4) As a result, they were unable to complete the testing by our targeted timeline.

Therefore, I just want to confirm that we are still intending to respond to the deficiencies, but we would need to use the second 180 day hold period granted to us through the COVID-19 situation.

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 08/11/2021 22:05
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thanks for your message. I'll need some time to review the teleconference minutes with my team and also obtain some feedback from our consulting toxicologist about the follow up questions. But I wanted to let you know I received your email and you may feel free to check in again next week.

I do have a clarification question about Follow Up Question (b)(4)

(b)(4)

Regarding the timeline clarification- I am also under the understanding that the COVID-19 guidance document you cited was still active and that would allow you an additional 180 days for the hold period. I have reached out to the 510(k) Staff multiple times to confirm and am still waiting on their response. Is there a customer service contact email for the customer collaboration portal specifically? You may try contacting them as well to have the date corrected on your end.

Thank you,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov



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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Friday, November 5, 2021 12:07 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

I hope you had a nice holiday!

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Following on from the teleconference we had a few actions to complete and get back to you with.

1) Teleconference minutes

Please find a draft of the the teleconference minutes below. Could you review and confirm if you require any changes made?

2) Follow-up questions on the teleconference discussion

As suggested during the teleconference there was the opportunity for a followup email clarification on a few minor points.

(b)(4)

The supporting information which provides further clarity on the questions above has been attached if required.

3) Timeline clarification as per previous email

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Thank you again for your assistance

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>, "Liu, Lixin" <Lixin.Liu@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 20/10/2021 22:43
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Michele

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Thank you for the prompt response to the clarifications! We'll take your points on board regarding future shelf life studies.

I do have a minor clarification question regarding our response timeline

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 20/10/2021 14:55
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you to you and your team for attending the teleconference yesterday. I wanted to follow up on two things I was discussing with my team:

(b)(4)

I will be on leave for the next two weeks and you may contact our team management (Lixin.Liu@fda.hhs.gov) if you have questions during that time.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/odmcustomerservice?ID=1624&S=E

From: Lee, Michele
Sent: Friday, October 15, 2021 4:47 PM
To: Martin.Mitchell@admedsol.com
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you for providing your questions in advance of the meeting. We look forward to discussing our responses with you next week.

Have a good weekend,
Michele

Michele Lee, Ph.D.

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Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov



* * * * *
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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Friday, October 15, 2021 12:00 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Please find the list of questions/clarifications attached below.

I hope you have a good weekend. I'm looking forwards to our discussion next week!

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 13/10/2021 22:35
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

I have scheduled the teleconference for next Tuesday October 19th at 9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour but our biocompatibility consultant/ team management needs to drop off for another call at 9:30am. Please send me the questions for discussion in advance of the meeting so that we can plan to discuss biocompatibility/ regulatory questions first before the relevant parties need to drop off.

Join Zoom Meeting
One tap mobile:
Meeting URL:
Meeting ID:
Passcode:
(b)(4)

Join by Telephone
For higher quality, dial a number based on your current location.
Dial:

Meeting ID:
Passcode:
(b)(4)
International numbers

Join from an H.323/SIP room system
H.323:

Meeting ID:
Passcode:
SIP:
Passcode:
(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Thanks,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
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Michele.Lee@fda.hhs.gov



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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 13, 2021 4:46 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Apologies Michele, one final thing I missed off my email... could you clarify how long the teleconference would be by default? Could we request 1 hour just incase some of the points end up taking longer to discuss?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 13/10/2021 20:35
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hi Michele

We're currently preparing our questions for the teleconference and will send these through in due course, however to assist with scheduling the relevant parties at FDA, I should let you know that we would definitely like to discuss the questions related to biocompatibility.

After discussion with the team we would like to request the teleconference on the Tuesday 19th October if that is possible? As we are based in the UK, we would also like to request that this is arranged between the hours of 2-5pm BST.

If this time slot is not available could you outline any alternative days/times which would be possible?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

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From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 08/10/2021 22:14
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hi Michele

Thank you for the offer. I think after today's meeting we may need a little more time to be better prepared for the teleconference.

We are reaching out to the **(b)(4)** for us as we feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible dates for you early next week.

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 06/10/2021 13:49
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference deadline up to October 19th. Let me know if you would like to select a date later than the 14thand I can check our management schedules.

Regarding review timelines, we are still on the 90 day review cycle and are planning to complete the review of your response with the 20 calendar days left on the clock. While we retain the right to add additional days, we are doing our best with the resources that we have to avoid delaying review timelines if possible.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov



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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 6, 2021 6:00 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com
Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Thank you again for your review. Our team are busy discussing the questions and we would definitely like to have a teleconference with the FDA. We're currently consolidating our understanding of the deficiencies and are determining what our potential questions to you would be. I hope to get the questions to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we look to schedule a teleconference with the FDA on Wednesday 13th or Thursday 14th? As we're based in the UK we would appreciate a timeslot within our working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines for this project.... regarding the FDA timeline I can see on the CCP tracker website that the FDA timeline is on day 70.

- Will FDA be sticking to the 90 day target and as a result only have 20 days left on the clock?
- Or, due to the current situation with the unprecedented resource limitations..... will you will assume 30 days to review the response as standard? Or perhaps stick to the 20 days but retain the right to add additional days?

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
To: <martin.mitchell@admedsol.com>, <helen.topping@admedsol.com>
Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
Date: 04/10/2021 21:44
Subject: K211878/S001 is on Hold Pending Your Response

October 4, 2021

We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Michele Lee.

*** This is a system-generated email notification ***[attachment "K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Advanced Medical Solutions Ltd

LiquiBand® XL (b)(4)

Traditional 510(k) Submission

June 2021

ADVANCED MEDICAL SOLUTIONS LIMITED
WESTERN WOOD WAY
LANGAGE SCIENCE PARK
PLYMOUTH
DEVON
PL7 5BG
U.K.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION 1.0: MEDICAL DEVICE USER FEE COVER SHEET (FORM 3601)

The Medical Device User Fee Cover Sheet required for this submission is provided on the next page.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Form Approved: OMB No. 0910-0511 Expiration Date: August 31, 2022. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/ucm370879.htm

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
ADVANCED MEDICAL SOLUTIONS LIMITED Premier Park, 33 Road One Winsford Industrial Estate Winsford Cheshire CW7 3RT GB	Adam Gregory 2.1 E-MAIL ADDRESS regulatory@admedsol.com 2.2 TELEPHONE NUMBER (include Area code) +441606-863500 2.3 FACSIMILE (FAX) NUMBER (Include Area code)
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)	

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] Real-Time (PMA, PMR, PDP)
[ ] De Novo Request	[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA [X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of your establishments have registered and paid the fee, or this is your first device and you will register and pay the fee within 30 days after entering into an operation that requires you to register and submit device listing information.)

[ ] NO (If you currently market a medical device and your establishment is required to register and submit device listing information, FDA will not accept your submission until you have paid all fees due to FDA. See http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates	[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paper Reduction Act (PRA) Staff

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

PRAStaff@fda.hhs.gov Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) 07-Jan-2021

Form FDA 3601 (08/19)

"Close Window" Print Cover sheet

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

SECTION 2.0: CDRH PREMARKET REVIEW SUBMISSION SHEET (FORM 3514)

The CDRH Premarket Review Submissions Sheet required for this submission is provided on the next page.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approved: OMB No. 0910-0120
Expiration Date: June 30, 2023
See PRA Statement on last page.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(If known)*
06/14/2021	(b)(4)	Not known

SECTION A — TYPE OF SUBMISSION

PMA & PDP
- ☐ Original
- ☐ Modular Submission
- ☐ Amendment
- ☐ Report (annual or PAS)
- ☐ Report Amendment
- ☐ Other:
  - ☐ Premarket Report (reprocessed SUD)
  - ☐ Licensing Agreement

PMA/PDP Supplement
- ☐ 180 day - PAS protocol or labeling change, location change, trade name change
- ☐ 180 day - Design or labeling change
- ☐ Special CBE
- ☐ Panel Track
- ☐ 30-day Notice
- ☐ Real-time Review
- ☐ Amendment to PMA/PDP Supplement

510(k)
- ☒ Original Submission:
  - ☒ Traditional
  - ☐ Special
  - ☐ Abbreviated
  - ☐ 3rd Party Traditional
  - ☐ 3rd Party Special
  - ☐ 3rd Party Abbreviated
  - ☐ Dual Track (Dual 510(k) and CLIA Waiver by Application)
- ☐ Amendment
- ☐ Supplement

CLIA

CLIA Categorization Record (CR)
- ☐ Original
- ☐ Amendment

CLIA Waiver by Application (CW)
- ☐ Original
- ☐ Amendment
- ☐ Supplement

Q-Submission
- ☐ Pre-Submission
- ☐ Informational Meeting
- ☐ Submission Issue Meeting
- ☐ Day 100 Meeting
- ☐ Agreement Meeting
- ☐ Determination Meeting
- ☐ Study Risk Determination
- ☐ Other *(Specify below)*

IDE
- ☐ Original IDE:
  - ☐ Amendment to Original IDE
- ☐ Supplement:
  - ☐ Amendment to Supplement
- ☐ Report:
  - ☐ Amendment to Report

HDE
- ☐ Original Submission
- ☐ Amendment to Original
- ☐ Report
- ☐ Report Amendment
- ☐ HDE Supplement:
  - ☐ 75-day Supplement
  - ☐ 30-day Notice
  - ☐ Special CBE
  - ☐ Amendment to Supplement

Class II Exemption Petition
- ☐ Original Submission
- ☐ Additional Information

Emergency Use Authorization
- ☐ Original
- ☐ Supplement
- ☐ Amendment
- ☐ Report

De Novo
- ☐ Original:
  - ☐ Direct
  - ☐ Post-NSE
- ☐ Amendment
- ☐ Supplement

Pre-Emergency Use Authorization
- ☐ Original
- ☐ Supplement
- ☐ Amendment

Other Submission
- ☐ 513(g)
- ☐ Appeal
- ☐ Other *(Briefly describe submission below)*

Expanded Access to Devices
- ☐ Compassionate Use Request **NOT associated with an IDE**
- ☐ Follow-up Report for Compassionate Use **NOT associated with an IDE**
- ☐ Emergency Use Follow-up Report **NOT associated with an IDE**

SECTION B — APPLICANT / SPONSOR

Company/Institution Name		Establishment Registration Number/FEI *(if known)*
Advanced Medical Solutions Limited		9617175
Street Address		**City**
Western Wood Way , Langage Science Park		Plymouth
State/Province	**ZIP/Postal Code**	**Country**
Devon	PL7 5BG	UK

Contact Name	Contact Title
Martin Mitchell	Senior Regulatory Affairs Associate
Division Name *(if applicable)*	**Phone Number *(including area code)***
	00 44 1752 309360
Fax Number *(including area code)*	**Contact Email Address**
00 44 1752 209956	martin.mitchell@admedsol.com

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SECTION C OFFICIAL CORRESPONDENT (e.g., may be a consultant and/or 510(k) Third Party) (if different from Section B)

Company/Institution Name		Establishment Registration Number/FEI *(if known)*
Street Address		City
State/Province	ZIP/Postal Code	Country

Contact 1 Name	Contact 1 Title
Contact 1 Division Name *(if applicable)*	Contact 1 Phone Number *(including area code)*
Contact 1 Fax Number *(including area code)*	Contact 1 Email Address
Contact 2 Name	Contact 2 Title
Contact 2 Division Name *(if applicable)*	Contact 2 Phone Number *(including area code)*
Contact 2 Fax Number *(including area code)*	Contact 2 Email Address
Contact 3 Name	Contact 3 Title
Contact 3 Division Name *(if applicable)*	Contact 3 Phone Number *(including area code)*
Contact 3 Fax Number *(including area code)*	Contact 3 Email Address

To add another set of Section C items, please click on the button to the right. May be repeated as needed. Add Section C

SECTION D INTENDED USE POPULATION

Check all that apply.

- ☐ Adults Only (greater than 21 years of age)
- ☐ Adults and Pediatrics
- ☐ Neonate/Newborn (birth through 28 days)
- ☐ Infant (from 29 days to 2 years of age)
- ☐ Child (from 2 years to 12 years of age)
- ☐ Adolescent (from 12 years to 18 years of age)
- ☐ Transitional Adolescent A (18 through 21 years of age)
- ☐ Transitional Adolescent B (18 through 21 years of age)
- ☒ Other *(Specify below)*

No limit on use in terms of intended use. However, as per ISO-10993 the safety assessment has been assessed from adult down to 10kg child.

SECTION E PRODUCT INFORMATION – APPLICABLE TO ALL SUBMISSIONS

	Trade Name
1	LiquiBand XL
2	
3	
4	
5	
	Common/Generic Name *(Include if no Trade Name)*

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SECTION F PRIOR RELATED SUBMISSIONS FOR THIS DEVICE OR STUDY

FDA document numbers of all prior related submissions *(regardless of outcome)* or state no prior submission in box 1.

1 (b)(4)	2 (b)(4)	3
4	5	6
7	8	9
10	11	12

SECTION G PRODUCT CLASSIFICATION – APPLICABLE TO ALL SUBMISSIONS

Product Code(s) *(when applicable) (If more than one, please separate with commas.)*

OMD

C.F.R. Section *(If applicable)*	Classification Panel/Medical Specialty
878.4011	General & Plastic Surgery

Device Class

☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

SECTION H1 REASON FOR APPLICATION – PMA, PDP, OR HDE

☐ New Device
☐ STED

☐ Post-approval Study Protocol

☐ HDE Request for Annual Distribution Number (ADN)

☐ Change in Design, Component, or Specification:
- ☐ Software/Hardware
- ☐ Color Additive
- ☐ Material
- ☐ Specifications
- ☐ Other *(Specify below)*

☐ Location Change:
- ☐ Manufacturer
- ☐ Sterilizer
- ☐ Packager

☐ Report Submission:
- ☐ Annual or Periodic
- ☐ Post-approval Study

☐ Process Change:
- ☐ Manufacturing
- ☐ Packaging
- ☐ Sterilization
- ☐ Vendor/Supplier Change
- ☐ Other *(Specify below)*

☐ Labeling Change:
- ☐ Indications
- ☐ Instructions
- ☐ PAS update
- ☐ Performance Characteristics
- ☐ Shelf Life
- ☐ Trade Name
- ☐ Other *(Specify below)*

☐ Amendment:
- ☐ Withdrawal
- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Address
- ☐ Request for Extension
- ☐ Response to FDA Correspondence
- ☐ Other *(Specify below)*

☐ Bundle Submission – *If this is selected, list in the spaces below any PMAs in the Bundle.*

1	2	3
4	5	6
7	8	9

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SECTION H2 REASON FOR APPLICATION – IDE

☐ Original IDE

☐ Supplement:
- ☐ New Study/New Protocol
- ☐ Change in Correspondent
- ☐ Change in Manufacturer
- ☐ Change in Sponsor
- ☐ Change in Design
- ☐ Change in Informed Consent
- ☐ Change in Manufacturing
- ☐ Change in Protocol
- ☐ 5-Day Notice – Device or Manufacturing
- ☐ 5-Day Notice – Protocol
- ☐ Compassionate Use Request (under an IDE)
- ☐ Live Case Request
- ☐ Request Deviation from Protocol
- ☐ Expansion of Study (Study/Sites)
- ☐ Extension of Time to Submit Annual Report or Respond to FDA Letter

Supplement *(Continued)*
- ☐ Request for Waiver
- ☐ IRB Certification
- ☐ Request for CMS Recategorization
- ☐ Study Resumed
- ☐ Study Suspension
- ☐ Other *(Specify below)*

☐ Report:
- ☐ Adverse Effect
- ☐ Final, Study Completed
- ☐ Annual Progress
- ☐ Interim Progress
- ☐ Semiannual Investigator List
- ☐ Failure to Obtain Informed Consent
- ☐ Compassionate Use Follow-up
- ☐ Emergency Use
- ☐ Live Case Follow-up
- ☐ Completion of Patient Enrollment
- ☐ Completion of Patient Follow-up
- ☐ Other *(Specify below)*

☐ Amendment to Original IDE:
- ☐ Amendment Before Final Decision
- ☐ Response to Refuse to Accept
- ☐ Response to Disapproval
- ☐ Response to Approval with Conditions
- ☐ Withdrawal
- ☐ Other *(Specify below)*

☐ Amendment to Supplement:
- ☐ Response to Disapproval
- ☐ Response to Approval with Conditions
- ☐ Withdrawal
- ☐ Amendment Before Final Decision (additional Information)
- ☐ Other *(Specify below)*

☐ Amendment to Report:
- ☐ Response to Deficiency Letter
- ☐ Withdrawal
- ☐ Amendment Before Final Decision (additional Information)
- ☐ Other *(Specify below)*

SECTION H3 REASON FOR SUBMISSION – Q-SUBMISSION

☐ Pre-Submission:
- ☐ Request Face-to-Face Meeting
- ☐ Request Teleconference
- ☐ Request Email Response
- ☐ Submit Meeting Minutes
- ☐ Request Meeting Minutes Disagreement T-con

☐ Submission Issue Meeting:
- ☐ Request Face-to-Face Meeting
- ☐ Request Teleconference
- ☐ Request Email Response
- ☐ Submit Meeting Minutes
- ☐ Request Meeting Minutes Disagreement T-con

☐ Additional Information

☐ Change in Legal Entity:
- ☐ Change in Correspondent
- ☐ Change in Sponsors
- ☐ Change in Manufacturer
- ☐ Other *(Specify below)*

☐ Agreement Meeting:
- ☐ Request Face-to-Face Meeting
- ☐ Request Teleconference

☐ Determination Meeting:
- ☐ Request Face-to-Face Meeting
- ☐ Request Teleconference

☐ Informational Meeting:
- ☐ Request Face-to-Face Meeting
- ☐ Request Teleconference
- ☐ Submit Meeting Minutes
- ☐ Request Meeting Minutes Disagreement T-Con

☐ Other *(Specify)*:

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SECTION H4 REASON FOR SUBMISSION – 510(k)

- [x] Original
- [ ] Withdrawal of Original
- [ ] Amendment Before Final Decision:
  - [ ] Change in Ownership
  - [ ] Change in Correspondent
  - [ ] Withdrawal
- [ ] Amendment After Final Decision
- [ ] Supplement:
  - [ ] Response to Refuse to Accept (RTA)
  - [ ] Response to Additional Information Request
  - [ ] Withdrawal
- [ ] Reprocessed SUD
- [ ] Corrective Action
- [ ] STED
- [ ] Third Party *(Complete Section C)*
- [ ] Other Reason *(Specify)*:

Information on devices to which substantial equivalence is claimed *(If known)*

	510(k) Number	*Trade Name*	*Submitter*	*Product Code*
Primary Predicate (A)	K191461	Exofin Fusion Skin Closure System	Chemence Medical, Inc	OMD
Predicate or Reference Device (B)	K183570	LiquiBand Plus	Advanced Medical Solutions Limited	MPN

To add another Predicate or Reference Device (B) entry row, please click on the button to the right. May be repeated as needed. Add Device Information

SECTION H5 DE NOVO SUBMISSIONS

- [ ] Post NSE De Novo: Number of the 510(k) that was NSE'd in the past 30 days:
- [ ] Withdrawal

SECTION H6 REASON FOR APPLICATION – CLIA

Includes CLIA Parent Document number, CR number, or CW number.

- [ ] **CLIA Categorization Record (CR):**
  - [ ] CLIA Categorization of marketed device (include marketing submission number)
  - [ ] CLIA Categorization of device exempt from premarket review
  - [ ] Additional information regarding an open CR (include CR number)
- [ ] **CLIA Waiver by Application (CW):**
  - [ ] Request for CLIA Waiver by Application for marketed device (include marketing submission number)
  - [ ] Request for Dual 510(k) Clearance and CLIA Waiver by Application (include Pre-submission number)
  - [ ] Response to FDA correspondence
  - [ ] Additional information regarding an open CW (include CW number)
- [ ] **Other Reason** *(Specify)*

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SECTION I MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

Applicable only to IDEs

Note: Submission of this information does not affect Registration and Listing.	FDA Document Number *(if known)*

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager/Relabeler

Company/Institution Name		Establishment Registration Number/FEI *(if known)*
Street Address		City
State/Province	ZIP/Postal Code	Country

Contact 1 Name	Contact 1 Title
Contact 1 Division Name *(if applicable)*	Contact 1 Phone Number *(including area code)*
Contact 1 Fax Number *(including area code)*	Contact 1 Email Address

Contact 2 Name	Contact 2 Title
Contact 2 Division Name *(if applicable)*	Contact 2 Phone Number *(including area code)*
Contact 2 Fax Number *(including area code)*	Contact 2 Email Address

Contact 3 Name	Contact 3 Title
Contact 3 Division Name *(if applicable)*	Contact 3 Phone Number *(including area code)*
Contact 3 Fax Number *(including area code)*	Contact 3 Email Address

To add another set of Section I items, please click on the button to the right. May be repeated as needed. Add Section I

SECTION J UTILIZATION OF STANDARDS

Note: Please see guidance document titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices" for details on the Declaration of Conformity.

How to fill out this section:

Recognition Number: State the FDA recognition number. If the standard is not recognized, write **NR**.

Declaration of Conformity or General Use: Select 'Declaration of Conformity' if including a "Declaration of Conformity to a Recognized Standard" statement. For all other uses, select 'General Use' and indicate if you have made deviations from the Recognized/Non-recognized standard.

Standard: State the Standards Development Organization (SDO), the Designation Number (including year), and the Title.

Location: State the section and/or the page number(s) in the submission where the standard is applied.

Examples

	Recognition Number	Declaration of Conformity or General Use		Standards Development Organization (SDO), Designation Number-Year, and Title	Location
1 X	8-185	Declaration of Conformity	*If General Use*, Deviation?	ASTM F451-08, standard specification for acrylic bone cement.	Section 3, p. 15
2 X	3-44	General Use	*If General Use*, Deviation? Yes	AAMI ANSI BP22:1994 (R) 2011 Blood Pressure Transducers	Section 4, p. 32

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Entries for Utilization of Standards

	Recognition Number	Declaration of Conformity or General Use		Standards Development Organization (SDO), Designation Number-Year, and Title	Location
1 X	14-340	General Use	*If General Use*, Deviation? No	ISO 20857:2010 - Sterilization of health care products - Dry heat - Requirements for the development, validation and routine control of	Sec. 14.2.1, Page 13-1
2 X	14-529	General Use	*If General Use*, Deviation? No	ISO 11135:2014 - Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine co	Sec. 14.2.2, Page 14-2
3 X	14-408	General Use	*If General Use*, Deviation? No	ISO 10993-7:2008 - Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals [Including: Technical Corrig	Sec. 14.2.2, Page 14-2
4 X	2-258	General Use	*If General Use*, Deviation? No	ISO 10993-1:2018 - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	Sec. 15.1, Page 15-1
5 X	2-245	General Use	*If General Use*, Deviation? No	ISO 10993-5:2009 - Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	Sec. 15.3, Page 15-3
6 X	2-174	General Use	*If General Use*, Deviation? No	ISO 10993-10:2010 - Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Sec. 15.3, Page 15-3
7 X	2-255	General Use	*If General Use*, Deviation? No	ISO 10993-11:2017 - Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	Sec. 15.3, Page 15-4
8 X	8-114	General Use	*If General Use*, Deviation? Yes	ASTM F2255-05 - Standard Test Method for Strength Properties of Tissue Adhesives in Lap Shear by Tension Loading	Sec. 18.4, Page 18-5
9 X	8-115	General Use	*If General Use*, Deviation? Yes	ASTM F2256-05 - Standard Test Method for Strength Properties of Tissue Adhesives in T-Peel by Tension Loading	Sec. 18.5, Page 18-6
10 X	8-116	General Use	*If General Use*, Deviation? Yes	ASTM F2258-05 - Standard Test Method for Strength Properties of Tissue Adhesives in Tension	Sec. 18.6, Page 18-7
11 X	8-136	General Use	*If General Use*, Deviation? Yes	ASTM F2458-05 - Standard Test Method for Wound Closure Strength of Tissue Adhesives and Sealants	Sec. 18.7, Page 18-8
12 X	NR	General Use	*If General Use*, Deviation? Yes	ASTM D3330/D3330M-04 - Standard Test Method for Peel Adhesion of Pressure-Sensitive Tape	Sec. 18.1, Page 18-1
13 X	NR	General Use	*If General Use*, Deviation? Yes	ASTM D3654/D3654M-06 - Standard Test Methods for Shear Adhesion of Pressure-Sensitive Tapes	Sec. 18.2, Page 18-2
14 X	10-87	General Use	*If General Use*, Deviation? Yes	ASTM D882-12, Standard Test Methods for Tensile Properties of Thin Plastic Sheeting	Sec. 18.3, Page 18-3
15 X	2-276	General Use	*If General Use*, Deviation? No	ISO 10993-18:2020 - Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a ri	Sec. 15.3, Page 15-4

To add another row for Section J, please click on the button to the right. May be repeated as needed.
(To remove a particular row, please click on the "X" button at the beginning of the row.)

Add Row/Standard

SECTION K UTILIZATION OF CDRH GUIDANCE DOCUMENTS

How to fill out this section:

Title: Enter the title of the guidance documents used in the preparation of your premarket submission. CDRH guidance documents can be found at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*.

Entries for Utilization of CDRH Guidance Documents

	Title of Guidance Document
1 X	Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
2 X	Tissue Adhesive with Adjunct Wound Closure Device Intended for the Topical Approximation of Skin - Class II Special Controls Guidance for Industry and FDA Staff.

To add another row for Section K, please click on the button to the right. May be repeated as needed.
(To remove a particular row, please click on the "X" button at the beginning of the row.)

Add Row/Document

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This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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SECTION 3.0: 510(K) COVER LETTER

The 510(k) cover letter required for this submission is provided on the next page.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Advanced Medical Solutions Ltd
Western Wood Way,
Langage Science Park,
Plympton, Plymouth,
Devon, PL7 5BG, UK
Tel : +44 (0)1752 209955 **Fax :** +44 (0)1752 209956
Web : www.admedsol.com

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center (DCC) – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
USA

Dear Sir/Madam,

Advanced Medical Solutions Limited (AMS) hereby submits this 510(k) Notification for the "LiquiBand® XL **(b)(4)** device in which it is demonstrated that it is substantially equivalent to the predicate "Exofin Fusion Skin Closure System" which was cleared under K191461. This is a new device and as such we have opted to submit this through the traditional 510(k) route.

(b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Advanced Medical Solutions Ltd

Advanced Medical Solutions Ltd
Western Wood Way,
Langage Science Park,
Plympton, Plymouth,
Devon, PL7 5BG, UK
Tel : +44 (0)1752 209955 **Fax :** +44 (0)1752 209956
Web : www.admedsol.com

Administrative Information

510(k) type:	Traditional
Device type:	Cutaneous Tissue Adhesive With Mesh
Confidentiality:	AMS Ltd considers the intent to market this device as confidential commercial information and request that it be treated as such by the FDA. AMS Ltd has taken precautions to protect the confidentiality of the intent to market the subject device. We understand the submission of false information is prohibited by 10 U.S.C. 1001 and 21 U.S.C. 331(q).
Regulatory Classification:	21 CFR 878.4011 – Tissue adhesive with adjunct wound closure device for topical approximation of skin
Device Class:	Class II
Panel	General and plastic surgery devices
Product Code:	OMD – Cutaneous tissue adhesive with mesh
FDA document numbers associated with prior formal correspondence	**(b)(4)**

Primary Correspondent Information

510(k) submitter	Advanced Medical Solutions Limited
Name	Martin Mitchell
Title	Senior Regulatory Affairs Associate
Phone number	+44 (0) 1752 30 9360
Email address	Martin.Mitchell@admedsol.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Advanced Medical Solutions Ltd

Advanced Medical Solutions Ltd
Western Wood Way,
Langage Science Park,
Plympton, Plymouth,
Devon, PL7 5BG, UK
Tel : +44 (0)1752 209955 **Fax :** +44 (0)1752 209956
Web : www.admedsol.com

Design and Use of the Device

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	✓	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		✓
Does the device contain components derived from a tissue or other biologic source?		✓
Is the device provided sterile?	✓	
Is the device intended for single use?	✓	
Is the device a reprocessed single use device?		✓
If yes, does this device type require reprocessed validation data?		N/A
Does the device contain a drug?		✓
Does the device contain a biologic?		✓
Does the device use software?		✓
Does the submission include clinical information?		✓
Is the device implanted?		✓

All of the information necessary for a substantial equivalence determination is included herein. In accordance with 745A(b)(3) of the FD&C Act, this submission has been provided solely in electronic format on a CD.

Thank you in advance for your consideration of our application and if you should you require any additional data in order to reach a determination of substantial equivalence, please do not hesitate to contact me at the contact information provided.

Sincerely,

(b)(6)

14-JUNE-2021

Martin Mitchell
Senior Regulatory Affairs Associate

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SECTION 4.0: INDICATIONS FOR USE STATEMENT

The Indications for use statement for LiquiBand® XL (b)(4) described in this submission is provided on the next page.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

(b)(4)

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SECTION 5.0: 510(K) SUMMARY

The 510(k) Summary is provided on the next page.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION 6.0: TRUTHFUL AND ACCURACY STATEMENT

As required by 21 CFR 807.87 (k), the Truthful and Accuracy Statement is provided on the next page.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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TRUTHFUL AND ACCURRACY STATEMENT

I certify that in my capacity as Regulatory Affairs Associate of Advanced Medical Solutions Limited, I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

Name	Martin Mitchell
Title	Senior Regulatory Affairs Associate
Company	Advanced Medical Solutions Limited
Signature	(b)(6)
Date	16 – JUNE – 2021

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION 7.0: CLASS III SUMMARY AND CERTIFICATION

A Class III certification summary is not required as the LiquiBand® XL (b)(4) device described in this submission is a Class II device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

SECTION 8.0: FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT

A financial certification or disclosure is not required for this Traditional 510(k) Premarket Notification because this submission does not contain a clinical study.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION 9.0: DECLARATIONS OF CONFORMITY AND SUMMARY REPORTS

This section does not apply, as this submission is not an Abbreviated 510(k).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION 10.0: DEVICE DESCRIPTION

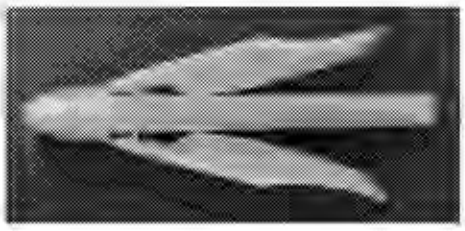
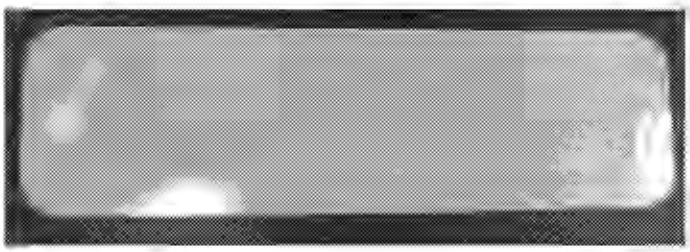
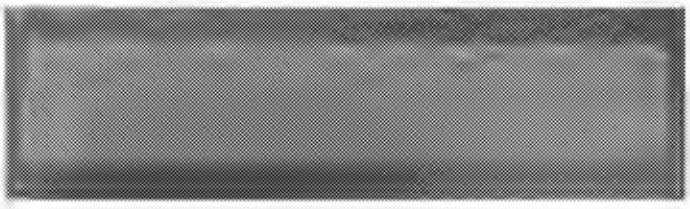
10.1 Device Name and Classification

Common or Usual Name:	Cutaneous Tissue Adhesive with Mesh
Proprietary Name:	LiquiBand® XL (b)(4)
Classification Name:	Tissue adhesive with adjunct wound closure device for topical approximation of skin (21 CFR 878.4011)
Classification Panel:	General and Plastic Surgery Devices Panel
Product Code:	OMD
Class:	II

10.2 Device Description

LiquiBand® XL (b)(4) is comprised of two components an applicator (which dispenses an adhesive) and a mesh.

Representative images of these components are provided below:

Adhesive applicator		
Mesh	Within release liner	
	Removed from release liner	

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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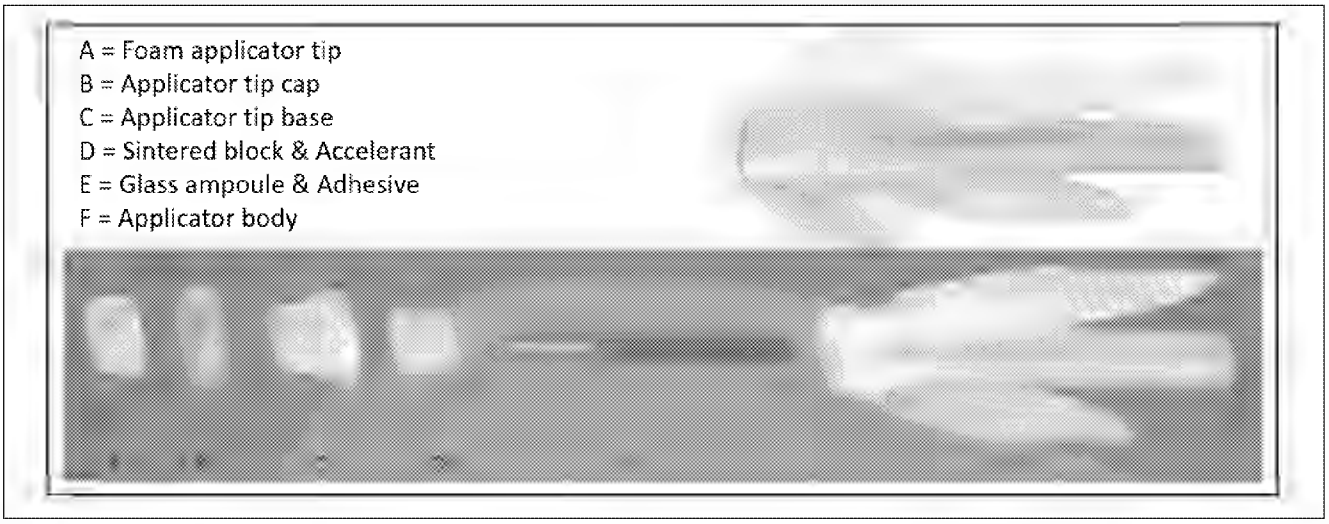
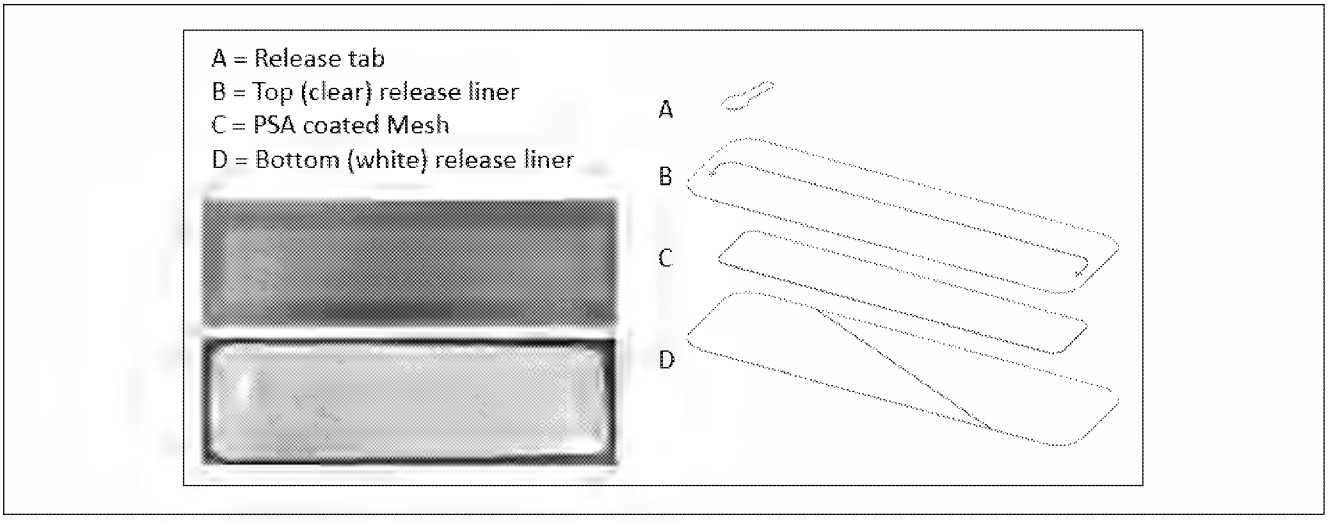
(b)(4)

A breakdown of the parts used within the adhesive applicator are provided below:



LiquiBand® XL (b)(4) also incorporates a mesh with a pressure sensitive adhesive coating that is applied to the approximated skin edges to provide temporary skin edge alignment until the liquid adhesive is applied to achieve skin closure.

A breakdown of the parts used within the mesh (and it's protective release liners) are provided below:



(b)(4)

During use, the mesh is applied to the approximated skin edges to provide temporary skin edge alignment. The applicator device is activated by squeezing the wings which compresses the body, which 'crushes' the ampoule held within the body of the applicator. Once activated, further squeezing of the wings expresses

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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the adhesive through the applicator tip in a controlled manner. The adhesive is applied along the length of the mesh, creating an even layer of adhesive which polymerizes and holds the mesh in place.

There are three variants of the device which are summarised below.

Product code	Components	Incision length
72014019	2 skin closure systems (each system comprises of 1 mesh and 1 applicator)	for incisions up to 20cm in length (contains 1 mesh for up to 1 x 20cm incision)
72014027	2 skin closure systems (each system comprises of 2 meshes and 2 applicators)	for incisions up to 20cm in length (contains 2 meshes for up to 2 x 20cm incisions)
72014046	2 skin closure systems (each system comprises of 3 meshes and 3 applicators)	for incisions up to 20cm in length (contains 3 meshes for up to 3 x 20cm incisions)

10.3 Mechanism of Action

The mesh component is coated with a pressure sensitive adhesive, which allows the mesh to bond to the tissue through the application of pressure.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

10.4 Composition of the cyanoacrylate based adhesive formulation

(b)(4)

Detailed information on each of the above components follows in the table below. Material Safety Data Sheets for the finished product and each compound are provided in Appendix A.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

10.5 Material characteristics of the adhesive

A summary of the material characteristic of the adhesive (in glass ampoule) is provided in the table below.

Material characteristic	Information
Viscosity	(b)(4)
Purity and analysis of residual content	
Moisture content	
Setting time	
Pyrogenicity	
Sterility	
Tensile strength of the adhesive	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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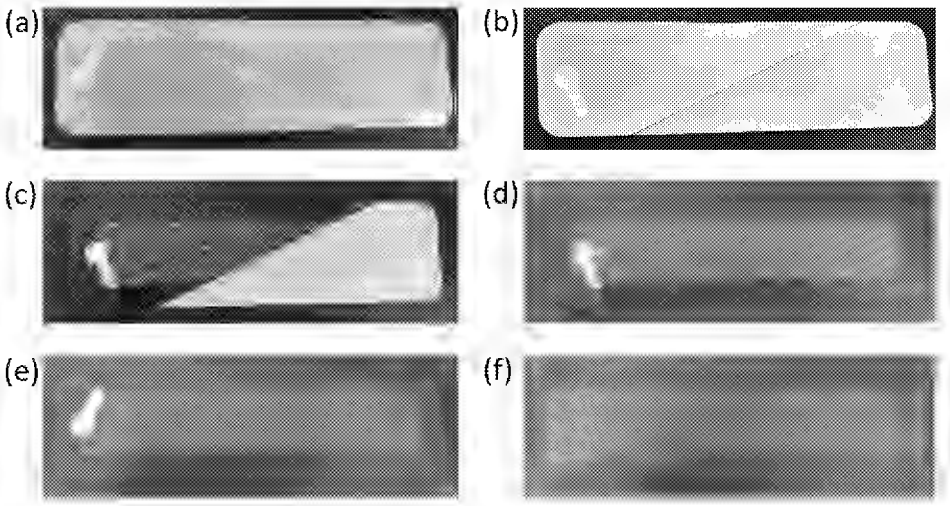
10.6 Material characteristics of the adjunct wound closure device

Material characteristics of the adjunct wound closure device are provided in the table below.

Appearance	 (a) Top side: showing the clear relase liner and the attached white release tab (b) Bottom side: showing the two segments of the white release liner (c) Bottom side: showing one segment of the white release liner removed, partially exposing the PSA coated side of the mesh (d) Bottom side: showing both segments of the white release liner removed, fully exposing the PSA coated side of the mesh (e) Top side: showing the clear release liner and the attached white release tab; with the PSA coated side of the mesh facing down to bond to enable bonding to the surface (f) Top side: showing removal of the clear release liner with the mesh bonded to the surface
Description	Polyester mesh hexagonal weaved mesh pressure sensitve adhesve (PSA) coating. The PSA coating is applied in a linear diagonal pattern which alternates between 3mm PSA coating and 5mm uncoated mesh
Dimensions	22 x 4 cm
Pyrogenicy **Peel tensile strength testing** **Sterility** **Regulatory staus**	**(b)(4)**
Construction	• Top (clear) relase liner with (white) release tab • Knitted polyester mesh with striped coating of pressure sensitive adhesive • Bottom (white) release liner

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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A summary of the components used in the adjunct wound closure device is provided in the table below. Technical data sheets and Certificates of conformity for the mesh components and the final manufactured adjunct wound closure device are provided in Appendix A.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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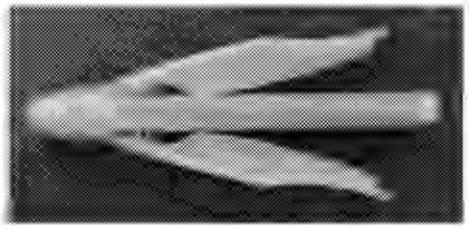
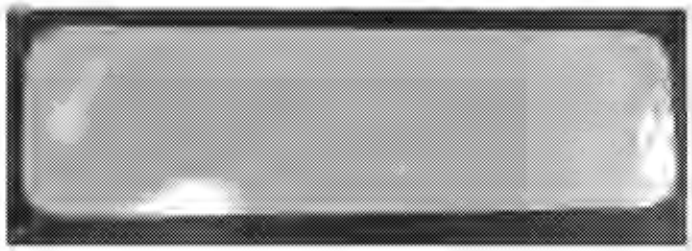
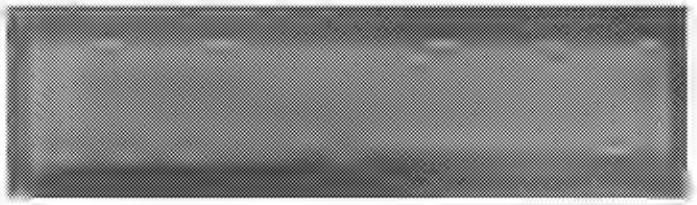
SECTION 11.0: EXECUTIVE SUMMARY / PREDICATE COMPARISON

11.1 Device Description

LiquiBand® XL (b)(4) is comprised of two components an applicator (which dispenses an adhesive) and a mesh.

Representative images of these components are provided below:

Adhesive applicator		
Mesh	In release liners	
	Removed from release liner	

The liquid topical skin adhesive is comprised of a monomeric (2-octyl cyanoacrylate) formulation and the colourant D&C Violet #2. It is contained within a glass ampoule which serves as a sterile barrier. The (b)(4)

This glass ampoule is housed within an applicator body with an attached applicator tip. The applicator tip consists of a hard plastic base which filters out glass particles and this is covered by a foam tip which assists in the application of the adhesive.

Inset into the applicator tip is a sintered block which contains an accelerant formulation which aids the polymerization of the adhesive as it is expressed through the sintered block and then through the applicator tip.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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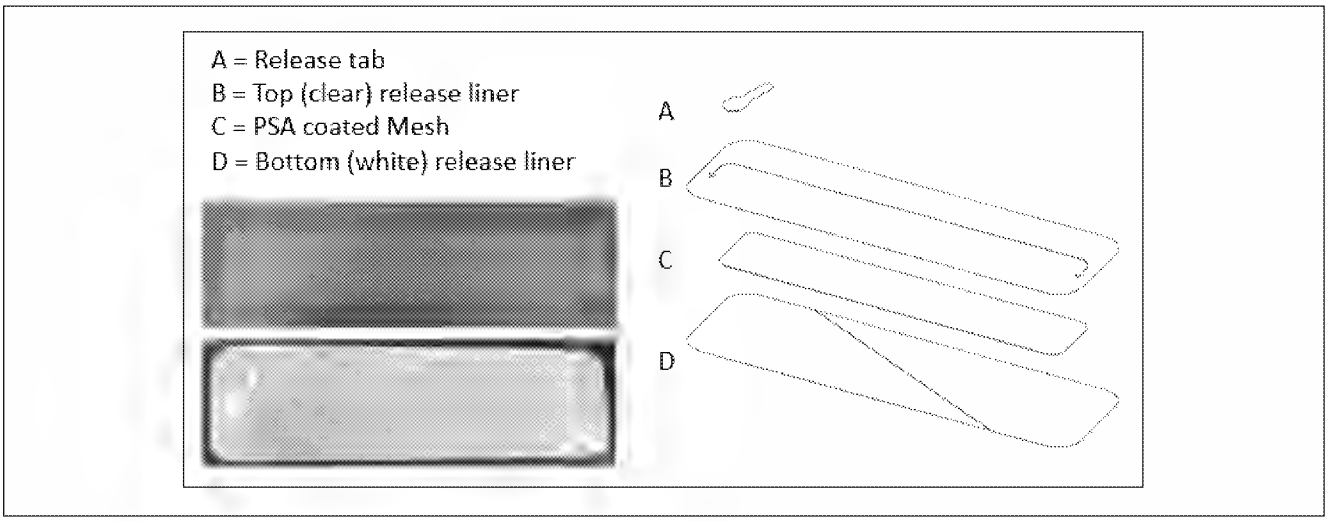
A breakdown of the parts used within the adhesive applicator are provided below:



LiquiBand® XL (b)(4) also incorporates a mesh with a pressure sensitive adhesive coating that is applied to the approximated skin edges to provide temporary skin edge alignment until the liquid adhesive is applied to achieve skin closure.

A breakdown of the parts used within the mesh (and it's protective release liners) are provided below:



The applicator and mesh are packaged within a paper/polyethylene pouch which serves as the sterile barrier (b)(4)

During use, the mesh is applied to the approximated skin edges to provide temporary skin edge alignment. The applicator device is activated by squeezing the wings which compresses the body, which 'crushes' the ampoule held within the body of the applicator. Once activated, further squeezing of the wings expresses the adhesive through the applicator tip in a controlled manner. The adhesive is applied along the length of the mesh, creating an even layer of adhesive which polymerizes and holds the mesh in place.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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There are three variants of the device which are summarised below.

Product code	Components	Incision length
72014019	2 skin closure systems (Each system comprises of 1 mesh and 1 applicator)	for incisions up to 20cm in length (contains 1 mesh for up to 1 x 20cm incision)
72014027	2 skin closure systems (Each system comprises of 2 meshes and 2 applicators)	for incisions up to 20cm in length (contains 2 meshes for up to 2 x 20cm incisions)
72014046	2 skin closure systems (Each system comprises of 3 meshes and 3 applicators)	for incisions up to 20cm in length (contains 3 meshes for up to 3 x 20cm incisions)

11.2 Device Comparison Table

A comparison of the subject and predicate device is provided below:

Manufacturer	Advanced Medical Solutions Ltd	Chemence Medical Inc
Device name	LiquiBand® XL (b)(4)	Exofin Fusion Skin Closure System
Device type and clearance number	Subject device	Primary predicate device (K191461)
Indications for use	• The Skin Closure System is intended for topical application only to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, and simple, thoroughly cleansed, trauma-induced lacerations. • The Skin Closure System should be used in conjunction with, but not in place of, deep dermal stitches. Additionally, the adjunct wound closure device component maintains temporary skin edge alignment along the length of the wound during application of the liquid adhesive.	Same
Product range	• **72014019**: Contains 2 skin closure systems (Each system comprises of 1 mesh and 1 applicator) for incisions up to 20cm in length • **72014027**: Contains 2 skin closure systems (Each system comprises of 2 meshes and 2 applicators) for incisions up to 20cm in length • **72014046**: Contains 2 skin closure systems (Each system comprises of 3 meshes and 3 applicators) for incisions up to 20cm in length	• **EF70401**: Contains 2 skin closure systems (Each system comprises of 1 mesh and 2 applicators) for incisions up to 20cm in length • **EF70430**: Contains 2 skin closure systems (Each system comprises of 2 meshes and 2 applicators) for incisions up to 28cm in length • **EF70466**: Contains 2 skin closure systems (Each system comprises of 2 meshes and 3 applicators) for incisions up to 58cm in length

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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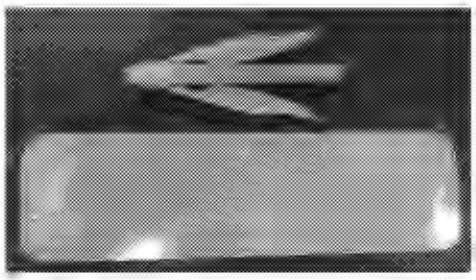
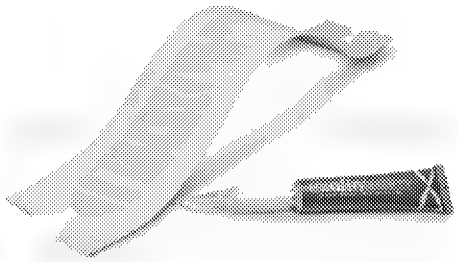
Representative device image		
Adhesive formulation	2-octyl cyanoacrylate adhesive with D&C Violet #2 colorant	2-octyl cyanoacrylate adhesive with D&C Violet #2 colorant
Accelerant formulation & design	(b)(4)	
Applicator material and design	Glass ampoule contained within a plastic applicator with foam tip	Aluminium tube with silicone tip
Mesh	Polyester mesh with pressure sensitive adhesive coating.	Polyester mesh with accelerant and pressure sensitive adhesive coating
Sterile barrier packaging material	Paper/poly pouch	Blister pack

Refer to Section 12 for a more detailed comparison between the subject and predicate device.

11.3 Performance Testing

Product testing has been performed in accordance with the FDA guidance document: Class II Special Controls Guidance Document: Tissue Adhesive with Adjunct Wound Closure Device Intended for the Topical Approximation of Skin, issued Nov 2010. Refer to section 18 and 19 for the details of the testing. A brief summary of the results are provided below:

510(k) Section	Test
18.1	ASTM D3330 / D3330M – 04 Standard Test Method for Peel Adhesion of Pressure-Sensitive Tape
18.2	ASTM D3654 / D3654M – 06 Standard Test Methods for Shear Adhesion of Pressure-Sensitive Tapes
18.3	ASTM D882 – 12 Standard Test Method for Tensile Properties of Thin Plastic Sheeting

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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		effective for its intended use.
18.4	ASTM F2255-05 Standard Test Method for Strength Properties of Tissue Adhesives in Lap-Shear by Tension Loading	(b)(4)
18.5	ASTM F2256-05 Standard Test Method for Strength Properties of Tissue Adhesives in T-Peel by Tension Loading	
18.6	ASTM F2258-05 Standard Test Method for Strength Properties of Tissue Adhesives in Tension	
18.7	ASTM F2458-05 Standard Test Method for Wound Closure Strength in Tissue Adhesives and Sealants	
18.8	Degradation Rate	
18.9	Heat of Polymerization	
18.10	Force to actuate and express	
18.11	Viscosity	
18.12	Polymerisation Set Time	
18.13	Microbial barrier testing	
18.14	Quality of Adhesive Film on Mesh	
18.15	Accelerant degradation	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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19.1	Animal wound healing study	(b)(4)

11.4 Note on Nomenclature

During the natural course of development, the devices have been referred to by other names. Therefore, the following table has been provided to explain what terms used within the documentation.

	Subject device	Reference device
Device name	(b)(4)	
Development name		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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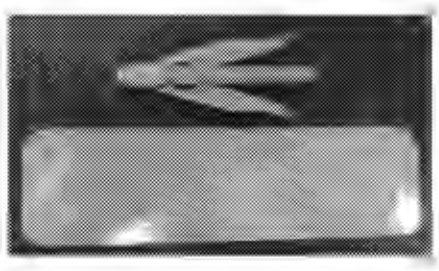
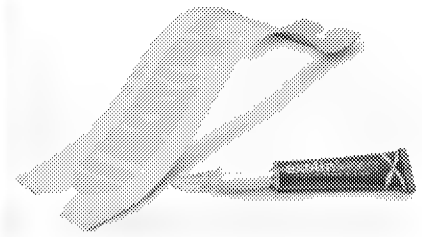
SECTION 12.0: SUBSTANTIAL EQUIVALENCE DISCUSSION

The following predicate devices have been cited within this submission

- Primary predicate device (K191461 – Exofin Fusion Skin Closure System)

A summary of the substantial equivalence between the subject and predicate device have been provided in the table below:

Information	Subject device	Predicate device
Manufacturer	Advanced Medical Solutions Ltd	Chemence Medical Inc
Device name	LiquiBand® XL (b)(4)	Exofin Fusion Skin Closure System
Device type and 510(k) #	Subject device	Primary predicate device (K191461)
Representative image		
Use		
Intended use	Topical approximation of skin	Topical approximation of skin
Indications for use	The Skin Closure System is intended for topical application only to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, and simple, thoroughly cleansed, trauma-induced lacerations. The Skin Closure System should be used in conjunction with, but not in place of, deep dermal stitches. Additionally, the adjunct wound closure device component maintains temporary skin edge alignment along the length of the wound during application of the liquid adhesive.	The Skin Closure System is intended for topical application only to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, and simple, thoroughly cleansed, trauma-induced lacerations. The Skin Closure System should be used in conjunction with, but not in place of, deep dermal stitches. Additionally, the adjunct wound closure device component maintains temporary skin edge alignment along the length of the wound during application of the liquid adhesive.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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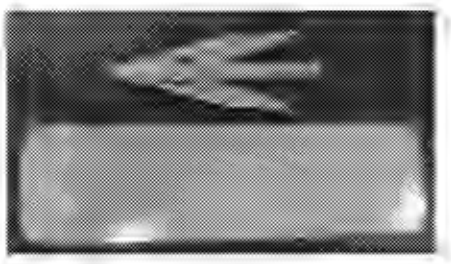
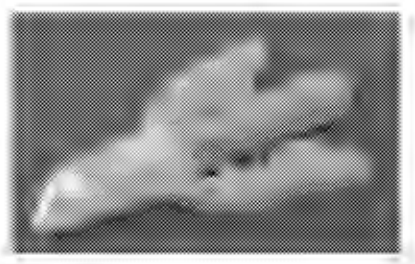
(b)(4)

The following reference devices have been cited within this submission

- Reference device (K183570 – LiquiBand Plus)

The reference device has been used in the testing discussed in Section 18.15, where discusses the degradation products of the accelerant on the device applicator.

A summary of the equivalence between the subject and reference device have been provided in the table below. In this submission, the reference device has been used as a comparison to the subject device in the force to actuate & express testing in section 18.10 and in support of the accelerant degradation in section 18.15.

Information		Subject device	Reference device
Manufacturer		Advanced Medical Solutions Ltd	Advanced Medical Solutions Ltd
Device name		LiquiBand® XL (b)(4)	LiquiBand® Plus
Device type and 510(k) #		Subject device	Reference device (K183570)
Representative image			
Use			
Intended use		Topical approximation of skin	Topical approximation of skin
Technology			
Tissue adhesive	Formulation	(b)(4)	
Accelerant	Formulation (ratio by weight)		
	Quantity		
	Location		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Tissue adhesive applicator	Material	(b)(4)
	Activation method	
	Expression method	
Sterile barrier packaging material		
Sterilisation method		

Discussion on the differences between the use, technology and performance is provided below

Use
The indications for use of the subject and predicate devices are identical.

Technology
Although the subject and predicate devices share some similar materials, the exact composition of the predicate device is not known as this information is confidential to the manufacturer. However, it was determined that the testing preformed in this 510(k) submission concludes that these minor differences have not affected safety or effectiveness.

Performance
The key performance attribute of the device is to hold closed easily approximated skin edges together, therefore, the bench test method ASTM F2458 (discussed in section 18.7) was chosen to show the performance which shows that the tensile strength of the subject device is higher than that of the predicate device.

It was determined through the testing performed in this 510(k) submission that the subject device was substantially equivalent to the predicate device and any minor differences did not affect safety or effectiveness.

Summary
In summary, the subject device LiquiBand® XL (b)(4) and the predicate device Exofin Fusion Skin Closure System are substantially equivalent in terms of their use, technology and performance.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION 13.0: LABELLING

13.1 Subject device labelling

The following proposed labelling for the subject device is provided in Appendix B:

Manufacturer	Advanced Medical Solutions Ltd		
Device name	LiquiBand® XL (b)(4)		
Product range	**72014019**: Contains 2 skin closure systems (Each system comprises of 1 mesh and 1 applicator) for incisions up to 20cm in length	**72014027**: Contains 2 skin closure systems (Each system comprises of 2 meshes and 2 applicators) for incisions up to 20cm in length	**72014046**: Contains 2 skin closure systems (Each system comprises of 3 meshes and 3 applicators) for incisions up to 20cm in length
Primary sterile packaging (Pouch)	Refer to appendix B		
Secondary packaging (Carton)	Refer to appendix B		
Instructions for use	Refer to appendix B		

13.2 Predicate Device IFU

The following IFU for the predicate devices are provided in Appendix B

Manufacturer	Chemence Medical Inc
Device name	Exofin Fusion Skin Closure System
Product range	• EF70401: Contains 2 skin closure systems (Each system comprises of 1 mesh and 2 applicators) for incisions up to 20cm in length • EF70430: Contains 2 skin closure systems (Each system comprises of 2 meshes and 2 applicators) for incisions up to 28cm in length • EF70466: Contains 2 skin closure systems (Each system comprises of 2 meshes and 3 applicators) for incisions up to 58cm in length
Instructions for use	Refer to appendix B

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION 14.0: STERILIZATION AND SHELF LIFE

14.1 Packaging Description

The subject device's packaging consists of a flexible paper/polyethylene pouch. The pouch consists of a paper sheet and a polyethylene sheet which are sealed together. Each pouch contains 1 applicator and 1 mesh. The pouches are stored in a cardboard carton with the IFU booklet.

14.2 Sterilization

The subject device utilizes a two step method of sterilization:

(1) Dry Heat which, which penetrates through the glass ampoule to sterilise the adhesive
(2) Ethylene Oxide, which penetrates through the sterile barrier packaging to sterilise the device and mesh

14.2.1 Dry heat sterilization of the adhesive

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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14.2.2. Ethylene oxide sterilization of the device and mesh

(b)(4)

14.3 Shelf Life

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

The shelf life protocol (b)(4) are found in Appendix C and a summary of the test results (b)(4) are provided below:

Results for the test parameters are summarised below:

(b)(4)

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION 15.0: BIOCOMPATBILITY

15.1 Introduction

The biological evaluation of LiquiBand® XL (b)(4) has been performed in accordance with

- ISO 10993-1:2018
- FDA guidance document: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (Issued Sep 2020)
- FDA guidance document: Class II Special Controls Guidance Document: Tissue Adhesive with Adjunct Wound Closure Device Intended for the Topical Approximation of Skin, issued Nov 2010.

The biological evaluation is summarised below is discussed in further detail in (b)(4) (b)(4).

LiquiBand® XL (b)(4) incorporates a self-adhering mesh that is applied to the approximated skin edges to provide temporary skin edge alignment of incisions until the liquid adhesive is applied to the mesh to hold the wound closed until the wound/incision is properly healed (typically 7 to 14 days). Therefore, following ISO 10993-1:

- The mesh component was classed as a surface device which comes into contact with breached or compromised surface for a limited contact duration (≤24 hours).
- The mesh and adhesive skin closure system device was classed as a surface device which comes into contact with breached or compromised surface for a prolonged contact duration (>24 hours to 30 days).

Therefore, the biological endpoints for consideration are as follows

(b)(4)

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15.2 Device components

A list of the device components and materials and the surface contact type has been provided in the table below:

Component		Type of contact	Skin contact	Material
Adhesive	Adhesive formulation	Direct	Prolonged (>24 hrs to 30 days)	(b)(4)
Accelerant	Accelerant formulation	Direct	Prolonged (>24 hrs to 30 days)	
Applicator	Foam applicator tip	Direct	Limited (≤24hrs)	
	Sintered block	Indirect	No Contact	
	Applicator body	Indirect	No Contact	
	Glass ampoule	Indirect	No Contact	
Adjunct wound closure device	Release tab	Indirect	No Contact	
	Release tab adhesive	Indirect	No Contact	
	Top (clear) release liner	Direct	Limited (≤24hrs)	
	Mesh	Direct	Prolonged (>24 hrs to 30 days)	
	Pressure sensitive adhesive	Direct	Prolonged (>24 hrs to 30 days)	
	Bottom (white) release liner	Indirect	No Contact	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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15.3 Biocompatibility testing

A summary of the biocompatibility testing performed on final finished sterile product for each of the required endpoints from ISO 10993-1 has been provided below:

Biological endpoint for consideration	Test performed	Summary and supporting data (Appendix C)	
		Mesh testing	Device (Mesh and adhesive) testing
Cytotoxicity	**ISO 10993-5** MTT cytotoxicity test	(b)(4)	
Sensitisation	**ISO 10993-10** Guinea pig maximization test		
Irritation or Intracutaneous Reactivity	**ISO 10993-10** Irritation testing was performed following the animal intracuatneous (intradermal) reactivity test		

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Material Mediated Pyrogenicity	**ISO 10993-11** Material Mediated Pyrogenicity testing	(b)(4)
Acute Systemic Toxicity	**ISO 10993-11** Acute systemic toxicity testing	
Subacute Toxicity	**ISO 10993-18** Chemical characterisation and toxicological risk assessment	

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			(b)(4)
Implantation	Porcine wound healing study	N/A	

Following FDA guidance assessment of the adhesive before/after polymerization and during degradation has been considered through the biological assessment:

- **Assessment after polymerisation:** (b)(4)

(b)(4)

- **After polymerisation and during degradation:** (b)(4)

(b)(4)

- **Before/after polymerisation and during degradation:** (b)(4)

(b)(4)

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(b)(4)

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(b)(4)

It is concluded that the biocompatibility assessment provides evidence that the device has a biological safety profile that meets the requirements of ISO 10993 and so is considered safe for its indications for use.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION 16.0: SOFTWARE

This section does not apply, as LiquiBand® XL (b)(4) does not contain software.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION 17.0: ELECTROMAGNETIC COMPATABILITY AND ELECTRICAL SAFTEY

This section is not applicable as LiquiBand® XL (b)(4) does not contain electrical components.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION 18.0: PERFORMANCE TESTING – BENCH

Performance testing was conducted in accordance with the FDA guidance document "Class II Special Controls Guidance Document: Tissue Adhesive with Adjunct Wound Closure Device Intended for the Topical Approximation of Skin, issued Nov 2010.

18.1 ASTM D3330 / D3330M – 04 Standard Test Method for Peel Adhesion of Pressure-Sensitive Tape

Protocol (b)(4) and report (b)(4) are provided in Appendix C

Objectives:

Perform comparative testing on LiquiBand® XL (b)(4) (mesh only) and Exofin Fusion Skin Closure System (mesh only) following ASTM D3330 / D3330M: Test Method A – Single Coated Tapes at 180° Angle.

Methods:

(b)(4)

Device	(b)(4)
LiquiBand® XL Skin Closure System (Batch 1)	
LiquiBand® XL Skin Closure System (Batch 2)	
LiquiBand® XL Skin Closure System (Batch 3)	
Exofin Fusion Skin Closure System	

Device	(b)(4)
LiquiBand® XL Skin Closure System (Batch 1)	
LiquiBand® XL Skin Closure System (Batch 2)	
LiquiBand® XL Skin Closure System (Batch 3)	
Exofin Fusion Skin Closure System	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION 19.0: PERFORMANCE TESTING – ANIMAL

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION 20.0: PERFORMANCE TESTING – CLINICAL

No prospective clinical trials were conducted in support of this Traditional 510(k).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION 21.0: OTHER

21.1 Risk Analysis Method and Device Characteristics to Control Risks

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hello Sam

Regarding your deadline where you planned

to have completed versions of the (b)(4) by COB today.

Have you managed to discuss the issue

in your department?

I'm wondering if there is any further

clarification we can provide to assist in the discussion; or perhaps a

call could be scheduled quickly to resolve the matter?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions

Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From:

 Martin Mitchell/WIN/UK/AMS
To:

 "Arepalli, Sambasiva"

<Sambasiva.Arepalli@fda.hhs.gov>
Cc:

 "K211878@docs.fda.gov"

<K211878@docs.fda.gov>, Rose Guang/WIN/UK/AMS@ams
Date:

 19/05/2022 11:28
Subject:

   RE: [EXTERNAL]

Re: K211878-s002
<hr noshade>

Hi Sam

For your ease of reference, please find

our response to (b)(4) (b)(4) (b)(4)

[attachment "AMS deficiency response.pdf"

deleted by Martin Mitchell/WIN/UK/AMS]

As requested I've highlighted the teleconference

meeting minutes showing the FDA agreement to use the (b)(4) (b)(4) IFU

[attachment "K211878 - 19Oct2021

Meeting Minutes - Final.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

I've also highlighted and provided the

pertinent pages (b)(4) (b)(4) time results.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From:

 Martin Mitchell/WIN/UK/AMS
To:

 "Arepalli, Sambasiva"

<Sambasiva.Arepalli@fda.hhs.gov>
Cc:

 "K211878@docs.fda.gov"

<K211878@docs.fda.gov>, Rose Guang/WIN/UK/AMS@ams
Date:

 19/05/2022 10:17
Subject:

   RE: [EXTERNAL]

Re: K211878-s002
<hr noshade>

Hi Sam

I'll call you today at 6am (11am UK

time); we thought it would be better to send you the updated documents

to help aid the discussion during the call.

The (b)(4) updated with your comments

(and as per our modifications we suggest below). I've provided a redlined

and clean copy of this:
[attachment "IFU - LiquiBand XL.pdf"

deleted by Martin Mitchell/WIN/UK/AMS] [attachment "IFU - LiquiBand

XL - Tracked.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

The 510(k) summary has been updated

with your comments
[attachment "510K Summary.pdf"

deleted by Martin Mitchell/WIN/UK/AMS]

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions

Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From:

 Martin Mitchell/WIN/UK/AMS
To:

 "Arepalli, Sambasiva"

<Sambasiva.Arepalli@fda.hhs.gov>
Cc:

 "K211878@docs.fda.gov"

<K211878@docs.fda.gov>, Rose Guang/WIN/UK/AMS@ams
Date:

 18/05/2022 22:37
Subject:

   RE: [EXTERNAL]

Re: K211878-s002
<hr noshade>

Hi

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Sam

Firstly, thank you for staying late

to continue to work with us on in the final stages of this submission.

It is much appreciated.

Please find attached (b)(4) with updated

comments from ourselves

[attachment "K211878-S002 - Revised

(b)(4) on 5-16-2022.jam.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

For most of the proposed updates we

will accept to make the changes. However there are two points we would

wish to clarify
Regarding the comment on

(b)(4)

serif">As discussed I'll call you tomorrow

to discuss your email below

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions

Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From:

 "Arepalli, Sambasiva"

<Sambasiva.Arepalli@fda.hhs.gov>
To:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

 "Martin.Mitchell@admedsol.com"

<Martin.Mitchell@admedsol.com>
Cc:

 "Arepalli, Sambasiva"

<Sambasiva.Arepalli@fda.hhs.gov>, "K211878@docs.fda.gov"

<K211878@docs.fda.gov>
Date:

 18/05/2022 20:39
Subject:

   RE: [EXTERNAL]

Re: K211878-s002
<hr noshade>

Hi Mr. Mitchell:
Please see attached for the labeling and

510kSummary with FDA edits.

Please address these edits and send me

both the edited versions and clean copies of the **(b)(4)**

by COB tomorrow (5-19-2022).

Please cc your response to K211878@docs.fda.gov.

Thx
Sam

Sam Arepalli, Ph.D.
FDA/CDRH/OPEQ/OHT4/PRSB2
Ph: 301 796 6434

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service is important to us. Please take a moment to provide feedback

regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u><u></u>

From: Martin.Mitchell@admedsol.com

<Martin.Mitchell@admedsol.com>
Sent: Tuesday, May 17, 2022 6:39 AM
To: Arepalli, Sambasiva <Sambasiva.Arepalli@fda.hhs.gov>
Subject: RE: [EXTERNAL] Re: K211878-s002

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or open attachments unless you recognize the sender and know the content

is safe.

Hi Sam

Just to be safe for the email trail.... so that your email has a response

The email with this information was send yesterday; however it is also

provided again below:

Please find a response to the two points we discussed over the phone

FDA deficiency 13

As discussed over the call it can be clarified that the times

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

presented

in the response are in minutes and not seconds

This can be clarified and is evidenced below in the (b)(4)

(b)(4)

face="Calibri">

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Arepalli,

Sambasiva" <<u>Sambasiva.Arepalli@fda.hhs.gov</u>>
To:

   "<a
href=mailto:Martin.Mitchell@admedsol.com><font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">>
Date:
   17/05/2022

10:32
Subject:
 RE:

[EXTERNAL] Re: K211878-s002 <hr noshade>
<font size=2
face="Calibri">

Hi Mr. Mitchell:
Can
you please give an update on the (b)(4) request? Could you

please send the information cob today? Please give me a call when you have

a minute.
Thx
Sam

Sam Arepalli, Ph.D.
FDA/CDRH/OPEQ/OHT4/PRSB2
Ph:
301 796 6434

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to provide feedback regarding the customer service you have received: <a
href="https://secure-
web.cisco.com/1v_0OwI01XyYIrR5QdcqPvkNkCoDtTGQHdIwHOyFmN5FDUBpuZ7wV3E9sq3sVmjZ84S9zyo-
1AgUmtlHaHzRPrVzusabtYklNemledc4HXtEHQ5xuvnggUn_UozBChwj4Ax2HmZ0FPJQAoj0c4yj4TSsiTFAame
lBPTtkLNiJ-
nvaNSabNX2MdWjf4pFySXsD/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3
D1624%26S%3DE"><font size=2 color=#0082bf
face="Calibri"><u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u></f
ont>

From: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri"><<font size=2
color=blue face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri">>

Sent: Monday, May 16, 2022 12:06 PM
To: Arepalli, Sambasiva
<<font size=2 color=blue
face="Calibri"><u>Sambasiva.Arepalli@fda.hhs.gov</u><font size=2
face="Calibri">>
Subject: [EXTERNAL] Re: K211878-s002

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 <font size=2
face="Arial">
Hi Sam

Just so you're aware it's 17:00 now so i'll be heading
home; however i'll

try to make myself available outside of hours so please don't hesitate

to get in touch if you have any further questions.

Additionally i'll be working
from home the next few days so I won't pick

up calls from my office number you used previously.

If you have any further
questions please email me or call me on my personal

mobile number (b)(6)

Best regards,<font size=2
color=#000080 face="Arial">

Martin Mitchell
Regulatory Affairs
Manager

Advanced Medical Solutions Ltd.
E-mail: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=2 color=#000080
face="Arial">
Tel: +44 (0) 1752 30 9360<font size=2
face="Calibri">

From:
       Martin

Mitchell/WIN/UK/AMS
To:
   "Arepalli,

Sambasiva" <<u>Sambasiva.Arepalli@fda.hhs.gov</u>>
Cc: "<u>K211878@docs.fda.gov</u>"

<<u>K211878@docs.fda.gov</u>>,

Rose Guang/WIN/UK/AMS@ams, Helen Topping/WIN/UK/AMS@ams
Date: 16/05/2022

16:28
Subject: Re:

K211878-s002 <hr noshade>

Hi Sam

Please find a response to the two points we discussed over the phone

FDA deficiency 13

As discussed over the call it can be clarified that the times presented

in the response are in minutes and not seconds

This can be clarified and is evidenced below in the (b)(4)

(b)(4)

=2

(b)(4)

(b)(4) ;
As requested, the (b)(4) revised   (b)(4)

[attachment "IFU.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Arepalli,

Sambasiva" <<u>Sambasiva.Arepalli@fda.hhs.gov</u>>
To: "<u>Martin.Mitchell@admedsol.com</u>"

<<u>Martin.Mitchell@admedsol.com</u>>
Cc: "Arepalli,

Sambasiva" <<u>Sambasiva.Arepalli@fda.hhs.gov</u>>,

"<u>K211878@docs.fda.gov</u>"

<<u>K211878@docs.fda.gov</u>>
Date: 16/05/2022

14:39
Subject: K211878-s002 <hr noshade>

Hi Mr. Martin:
 (b)(4)

(b)(4)

(b)(4)

(b)(4)

Thx
Sam

Sam Arepalli, Ph.D.
FDA/CDRH/OPEQ/OHT4/PRSB2
Ph: 301 796 6434

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to provide feedback regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

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recipient, please notify the sender immediately and delete it from your

mailbox or any other storage mechanism.<font size=2
face="Calibri">

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href=http://www.admedsol.com/><font size=2 color=blue
face="Calibri"><u>http://www.admedsol.com</u>.

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recipient, please notify the sender immediately and delete it from your

mailbox or any other storage mechanism.[attachment "K211878-S002 -

Revised labeling received on 5-16-2022.jam.pdf" deleted by Martin

Mitchell/WIN/UK/AMS] [attachment "K211878.510kSummary(Final).jam.pdf"

deleted by Martin Mitchell/WIN/UK/AMS]

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Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

From: Helen.Topping@admedsol.com
To: Lee, Michele
Cc: k211878@docs.fda.gov; Martin.Mitchell@admedsol.com; Rose.Guang@admedsol.com
Subject: RE: [EXTERNAL] Re: K211878/S001 Review Status
Date: Tuesday, September 28, 2021 2:48:42 PM
Attachments: ATT00001.png
ATT00007.png

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Hi Michelle,

I realise we're in unprecedented times and I do want to be respectful to FDA's challenges. As this project is business critical for us, could you reassure me that Monday's timeframe will not move again?

Best regards
Helen

Helen Topping
Senior Regulatory Affairs Manager
Advanced Medical Solutions
Tel: **+44 (0) 7721261214**
Email: **helen.topping@admedsol.com**

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>, "Helen.Topping@admedsol.com" <Helen.Topping@admedsol.com>, "Rose.Guang@admedsol.com" <Rose.Guang@admedsol.com>
Cc: "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 28/09/2021 16:45
Subject: RE: [EXTERNAL] Re: K211878/S001 Review Status

Hello Martin, Helen, & Rose:

I am writing to inform you of a revision to the review timeline for your 510(k) Submission K211878/S001. Unfortunately, we are unable to complete the substantive review by the previously revised timeline of September 29th. We now anticipate completion of the substantive review by next Monday, October 4th. We apologize for any inconveniences caused because of the multiple extensions of review timeline and appreciate your understanding as the Agency works through resource limitations during this time.

Best Regards,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov





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https://www.research.net/s/cdrh-customerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Sent: Tuesday, September 21, 2021 10:03 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: k211878@docs.fda.gov; Helen.Topping@admedsol.com; Rose.Guang@admedsol.com
Subject: [EXTERNAL] Re: K211878/S001 Review Status

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Hello Michele

Thank you for your email to keep us updated with progress.

Please note that next week i'll be out on annual leave... therefore, could you also place Helen and Rose (on this email) on copy with any further communication you send over.

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 20/09/2021 22:31
Subject: K211878/S001 Review Status

Hello Martin:

I want to inform you of a slightly revised review timeline for your 510(k) submission K211878/S001. Due to a limitation of Agency resources, we are unable to complete the substantive review by September 24th. We want to inform you that we expect to complete the review by next Wednesday, September 29th. We apologize for any inconveniences because of the extension of timeline.

Best Regards,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov





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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hi Michele

I have a further question regarding how COVID affects timelines below.

Knowing that FDA have are allowing a further 180 day timeline to respond to deficiencies due to COVID.... is there any scope or provision for timeline adjustments relating to a SIR review time?

More specifically, regarding an SIR submission i've seen in the guidance document that if the SIR is received before the 60 day timepoint after issuance of the deficiency letter, this would result in a 21 day FDA review time; whereas if we submit the SIR after this date this results in a 70 day FDA review time.

We have faced some delays in being able to meet the deadline of submitting an SIR before the 60 day timepoint. Where, we've spent some time liasing with yourselves through teleconference and email about the issues noted and covid has impacted our ability and our (b)(4) ability to move quickly on these matters.

Therefore I'd like to enquire as to whether the FDA are allowing extensions to the time to receive an SIR (currently 60 days after issuance of the deficiency) where the SIR would still receive a 21 day FDA review time?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 16/11/2021 19:03
Subject: RE: [EXTERNAL] K211878 timeline - COVID-19

Hello Martin,

Thanks for the update and good to know this information. I also received your previous email with additional information about the (b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4). I am still waiting on feedback from our (b)(4) but hope to have more information to provide you mid next week.

Best,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Monday, November 15, 2021 3:54 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Subject: Fw: [EXTERNAL] K211878 timeline - COVID-19

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Hi Michele

I got an update regarding timeline from the CCP email address.

FYI we are exploring a number of backup strategies to resolve (b)(4) deficiencies.... and some of these take us past the 180 day hold period.

As per the request below, I'll let you know closer to the time if we end up needing to request the additional 180 days.

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

----- Forwarded by Martin Mitchell/WIN/UK/AMS on 15/11/2021 08:31 -----

From: "CCP" <CCP@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Date: 12/11/2021 21:08
Subject: RE: [EXTERNAL] K211878 timeline - COVID-19

Good day to you Martin,

The extra 180 days for response are added as needed, and then only shortly before the original 180 days expires.

--
Happy trails,
~Nels Anderson
Regulatory Systems & Data Management Staff
Center for Devices and Radiological Health | Office of Product Evaluation and Quality| Office of Regulatory Programs

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Friday, November 12, 2021 09:49
To: CCP <CCP@fda.hhs.gov>
Subject: [EXTERNAL] K211878 timeline - COVID-19

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Hello

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Regarding the timeline showing for K211878 I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I (and the lead reviewer Michele Lee) were under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify that the 180 timeline in the customer collaboration portal won't trigger premature closure of the 510(k) before the actual 360 day timeline expires?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hello Martin,

Unfortunately, it is not possible for me to take on lead review of this submission. As previously mentioned, I am currently working in another Office within FDA and do not conduct premarket reviews of medical devices in my current role.

It is not uncommon for new lead reviewers to be assigned to submissions returning from hold. The internal documentation serves as a complete record of the previous interactions during prior review of a submission. If you have further questions regarding the review process for your submission, you may contact the Assistant Director for the Plastic Surgery Skin & Wound Devices Team, Dr. Julie Morabito (Julie.Morabito@fda.hhs.gov<mailto:Julie.Morabito@fda.hhs.gov>).

Best,

Michele

Michele Lee, Ph.D. (she/her/hers)

Regulatory Science Program Manager

Partnerships to Advance Innovation and Regulatory Science (PAIRS)

Center for Devices and Radiological Health

Office of Strategic Partnerships and Technology Innovation

Division of All Hazards Response, Science, and Strategic Partnerships

U.S. Food and Drug Administration

michele.lee@fda.hhs.gov<mailto:michele.lee@fda.hhs.gov>

[cid:image001.png@01D848D1.E85A8200]<http://www.fda.gov/>

[cid:image002.jpg@01D848D1.E85A8200]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D848D1.E85A8200] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D848D1.E85A8200] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D848D1.E85A8200] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D848D1.E85A8200]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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https://www.research.net/s/cdrhcustomerservice?ID=7013&S=E.

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Tuesday, April 5, 2022 8:31 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: k211878@docs.fda.gov; Rose.Guang@admedsol.com; Helen.Topping@admedsol.com

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele,

We have been pleased to have you as the lead reviewer for RTA review, technical review, and responses to deficiency discussions since July 2021, as well as having you for the

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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review for our previous 510(k) submission of the same product.

(b)(4)

* Jun 2021 - We submitted K211878 in response the (b)(4)

(b)(4)

* Oct 2021 - Further deficiencies were raised on the new K211878 submission

We currently have only 20 days of FDA review time left on our product and have been advised that we will now be assigned a new reviewer. As you can imagine this causing us a high level of concern given you have a detailed knowledge of our submissions and of the current outstanding questions. Our concern being that a new reviewer will not have the same detailed knowledge of our submission or of the outstanding questions and hence this may cause unnecessary further delay.

We have been very satisfied with the support we have received from yourself and we would ask that you remain on our file for the final 20 days if at all possible, or an explanation of why this is not possible with some reassurances that a new assessor will not cause unnecessary delays whilst they gain detailed knowledge of our file.

Your expedited response to this request would be appreciated.

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 25/03/2022 16:47

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

A new lead reviewer will not be assigned until a follow up submission is received. So there is currently not a primary contact unless there is an active submission under FDA review. All of our correspondence and the prior related review have been documented internally, so you can be assured that the history of the prior review and contact is

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available to the future lead reviewer.

Best,

Michele

From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>
<Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Friday, March 25, 2022 12:21 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

I've seen on the FDA customer collaboration portal that the time has automatically been added, but just thought it would be prudent to also inform you of the situation.

Could I ask who the primary contact is now? Will you be assisting or have any involvement with the review of our response?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>"
<Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>"
<k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 25/03/2022 15:59

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

I am sorry to hear about the (b)(4), I hope all is able to be resolved soon.

Thank you for the update. I am actually working in a different division within FDA and no longer the primary contact for this submission. I believe that the 180 days is automatically granted for responses to AINN hold but you can also confirm with the

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510(k) Program staff (510k_Program@fda.hhs.gov<mailto:510k_Program@fda.hhs.gov>, telephone: 301-796-5640) to make sure.

Best,

Michele

Michele Lee, Ph.D.(she/her/hers)

Regulatory Science Program Manager

Partnerships to Advance Innovation and Regulatory Science (PAIRS)

Center for Devices and Radiological Health

Office of Strategic Partnerships and Technology Innovation

Division of All Hazards Response, Science, and Strategic Partnerships

U.S. Food and Drug Administration

michele.lee@fda.hhs.gov<mailto:michele.lee@fda.hhs.gov>

[cid:image001.png@01D848D1.E85A8200]<http://www.fda.gov/>

[cid:image002.jpg@01D848D1.E85A8200]<https://www.facebook.com/FDA>[cid:image003.jpg@01D848D1.E85A8200]<https://twitter.com/US_FDA> [cid:image004.jpg@01D848D1.E85A8200]<http://www.youtube.com/user/USFoodandDrugAdmin> [cid:image005.jpg@01D848D1.E85A8200]<http://www.flickr.com/photos/fdaphotos/> [cid:image006.jpg@01D848D1.E85A8200]<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Friday, March 25, 2022 11:28 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

I'd like to provide an update on our progress with responding to the deficiencies raised on K211878

We were on track to have a deficiency response submitted to the FDA by the 180 day hold period deadline of 2nd April 2022.

However, the organisation performing the (b)(4) have been affected by (b)(4). As a result, they were unable to complete the testing by our targeted timeline.

Therefore, I just want to confirm that we are still intending to respond to the

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deficiencies, but we would need to use the second 180 day hold period granted to us through the COVID-19 situation.

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 08/11/2021 22:05

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

Thanks for your message. Iâ€™ll need some time to review the teleconference minutes with my team and also obtain some feedback from our consulting toxicologist about the follow up questions. But I wanted to let you know I received your email and you may feel free to check in again next week.

I do have a clarification question about Follow Up (b)(4)

(b)(4)

Regarding the timeline clarification- I am also under the understanding that the COVID-19 guidance document you cited was still active and that would allow you an additional 180 days for the hold period. I have reached out to the 510(k) Staff multiple times to confirm and am still waiting on their response. Is there a customer service contact email for the customer collaboration portal specifically? You may try contacting them as well to have the date corrected on your end.

Thank you,

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Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D848D1.E85A8200]<http://www.fda.gov/>

[cid:image002.jpg@01D848D1.E85A8200]<https://www.facebook.com/FDA>[cid:image003.jpg@01D848D1.E85A8200]<https://twitter.com/US_FDA>[cid:image004.jpg@01D848D1.E85A8200]<http://www.youtube.com/user/USFoodandDrugAdmin>[cid:image005.jpg@01D848D1.E85A8200]<http://www.flickr.com/photos/fdaphotos/> [cid:image006.jpg@01D848D1.E85A8200]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From:
Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Friday, November 5, 2021 12:07 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

I hope you had a nice holiday!

Following on from the teleconference we had a few actions to complete and get back to you with.

1) Teleconference minutes

Please find a draft of the the teleconference minutes below. Could you review and confirm if you require any changes made?

2) Follow-up questions on the teleconference discussion

As suggested during the teleconference there was the opportunity for a followup email

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clarification on a few minor points.

(b)(4)

The supporting information which provides further clarity on the questions above has been attached if required.

3) Timeline clarification as per previous email

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active

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which would provide us with an additional 180 day hold period?

* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Thank you again for your assistance

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>, "Liu, Lixin" <Lixin.Liu@fda.hhs.gov<mailto:Lixin.Liu@fda.hhs.gov>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 20/10/2021 22:43

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Michele

Thank you for the prompt response to the clarifications! We'll take your points on board regarding future shelf life studies.

I do have a minor clarification question regarding our response timeline

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Best regards,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 20/10/2021 14:55

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

Thank you to you and your team for attending the teleconference yesterday. I wanted to follow up on two things I was discussing with my team:

(b)(4)

I will be on leave for the next two weeks and you may contact our team management (Lixin.Liu@fda.hhs.gov<mailto:Lixin.Liu@fda.hhs.gov>) if you have questions during that time.

Best,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D848D1.E85A8200]<http://www.fda.gov/>

[cid:image002.jpg@01D848D1.E85A8200]<https://www.facebook.com/FDA>[cid:image003.jpg@01D848D1.E85A8200]<https://twitter.com/US_FDA>[cid:image004.jpg@01D848D1.E85A8200]<http://www.youtube.com/user/USFoodandDrugAdmin>[cid:image005.jpg@01D848D1.E85A8200]<http://www.flickr.com/photos/fdaphotos/>[cid:image006.jpg@01D848D1.E85A8200]<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: Lee, Michele

Sent: Friday, October 15, 2021 4:47 PM

To: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you for providing your questions in advance of the meeting. We look forward to discussing our responses with you next week.

Have a good weekend,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

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Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

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[cid:image002.jpg@01D848D1.E85A8200]<https://www.facebook.com/FDA>[cid:image003.jpg@01D848D1.E85A8200]<https://twitter.com/US_FDA>[cid:image004.jpg@01D848D1.E85A8200]<http://www.youtube.com/user/USFoodandDrugAdmin>[cid:image005.jpg@01D848D1.E85A8200]<http://www.flickr.com/photos/fdaphotos/>[cid:image006.jpg@01D848D1.E85A8200]<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Friday, October 15, 2021 12:00 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Please find the list of questions/clarifications attached below.

I hope you have a good weekend. I'm looking forwards to our discussion next week!

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 13/10/2021 22:35

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

I have scheduled the teleconference for next Tuesday October 19that 9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour but our biocompatibility consultant/ team management needs to drop off for another call at 9:30am. Please send me the questions for discussion in advance of the meeting so that we can plan to discuss biocompatibility/ regulatory questions first before the relevant parties need to drop off.

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Join Zoom

(b)(4)

Thanks,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

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[cid:image002.jpg@01D848D1.E85A8200]<https://www.facebook.com/FDA>[cid:image003.jpg@01D848D1.E85A8200]<https://twitter.com/US_FDA>[cid:image004.jpg@01D848D1.E85A8200]<http://www.youtube.com/user/USFoodandDrugAdmin>[cid:image005.jpg@01D848D1.E85A8200]<http://www.flickr.com/photos/fdaphotos/>[cid:image006.jpg@01D848D1.E85A8200]<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Wednesday, October 13, 2021 4:46 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Apologies Michele, one final thing I missed off my email... could you clarify how long the teleconference would be by default? Could we request 1 hour just incase some of the points end up taking longer to discuss?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

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Date: 13/10/2021 20:35

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hi Michele

We're currently preparing our questions for the teleconference and will send these through in due course, however to assist with scheduling the relevant parties at FDA, I should let you know that we would definitely like to discuss the questions related to biocompatibility.

After discussion with the team we would like to request the teleconference on the Tuesday 19th October if that is possible? As we are based in the UK, we would also like to request that this is arranged between the hours of 2-5pm BST.

If this time slot is not available could you outline any alternative days/times which would be possible?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 08/10/2021 22:14

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Thank you for the offer. I think after today's meeting we may need a little more time to be better prepared for the teleconference.

We are reaching out to the **(b)(4)** for us as we feel that it may

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be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible dates for you early next week.

Best regards,

Martin Mitchell

Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 06/10/2021 13:49

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference deadline up to October 19th. Let me know if you would like to select a date later than the 14thand I can check our management schedules.

Regarding review timelines, we are still on the 90 day review cycle and are planning to complete the review of your response with the 20 calendar days left on the clock. While we retain the right to add additional days, we are doing our best with the resources that we have to avoid delaying review timelines if possible.

Best,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D848D1.E85A8200]<http://www.fda.gov/>

[cid:image002.jpg@01D848D1.E85A8200]<https://www.facebook.com/FDA>[cid:image003.jpg@01D848D1.E85A8200]<https://twitter.com/US_FDA>[cid:image004.jpg@01D848D1.E85A8200]<http://www.youtube.com/user/USFoodandDrugAdmin>[cid:image005.jpg@01D848D1.E85A8200]<http://www.flickr.com/photos/fdaphotos/>[cid:image006.jpg@01D848D1.E85A8200]<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Wednesday, October 6, 2021 6:00 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>

Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

CAUTION:This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Michele

Thank you again for your review. Our team are busy discussing the questions and we would definitely like to have a teleconference with the FDA. We're currently consolidating our understanding of the deficiencies and are determining what our potential questions to you would be. I hope to get the questions to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we look to schedule a teleconference with the FDA on Wednesday 13th or Thursday 14th? As we're based in the UK we would appreciate a timeslot within our working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines for this project.... regarding the FDA timeline I can see on the CCP tracker website that the FDA timeline is on day 70.

* Will FDA be sticking to the 90 day target and as a result only have 20 days left on the clock?

* Or, due to the current situation with the unprecedented resource limitations..... will you will assume 30 days to review the response as standard? Or perhaps stick to the 20 days but retain the right to add additional days?

Best regards,

Martin Mitchell

Senior Regulatory Affairs Associate

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Michele Lee [MICHELE.LEE]"
<michele.lee@fda.hhs.gov<mailto:michele.lee@fda.hhs.gov>>

To: <martin.mitchell@admedsol.com<mailto:martin.mitchell@admedsol.com>>,
<helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>

Cc: "Michele Lee [MICHELE.LEE]"
<michele.lee@fda.hhs.gov<mailto:michele.lee@fda.hhs.gov>>

Date: 04/10/2021 21:44

Subject: K211878/S001 is on Hold Pending Your Response

October 4, 2021

We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Michele Lee.

*** This is a system-generated email notification ***[attachment "K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

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U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration
CDRH/OPEQ/OHTIV/DHTIVB
WO66 RM4529
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-5130

Premarket Notification 510(k) Review

Date: October 1, 2021

Reviewer: Michele Lee

Subject: Traditional 510(k)# K211878/S001

Applicant: Advanced Medical Solutions Limited	**Device Trade Name:** LiquiBand XL
Contact Name: Martin Mitchell	**Contact Title:** Senior Regulatory Affairs Associate
Correspondent Firm: Advanced Medical Solutions Limited	**Phone:** **Email:** martin.mitchell@admedsol.com
Received Date: July 26, 2021	**Due Date:** October 24, 2021
Pro Code(s): OMD **Class:** II **Reg #:** 878.4011	**Reg Name:** Tissue Adhesive With Adjunct Wound Closure Device For Topical Approximation Of Skin

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K191461	OMD	Exofin Fusion Skin Closure System	Chemence Medical, Inc.
K183570	MPN	LiquiBand Plus	Advanced Medical Solutions Limited

(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(5)

Digital Signature Concurrence Table (Doc ID: 04500.14.05)	
This document represents a high-level summary of the Agency's determination on whether the applicant's device is substantially equivalent to a legally marketed predicate device. In determining whether the subject device is substantially equivalent to a predicate device, we carefully considered the relevant regulatory and statutory criteria for Agency decision-making under 21 CFR part 807 and section 513(i) of the Federal Food, Drug and Cosmetic Act (FD&C Act). We considered the burden that may be incurred by the applicant's attempt to follow the premarket notification process. The deficiencies provided in this review, if any, represent the required minimum information necessary to support a substantial equivalence determination. Therefore, we believe that we have considered the least burdensome requirements, under section 513(i)(1)(D) of the FD&C Act, for a 510(k) determination of substantial equivalence.	
Reviewer Sign-Off	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Michele Lee -S Digitally signed by Michele Lee -S
Date: 2021.10.04 16:23:25 -04'00'

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hi Sam

<font size=2 face="sans-serif">As per the email chain below (b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hi Michele

I've seen on the FDA customer collaboration portal that the time has automatically been added, but just thought it would be prudent to also inform you of the situation.

Could I ask who the primary contact is now? Will you be assisting or have any involvement with the review of our response?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 25/03/2022 15:59
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

I am sorry to hear about the (b)(4) I hope all is able to be resolved soon.

Thank you for the update. I am actually working in a different division within FDA and no longer the primary contact for this submission. I believe that the 180 days is automatically granted for responses to AINN hold but you can also confirm with the 510(k) Program staff (510k_Program@fda.hhs.gov, telephone: 301-796-5640) to make sure.

Best,
Michele

Michele Lee, Ph.D. (she/her/hers)
Regulatory Science Program Manager
Partnerships to Advance Innovation and Regulatory Science (PAIRS)

Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Office of Strategic Partnerships and Technology Innovation

Division of All Hazards Response, Science, and Strategic Partnerships

U.S. Food and Drug Administration

michele.lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Friday, March 25, 2022 11:28 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: k211878@docs.fda.gov

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

I'd like to provide an update on our progress with responding to the deficiencies raised on K211878

We were on track to have a deficiency response submitted to the FDA by the 180 day hold period deadline of 2nd April 2022.

However, the organisation performing the (b)(4) (b)(4) have been affected by (b)(4). As a result, they were unable to complete the testing by our targeted timeline.

Therefore, I just want to confirm that we are still intending to respond to the deficiencies, but we would need to use the second 180 day hold period granted to us through the COVID-19 situation.

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 08/11/2021 22:05

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thanks for your message. Iâ€™ll need some time to review the teleconference minutes with my team and also obtain some feedback from our consulting toxicologist about the follow up questions. But I wanted to let you know I received your email and you may feel free to check in again next week.

I do have a clarification question about Follow Up (b)(4)

(b)(4)

Regarding the timeline clarification- I am also under the understanding that the COVID-19 guidance document you cited was still active and that would allow you an additional 180 days for the hold period. I have reached out to the 510(k) Staff multiple times to confirm and am still waiting on their response. Is there a customer service contact email for the customer collaboration portal specifically? You may try contacting them as well to have the date corrected on your end.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Thank you,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Friday, November 5, 2021 12:07 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: helen.topping@admedsol.com; k211878@docs.fda.gov

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

I hope you had a nice holiday!

Following on from the teleconference we had a few actions to complete and get back to you with.

1) Teleconference minutes

Please find a draft of the the teleconference minutes below. Could you review and confirm if you require any changes made?

2) Follow-up questions on the teleconference discussion

As suggested during the teleconference there was the opportunity for a followup email clarification on a few minor points.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

The supporting information which provides further clarity on the questions above has been attached if required.

3) Timeline clarification as per previous email

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Thank you again for your assistance

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>, "Liu, Lixin" <Lixin.Liu@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 20/10/2021 22:43

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Michele

Thank you for the prompt response to the clarifications! We'll take your points on board regarding future shelf life studies.

I do have a minor clarification question regarding our response timeline

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 20/10/2021 14:55

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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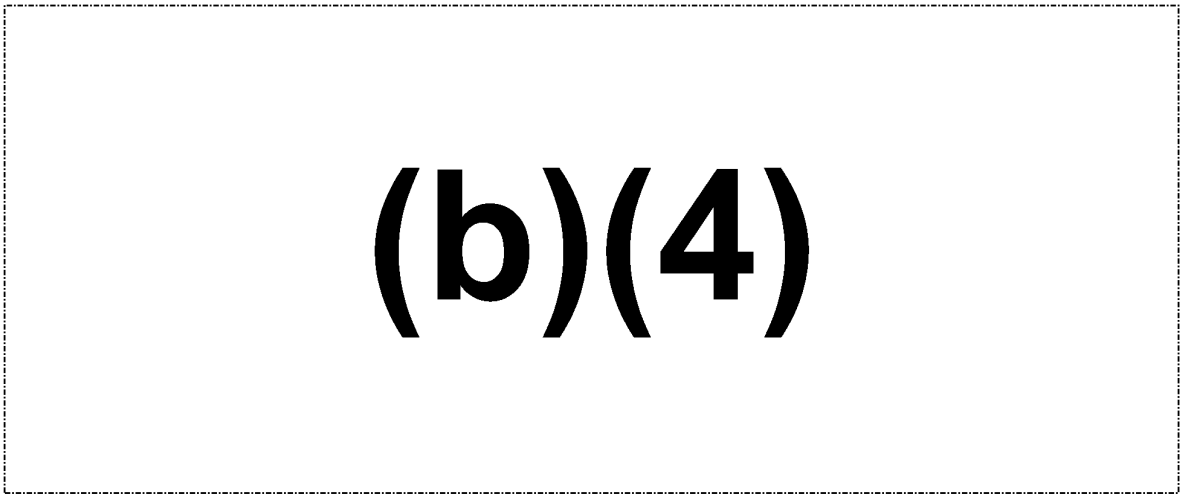
Thank you to you and your team for attending the teleconference yesterday.

I wanted to follow up on two things I was discussing with my team:



I will be on leave for the next two weeks and you may contact our team management (Lixin.Liu@fda.hhs.gov) if you have questions during that time.

Best,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Lee, Michele

Sent: Friday, October 15, 2021 4:47 PM

To: Martin.Mitchell@admedsol.com

Cc: helen.topping@admedsol.com; k211878@docs.fda.gov

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

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Thank you for providing your questions in advance of the meeting. We look forward to discussing our responses with you next week.

Have a good weekend,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>

Sent: Friday, October 15, 2021 12:00 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: helen.topping@admedsol.com; k211878@docs.fda.gov

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Please find the list of questions/clarifications attached below.

I hope you have a good weekend. I'm looking forwards to our discussion next week!

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 13/10/2021 22:35

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

I have scheduled the teleconference for next Tuesday October 19that 9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour but our biocompatibility consultant/ team management needs to drop off for another call at 9:30am. Please send me the questions for discussion in advance of the meeting so that we can plan to discuss biocompatibility/ regulatory questions first before the relevant parties need to drop off.

Join Zoom Meeting

One tap mobile:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Thanks,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

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Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>

Sent: Wednesday, October 13, 2021 4:46 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: helen.topping@admedsol.com; k211878@docs.fda.gov

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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click links or open attachments unless you recognize the sender and know the content is safe.

Apologies Michele, one final thing I missed off my email... could you clarify how long the teleconference would be by default? Could we request 1 hour just incase some of the points end up taking longer to discuss?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 13/10/2021 20:35
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hi Michele

We're currently preparing our questions for the teleconference and will send these through in due course, however to assist with scheduling the relevant parties at FDA, I should let you know that we would definitely like to discuss the questions related to biocompatibility.

After discussion with the team we would like to request the teleconference on the Tuesday 19th October if that is possible? As we are based in the UK, we would also like to request that this is arranged between the hours of 2-5pm BST.

If this time slot is not available could you outline any alternative days/times which would be possible?

Best regards,

Martin Mitchell

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 08/10/2021 22:14

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hi Michele

Thank you for the offer. I think after today's meeting we may need a little more time to be better prepared for the teleconference.

We are reaching out to the (b)(4) for us as we feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible dates for you early next week.

Best regards,

Martin Mitchell

Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Date: 06/10/2021 13:49

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference deadline up to October 19th. Let me know if you would like to select a date later than the 14thand I can check our management schedules.

Regarding review timelines, we are still on the 90 day review cycle and are planning to complete the review of your response with the 20 calendar days left on the clock. While we retain the right to add additional days, we are doing our best with the resources that we have to avoid delaying review timelines if possible.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 6, 2021 6:00 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com
Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hi Michele

Thank you again for your review. Our team are busy discussing the questions and we would definitely like to have a teleconference with the FDA. We're currently consolidating our understanding of the deficiencies and are determining what our potential questions to you would be. I hope to get the questions to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we look to schedule a teleconference with the FDA on Wednesday 13th or Thursday 14th? As we're based in the UK we would appreciate a timeslot within our working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines for this project.... regarding the FDA timeline I can see on the CCP tracker website that the FDA timeline is on day 70.
Will FDA be sticking to the 90 day target and as a result only have 20 days left on the clock?
Or, due to the current situation with the unprecedented resource limitations..... will you will assume 30 days to review the response as standard? Or perhaps stick to the 20 days but retain the right to add additional days?

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
To: <martin.mitchell@admedsol.com>, <helen.topping@admedsol.com>
Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
Date: 04/10/2021 21:44
Subject: K211878/S001 is on Hold Pending Your Response

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

October 4, 2021

We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Michele Lee.

*** This is a system-generated email notification ***[attachment "K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hi Sam

For your ease of reference, please find our response to deficiency 11 below where we discuss the teleconference minutes and the data from the (b)(4)

As requested I've highlighted the teleconference meeting minutes showing the FDA agreement to use the more clinically relevant (b)(4) (b)(4)

I've also highlighted and provided the pertinent pages from (b)(4) (b)(4)

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>
Cc: "K211878@docs.fda.gov" <K211878@docs.fda.gov>, Rose Guang/WIN/UK/AMS@ams
Date: 19/05/2022 10:17
Subject: RE: [EXTERNAL] Re: K211878-s002

Hi Sam

I'll call you today at 6am (11am UK time); we thought it would be better to send you the updated documents to help aid the discussion during the call.

The IFU has been updated with your comments (and as per our modifications we suggest below). I've provided a redlined and clean copy of this: [attachment "IFU - LiquiBand XL.pdf" deleted by Martin Mitchell/WIN/UK/AMS] [attachment "IFU - LiquiBand XL - Tracked.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

The (b)(4) has been updated with your comments

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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[attachment "510K Summary.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>

Cc: "K211878@docs.fda.gov" <K211878@docs.fda.gov>, Rose Guang/WIN/UK/AMS@ams

Date: 18/05/2022 22:37

Subject: RE: [EXTERNAL] Re: K211878-s002

Hi Sam

Firstly, thank you for staying late to continue to work with us on in the final stages of this submission. It is much appreciated.

Please find attached the IFU with updated comments from ourselves

[attachment "K211878-S002 - (b)(4) received on 5-16-2022.jam.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

For most of the proposed updates we will accept to make the changes. However there are two points we would wish to clarify

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

As discussed I'll call you tomorrow to discuss your email below

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>, "K211878@docs.fda.gov" <K211878@docs.fda.gov>

Date: 18/05/2022 20:39

Subject: RE: [EXTERNAL] Re: K211878-s002

Hi Mr. Mitchell:

Please see attached for the (b)(4) with FDA edits.

Please address these edits and send me both the edited versions and clean copies of the (b)(4) by COB tomorrow (5-19-2022).

Please cc your response to K211878@docs.fda.gov.

Thx

Sam

Sam Arepalli, Ph.D.

FDA/CDRH/OPEQ/OHT4/PRSB2

Ph: 301 796 6434

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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https://secure-web.cisco.com/1uQIvbuMdtI2ElEoQe9mrsX0xHhrxSGXdOXk8diqMgnCDgDcUiJbErp0X7sNjRXyovPhcJfzouF5K0xNN2GjY3VpZNNpWaH2uCRTvK74GIzBj5VGsbq4SelX7ukrz7PBNERiix3cxyO1jOVee-eG4-lF5Ml8EJcTo7Trfnu_xXJBeRb5CjSfXdUqRKijPgGS52VsjmDqStMth1873-o8I7w/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1624%26S%3DE

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Tuesday, May 17, 2022 6:39 AM

To: Arepalli, Sambasiva <Sambasiva.Arepalli@fda.hhs.gov>

Subject: RE: [EXTERNAL] Re: K211878-s002

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Hi Sam

Just to be safe for the email trail.... so that your email has a response

The email with this information was send yesterday; however it is also provided again below:

Please find a response to the two points we discussed over the phone

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

As requested, the (b)(4)

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Date: 17/05/2022 10:32
Subject: RE: [EXTERNAL] Re: K211878-s002

Hi Mr. Mitchell:
Can you please give an update on the (b)(4) request? Could you please send the information cob today? Please give me a call when you have a minute.
Thx
Sam

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Sam Arepalli, Ph.D.

FDA/CDRH/OPEQ/OHT4/PRSB2

Ph: 301 796 6434

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Monday, May 16, 2022 12:06 PM

To: Arepalli, Sambasiva <Sambasiva.Arepalli@fda.hhs.gov>

Subject: [EXTERNAL] Re: K211878-s002

CAUTION:This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Sam

Just so you're aware it's 17:00 now so i'll be heading home; however i'll try to make myself available outside of hours so please don't hesitate to get in touch if you have any further questions.

Additionally i'll be working from home the next few days so I won't pick up calls from my office number you used previously.

If you have any further questions please email me or call me on my personal mobile number (b)(6)

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>

Cc: "K211878@docs.fda.gov" <K211878@docs.fda.gov>, Rose Guang/WIN/UK/AMS@ams, Helen Topping/WIN/UK/AMS@ams

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Date: 16/05/2022 16:28

Subject: Re: K211878-s002

Hi Sam

Please find a response to the two points we discussed over the phone

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

As requested, the (b)(4)

[attachment "IFU.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

Cc: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>, "K211878@docs.fda.gov" <K211878@docs.fda.gov>

Date: 16/05/2022 14:39

Subject: K211878-s002

Hi Mr. Martin:

Please address the following:

(b)(4)

Thx

Sam

Sam Arepalli, Ph.D.

FDA/CDRH/OPEQ/OHT4/PRSB2

Ph: 301 796 6434

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Contains Nonbinding Recommendations

Print Form

510(k) Acceptance Checklist

Not for use with Third Party 510(k)s

Choose Submission Type: ☒ **Traditional** ☐ **Abbreviated** ☐ **Special**

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K211878/S001 Date Received by DCC: Jul 26, 2021

Lead Reviewer: John Azeke

Center: CDRH Office: OHT 4 Division: DHT4B

Decision:

◉ Accept. If Accept, notify submitter.

○ Refuse to Accept. If Refuse to Accept, notify submitter electronically and include a copy of this checklist.

Is an Addendum attached?: ○ Yes ◉ No Click paperclip icon on the left panel if Addendum is attached.

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

Preliminary Questions

Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDA's preliminary assessment of these questions at the time of administrative review.)	Yes	No	N/A
1 Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product (per 21 CFR 3.2(e)), or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action, and inform management. *Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If the product does not appear to be a device or such a combination product, mark "No."	☒	☐	
Comments:			
2 Is the submission with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If submission should not be reviewed by your Center mark "No."	☒	☐	
Comments:			

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3 If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: **a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?** **b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide a summary of Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."	☐	☐	☒
Comments:			
4 Is the submission for a combination product that contains as a constituent part a drug that has the same active moiety as an approved drug with exclusivity as described in 21 USC 503(g)(5)(C)(ii)-(v) (section 503(g)(5)(C)(ii)-(v) of the FD&C Act)? If "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide the summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below*.	☐	☐	☒
Comments:			
5 Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), consult with the appropriate CDRH or CBER staff during the acceptance review, provide a summary of the discussion with them, and indicate their recommendation/action in the comment section below. If 510(k) is not the appropriate regulatory submission, mark "No."	☒	☐	
Comments:			
6 Is there a pending PMA for the same device with the same indications for use? If "Yes," consult your management and CDRH Office of Product Evaluation and Quality/Office of Regulatory Programs/Division of Regulatory Programs 1 (Submission Support) (OPEQ/ORP/DRP1) or appropriate CBER staff to determine the appropriate action.	☐	☒	
Comments:			
7 If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If "Yes," consult with the CDRH Office of Product Evaluation and Quality/ Office of Clinical Evidence and Analysis/Division of Clinical Science and Quality (OPEQ/OCEA/DCEA1) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action, provide a summary of the discussion with them, and indicate their recommendation/action. If no clinical studies have been submitted, mark "N/A." Check on the AIP list at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/application-integrity-policy/application-integrity-policy-list.	☐	☐	☒
Comments:			

- If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.
- If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.
- If the answer to 4 is "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer, provide a summary of the discussion with them, and indicate their recommendation/action.
- If the answer to 5 is "No," the lead reviewer should consult management and other Center resources to determine the appropriate action.
- If the answer to 6 is "Yes," then stop review of the 510(k), contact the CDRH/OPEQ/ORP/DRP1, or appropriate CBER staff.
- If the answer to 7 is "Yes," then contact CDRH/OPEQ/OCEA/DCEA1 or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DCEA1 or BMB Staff, and indicate their recommendation/action.

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Organizational Elements

Failure to include these items should not result in an RTA designation.

*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	*Page #
1) Submission contains a Table of Contents	☒	☐	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	☒	☐	
3) All pages of the submission are numbered. *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2…).*	☒	☐	
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special). *If type of 510(k) is not designated, review as a Traditional 510(k).*	☒	☐	
Comments:			

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
A. Administrative					
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	☒	☐		☐	
2) Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form (Form 3514, available at https://www.fda.gov/media/72421/download)):				☐	
a) Device trade/proprietary name	☒	☐			
b) Device class and panel OR Classification regulation OR Statement that device has not been classified with rationale for that conclusion	☒	☐			
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/alternative-certain-prescription-device-labeling-requirements.) *See recommended* format (https://www.fda.gov/media/86323/download).	☒	☐		☐	
4) Submission contains a 510(k) Summary or 510(k) Statement.	☒	☐		☐	
5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(l) *See recommended format (https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-truthful-and-accurate-statement).*	☒	☐		☐	
6) Submission is a Class III 510(k) device.	☐		☒	☐	
7) Submission contains clinical data	☐		☒	☐	
8) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Q-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device.	☒	☐		☐	
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed.	☒	☐	☐		
9) The submission utilizes voluntary consensus standard(s) (See section 514(c) of the FD&C Act). *This includes both FDA-recognized and non-recognized consensus standards.*	☒		☐	☐	
a) The submission cites FDA-recognized voluntary consensus standard(s).	☒		☐		
i) The submission includes a Declaration of Conformity (DOC) as outlined in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices. **OR** If citing general use of a standard as noted in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," the basis of such use is included along with the underlying information or data that supports how the standard was used.	☒	☐			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
b) The submission cites non-FDA-recognized voluntary consensus standard(s).	☐		☒		
Combination Product Provisions - Per 503(g) of the FD&C Act. Select "N/A" if the product is not a combination product. 21 CFR 3.2(e). The remaining criteria in this section will be omitted from the checklist if "N/A" is selected. If you are unsure if the product is a combination product, consult with the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.			☒		
B. Device Description					
12) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding the device description that is applicable to the subject device.	☒		☐	☐	
a) The submission addresses device description recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	☒	☐	☐		
b) The submission includes device description information that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	☒	☐	☐		
13) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).	☒	☐		☐	
14) The submission includes descriptive information for the device, including the following:				☐	
a) A description of the principle of operation or mechanism of action for achieving the intended effect.	☒	☐			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	☒	☐	☐		
c) A list and description of each device for which clearance is requested.	☒	☐	☐		
d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).	☒	☐			
15) Device is intended to be marketed with accessories and/or as part of a system.	☐		☒	☐	
C. Substantial Equivalence Discussion					
16) Submitter has identified a predicate device(s), including the following information:				☐	

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a) Predicate device identifier provided (e.g., 510(k) number, De Novo number, reclassified PMA number, classification regulation reference, if exempt (e.g., 21 CFR 872.3710), or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online (https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/preamendment-status).*	☒	☐			
b) The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).	☒	☐			
17) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See the FDA guidance document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k for more information on comparing intended use and technological characteristics.*				☐	
a) Indications for Use	☒	☐			
b) Technology, including technical specifications, features, materials, and principles of operation	☒	☐			
D. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)					
18) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	☒	☐		☐	
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	☒	☐			
b) Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) **AND** - Includes adequate directions for use (see 21 CFR 801.5) **OR** - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D	☒	☐			
19) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	☒	☐		☐	
20) Labeling includes the prescription statement [see 21 CFR 801.109(b)(1)] or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's guidance "Alternative to Certain Prescription Device Labeling Requirements," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/alternative-certain-prescription-device-labeling-requirements.	☒	☐	☐	☐	
21) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding labeling that is applicable to the subject device.	☒		☐		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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a) The submission addresses labeling recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	☒	☐	☐		
b) The submission includes labeling information that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	☒	☐	☐		
22) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.	☐	☐	☒	☐	
E. Sterilization					
If an *in vitro* diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.			☐		
☒ Provided sterile, intended to be single-use					
☐ Requires processing during its use-life					
☐ Non-sterile when used (and no processing required)					
☐ Information regarding the sterility status of the device is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Sterility status not needed for this device (e.g., software-only device)					
☐ Sterility status needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *Please refer to the FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling, for additional information.*					
23) Assessment of the need for cleaning and subsequent disinfection or sterilization information				☐	
a) Identification of device and/or accessories, if applicable, that are provided sterile.	☒	☐	☐		
b) Identification of device and/or accessories, if applicable, that are end user sterilized or disinfected.	☐	☐	☒		
c) Identification of device, and/or accessories, if applicable, that are reusable.	☐	☐	☒		
24) If the device and/or accessories, if applicable, are provided sterile:			☐	☐	
a) Sterilization method is stated for each device (including dose for radiation sterilization).	☒	☐			

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
b) A description of method to validate the sterilization parameters is provided for each proposed sterilization method (e.g., half-cycle method and full citation of FDA-recognized standard, including date).	☒	☐			
c) For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.	☒	☐	☐		
d) Sterility Assurance Level (SAL) is stated.	☒	☐			
e) Submission includes description of packaging.	☒	☐			
f) For products labeled "non-pyrogenic," a description of the method used to make the determination stated (e.g., limulus amebocyte lysate [LAL]).	☐	☐	☒		
25) If the device and/or accessory, if applicable, is reusable or end user sterilized or disinfected:			☒	☐	
a) Cleaning method is provided in labeling for each device and/or accessory, if applicable.	☐	☐	☒		
b) Disinfection method is provided in labeling for each device and/or accessory, if applicable.	☐	☐	☒		
c) Sterilization method is provided in labeling for each device and/or accessory, if applicable.	☐	☐	☒		
d) Device types in this submission are listed in the Federal Register (FR) Notice entitled "Validated Instructions for Use and Validation Data Requirements for Certain Reusable Medical Devices in Premarket Notifications" (Reprocessing FR Notice, available at https://www.federalregister.gov / documents/2017/06/09/2017-12007/medical-devices-validated-instructions-for-use-and-validation-data-requirements-for-certain-reusable).	☐		☒		
26) The device has a device-specific guidance document, special controls, and/or requirement in a device-specific regulation regarding sterility and/or reprocessing that is applicable to the subject device.	☒		☐	☐	
a) The submission addresses sterility and/or reprocessing recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	☒	☐	☐		
b) The submission includes sterility and/or reprocessing information that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	☒	☐	☐		
F. Shelf Life					
27) Proposed shelf life/expiration date stated **OR** Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation	☒	☐	☐	☐	

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
28) For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf life.	☒	☐	☐	☐	
29) Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). **OR** Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	☒	☐		☐	
G. Biocompatibility					
If an vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.			☐		
Submission states that there: (one of the below must be checked)		☐		☐	
☒ Are direct or indirect tissue-contacting components.					
☐ Are no direct or indirect tissue-contacting components.					
☐ Information regarding tissue contact status of the device is not provided (if this box checked, please also check one of the two boxes below).					
☐ Tissue contact information not needed for this device (e.g., software-only device)					
☐ Tissue contact information needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
30) Submission includes a list identifying each of tissue-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.	☒	☐		☐	
31) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration) for each tissue-contacting device component (e.g., implant, delivery catheter)	☒	☐		☐	

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
32) For a biocompatibility assessment of tissue-contacting components, submission includes: – Each relevant endpoint for the device (as identified in device-specific guidance, or Attachment A of the FDA guidance document entitled "Use of International Standard ISO 10993-1, `Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and), has been addressed. - For any testing performed, test protocol (including identification and description of test article including whether the test article is the device in its final finished form using the recommended approach in Attachment F of "Use of International Standard ISO 10993-1, `Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" methods, and pass/fail criteria), and analysis of results (including tables with data points and statistical analyses, where appropriate), as described in Attachment E of the guidance document entitled "Use of International Standard ISO 10993-1, `Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" provided for each completed test. **OR** A statement that biocompatibility testing is not needed with a rationale that considers all relevant endpoints (e.g., materials and manufacturing/processing are identical to the predicate).	☒	☐		☐	
H. Software					
Submission states that the device: (one of the below must be checked)		☐		☐	
☐ Does contain software/firmware					
☒ Does not contain software/firmware					
☐ Information on whether device contains software/firmware is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Software/firmware information not needed for this device (e.g., surgical suture, condom)					
☐ Software/firmware information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
I. Cybersecurity					
Submission states that the device: *(one of the below must be checked)*		☐		☐	
☐ Does contain any external wired and/or wireless communication interfaces (Wired: USB, ethernet, SD, CD, RGA, etc. or Wireless: Wi-Fi, Bluetooth, RF, inductive, Cloud, etc.)					
☒ Does not contain external interfaces as described above					
☐ Information on whether device has external interfaces is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Cybersecurity information not needed for this device (e.g., surgical suture, condom)					
☐ Cybersecurity information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
J. Electrical Safety and EMC					
Electrical Safety Submission states that the device: *(one of the below must be checked)*		☐		☐	
☐ Does require electrical safety evaluation					
☒ Does not require electrical safety evaluation					
☐ Information on whether device requires electrical safety evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Electrical safety information not needed for this device (e.g., surgical suture, condom)					
☐ Electrical safety information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
EMC Submission states that the device: (one of the below must be checked)		☐		☐	
☐ Does require EMC evaluation					
☒ Does not require EMC evaluation					
☐ Information on whether device requires EMC evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ EMC information not needed for this device (e.g., surgical suture, condom)					
☐ EMC information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
K. Performance Data - General					
If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.			☐		
38) Summaries of the non-clinical laboratory studies and full test reports* are provided. *Summary and full test report content recommendations can be found in FDA's guidance "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket. If a submitter chooses to declare conformity to a voluntary consensus standard that FDA has recognized, submission of a full test report may not be necessary. Refer to 9a. See FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.	☒	☐	☐	☐	
a) Submission includes an explanation of how the data generated from each test supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.).	☒	☐			

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
39) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding performance data that is applicable to the subject device.	☒		☐	☐	
a) The submission addresses performance data recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	☒	☐	☐		
b) The submission includes performance data that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	☒	☐	☐		
40) If literature is referenced in the submission, submission includes:			☒		
41) For each completed animal study, the submission provides the following:			☐	☐	
a) Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120.	☒	☐			
b) Submission includes final study report which includes all elements outlined in 21 CFR 58.185.	☒	☐			
c) Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.	☒	☐			

L. Performance Characteristics - In Vitro Diagnostic Devices Only

(Also see 21 CFR 809.10(b)(12))

Submission states that the device: (one of the below must be checked)		
☐	is an in vitro diagnostic device.	
☒	is not an in vitro diagnostic device.	
If "is not" is selected, the performance data-related criteria below are omitted from the checklist.		

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Digital Signature Concurrence Table

Reviewer Sign-Off	John Azeke -S	Digitally signed by John Azeke -S Date: 2021.08.09 18:12:05 -04'00'
Management Sign-Off (digital signature optional)*	Lixin Liu -S	Digitally signed by Lixin Liu -S Date: 2021.08.09 20:56:55 -04'00'

* Management review of checklist and concurrence with with decision required.

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Web : www.admedsol.com

Meeting Minutes

Submission Number:	K211878 / S001
Submission Type:	510(k)
Product Name:	LiquiBand XL
Submitter:	Martin Mitchell
Meeting Date / Time:	14:00 BST on the 19th of October 2021
Meeting Format:	Teleconference via Zoom
Date FDA feedback was Sent:	4th October 2021

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

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(b)(4)

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(b)(4)

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(b)(4)

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference deadline up to October 19th. Let me know if you would like to select a date later than the 14th and I can check our management schedules.

Regarding review timelines, we are still on the 90 day review cycle and are planning to complete the review of your response with the 20 calendar days left on the clock. While we retain the right to add additional days, we are doing our best with the resources that we have to avoid delaying review timelines if possible.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 6, 2021 6:00 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com
Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Michele

Thank you again for your review. Our team are busy discussing the questions and we would definitely like to have a teleconference with the FDA. We're currently consolidating our understanding of the deficiencies and are determining what our potential questions to you would be. I hope to get the questions to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we look to schedule a teleconference with the FDA on Wednesday 13th or Thursday 14th? As we're based in the UK we would appreciate a timeslot within our working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines for this project.... regarding the FDA timeline I can see on the CCP tracker website that the FDA timeline is on day 70.

- Will FDA be sticking to the 90 day target and as a result only have 20 days left on the clock?
- Or, due to the current situation with the unprecedented resource limitations..... will you will assume 30 days to review the response as standard? Or perhaps stick to the 20 days but retain the right to add additional days?

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
To: <martin.mitchell@admedsol.com>, <helen.topping@admedsol.com>
Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
Date: 04/10/2021 21:44
Subject: K211878/S001 is on Hold Pending Your Response

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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October 4, 2021

We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Michele Lee.

*** This is a system-generated email notification ***[attachment "K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

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Contains Nonbinding Recommendations

Print Form

510(k) Acceptance Checklist

Not for use with Third Party 510(k)s

Choose Submission Type: ☒ **Traditional** ☐ **Abbreviated** ☐ **Special**

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K211878 Date Received by DCC: Jun 21, 2021

Lead Reviewer: Michele Lee

Center: CDRH Office: OHT 4 Division: DHT4B

Decision:

○ Accept. If Accept, notify submitter.

◉ Refuse to Accept. If Refuse to Accept, notify submitter electronically and include a copy of this checklist.

Is an Addendum attached?: ○ Yes ◉ No Click paperclip icon on the left panel if Addendum is attached.

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

Preliminary Questions

Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDA's preliminary assessment of these questions at the time of administrative review.)	Yes	No	N/A
1 Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product (per 21 CFR 3.2(e)), or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action, and inform management. *Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If the product does not appear to be a device or such a combination product, mark "No."	☒	☐	
Comments:			
2 Is the submission with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If submission should not be reviewed by your Center mark "No."	☒	☐	
Comments:			

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3 If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: **a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?** **b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide a summary of Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."	☐	☐	☒
Comments:			
4 Is the submission for a combination product that contains as a constituent part a drug that has the same active moiety as an approved drug with exclusivity as described in 21 USC 503(g)(5)(C)(ii)-(v) (section 503(g)(5)(C)(ii)-(v) of the FD&C Act)? If "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide the summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below*.	☐	☐	☒
Comments:			
5 Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), consult with the appropriate CDRH or CBER staff during the acceptance review, provide a summary of the discussion with them, and indicate their recommendation/action in the comment section below. If 510(k) is not the appropriate regulatory submission, mark "No."	☒	☐	
Comments:			
6 Is there a pending PMA for the same device with the same indications for use? If "Yes," consult your management and CDRH Office of Product Evaluation and Quality/Office of Regulatory Programs/Division of Regulatory Programs 1 (Submission Support) (OPEQ/ORP/DRP1) or appropriate CBER staff to determine the appropriate action.	☐	☒	
Comments:			
7 If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If "Yes," consult with the CDRH Office of Product Evaluation and Quality/ Office of Clinical Evidence and Analysis/Division of Clinical Science and Quality (OPEQ/OCEA/DCEA1) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action, provide a summary of the discussion with them, and indicate their recommendation/action. If no clinical studies have been submitted, mark "N/A." Check on the AIP list at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/application-integrity-policy/application-integrity-policy-list.	☐	☐	☒
Comments:			

- If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.
- If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.
- If the answer to 4 is "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer, provide a summary of the discussion with them, and indicate their recommendation/action.
- If the answer to 5 is "No," the lead reviewer should consult management and other Center resources to determine the appropriate action.
- If the answer to 6 is "Yes," then stop review of the 510(k), contact the CDRH/OPEQ/ORP/DRP1, or appropriate CBER staff.
- If the answer to 7 is "Yes," then contact CDRH/OPEQ/OCEA/DCEA1 or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DCEA1 or BMB Staff, and indicate their recommendation/action.

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Organizational Elements

Failure to include these items should not result in an RTA designation.

*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	*Page #
1) Submission contains a Table of Contents	☒	☐	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	☒	☐	
3) All pages of the submission are numbered. *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2…).*	☒	☐	
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special). *If type of 510(k) is not designated, review as a Traditional 510(k).*	☒	☐	
Comments:			

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
A. Administrative					
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	☒	☐		☐	
2) Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form (Form 3514, available at https://www.fda.gov/media/72421/download)):				☐	
a) Device trade/proprietary name	☒	☐			
b) Device class and panel OR Classification regulation OR Statement that device has not been classified with rationale for that conclusion	☒	☐			
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/alternative-certain-prescription-device-labeling-requirements.) *See recommended* format (https://www.fda.gov/media/86323/download).	☒	☐		☐	
4) Submission contains a 510(k) Summary or 510(k) Statement.	☒	☐		☐	
5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(l) *See recommended format (https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-truthful-and-accurate-statement).*	☒	☐		☐	
6) Submission is a Class III 510(k) device.	☐		☒	☐	
7) Submission contains clinical data	☐		☒	☐	
8) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Q-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device.	☒	☐		☐	
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed.	☒	☐	☐		
9) The submission utilizes voluntary consensus standard(s) (See section 514(c) of the FD&C Act). *This includes both FDA-recognized and non-recognized consensus standards.*	☒		☐	☐	
a) The submission cites FDA-recognized voluntary consensus standard(s).	☒		☐		
i) The submission includes a Declaration of Conformity (DOC) as outlined in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices. **OR** If citing general use of a standard as noted in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," the basis of such use is included along with the underlying information or data that supports how the standard was used.	☒	☐			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
b) The submission cites non-FDA-recognized voluntary consensus standard(s).	☐		☒		
Combination Product Provisions - Per 503(g) of the FD&C Act. Select "N/A" if the product is not a combination product. 21 CFR 3.2(e). The remaining criteria in this section will be omitted from the checklist if "N/A" is selected. If you are unsure if the product is a combination product, consult with the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.			☒		
B. Device Description					
12) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding the device description that is applicable to the subject device.	☒		☐	☒	
a) The submission addresses device description recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	☐	☒	☐		
b) The submission includes device description information that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	☒	☐	☐		
Comments:	(b)(4)				
13) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).	☒	☐		☐	
14) The submission includes descriptive information for the device, including the following:				☐	
a) A description of the principle of operation or mechanism of action for achieving the intended effect.	☒	☐			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	☒	☐	☐		
c) A list and description of each device for which clearance is requested.	☒	☐	☐		

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).	☒	☐			
15) Device is intended to be marketed with accessories and/or as part of a system.	☐		☒	☐	
C. Substantial Equivalence Discussion					
16) Submitter has identified a predicate device(s), including the following information:				☐	
a) Predicate device identifier provided (e.g., 510(k) number, De Novo number, reclassified PMA number, classification regulation reference, if exempt (e.g., 21 CFR 872.3710), or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online (https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/preamendment-status).*	☒	☐			
b) The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).	☒	☐			
17) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See the FDA guidance document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k for more information on comparing intended use and technological characteristics.*				☐	
a) Indications for Use	☒	☐			
b) Technology, including technical specifications, features, materials, and principles of operation	☒	☐			
D. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)					
18) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	☒	☐		☐	
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	☒	☐			
b) Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) **AND** - Includes adequate directions for use (see 21 CFR 801.5) **OR** - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D	☒	☐			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
19) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	☒	☐		☐	
20) Labeling includes the prescription statement [see 21 CFR 801.109(b)(1)] or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's guidance "Alternative to Certain Prescription Device Labeling Requirements," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/alternative-certain-prescription-device-labeling-requirements.	☒	☐	☐	☐	
21) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding labeling that is applicable to the subject device.	☒		☐		
a) The submission addresses labeling recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	☒	☐	☐		
b) The submission includes labeling information that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	☒	☐	☐		
22) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.	☐	☐	☒	☐	
E. Sterilization					
If an *in vitro* diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.			☐		
☒ Provided sterile, intended to be single-use					
☐ Requires processing during its use-life					
☐ Non-sterile when used (and no processing required)					
☐ Information regarding the sterility status of the device is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Sterility status not needed for this device (e.g., software-only device)					
☐ Sterility status needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *Please refer to the FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling, for additional information.*					
23) Assessment of the need for cleaning and subsequent disinfection or sterilization information				☐	

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
a) Identification of device and/or accessories, if applicable, that are provided sterile.	☒	☐	☐		
b) Identification of device and/or accessories, if applicable, that are end user sterilized or disinfected.	☐	☐	☒		
c) Identification of device, and/or accessories, if applicable, that are reusable.	☐	☐	☒		
24) If the device and/or accessories, if applicable, are provided sterile:			☐	☐	
a) Sterilization method is stated for each device (including dose for radiation sterilization).	☒	☐			
b) A description of method to validate the sterilization parameters is provided for each proposed sterilization method (e.g., half-cycle method and full citation of FDA-recognized standard, including date).	☒	☐			
c) For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.	☒	☐	☐		
d) Sterility Assurance Level (SAL) is stated.	☒	☐			
e) Submission includes description of packaging.	☒	☐			
f) For products labeled "non-pyrogenic," a description of the method used to make the determination stated (e.g., limulus amebocyte lysate [LAL]).	☐	☐	☒		
25) If the device and/or accessory, if applicable, is reusable or end user sterilized or disinfected:			☒	☐	
a) Cleaning method is provided in labeling for each device and/or accessory, if applicable.	☐	☐	☒		
b) Disinfection method is provided in labeling for each device and/or accessory, if applicable.	☐	☐	☒		
c) Sterilization method is provided in labeling for each device and/or accessory, if applicable.	☐	☐	☒		
d) Device types in this submission are listed in the Federal Register (FR) Notice entitled "Validated Instructions for Use and Validation Data Requirements for Certain Reusable Medical Devices in Premarket Notifications" (Reprocessing FR Notice, available at https://www.federalregister.gov / documents/2017/06/09/2017-12007/medical-devices-validated-instructions-for-use-and-validation-data-requirements-for-certain-reusable).	☐		☒		
26) The device has a device-specific guidance document, special controls, and/or requirement in a device-specific regulation regarding sterility and/or reprocessing that is applicable to the subject device.	☒		☐	☐	
a) The submission addresses sterility and/or reprocessing recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	☒	☐	☐		

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
b) The submission includes sterility and/or reprocessing information that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	☒	☐	☐		
F. Shelf Life					
27) Proposed shelf life/expiration date stated **OR** Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation	☒	☐	☐	☐	
28) For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf life.	☐	☒	☐	☒	
Comments:	(b)(4)				
29) Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). **OR** Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	☐	☒		☒	
Comments:	(b)(4)				
G. Biocompatibility					
If an vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.			☐		
Submission states that there: (one of the below must be checked)		☐		☐	
☒ Are direct or indirect tissue-contacting components.					
☐ Are no direct or indirect tissue-contacting components.					
☐ Information regarding tissue contact status of the device is not provided (if this box checked, please also check one of the two boxes below).					
☐ Tissue contact information not needed for this device (e.g., software-only device)					
☐ Tissue contact information needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
30) Submission includes a list identifying each of tissue-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.	☒	☐		☐	
31) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration) for each tissue-contacting device component (e.g., implant, delivery catheter)	☒	☐		☐	
32) For a biocompatibility assessment of tissue-contacting components, submission includes: – Each relevant endpoint for the device (as identified in device-specific guidance, or Attachment A of the FDA guidance document entitled "Use of International Standard ISO 10993-1, `Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and), has been addressed. - For any testing performed, test protocol (including identification and description of test article including whether the test article is the device in its final finished form using the recommended approach in Attachment F of "Use of International Standard ISO 10993-1, `Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" methods, and pass/fail criteria), and analysis of results (including tables with data points and statistical analyses, where appropriate), as described in Attachment E of the guidance document entitled "Use of International Standard ISO 10993-1, `Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" provided for each completed test. **OR** A statement that biocompatibility testing is not needed with a rationale that considers all relevant endpoints (e.g., materials and manufacturing/processing are identical to the predicate).	☒	☐		☐	
H. Software					
Submission states that the device: (one of the below must be checked)		☐		☐	
☐ Does contain software/firmware					
☒ Does not contain software/firmware					
☐ Information on whether device contains software/firmware is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Software/firmware information not needed for this device (e.g., surgical suture, condom)					
☐ Software/firmware information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
I. Cybersecurity					
Submission states that the device: *(one of the below must be checked)*		☐		☐	
☐ Does contain any external wired and/or wireless communication interfaces (Wired: USB, ethernet, SD, CD, RGA, etc. or Wireless: Wi-Fi, Bluetooth, RF, inductive, Cloud, etc.)					
☒ Does not contain external interfaces as described above					
☐ Information on whether device has external interfaces is not provided. (If this box is checked, please also check one of the two boxes below.)					

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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☐ Cybersecurity information not needed for this device (e.g., surgical suture, condom)					
☐ Cybersecurity information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
J. Electrical Safety and EMC					
Electrical Safety Submission states that the device: *(one of the below must be checked)*		☐		☐	
☐ Does require electrical safety evaluation					
☒ Does not require electrical safety evaluation					
☐ Information on whether device requires electrical safety evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Electrical safety information not needed for this device (e.g., surgical suture, condom)					
☐ Electrical safety information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
EMC Submission states that the device: (one of the below must be checked)		☐		☐	
☐ Does require EMC evaluation					
☒ Does not require EMC evaluation					
☐ Information on whether device requires EMC evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ EMC information not needed for this device (e.g., surgical suture, condom)					
☐ EMC information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
K. Performance Data - General					
If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.			☐		

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
38) Summaries of the non-clinical laboratory studies and full test reports* are provided. *Summary and full test report content recommendations can be found in FDA's guidance "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket. If a submitter chooses to declare conformity to a voluntary consensus standard that FDA has recognized, submission of a full test report may not be necessary. Refer to 9a. See FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.	☒	☐	☐	☐	
a) Submission includes an explanation of how the data generated from each test supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.).	☒	☐			
39) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding performance data that is applicable to the subject device.	☒		☐	☐	
a) The submission addresses performance data recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	☒	☐	☐		
b) The submission includes performance data that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	☒	☐	☐		
40) If literature is referenced in the submission, submission includes:			☒		
41) For each completed animal study, the submission provides the following:			☐	☐	
a) Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120.	☒	☐			
b) Submission includes final study report which includes all elements outlined in 21 CFR 58.185.	☒	☐			
c) Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.	☒	☐			
L. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**					
Submission states that the device: (one of the below must be checked)				☐	
☐ is an in vitro diagnostic device					

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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☒ is not an in vitro diagnostic device.					
If "is not" is selected, the performance data-related criteria below are omitted from the checklist.					

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Digital Signature Concurrence Table

Reviewer Sign-Off	Michele Lee -S Digitally signed by Michele Lee -S Date: 2021.07.06 15:04:54 -04'00'
Management Sign-Off (digital signature optional)*	

* Management review of checklist and concurrence with with decision required.

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U.S. FOOD & DRUG ADMINISTRATION

RE: K211878 S2

Product: LiquiBand® XL Skin Closure System

Date: 5/16/2022

To: Arepalli, Sambasiva

CDRH/OPEQ/OHTIV/DHTIVB

From: **Steven Wood**, PhD
Research Biologist CDRH/OSEL/DBCMS

(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

July 6, 2021</br></br>

Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your submission K211878. Our review indicates that your submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit one eCopy of your response, referencing your submission K211878, addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration

Center for Devices and Radiological Health

Document Control Center - WO66-G609

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

Your submission will remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist by 01/02/2022, we will consider this submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your submission. We will contact you if we require any additional information during the course of our administrative review. FDA aims to apply the least burdensome principles when requesting additional information.

The lead reviewer assigned to your submission is me, Michele Lee. The file is being reviewed in Office of Health Technology 4, Division of Health Technology 4 B. The first line supervisor is the Assistant Director, Plastic Surgery Skin and Wound Devices. You may contact me at any point during the review if you have questions or concerns. You can provide valuable support for CDRH to continue to improve our programs by raising to the attention of management relevant issues that arise during the course of this review. If you feel there is an unresolved issue or a matter that requires additional attention, you should contact the Assistant Director. If your concern or issue is not addressed by the Assistant Director, you should contact the Division Director or OHT Director. The contact information for each management level can be found in the CDRH Management Directory.

For additional information about the Refuse to Accept Policy for for 510(k)s please refer to the guidance document available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf.

If you have general questions about the review process for your submission, you should contact OPEQSubmissionSupport@fda.hhs.gov.

 *** This is a system-generated email notification ***

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Hello Martin,

A new lead reviewer will not be assigned until a follow up submission is received. So there is currently not a primary contact unless there is an active submission under FDA review. All of our correspondence and the prior related review have been documented internally, so you can be assured that the history of the prior review and contact is available to the future lead reviewer.

Best,
Michele

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Friday, March 25, 2022 12:21 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Michele

I've seen on the FDA customer collaboration portal that the time has automatically been added, but just thought it would be prudent to also inform you of the situation.

Could I ask who the primary contact is now? Will you be assisting or have any involvement with the review of our response?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 25/03/2022 15:59
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

I am sorry to hear about the cyber attack. I hope all is able to be resolved soon.

Thank you for the update. I am actually working in a different division within FDA and no longer the primary contact for this submission. I believe that the 180 days is automatically granted for responses to AINN hold but you can also confirm with the 510(k) Program staff (510k_Program@fda.hhs.gov, telephone: 301-796-5640) to make sure.

Best,
Michele

Michele Lee, Ph.D.*(she/her/hers)*
Regulatory Science Program Manager
Partnerships to Advance Innovation and Regulatory Science (PAIRS)

Center for Devices and Radiological Health
Office of Strategic Partnerships and Technology Innovation
Division of All Hazards Response, Science, and Strategic Partnerships
U.S. Food and Drug Administration
michele.lee@fda.hhs.gov



* * * * *

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?ID=7013&S=E.

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Friday, March 25, 2022 11:28 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

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Hi Michele

I'd like to provide an update on our progress with responding to the deficiencies raised on K211878

We were on track to have a deficiency response submitted to the FDA by the 180 day hold period deadline of 2nd April 2022.

However, the organisation performing the (b)(4) have been affected by (b)(4) As a result, they were unable to complete the testing by our targeted timeline.

Therefore, I just want to confirm that we are still intending to respond to the deficiencies, but we would need to use the second 180 day hold period granted to us through the COVID-19 situation.

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 08/11/2021 22:05
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thanks for your message. I'll need some time to review the teleconference minutes with my team and also obtain some feedback from our consulting toxicologist about the follow up questions. But I wanted to let you know I received your email and you may feel free to check in again next week.

I do have a clarification question about Follow Up (b)(4)

(b)(4)

Regarding the timeline clarification- I am also under the understanding that the COVID-19 guidance document you cited was still active and that would allow you an additional 180 days for the hold period. I have reached out to the 510(k) Staff multiple times to confirm and am still waiting on their response. Is there a customer service contact email for the customer collaboration portal specifically? You may try contacting them as well to have the date corrected on your end.

Thank you,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Friday, November 5, 2021 12:07 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

I hope you had a nice holiday!

Following on from the teleconference we had a few actions to complete and get back to you with.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1) Teleconference minutes

Please find a draft of the the teleconference minutes below. Could you review and confirm if you require any changes made?

2) Follow-up questions on the teleconference discussion

As suggested during the teleconference there was the opportunity for a followup email clarification on a few minor points.

(b)(4)

The supporting information which provides further clarity on the questions above has been attached if required.

3) Timeline clarification as per previous email

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Thank you again for your assistance

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>, "Liu, Lixin" <Lixin.Liu@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 20/10/2021 22:43
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Michele

Thank you for the prompt response to the clarifications! We'll take your points on board regarding future shelf life studies.

I do have a minor clarification question regarding our response timeline

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 20/10/2021 14:55
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you to you and your team for attending the teleconference yesterday. I wanted to follow up on two things I was discussing with my team:

(b)(4)

I will be on leave for the next two weeks and you may contact our team management (Lixin.Liu@fda.hhs.gov) if you have questions during that time.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

* ° * * °

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From: Lee, Michele
Sent: Friday, October 15, 2021 4:47 PM
To: Martin.Mitchell@admedsol.com
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you for providing your questions in advance of the meeting. We look forward to discussing our responses with you next week.

Have a good weekend,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov



* * * * *

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Friday, October 15, 2021 12:00 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Please find the list of questions/clarifications attached below.

I hope you have a good weekend. I'm looking forwards to our discussion next week!

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 13/10/2021 22:35
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

I have scheduled the teleconference for next Tuesday October 19th at 9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour but our biocompatibility consultant/ team management needs to drop off for another call at 9:30am. Please send me the questions for discussion in advance of the meeting so that we can plan to discuss biocompatibility/ regulatory questions first before the relevant parties need to drop off.

Join Zoom Meeting
One tap mobile:
Meeting URL:
Meeting ID:
Passcode:
(b)(4)

Join by Telephone
For higher quality, dial a number based on your current location.
Dial:

Meeting ID:
Passcode:
(b)(4)
international numbers

Join from an H.323/SIP room system
H.323:

Meeting ID:
Passcode:
SIP:
Passcode:
(b)(4)

Thanks,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
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Michele.Lee@fda.hhs.gov



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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 13, 2021 4:46 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Apologies Michele, one final thing I missed off my email... could you clarify how long the teleconference would be by default? Could we request 1 hour just incase some of the points end up taking longer to discuss?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 13/10/2021 20:35
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hi Michele

We're currently preparing our questions for the teleconference and will send these through in due course, however to assist with scheduling the relevant parties at FDA, I should let you know that we would definitely like to discuss the questions related to biocompatibility.

After discussion with the team we would like to request the teleconference on the Tuesday 19th October if that is possible? As we are based in the UK, we would also like to request that this is arranged between the hours of 2-5pm BST.

If this time slot is not available could you outline any alternative days/times which would be possible?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 08/10/2021 22:14

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hi Michele

Thank you for the offer. I think after today's meeting we may need a little more time to be better prepared for the teleconference.

We are reaching out to the **(b)(4)** us as we feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible dates for you early next week.

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 06/10/2021 13:49
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference deadline up to October 19th. Let me know if you would like to select a date later than the 14thand I can check our management schedules.

Regarding review timelines, we are still on the 90 day review cycle and are planning to complete the review of your response with the 20 calendar days left on the clock. While we retain the right to add additional days, we are doing our best with the resources that we have to avoid delaying review timelines if possible.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 6, 2021 6:00 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com
Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Thank you again for your review. Our team are busy discussing the questions and we would definitely like to have a teleconference with the FDA. We're currently consolidating our understanding of the deficiencies and are determining what our potential questions to you would be. I hope to get the questions to you by Monday 11th at the latest.

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Therefore, with the 10 day teleconference deadline in mind.... could we look to schedule a teleconference with the FDA on Wednesday 13th or Thursday 14th? As we're based in the UK we would appreciate a timeslot within our working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines for this project.... regarding the FDA timeline I can see on the CCP tracker website that the FDA timeline is on day 70.

- Will FDA be sticking to the 90 day target and as a result only have 20 days left on the clock?
- Or, due to the current situation with the unprecedented resource limitations..... will you will assume 30 days to review the response as standard? Or perhaps stick to the 20 days but retain the right to add additional days?

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
To: <martin.mitchell@admedsol.com>, <helen.topping@admedsol.com>
Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
Date: 04/10/2021 21:44
Subject: K211878/S001 is on Hold Pending Your Response

October 4, 2021

We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Michele Lee.

*** This is a system-generated email notification ***[attachment "K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hello Martin,

Thank you for your follow up email and your patience. It is an extremely busy time for the Agency this time of year.

I took a look at your comments and it seems your request on item #2 is for review of additional information in your response to our feedback rather than for clarification. In order to conduct review of the evidence provided in your response, we would need to issue a consult for a submission under active review. Currently, the Agency does not have resources to conduct informal review of submissions on hold. I recommend that you provide this justification and supporting evidence in your supplemental response for this submission and it will be reviewed when your submission is under active review.

Best,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D7F330.9F180410]<http://www.fda.gov/>

[cid:image002.jpg@01D7F330.9F180410]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D7F330.9F180410] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7F330.9F180410] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7F330.9F180410] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D7F330.9F180410]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Friday, December 17, 2021 4:58 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: helen.topping@admedsol.com; k211878@docs.fda.gov

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Good morning Michele

I was just emailing to ask if you picked up this email and forwarded this onto your consulting toxicologist?

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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If so do you think it may be possible to expect feedback before the end of this year?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 07/12/2021 17:08

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Michele

Thank you for your support on our questions below. Its been invaluable to our team to get this crucial feedback in such a short timeline.

After reading your response (provided in red fontbelow) we have provided a response on points 2 and 4 which have been provided in blue font to which we would like to get clarification on.

Supporting evidence is provided below if required.

[attachment "Supporting evidence.pdf" deleted by Martin Mitchell/WIN/UK/AMS]
[attachment "(b)(4)" deleted by Martin Mitchell/WIN/UK/AMS]

Additionally, please also find the finalised meeting minutes below

[attachment "K211878 - 19Oct2021 Meeting Minutes - Final.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

Thank you in advance for all your support.

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 24/11/2021 18:00

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

Please find the responses to your questions below in red font and revised meeting minutes attached. Hope this is helpful!

Best,

Michele

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

(b)(4). As requested, this clarification will also be provided within the future supplement in addition to the rationale above.

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D7F330.9F180410]<http://www.fda.gov/>

[cid:image002.jpg@01D7F330.9F180410]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D7F330.9F180410] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7F330.9F180410] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7F330.9F180410] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D7F330.9F180410]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>
<Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Friday, November 12, 2021 10:15 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>;
k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

Regarding the timeline clarification i've taken a look on the customer collaboration portal but there was only an email to provide feedback on the portal. Nevertheless i've emailed as i'm a little concerned about what may happen if the portal shows that the 180 day hold periods has expired and we haven't yet submitted our response..... is there a risk that the 510(k) may be inadvertently withdrawn?

We have prepared our response to your question below which I hope you find helpful.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

(b)(4)

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 08/11/2021 22:05

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

Thanks for your message. Iâ€™ll need some time to review the teleconference minutes with my team and also obtain some feedback from our consulting toxicologist about the follow up questions. But I wanted to let you know I received your email and you may feel free to check in again next week.

I do have a clarification question about Follow Up (b)(4)

(b)(4)

Regarding the timeline clarification- I am also under the understanding that the COVID-19 guidance document you cited was still active and that would allow you an additional 180 days for the hold period. I have reached out to the 510(k) Staff multiple times to confirm and am still waiting on their response. Is there a customer service contact email for the customer collaboration portal specifically? You may try contacting them as well to have the date corrected on your end.

Thank you,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D7F330.9F180410]<http://www.fda.gov/>

[cid:image002.jpg@01D7F330.9F180410]<https://www.facebook.com/FDA>[cid:image003.jpg@01D7F330.9F180410]<https://twitter.com/US_FDA> [cid:image004.jpg@01D7F330.9F180410]<http://www.youtube.com/user/USFoodandDrugAdmin> [cid:image005.jpg@01D7F330.9F180410]<http://www.flickr.com/photos/fdaphotos/> [cid:image006.jpg@01D7F330.9F180410]<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Friday, November 5, 2021 12:07 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

I hope you had a nice holiday!

Following on from the teleconference we had a few actions to complete and get back to you with.

1) Teleconference minutes

Please find a draft of the the teleconference minutes below. Could you review and confirm if you require any changes made?

2) Follow-up questions on the teleconference discussion

As suggested during the teleconference there was the opportunity for a followup email clarification on a few minor points.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

The supporting information which provides further clarity on the questions above has been attached if required.

3) Timeline clarification as per previous email

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

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Thank you again for your assistance

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>, "Liu, Lixin" <Lixin.Liu@fda.hhs.gov<mailto:Lixin.Liu@fda.hhs.gov>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 20/10/2021 22:43

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Michele

Thank you for the prompt response to the clarifications! We'll take your points on board regarding future shelf life studies.

I do have a minor clarification question regarding our response timeline

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 20/10/2021 14:55

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

_____

Hello Martin,

Thank you to you and your team for attending the teleconference yesterday. I wanted to follow up on two things I was discussing with my team:

(b)(4)

I will be on leave for the next two weeks and you may contact our team management (Lixin.Liu@fda.hhs.gov<mailto:Lixin.Liu@fda.hhs.gov>) if you have questions during that time.

Best,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

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[cid:image002.jpg@01D7F330.9F180410]<https://www.facebook.com/FDA>[cid:image003.jpg@01D7F330.9F180410]<https://twitter.com/US_FDA>[cid:image004.jpg@01D7F330.9F180410]<http://

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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www.youtube.com/user/USFoodandDrugAdmin>[cid:image005.jpg@01D7F330.9F180410]<http://www
.flickr.com/photos/fdaphotos/> [cid:image006.jpg@01D7F330.9F180410]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: Lee, Michele

Sent: Friday, October 15, 2021 4:47 PM

To: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you for providing your questions in advance of the meeting. We look forward to discussing our responses with you next week.

Have a good weekend,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D7F330.9F180410]<http://www.fda.gov/>

[cid:image002.jpg@01D7F330.9F180410]<https://www.facebook.com/FDA>[cid:image003.jpg@01D
7F330.9F180410]<https://twitter.com/US_FDA>[cid:image004.jpg@01D7F330.9F180410]<http://
www.youtube.com/user/USFoodandDrugAdmin>[cid:image005.jpg@01D7F330.9F180410]<http://www
.flickr.com/photos/fdaphotos/> [cid:image006.jpg@01D7F330.9F180410]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admed
sol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Friday, October 15, 2021 12:00 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>;

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Please find the list of questions/clarifications attached below.

I hope you have a good weekend. I'm looking forwards to our discussion next week!

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 13/10/2021 22:35

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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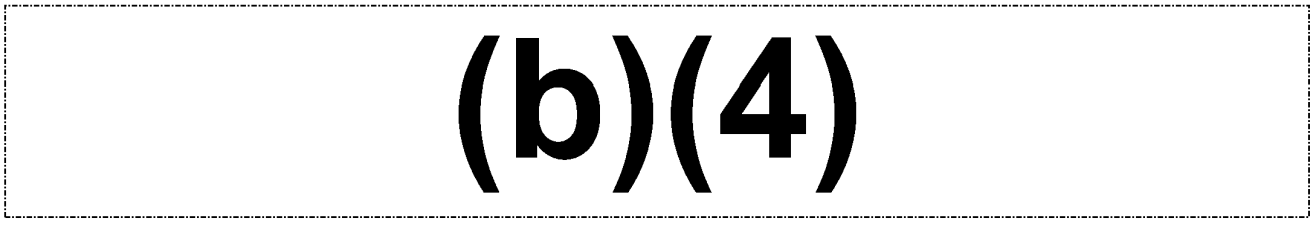
Hello Martin,

I have scheduled the teleconference for next Tuesday October 19that 9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour but our biocompatibility consultant/ team management needs to drop off for another call at 9:30am. Please send me the questions for discussion in advance of the meeting so that we can plan to discuss biocompatibility/ regulatory questions first before the relevant parties need to drop off.

Join Zoom



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Thanks,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

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Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

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[cid:image002.jpg@01D7F330.9F180410]<https://www.facebook.com/FDA>[cid:image003.jpg@01D7F330.9F180410]<https://twitter.com/US_FDA>[cid:image004.jpg@01D7F330.9F180410]<http://www.youtube.com/user/USFoodandDrugAdmin>[cid:image005.jpg@01D7F330.9F180410]<http://www.flickr.com/photos/fdaphotos/>[cid:image006.jpg@01D7F330.9F180410]<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Wednesday, October 13, 2021 4:46 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Apologies Michele, one final thing I missed off my email... could you clarify how long the teleconference would be by default? Could we request 1 hour just incase some of the points end up taking longer to discuss?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 13/10/2021 20:35

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hi Michele

We're currently preparing our questions for the teleconference and will send these through in due course, however to assist with scheduling the relevant parties at FDA, I should let you know that we would definitely like to discuss the questions related to biocompatibility.

After discussion with the team we would like to request the teleconference on the Tuesday 19th October if that is possible? As we are based in the UK, we would also like to request that this is arranged between the hours of 2-5pm BST.

If this time slot is not available could you outline any alternative days/times which would be possible?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 08/10/2021 22:14

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hi Michele

Thank you for the offer. I think after today's meeting we may need a little more time to be better prepared for the teleconference.

We are reaching out to the (b)(4) for us as we feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible dates for you early next week.

Best regards,

Martin Mitchell

Senior Regulatory Affairs Associate

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 06/10/2021 13:49

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference deadline up to October 19th. Let me know if you would like to select a date later than the 14thand I can check our management schedules.

Regarding review timelines, we are still on the 90 day review cycle and are planning to complete the review of your response with the 20 calendar days left on the clock. While we retain the right to add additional days, we are doing our best with the resources that we have to avoid delaying review timelines if possible.

Best,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

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[cid:image002.jpg@01D7F330.9F180410]<https://www.facebook.com/FDA>[cid:image003.jpg@01D7F330.9F180410]<https://twitter.com/US_FDA>[cid:image004.jpg@01D7F330.9F180410]<http://www.youtube.com/user/USFoodandDrugAdmin>[cid:image005.jpg@01D7F330.9F180410]<http://www

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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.flickr.com/photos/fdaphotos/>[cid:image006.jpg@01D7F330.9F180410]<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Wednesday, October 6, 2021 6:00 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>

Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Thank you again for your review. Our team are busy discussing the questions and we would definitely like to have a teleconference with the FDA. We're currently consolidating our understanding of the deficiencies and are determining what our potential questions to you would be. I hope to get the questions to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we look to schedule a teleconference with the FDA on Wednesday 13th or Thursday 14th? As we're based in the UK we would appreciate a timeslot within our working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines for this project.... regarding the FDA timeline I can see on the CCP tracker website that the FDA timeline is on day 70.

* Will FDA be sticking to the 90 day target and as a result only have 20 days left on the clock?

* Or, due to the current situation with the unprecedented resource limitations..... will you will assume 30 days to review the response as standard? Or perhaps stick to the 20 days but retain the right to add additional days?

Best regards,

Martin Mitchell

Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov<mailto:michele.lee@fda.hhs.gov>>

To: <martin.mitchell@admedsol.com<mailto:martin.mitchell@admedsol.com>>, <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov<mailto:michele.lee@fda.hhs.gov>>

Date: 04/10/2021 21:44

Subject: K211878/S001 is on Hold Pending Your Response

October 4, 2021

We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Michele Lee.

*** This is a system-generated email notification ***[attachment "K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Advanced Medical Solutions Ltd
Western Wood Way,
Langage Science Park,
Plympton, Plymouth,
Devon, PL7 5BG, UK
Tel : +44 (0)1752 209955 **Fax :** +44 (0)1752 209956
Web : www.admedsol.com

Meeting Minutes

Submission Number:	K211878 / S001
Submission Type:	510(k)
Product Name:	LiquiBand XL
Submitter:	Martin Mitchell
Meeting Date / Time:	14:00 BST on the 19th of October 2021
Meeting Format:	Teleconference via Zoom
Date FDA feedback was Sent:	4th October 2021

FDA attendees:

- Dr. Michele Lee, Lead Reviewer
- Dr. Lixin Liu, Acting Assistant Director, Plastic Surgery Skin & Wound Devices Team
- Dr. Diego Rua, Toxicology Consultant

Advanced Medical Solutions attendees:

- Martin Mitchell, RA Manager

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Martin.Mitchell@admedsol.com [Martin.Mitchell@admedsol.com]
Sent: 5/19/2022 10:28:42 AM
To: Arepalli, Sambasiva [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d64e0490c9cf498eba4dc7db4813db4b-sra_39e5703]
CC: K211878@docs.fda.gov; Rose.Guang@admedsol.com
Subject: RE: [EXTERNAL] Re: K211878-s002
Attachments: K211878 - 19Oct2021 Meeting Minutes - Final.pdf; AMS deficiency response.pdf; Report (b)(4) .pdf

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Sam

For your ease of reference, please find our response to deficiency 11 below where we discuss the teleconference minutes and the data (b)(4)

As requested I've highlighted the teleconference meeting minutes showing the FDA agreement to use the more clinically (b)(4)

I've also highlighted and provided the pertinent pages from the (b)(4) (b)(4)

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>
Cc: "K211878@docs.fda.gov" <K211878@docs.fda.gov>, Rose Guang/WIN/UK/AMS@ams
Date: 19/05/2022 10:17
Subject: RE: [EXTERNAL] Re: K211878-s002

Hi Sam

I'll call you today at 6am (11am UK time); we thought it would be better to send you the updated documents to help aid the discussion during the call.

The IFU has been updated with your comments (and as per our modifications we suggest below). I've provided a redlined and clean copy of this:

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
[attachment "IFU - LiquiBand XL.pdf" deleted by Martin Mitchell/WIN/UK/AMS] [attachment "IFU - LiquiBand XL - Tracked.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

The 510(k) summary has been updated with your comments
[attachment "510K Summary.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>
Cc: "K211878@docs.fda.gov" <K211878@docs.fda.gov>, Rose Guang/WIN/UK/AMS@ams
Date: 18/05/2022 22:37
Subject: RE: [EXTERNAL] Re: K211878-s002

Hi Sam

Firstly, thank you for staying late to continue to work with us on in the final stages of this submission. It is much appreciated.

Please find attached the IFU with updated comments from ourselves

[attachment "K211878-S002 - Revised labeling received on 5-16-2022.jam.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

For most of the proposed updates we will accept to make the changes. However there are two points we would wish to clarify

(b)(4)

As discussed I'll call you tomorrow to discuss your email below

Best regards,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>, "K211878@docs.fda.gov" <K211878@docs.fda.gov>
Date: 18/05/2022 20:39
Subject: RE: [EXTERNAL] Re: K211878-s002

Hi Mr. Mitchell:
Please see attached for the labeling and 510kSummary with FDA edits.

Please address these edits and send me both the edited versions and clean copies of the labeling and the 510kSummary by COB tomorrow (5-19-2022).

Please cc your response to K211878@docs.fda.gov.

Thx
Sam

Sam Arepalli, Ph.D.
FDA/CDRH/OPEQ/OHT4/PRSB2
Ph: 301 796 6434

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Tuesday, May 17, 2022 6:39 AM
To: Arepalli, Sambasiva <Sambasiva.Arepalli@fda.hhs.gov>
Subject: RE: [EXTERNAL] Re: K211878-s002

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Hi Sam

Just to be safe for the email trail.... so that your email has a response

The email with this information was send yesterday; however it is also provided again below:

Please find a response to the two points we discussed over the phone

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

As requested, the IFU has been revised with the updated warning

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Date: 17/05/2022 10:32
Subject: RE: [EXTERNAL] Re: K211878-s002

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Hi Mr. Mitchell:
Can you please give an update on the revised labeling request? Could you please send the information cob today? Please give me a call when you have a minute.
Thx
Sam

Sam Arepalli, Ph.D.
FDA/CDRH/OPEQ/OHT4/PRSB2
Ph: 301 796 6434

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Monday, May 16, 2022 12:06 PM
To: Arepalli, Sambasiva <Sambasiva.Arepalli@fda.hhs.gov>
Subject: [EXTERNAL] Re: K211878-s002

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Hi Sam

Just so you're aware it's 17:00 now so i'll be heading home; however i'll try to make myself available outside of hours so please don't hesitate to get in touch if you have any further questions.

Additionally i'll be working from home the next few days so I won't pick up calls from my office number you used previously.

If you have any further questions please email me or call me on my personal mobile number **(b)(6)**

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>
Cc: "K211878@docs.fda.gov" <K211878@docs.fda.gov>, Rose Guang/WIN/UK/AMS@ams, Helen Topping/WIN/UK/AMS@ams
Date: 16/05/2022 16:28
Subject: Re: K211878-s002

Hi Sam

Please find a response to the two points we discussed over the phone

(b)(4)

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

As requested, the IFU has been revised with the updated warning

[attachment "IFU.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov>, "K211878@docs.fda.gov" <K211878@docs.fda.gov>
Date: 16/05/2022 14:39
Subject: K211878-s002

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hi Mr. Martin:
Please address the following:

(b)(4)

Thx
Sam

Sam Arepalli, Ph.D.
FDA/CDRH/OPEQ/OHT4/PRSB2
Ph: 301 796 6434

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Advanced Medical Solutions Ltd
Western Wood Way,
Langage Science Park,
Plympton, Plymouth,
Devon, PL7 5BG, UK
Tel : +44 (0)1752 209955 **Fax :** +44 (0)1752 209956
Web : www.admedsol.com

Meeting Minutes

Submission Number:	K211878 / S001
Submission Type:	510(k)
Product Name:	LiquiBand XL
Submitter:	Martin Mitchell
Meeting Date / Time:	14:00 BST on the 19th of October 2021
Meeting Format:	Teleconference via Zoom
Date FDA feedback was Sent:	4th October 2021

FDA attendees:

- Dr. Michele Lee, Lead Reviewer
- Dr. Lixin Liu, Acting Assistant Director, Plastic Surgery Skin & Wound Devices Team
- Dr. Diego Rua, Toxicology Consultant

Advanced Medical Solutions attendees:

- Martin Mitchell, RA Manager

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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FDA deficiency:

(b)(4)

Applicant response:

(b)(4)

Supporting document
FDA teleconference meeting minutes (4th October 2021)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hello Michele

Regarding the recent deficiency question on our medical device submission which is currently under review with the FDA:

(b)(4)

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

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Major Deficiencies	FDA question / clarification

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Michele:

Just confirming you are looking at 1:30 pm Eastern time.

(b)(4) That time would work for me; please confirm your availability.

(b)(4)

(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov>

Sent: Friday, November 5, 2021 11:08 AM

To: (b)(4); k211878@docs.fda.gov

Cc: (b)(4)

(b)(4)

Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

This message is from an EXTERNAL SENDER â€" be CAUTIOUS, particularly with links and attachments

---

Hello (b)(4),

I have another meeting before that scheduled time. I can do a half hour earlier (6:30pm UTC+1) on Wednesday or a different time on another day next week?

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image011.png@01D7D23C.09C5AEE0]<http://www.fda.gov/>

[cid:image012.jpg@01D7D23C.09C5AEE0]<https://www.facebook.com/FDA>
[cid:image013.jpg@01D7D23C.09C5AEE0] <https://twitter.com/US_FDA>
[cid:image014.jpg@01D7D23C.09C5AEE0] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image015.jpg@01D7D23C.09C5AEE0] <http://www.flickr.com/photos/fdaphotos/>
[cid:image016.jpg@01D7D23C.09C5AEE0]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: (b)(4)

Sent: Friday, November 5, 2021 11:02 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Cc: (b)(4)
(b)(4)

Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Michele,

many thanks for sending the invite.

I fear, IÂ´ve made a mistake, when communicating the time.

Could we schedule one hour earlier?

Kind regards.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

From: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Sent: Freitag, 5. November 2021 15:59

To: (b)(4)
k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Cc: (b)(4)
(b)(4)

Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

This message is from an EXTERNAL SENDER â€" be CAUTIOUS, particularly with links and attachments

Hello (b)(4)

Sure, we can discuss via teleconference on 10 Nov 2021 at 7pm UTC+1/ 2pm EDT. I sent a ZoomGov invite via email and also copied the call-in information below.

[Image removed by sender.]<https://zoom.us/>

Hi there,

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov> is inviting you to a scheduled ZoomGov meeting.

Join Zoom

(b)(4)

or

568

0

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

Best Regards,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image011.png@01D7D23C.09C5AEE0]<http://www.fda.gov/>

[cid:image012.jpg@01D7D23C.09C5AEE0]<https://www.facebook.com/FDA>
[cid:image013.jpg@01D7D23C.09C5AEE0] <https://twitter.com/US_FDA>
[cid:image014.jpg@01D7D23C.09C5AEE0] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image015.jpg@01D7D23C.09C5AEE0] <http://www.flickr.com/photos/fdaphotos/>
[cid:image016.jpg@01D7D23C.09C5AEE0]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: (b)(4)

Sent: Friday, November 5, 2021 10:10 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Cc: (b)(4)

(b)(4)

Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Michele,

Many thanks for your message.

Martin, thank you for the connection.

Michele, would you be available next Wednesday, 10 November 2021, at 7 pm (UTC+1)?

Then I would send an invitation.

Kind regards.

(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Sent: Freitag, 5. November 2021 14:33

To: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Cc: (b)(4)

(b)(4)

Subject: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

This message is from an EXTERNAL SENDER â€" be CAUTIOUS, particularly with links and attachments

---

Hello all,

Thank you, Martin, for the connection.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

Best Regards,

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image011.png@01D7D23C.09C5AEE0]<http://www.fda.gov/>

[cid:image012.jpg@01D7D23C.09C5AEE0]<https://www.facebook.com/FDA>
[cid:image013.jpg@01D7D23C.09C5AEE0] <https://twitter.com/US_FDA>
[cid:image014.jpg@01D7D23C.09C5AEE0] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image015.jpg@01D7D23C.09C5AEE0] <http://www.flickr.com/photos/fdaphotos/>
[cid:image016.jpg@01D7D23C.09C5AEE0]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>
<Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Thursday, November 4, 2021 11:29 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>;
k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Cc: (b)(4)

(b)(4)

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

Regarding the recent deficiency question on our medical device submission which is currently under review with the FDA:

(b)(4)

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Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

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Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

APPENDIX C – TEST REPORTS

The following reports for cited for this submission are provided on the next page.

Relevant Section	Report Title	Report Number	Page
Section 14	Shelf life	(b)(4)	24-3 24-23
Section 15	Mesh – Cytotoxicity		24-42
	Mesh – Sensitisation		24-77
	Mesh – Intracutaneous Reactivity		24-119
	Mesh – Material Mediated Pyrogenicity		24-159
	Mesh – Acute Systemic Toxicity		24-194
	Device – Cytotoxicity		24-230
	Device – Sensitisation		24-266
	Device – Intracutaneous Reactivity		24-312
	Device – Material Mediated Pyrogenicity		24-353
	Device – Acute Systemic Toxicity		24-390
	Device – Chemical Characterisation		24-428
	Toxicological Risk Assessment		24-485
	Biological Evaluation Report		24-539
	Biological risk assessment		24-576
	Solvent compatibility assessment		24-581 24-588
	CSO Extraction colour change assessment		24-603
Section 18	ASTM D3330 / D3330M – 04 Standard Test Method for Peel Adhesion of Pressure-Sensitive Tape ASTM D3654 / D3654M – 06 Standard Test Methods for Shear Adhesion of Pressure-Sensitive Tapes ASTM D882 – 12 Standard Test Method for Tensile Properties of Thin Plastic Sheeting		24-608 24-622
	ASTM F2255-05 Standard Test Method for Strength Properties of Tissue Adhesives in Lap-Shear by Tension Loading		24-655 24-668
	ASTM F2256-05 Standard Test Method for Strength Properties of Tissue Adhesives in T-Peel by Tension Loading		24-681 24-694
	ASTM F2258-05 Standard Test Method for Strength Properties of Tissue Adhesives in Tension		24-707 24-720
	ASTM F2458-05 Standard Test Method for Wound Closure Strength in Tissue Adhesives and Sealants		24-733 24-742
	Degradation Rate		24-755
	Heat of Polymerization, Polymerisation Set Time, Force To Actuate		24-888 24-903
	Microbial barrier testing		24-294 24-931 24-940

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

	Quality of Adhesive Film on Mesh	(b)(4)	24-949 24-954
	Accelerant degradation		24-967
Section 19	Animal wound healing study		24-1015 24-1057

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Advanced Medical Solutions (Plymouth) Ltd.

Design Validation Protocol

PROTOCOL TO EVALUATE THE STABILITY PROFILE OF LIQUIBAND XL FINAL FINISHED DEVICE WITH (b)(4)	Doc No:	(b)(4)
	Rev No:	

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Advanced Medical Solutions (Plymouth) Ltd.

Design Validation Report

FINAL DEVICE STABILITY REPORT FOR (b)(4) (b)(4)	Doc No:	(b)(4)
	Rev No:	

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

FINAL GLP REPORT: (b)(4)
AMENDED

L929 NEUTRAL RED UPTAKE TEST (b)(4) – ISO

Test Article
LIQUIBAND XL (Adhesive Mesh Component Only)

21 CFR Part 58 Compliance
Good Laboratory Practice for Nonclinical Laboratory Studies

Report Date
1/21/2021

Amended Final Report Date
2/18/2021

Study Director
(b)(4)

Sponsor
Advanced Medical Solutions Limited
2 Western Wood Way, Langage Science Park
Plymouth, PL7 5BG
United Kingdom

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

(b)(4) TEST PROTOCOL
FDA GLP REGULATIONS
FILE COPY/CONFIDENTIAL PROPERTY (b)(4)

L929 NEUTRAL RED UPTAKE TEST (b)(4) - ISO

(b)(4) PROTOCOL NUMBER: (b)(4)

21 CFR Part 58 Compliance
Good Laboratory Practice for Nonclinical Laboratory Studies

MANAGEMENT OF THE STUDY

Test Facility
(b)(4)

Sponsor
Advanced Medical Solutions Limited
2 Western Wood Way,
Langage Science Park
Plymouth, PL7 5BG
United Kingdom

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

FINAL GLP REPORT: (b)(4)

KLIGMAN MAXIMIZATION TEST – ISO

Test Article
LIQUIBAND XL (Adhesive Mesh Component Only)

21 CFR Part 58 Compliance
Good Laboratory Practice for Nonclinical Laboratory Studies

Final Report Date
3/26/2021

Study Director
(b)(4)

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Test Article
LIQUIBAND XL (Adhesive Mesh Component Only)

21 CFR Part 58 Compliance
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APPENDIX A – COMPONENT DATASHEETS

The component datasheets for the materials discussed in section 10.4 (adhesive and accelerant) are provided below:

Component	Material	Datasheet	Page

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DETERMINATION OF THE SET TIME AND HEAT OF POLYMERISATION OF LIQUIBAND XL ON PORCINE SKIN	**Doc No:** **Rev No:**	**(b)(4)**

(b)(4)

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APPENDIX D – (b)(4) RESPONSE

Within (b)(4) a number of questions were raised which the FDA responded to. The following table provides an explanation as to how each of the questions has been addressed within this 510(k) submission.

AMS Question and FDA response	Explanation as to what has been addressed within this submission
(b)(4)	

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug
Administration

Memorandum

Title of Memo Toxicological Risk Assessment Consult, 510k Original

Date: Memo: 5/13/2022
Due: 5/13/2022
Requested: 5/09/2022

To: Sam Arepalli, PhD
CDRH\OHT4\DHT4B\THT4B4

From: Diego Rua, PhD MBA
CDRH/OSEL/DBCMS
240-402-2454

Diego Rua -S
Digitally signed by Diego Rua -S
Date: 2022.05.13 17:33:14 -04'00'

Re: K211878/S002
Advanced Medical Solutions Limited
LiquiBand XL

(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hello (b)(4)

Ok, I have changed the Zoom call time to 1:30pm EST on Wednesday. The call in information should still be the same.

Thanks,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov



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From: (b)(4)
Sent: Monday, November 8, 2021 3:19 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>; (b)(4) k211878@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear both,

Yes, that would work for me as well.
Many thanks.

Kind regards.

(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov>
Sent: Freitag, 5. November 2021 17:19
To: (b)(4) k211878@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

This message is from an EXTERNAL SENDER – be CAUTIOUS, particularly with links and attachments

---

Hello (b)(4)

Yes, I was thinking 1:30pm EST on Wednesday 11/10.

Thanks,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov



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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: (b)(4)
Sent: Friday, November 5, 2021 11:57 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>; (b)(4); k211878@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

CAUTION. This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Michele:

Just confirming you are looking at 1:30 pm Eastern time.

(b)(4) That time would work for me; please confirm your availability.

(b)(4)

(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov>
Sent: Friday, November 5, 2021 11:08 AM
To: (b)(4); k211878@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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---

Hello (b)(4)

I have another meeting before that scheduled time. I can do a half hour earlier (6:30pm UTC+1) on Wednesday or a different time on another day next week?

Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov



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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: (b)(4)
Sent: Friday, November 5, 2021 11:02 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>; k211878@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Michele,

many thanks for sending the invite.

I fear, I´ve made a mistake, when communicating the time.
Could we schedule one hour earlier?

Kind regards.

(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov>
Sent: Freitag, 5. November 2021 15:59
To: (b)(4); k211878@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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---

Hello (b)(4)

Sure, we can discuss via teleconference on 10 Nov 2021 at 7pm UTC+1/ 2pm EDT. I sent a ZoomGov invite via email and also copied the call-in information below.

Image removed

Hi there,

Michele.Lee@fda.hhs.gov is inviting you to a scheduled ZoomGov meeting.

Join Zoom Meeting

One tap mobile:

Meeting URL:

Meeting ID:
Passcode:

(b)(4)

Join by Telephone

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

For higher quality, dial a number based on your current location.

Dial: (b)(4)

Meeting ID:

Passcode:

International numbers

Join from an H.323/SIP room system

H.323:

Meeting ID: (b)(4)

Passcode:

SIP:

Passcode:

Best Regards,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: (b)(4) >
Sent: Friday, November 5, 2021 10:10 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>; k211878@docs.fda.gov
Cc: (b)(4) ; Martin.Mitchell@admedsol.com
Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Dear Michele,

Many thanks for your message.
Martin, thank you for the connection.

Michele, would you be available next Wednesday, 10 November 2021, at 7 pm (UTC+1)?
Then I would send an invitation.

Kind regards.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov>
Sent: Freitag, 5. November 2021 14:33
To: Martin.Mitchell@admedsol.com; k211878@docs.fda.gov
Cc: (b)(4)
Subject: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

This message is from an EXTERNAL SENDER – be CAUTIOUS, particularly with links and attachments

---

Hello all,

Thank you, Martin, for the connection.

(b)(4)

Best Regards,

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/oirhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Thursday, November 4, 2021 11:29 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>; k211878@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

Regarding the recent deficiency question on our medical device submission which is currently under review with the FDA:

(b)(4)

Best regards,

Martin Mitchell

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Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

Visit us at: http://www.admedsol.com. This e-mail, including any attached files, is confidential and intended for the exclusive use of the addressee(s) only. If you are not the intended recipient, please notify the sender immediately and delete it from your mailbox or any other storage mechanism.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your ResponseLee, Michele
to: Martin.Mitchell@admedsol.com 28/11/2021 22:57
Cc: "k211878@docs.fda.gov"
From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Hi Martin,

(b)(4)

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Friday, November 26, 2021 6:41 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

(b)(4)

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hi Martin,
Yes, this file landed in the Team's queue today, and I'll assign a new Lead Reviewer today.

Regards,
Julie

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Thursday, May 5, 2022 5:43 AM
To: Morabito, Julie <Julie.Morabito@fda.hhs.gov>
Cc: Helen.Topping@admedsol.com; k211878@docs.fda.gov; Rose.Guang@admedsol.com
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Julie

I've seen on the customer collaboration portal that our response has been acknowledged by the FDA and the clock has started moving.

Can we assume that a new reviewer has been successfully assigned?



Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Morabito, Julie" <Julie.Morabito@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "Helen.Topping@admedsol.com" <Helen.Topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>, "Rose.Guang@admedsol.com" <Rose.Guang@admedsol.com>, "Lee, Michele" <Michele.Lee@fda.hhs.gov>
Date: 14/04/2022 01:01
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

Thanks for reaching out. I'll be glad to assist in answering your questions.

- Will there be any delays in assigning a new reviewer?
  We do not anticipate a delay in assigning a new reviewer.
- Are there still resource constraints at the FDA?
  Speaking regarding our team, we are still working through resource constraints and doing our best to meet deadlines.
- Would a new reviewer who is not familiar with the product/deficiencies require a longer period of time to perform the review?
  We will do our best to align the new reviewer that is familiar and experienced with the review product, to limit delay to the extent possible.

I hope this is helpful, but please let me know if you'd like to discuss further.

Best,
Julie

Julie Morabito, PhD, RAC (she/her/hers)
Assistant Director

Plastic Surgery Skin and Wound Devices Team
OHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak Bldg. 66, Rm. 4668 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Ph. (240) 402-3839 | Cell (b)(6)
julie.morabito@fda.hhs.gov

Formerly:
Assistant Director, Outreach and Partnerships Team 2 (PreSum)
DCER: Division of Clinical Science and Quality | OCEA: Office of Clinical Evidence and Analysis
Office of Product Evaluation and Quality



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received here.

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Wednesday, April 13, 2022 3:32 PM
To: Morabito, Julie <Julie.Morabito@fda.hhs.gov>
Cc: Helen.Topping@admedsol.com; k211878@docs.fda.gov; Rose.Guang@admedsol.com; Lee, Michele <Michele.Lee@fda.hhs.gov>
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele and Julie

Thank you Michele for providing further clarification on the matter regarding maintenance of a lead reviewer. We are sad to lose you as our lead reviewer and wish you the best in your new role within the FDA.

During the initial review of the 510(k) it was flagged that the FDA had resource challenges which resulted in the review taking 70 days instead of the targeted 60 days....When we discussed this previously it was stated that when we submit our deficiency response the FDA would still target to complete the review within the remaining 20 days, however.... it was also flagged that if resource constraints still existed this could take longer than 20 days.

To keep the FDA informed about our progress we are planning to submit our response to the deficiency questions in around 3 weeks time. We would like to enquire about FDA's ability to complete the review within 20 days?

- Will there be any delays in assigning a new reviewer?
- Are there still resource constraints at the FDA?
- Would a new reviewer who is not familiar with the product/deficiencies require a longer period of time to perform the review?

The timely completion of your review would be massively appreciated as the large wound market is critical to urgent patient demand, AMS and our partners who are very keen to provide the improved product to hospitals across the United States.

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "k211878@docs.fda.gov" <k211878@docs.fda.gov>, "Rose.Guang@admedsol.com" <Rose.Guang@admedsol.com>, "Helen.Topping@admedsol.com" <Helen.Topping@admedsol.com>, "Morabito, Julie" <Julie.Morabito@fda.hhs.gov>
Date: 05/04/2022 14:47
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Unfortunately, it is not possible for me to take on lead review of this submission. As previously mentioned, I am currently working in another Office within FDA and do not conduct premarket reviews of medical devices in my current role.

It is not uncommon for new lead reviewers to be assigned to submissions returning from hold. The internal documentation serves as a complete record of the previous interactions during prior review of a submission. If you have further questions regarding the review process for your submission, you may contact the Assistant Director for the Plastic Surgery Skin & Wound Devices Team, Dr. Julie Morabito (Julie.Morabito@fda.hhs.gov).

Best,
Michele

Michele Lee, Ph.D.*(she/her/hers)*
Regulatory Science Program Manager
Partnerships to Advance Innovation and Regulatory Science (PAIRS)

Center for Devices and Radiological Health
Office of Strategic Partnerships and Technology Innovation
Division of All Hazards Response, Science, and Strategic Partnerships
U.S. Food and Drug Administration
michele.lee@fda.hhs.gov

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118



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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Tuesday, April 5, 2022 8:31 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: k211878@docs.fda.gov; Rose.Guang@admedsol.com; Helen.Topping@admedsol.com
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele,

We have been pleased to have you as the lead reviewer for RTA review, technical review, and responses to deficiency discussions since July 2021, as well as having you for the review for our previous 510(k) submission of the same product.

(b)(4)

- Jun 2021 - We submitted K211878 in response the **(b)(4)**
- Oct 2021 - Further deficiencies were raised on the new K211878 submission

We currently have only 20 days of FDA review time left on our product and have been advised that we will now be assigned a new reviewer. As you can imagine this causing us a high level of concern given you have a detailed knowledge of our submissions and of the current outstanding questions. Our concern being that a new reviewer will not have the same detailed knowledge of our submission or of the outstanding questions and hence this may cause unnecessary further delay.

We have been very satisfied with the support we have received from yourself and we would ask that you remain on our file for the final 20 days if at all possible, or an explanation of why this is not possible with some reassurances that a new assessor will not cause unnecessary delays whilst they gain detailed knowledge of our file.

Your expedited response to this request would be appreciated.

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 25/03/2022 16:47
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

A new lead reviewer will not be assigned until a follow up submission is received. So there is currently not a primary contact unless there is an active submission under FDA review. All of our correspondence and the prior related review have been documented internally, so you can be assured that the history of the prior review and contact is available to the future lead reviewer.

Best,
Michele

From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Friday, March 25, 2022 12:21 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

I've seen on the FDA customer collaboration portal that the time has automatically been added, but just thought it would be prudent to also inform you of the situation.

Could I ask who the primary contact is now? Will you be assisting or have any involvement with the review of our response?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 25/03/2022 15:59
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

I am sorry to hear about the (b)(4) I hope all is able to be resolved soon.

Thank you for the update. I am actually working in a different division within FDA and no longer the primary contact for this submission. I believe that the 180 days is automatically granted for responses to AINN hold but you can also confirm with the 510(k) Program staff (510k_Program@fda.hhs.gov, telephone: 301-796-5640) to make sure.

Best,
Michele

Michele Lee, Ph.D.*(she/her/hers)*
Regulatory Science Program Manager
Partnerships to Advance Innovation and Regulatory Science (PAIRS)

Center for Devices and Radiological Health
Office of Strategic Partnerships and Technology Innovation
Division of All Hazards Response, Science, and Strategic Partnerships
U.S. Food and Drug Administration
michele.lee@fda.hhs.gov



* * * * *

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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Friday, March 25, 2022 11:28 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

I'd like to provide an update on our progress with responding to the deficiencies raised on K211878

We were on track to have a deficiency response submitted to the FDA by the 180 day hold period deadline of 2nd April 2022.

However, the organisation performing the (b)(4) have been affected by a (b)(4) As a result, they were unable to complete the testing by our targeted timeline.

Therefore, I just want to confirm that we are still intending to respond to the deficiencies, but we would need to use the second 180 day hold period granted to us through the COVID-19 situation.

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>

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Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 08/11/2021 22:05
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thanks for your message. I'll need some time to review the teleconference minutes with my team and also obtain some feedback from our consulting toxicologist about the follow up questions. But I wanted to let you know I received your email and you may feel free to check in again next week.

I do have a clarification question about Follow Up (b)(4)

(b)(4)

Regarding the timeline clarification- I am also under the understanding that the COVID-19 guidance document you cited was still active and that would allow you an additional 180 days for the hold period. I have reached out to the 510(k) Staff multiple times to confirm and am still waiting on their response. Is there a customer service contact email for the customer collaboration portal specifically? You may try contacting them as well to have the date corrected on your end.

Thank you,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

* * * * *
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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Friday, November 5, 2021 12:07 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

I hope you had a nice holiday!

Following on from the teleconference we had a few actions to complete and get back to you with.

1) Teleconference minutes

Please find a draft of the the teleconference minutes below. Could you review and confirm if you require any changes made?

2) Follow-up questions on the teleconference discussion

As suggested during the teleconference there was the opportunity for a followup email clarification on a few minor points.

(b)(4)

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(b)(4)

The supporting information which provides further clarity on the questions above has been attached if required.

3) Timeline clarification as per previous email

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Thank you again for your assistance

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>, "Liu, Lixin" <Lixin.Liu@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 20/10/2021 22:43
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Michele

Thank you for the prompt response to the clarifications! We'll take your points on board regarding future shelf life studies.

I do have a minor clarification question regarding our response timeline

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

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From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 20/10/2021 14:55
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you to you and your team for attending the teleconference yesterday. I wanted to follow up on two things I was discussing with my team:

(b)(4)

I will be on leave for the next two weeks and you may contact our team management (Lixin.Liu@fda.hhs.gov) if you have questions during that time.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Lee, Michele
Sent: Friday, October 15, 2021 4:47 PM
To: Martin.Mitchell@admedsol.com
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you for providing your questions in advance of the meeting. We look forward to discussing our responses with you next week.

Have a good weekend,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Friday, October 15, 2021 12:00 PM

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Please find the list of questions/clarifications attached below.

I hope you have a good weekend. I'm looking forwards to our discussion next week!

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 13/10/2021 22:35
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

I have scheduled the teleconference for next Tuesday October 19th at 9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour but our biocompatibility consultant/ team management needs to drop off for another call at 9:30am. Please send me the questions for discussion in advance of the meeting so that we can plan to discuss biocompatibility/ regulatory questions first before the relevant parties need to drop off.

Join Zoom Meeting
One tap mobile:
Meeting URL: (b)(4)
Meeting ID:
Passcode:

Join by Telephone
For higher quality, dial a number based on your current location.
Dial:
Meeting ID: (b)(4)
Passcode:
International numbers

Join from an H.323/SIP room system
H.323:
Meeting ID: (b)(4)
Passcode:
SIP:
Passcode:

Thanks,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118



* * * * *
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https://www.research.net/s/odmcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 13, 2021 4:46 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Apologies Michele, one final thing I missed off my email... could you clarify how long the teleconference would be by default? Could we request 1 hour just incase some of the points end up taking longer to discuss?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 13/10/2021 20:35
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hi Michele

We're currently preparing our questions for the teleconference and will send these through in due course, however to assist with scheduling the relevant parties at FDA, I should let you know that we would definitely like to discuss the questions related to biocompatibility.

After discussion with the team we would like to request the teleconference on the Tuesday 19th October if that is possible? As we are based in the UK, we would also like to request that this is arranged between the hours of 2-5pm BST.

If this time slot is not available could you outline any alternative days/times which would be possible?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 08/10/2021 22:14
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hi Michele

Thank you for the offer. I think after today's meeting we may need a little more time to be better prepared for the teleconference.

We are reaching out to the (b)(4) for us as we feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible dates for you early next week.

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 06/10/2021 13:49
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference deadline up to October 19th. Let me know if you would like to select a date later than the 14thand I can check our management schedules.

Regarding review timelines, we are still on the 90 day review cycle and are planning to complete the review of your response with the 20 calendar days left on the clock. While we retain the right to add additional days, we are doing our best with the resources that we have to avoid delaying review timelines if possible.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 6, 2021 6:00 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com
Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Thank you again for your review. Our team are busy discussing the questions and we would definitely like to have a teleconference with the FDA. We're currently consolidating our understanding of the deficiencies and are determining what our potential questions to you would be. I hope to get the questions to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we look to schedule a teleconference with the FDA on Wednesday 13th or Thursday 14th? As we're based in the UK we would appreciate a timeslot within our working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines for this project.... regarding the FDA timeline I can see on the CCP tracker website that the FDA timeline is on day 70.

- Will FDA be sticking to the 90 day target and as a result only have 20 days left on the clock?
- Or, due to the current situation with the unprecedented resource limitations..... will you will assume 30 days to review the response as standard? Or perhaps stick to the 20 days but retain the right to add additional days?

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
To: <martin.mitchell@admedsol.com>, <helen.topping@admedsol.com>
Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
Date: 04/10/2021 21:44
Subject: K211878/S001 is on Hold Pending Your Response

October 4, 2021

We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Michele Lee.

*** This is a system-generated email notification ***[attachment "K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

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Dear Michelle,

Thank you for

informing us, we look forward to hearing from you on Monday.

Best regards
Helen

Helen Topping

 Senior Regulatory Affairs Manager

 Advanced Medical Solutions

 Tel: +44 (0) 7721261214

 Email: helen.topping@admedsol.com<table width=850 style="border-collapse:collapse;"><tr height=8><td width=848 style="border-style:none none none none;border-color:#000000;border-width:0px 0px 0px 0px;padding:1px 1px;"></table>

From:

       "Lee,

Michele" <Michele.Lee@fda.hhs.gov>
To:

       "Martin.Mitchell@admedsol.com"

<Martin.Mitchell@admedsol.com>, "Helen.Topping@admedsol.com"

<Helen.Topping@admedsol.com>, "Rose.Guang@admedsol.com"

<Rose.Guang@admedsol.com>
Cc:

       "k211878@docs.fda.gov"

<k211878@docs.fda.gov>
Date:

       28/09/2021

16:45
Subject:

       RE:

[EXTERNAL] Re: K211878/S001 Review Status
<hr noshade>

 Hello

Martin, Helen, & Rose: I

am writing to inform you of a revision to the review timeline for your

510(k) Submission K211878/S001. Unfortunately, we are unable to complete

the substantive review by the previously revised timeline of September

29th. We now anticipate completion of the substantive review

by next Monday, October 4th. We apologize for any inconveniences

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

caused because of the multiple extensions of review timeline and appreciate

your understanding as the Agency works through resource limitations during

this time.   Best

Regards, Michele   Michele

Lee, Ph.D. Lead

Reviewer / Materials Engineer   Plastic

Surgery Skin and Wound Devices Team DHT4B:

Division of Infection Control and Plastic Surgery Devices OHT4:

Office of Surgical and Infection Control Devices Office

of Product Evaluation and Quality   CDRH

| Food and Drug Administration White

Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993 <u>Michele.Lee@fda.hhs.gov</u>   <img src=cid:_4_1381A7DC1381A46C005D31988025875E style="border:0px solid;">
<u>
</u><img src=cid:_2_1381AC741381A46C005D31988025875E style="border:0px solid;"> <img src=cid:_2_1381B0DC1381A46C005D31988025875E style="border:0px solid;"> <img src=cid:_2_1381B5441381A46C005D31988025875E style="border:0px solid;"> <img src=cid:_2_1381B9AC1381A46C005D31988025875E style="border:0px solid;"> <img src=cid:_2_1381BE141381A46C005D31988025875E style="border:0px solid;"> Excellent

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feedback regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

   From:Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Tuesday, September 21, 2021 10:03 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: k211878@docs.fda.gov; Helen.Topping@admedsol.com; Rose.Guang@admedsol.com
Subject: [EXTERNAL] Re: K211878/S001 Review Status   CAUTION:This email originated from outside of the organization. Do not click links

or open attachments unless you recognize the sender and know the content

is safe.   Hello

Michele

Thank you for your email to keep us updated with progress.

Please note that next week i'll be out on annual leave... therefore, could

you also place Helen and Rose (on this email) on copy with any further

communication you send over.

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>
To: "<u>Martin.Mitchell@admedsol.com</u>"

<<u>Martin.Mitchell@admedsol.com</u>>
Cc: "<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 20/09/2021

22:31
Subject: <span style=" font-size:8pt;font-

family:Arial">K211878/S001

Review Status <hr noshade>

Hello Martin:

I want to inform you of a slightly revised review timeline for your 510(k)

submission K211878/S001. Due to a limitation of Agency resources, we are

unable to complete the substantive review by September 24th.

We want to inform you that we expect to complete the review by next Wednesday,

September 29th. We apologize for any inconveniences because

of the extension of timeline.

Best Regards,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993<u>
</u><u>Michele.Lee@fda.hhs.gov</u>
 <u>
</u><img src=cid:_4_1384CF941384C26C005D31988025875E width=192 height=43 style="border:0px solid;"><u>
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</u><img src=cid:_2_1384D4441384C26C005D31988025875E style="border:0px solid;"><img src=cid:_2_1384D8AC1384C26C005D31988025875E style="border:0px solid;"> <img src=cid:_2_1384DD141384C26C005D31988025875E style="border:0px solid;"><img src=cid:_2_1384E17C1384C26C005D31988025875E style="border:0px solid;"> <img src=cid:_2_1384E5E41384C26C005D31988025875E style="border:0px solid;">
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Hi Michele

I've seen on the FDA customer collaboration

portal that the time has automatically been added, but just thought it

would be prudent to also inform you of the situation.

Could I ask who the primary contact

is now? Will you be assisting or have any involvement with the review of

our response?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions

Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From:

 "Lee, Michele"

<Michele.Lee@fda.hhs.gov>
To:

 "Martin.Mitchell@admedsol.com"

<Martin.Mitchell@admedsol.com>
Cc:

 "k211878@docs.fda.gov"

<k211878@docs.fda.gov>
Date:

 25/03/2022 15:59
Subject:

   RE: [EXTERNAL]

Re: K211878/S001 is on Hold Pending Your Response
<hr noshade>

Hello Martin,

I am sorry to hear about the (b)(4)

I hope all is able to be resolved soon.

Thank you for the update. I am actually

working in a different division within FDA and no longer the primary contact

for this submission. I believe that the 180 days is automatically granted

for responses to AINN hold but you can also confirm with the 510(k) Program

staff (<u>510k_Program@fda.hhs.gov</u>,

telephone: 301-796-5640) to make sure.

Best,
Michele

Michele Lee, Ph.D.(she/her/hers)
Regulatory Science Program Manager
Partnerships to Advance Innovation

and Regulatory Science (PAIRS)

Center for Devices and Radiological

Health
Office of Strategic Partnerships and

Technology Innovation
Division of All Hazards Response, Science,

and Strategic Partnerships
U.S. Food and Drug Administration
<u>michele.lee@fda.hhs.gov</u>

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</u><img src=cid:_2_0DA68D500DA685600059D03B80258810 style="border:0px solid;"> <img src=cid:_2_0DA6919C0DA685600059D03B80258810 style="border:0px solid;"> <img src=cid:_2_0DA695E80DA685600059D03B80258810 style="border:0px solid;"> <img src=cid:_2_0DA69A340DA685600059D03B80258810 style="border:0px solid;"> <img src=cid:_2_0DA69E800DA685600059D03B80258810 style="border:0px solid;">

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service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=7013&S=E</u>.

From: Martin.Mitchell@admedsol.com

<Martin.Mitchell@admedsol.com>
Sent: Friday, March 25, 2022 11:28 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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is safe.

Hi Michele

I'd like to provide an update on our progress with responding to the deficiencies

raised on K211878

We were on track to have a deficiency response submitted to the FDA by

the 180 day hold period deadline of 2nd April 2022.

However, the organisation (b)(4) (b)(4) have been affected by (b)(4).

As a result, they were unable to complete the testing by our targeted timeline.

Therefore, I just want to confirm that we are still intending to respond

to the deficiencies, but we would need to use the second 180 day hold period

granted to us through the COVID-19 situation.

Best regards,

Martin

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Mitchell
Regulatory Affairs Manager<font size=2
face="Calibri">

Advanced
Medical Solutions Ltd.
E-mail: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=2 color=#000080
face="Arial">
Tel: +44 (0) 1752 30 9360<font size=2
face="Calibri">

From:
       "Lee,

Michele" <<font size=1 color=blue
face="Arial"><u>Michele.Lee@fda.hhs.gov</u><font size=1
face="Arial">>
To:
   "<a
href=mailto:Martin.Mitchell@admedsol.com><font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">>
Cc:
   "<a
href=mailto:helen.topping@admedsol.com><font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">>,

"<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u>"

<<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u><font size=1
face="Arial">>
Date:
   08/11/2021

22:05
Subject:
 RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response<div
align=center><hr noshade>

Hello Martin,

Thanks for your message. Iâ€™ll need
some time to review the teleconference

minutes with my team and also obtain some feedback from our consulting

toxicologist about the follow up questions. But I wanted to let you know

I received your email and you may feel free to check in again next week.

I do have a clarification question about Follow Up (b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

(b)(4)

Regarding the timeline clarification- I am also under the understanding

that the COVID-19 guidance document you cited was still active and that

would allow you an additional 180 days for the hold period. I have reached

out to the 510(k) Staff multiple times to confirm and am still waiting

on their response. Is there a customer service contact email for the customer

collaboration portal specifically? You may try contacting them as well

to have the date corrected on your end.

Thank you,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993<u>
</u><u>Michele.Lee@fda.hhs.gov</u>
 <u>
</u><img src=cid:_4_0DA6F2780DA6E2940059D03B80258810 width=192 height=43 style="border:0px solid;"><u>
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</u><img src=cid:_2_0E6C42240DA6E2940059D03B80258810 style="border:0px solid;"><img src=cid:_2_0E6C46700DA6E2940059D03B80258810 style="border:0px solid;"> <img src=cid:_2_0E6C4ABC0DA6E2940059D03B80258810 style="border:0px solid;"><img src=cid:_2_0E6C4F080DA6E2940059D03B80258810 style="border:0px solid;"> <img src=cid:_2_0E6C53540DA6E2940059D03B80258810 style="border:0px solid;">
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to provide feedback regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

From: <u>Martin.Mitchell@admedsol.com</u><<u>Martin.Mitchell@admedsol.com</u>>

Sent: Friday, November 5, 2021 12:07 PM
To: Lee, Michele <<u>Michele.Lee@fda.hhs.gov</u>>
Cc: <u>helen.topping@admedsol.com</u>;

<u>k211878@docs.fda.gov</u>
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response
 <font size=2 color=#806210

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face="Calibri">
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Hello Michele

I hope you had a nice holiday!

Following on from the teleconference we had a few actions to complete and

get back to you with.

1) Teleconference minutes

Please find a draft of the the teleconference minutes below. Could you

review and confirm if you require any changes made?

2) Follow-up questions on the teleconference discussion

As suggested during the teleconference there was the opportunity for a

followup email clarification on a few minor points.
1.   In alignment with FDA recommendation, the

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

(b)(4)

The supporting information which provides further clarity on the questions

above has been attached if required.

3) Timeline clarification as per previous email

I can see on the customer collaboration portal that we have a 180 day hold

period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below

was active which would provide us with an additional 180 day hold period?
<u>https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices</u>
Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Thank you again for your assistance

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: Martin

Mitchell/WIN/UK/AMS
To: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>,

"Liu, Lixin" <<u>Lixin.Liu@fda.hhs.gov</u>>
Cc:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

   "<a
href=mailto:helen.topping@admedsol.com><font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">>,

"<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u>"

<<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u><font size=1
face="Arial">>
Date:
   20/10/2021

22:43
Subject:
 RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response<font size=2
face="Calibri"> <hr noshade>
<font size=2
face="Calibri">

Hello Michele

Thank
you for the prompt response to the clarifications! We'll take your

points on board regarding future shelf life studies.

I do have a minor
clarification question regarding our response timeline

I can see on the customer
collaboration portal that we have a 180 day hold

period which ends on the 2nd of April 2022.

However, I was under the
understanding that the guidance document below

was active which would provide us with an additional 180 day hold period?<u>
</u><font size=2 color=blue
face="Calibri"><u>
</u><a href="https://www.fda.gov/regulatory-
information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-
formal-meetings-and-user-fee-applications-medical-devices"><font size=2 color=blue
face="Arial"><u>https://www.fda.gov/regulatory-information/search-fda-guidance-
documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-
applications-medical-devices</u>

Could you
clarify if we have 180 days or 360 days to respond to the deficiencies?

Best
regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-
mail: <font size=2 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=2 color=#000080
face="Arial">
Tel: +44 (0) 1752 30 9360<font size=2
face="Calibri">

<font size=1 color=#5f5f5f
face="Arial">

From: <font size=1
face="Arial">"Lee,

Michele" <<font size=1 color=blue
face="Arial"><u>Michele.Lee@fda.hhs.gov</u><font size=1
face="Arial">>
To:
   "<a
href=mailto:Martin.Mitchell@admedsol.com><font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">>
Cc:
   "<a
href=mailto:helen.topping@admedsol.com><font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">>,

"<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 20/10/2021

14:55
Subject: RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hello Martin,

Thank you to you and your team for attending the teleconference yesterday.

I wanted to follow up on two things I was discussing with my team:
1.   Regarding

(b)(4)

(b)(4)

I will be on leave for the next two weeks and you may contact our team

management (<u>Lixin.Liu@fda.hhs.gov</u>)

if you have questions during that time.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993<u>
</u><u>Michele.Lee@fda.hhs.gov</u><u>
</u><u>
</u><img src=cid:_4_086416E4086407B00059D03B80258810 style="border:0px solid;"><u>
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</u><img src=cid:_2_08641B74086407B00059D03B80258810 style="border:0px solid;"><img src=cid:_2_08641FA8086407B00059D03B80258810 style="border:0px solid;"><img src=cid:_2_086423F4086407B00059D03B80258810 style="border:0px solid;"><img src=cid:_2_08642828086407B00059D03B80258810 style="border:0px solid;"> <img src=cid:_2_08642C74086407B00059D03B80258810 style="border:0px solid;">
Excellent customer service is important to us. Please take a moment

to provide feedback regarding the customer service you have received: <a
href="https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E"
target=_blank><font size=2 color=#0082bf
face="Helvetica"><u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u><
/font>

From: Lee, Michele

Sent: Friday, October 15, 2021 4:47 PM
To: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri">
Cc: <u>helen.topping@admedsol.com</u>;

<font size=2 color=blue
face="Calibri"><u>k211878@docs.fda.gov</u><font size=2
face="Calibri">
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending
Your Response

Hello Martin,

Thank you for providing your questions in
advance of the meeting. We look

forward to discussing our responses with you next week.

Have a good
weekend,
Michele

Michele
Lee, Ph.D.
Lead Reviewer / Materials
Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of
Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and
Infection Control Devices
Office of Product Evaluation and Quality

CDRH |
Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver
Spring, MD 20993<u>
</u><a
href=mailto:Michele.Lee@fda.hhs.gov><font size=2 color=blue face="Segoe
UI"><u>Michele.Lee@fda.hhs.gov</u><font size=2 color=blue
face="Calibri"><u>
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color=blue face="Calibri"><u>
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</u><img
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style="border:0px solid;"><a
href=http://www.youtube.com/user/USFoodandDrugAdmin><img
src=cid:_2_08644F0C086407B00059D03B80258810 style="border:0px solid;"><a
href=http://www.flickr.com/photos/fdaphotos/><img
src=cid:_2_08645340086407B00059D03B80258810 style="border:0px solid;"><font size=1
color=#4f4f4f face="Arial"> <a
href=http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm><img
src=cid:_2_0864578C086407B00059D03B80258810 style="border:0px solid;"><font size=2
color=#4f4f4f face="Calibri">
Excellent customer service is important to us.
 Please take a moment

to provide feedback regarding the customer service you have received: <a
href="https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E"
target=_blank><font size=2 color=#0082bf
face="Helvetica"><u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u><
/font>

From: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri"><<font size=2
color=blue face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri">>

Sent: Friday, October 15, 2021 12:00 PM
To: Lee, Michele
<<font size=2 color=blue
face="Calibri"><u>Michele.Lee@fda.hhs.gov</u><font size=2
face="Calibri">>
Cc: <a
href=mailto:helen.topping@admedsol.com><font size=2 color=blue
face="Calibri"><u>helen.topping@admedsol.com</u><font size=2
face="Calibri">;

<font size=2 color=blue
face="Calibri"><u>k211878@docs.fda.gov</u><font size=2
face="Calibri">
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Your Response<font size=2 color=#806210
face="Calibri">

CAUTION:This email originated
from outside

of the organization. Do not click links or open attachments unless you

recognize the sender and know the content is safe.<font size=2
face="Arial">

Hi Michele

Please find the list of questions/clarifications
attached below.

I hope you have a good weekend. I'm looking forwards to our
discussion

next week!
<font size=2
face="Arial">

Best regards,<font size=2 color=#000080
face="Arial">

Martin Mitchell
Regulatory Affairs
Manager

Advanced Medical Solutions Ltd.
E-mail: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=2 color=#000080
face="Arial">
Tel: +44 (0) 1752 30 9360<font size=2
face="Calibri">

From:
       "Lee,

Michele" <<font size=1 color=blue
face="Arial"><u>Michele.Lee@fda.hhs.gov</u><font size=1
face="Arial">>
To:
   "<a
href=mailto:Martin.Mitchell@admedsol.com><font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">>
Cc:
   "<a
href=mailto:helen.topping@admedsol.com><font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">"

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face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">>,

"<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u>"

<<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u><font size=1
face="Arial">>
Date:
   13/10/2021

22:35
Subject:
 RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response<font size=2
face="Calibri"> <hr noshade>
<font size=2
face="Calibri">

Hello Martin,

I have scheduled the
teleconference for next Tuesday October 19that

9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour but

our biocompatibility consultant/ team management needs to drop off for

another call at 9:30am. Please send me the questions for discussion in

advance of the meeting so that we can plan to discuss biocompatibility/

regulatory questions first before the relevant parties need to drop off.

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color:#000000;border-width:0px 0px 0px 0px;padding:0px 0px;"><a
href="https://fda.zoomgov.com/j/1609831829?pwd=Mk16N1pXYnUrY2h2TFoyQTRaUCt5QT09"
target=_blank><u>Join

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
Zoom Meeting</u> <tr

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

face="Arial">429761</table><p>

Thanks,
Michele<font size=2 color=#0082bf face="Segoe
UI">

Michele Lee, Ph.D.
Lead
Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices
Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4:
Office of Surgical and Infection Control Devices
Office of Product Evaluation and
Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire
Avenue | Silver Spring, MD 20993<u>
</u><a
href=mailto:Michele.Lee@fda.hhs.gov><font size=2 color=blue face="Segoe
UI"><u>Michele.Lee@fda.hhs.gov</u><font size=3
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href=http://www.flickr.com/photos/fdaphotos/><img
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color=#4f4f4f face="Arial"><a
href=http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm><img
src=cid:_2_0DD0F7F00D725EB40059D03B80258810 style="border:0px solid;"><font size=2
color=#4f4f4f>
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take a moment

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href="https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E"
target=_blank><font size=2 color=#0082bf
face="Helvetica"><u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u><
/font>

From: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2
color=blue><u>Martin.Mitchell@admedsol.com</u><<a
href=mailto:Martin.Mitchell@admedsol.com><font size=2
color=blue><u>Martin.Mitchell@admedsol.com</u>>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Sent: Wednesday, October 13, 2021 4:46 PM
To: Lee, Michele <<u>Michele.Lee@fda.hhs.gov</u>>
Cc:<u>helen.topping@admedsol.com</u>;

<u>k211878@docs.fda.gov</u>
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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and know the content is safe.

Apologies Michele, one final thing I missed off my email... could you clarify

how long the teleconference would be by default? Could we request 1 hour

just incase some of the points end up taking longer to discuss?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: Martin

Mitchell/WIN/UK/AMS
To: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>
Cc: "<u>helen.topping@admedsol.com</u>"

<<u>helen.topping@admedsol.com</u>>,

"<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 13/10/2021

20:35
Subject: RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hi Michele

We're currently preparing our questions for the teleconference and will

send these through in due course, however to assist with scheduling the

relevant parties at FDA, I should let you know that we would definitely

like to discuss the questions related to biocompatibility.

After discussion with the team we would like to request the teleconference

on the Tuesday 19th October

if that is possible? As we are based in

the UK, we would also like to request that this is arranged between the

hours of 2-5pm BST<font size=2
face="Arial">.

If this time slot is not available could you outline any alternative days/times

which would be possible?

Best regards,<font size=2 color=#000080
face="Arial">

Martin Mitchell
Regulatory Affairs
Manager

Advanced Medical Solutions Ltd.
E-mail: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=2 color=#000080
face="Arial">
Tel: +44 (0) 1752 30 9360<font size=2
face="Calibri">

<font size=1 color=#5f5f5f
face="Arial">

From: <font size=1
face="Arial">Martin

Mitchell/WIN/UK/AMS
To:
   "Lee,

Michele" <<font size=1 color=blue
face="Arial"><u>Michele.Lee@fda.hhs.gov</u><font size=1
face="Arial">>
Cc:
   "<a
href=mailto:helen.topping@admedsol.com><font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">>,

"<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u>"

<<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u><font size=1
face="Arial">>
Date:
   08/10/2021

22:14
Subject:
 RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response<font size=2
face="Calibri"> <hr noshade>
<font size=2
face="Calibri">

Hi
Michele

Thank you for the offer. I think after today's meeting we may need a
little

more time to be better prepared for the teleconference.

We are reaching out to
the (b)(4) for us as we

feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible

dates for you early next week.

Best regards,<font size=2 color=#000080
face="Arial">

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=2 color=#000080
face="Arial">
Tel: +44 (0) 1752 30 9360<font size=2
face="Calibri">

<font size=1 color=#5f5f5f
face="Arial">

From: <font size=1
face="Arial">"Lee,

Michele" <<font size=1 color=blue
face="Arial"><u>Michele.Lee@fda.hhs.gov</u><font size=1
face="Arial">>
To:
   "<a
href=mailto:Martin.Mitchell@admedsol.com><font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">"

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

<<u>Martin.Mitchell@admedsol.com</u>>
Cc: "<u>helen.topping@admedsol.com</u>"

<<u>helen.topping@admedsol.com</u>>,

"<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 06/10/2021

13:49
Subject: RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference

deadline up to October 19th. Let me know if you would like to

select a date later than the 14thand I can check our management

schedules.

Regarding review timelines, we are still on the 90 day review cycle and

are planning to complete the review of your response with the 20 calendar

days left on the clock. While we retain the right to add additional days,

we are doing our best with the resources that we have to avoid delaying

review timelines if possible.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993<u>
</u><u>Michele.Lee@fda.hhs.gov</u><u>
</u><u>
</u><img src=cid:_4_0CEB4CBC0CEB41580059D03B80258810 style="border:0px solid;"><u>
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</u><img src=cid:_2_0CEB514C0CEB41580059D03B80258810 style="border:0px solid;"><img src=cid:_2_0CEB55800CEB41580059D03B80258810 style="border:0px solid;"><img src=cid:_2_0CEB59B40CEB41580059D03B80258810 style="border:0px solid;"><img src=cid:_2_0CEB5DE80CEB41580059D03B80258810 style="border:0px solid;"><img src=cid:_2_0CEB621C0CEB41580059D03B80258810 style="border:0px solid;">
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to provide feedback regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u></fon

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

t>

From: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri"><<font size=2
color=blue face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri">>

Sent: Wednesday, October 6, 2021 6:00 AM
To: Lee, Michele
<<font size=2 color=blue
face="Calibri"><u>Michele.Lee@fda.hhs.gov</u><font size=2
face="Calibri">>
Cc: <a
href=mailto:helen.topping@admedsol.com><font size=2 color=blue
face="Calibri"><u>helen.topping@admedsol.com</u><font size=2
face="Calibri">
Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your
Response

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of the organization. Do not click links or open attachments unless you

recognize the sender and know the content is safe.<font size=2
face="Arial">

Hi Michele

Thank you again for your review. Our team are
busy discussing the questions

and we would definitely like to have a teleconference with the FDA. We're

currently consolidating our understanding of the deficiencies and are determining

what our potential questions to you would be. I hope to get the questions

to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference
deadline in mind.... could we

look to schedule a teleconference with the FDA on Wednesday 13th or Thursday

14th? As we're based in the UK we would appreciate a timeslot within our

working hours which finish at 17:00 BST.

Additionally, I have a small question
to allow us to predict timelines

for this project.... regarding the FDA timeline I can see on the CCP tracker

website that the FDA timeline is on day 70.<font size=2
face="Calibri">
Will FDA be sticking to the 90
day target

and as a result only have 20 days left on the clock?
<font size=2
face="Arial">Or, due to the current situation with the

unprecedented resource limitations..... will you will assume 30 days to

review the response as standard? Or perhaps stick to the 20 days but retain

the right to add additional days?
Best
regards,

Martin Mitchell

Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.

E-mail: <font size=2
color=#0082bf face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=2
color=#000080 face="Arial">
Tel: +44 (0) 1752 30 9360<font size=1
color=#5f5f5f face="Arial">

From:
 "Michele

Lee [MICHELE.LEE]" <<font size=1
color=#0082bf face="Arial"><u>michele.lee@fda.hhs.gov</u><font size=1
face="Arial">>
To:
   <<a
href=mailto:martin.mitchell@admedsol.com><font size=1 color=#0082bf
face="Arial"><u>martin.mitchell@admedsol.com</u><font size=1
face="Arial">>,

<<font size=1 color=#0082bf
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">>
Cc:

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
   "Michele

Lee [MICHELE.LEE]" <<u>michele.lee@fda.hhs.gov</u>>
Date: 04/10/2021

21:44
Subject: K211878/S001

is on Hold Pending Your Response <hr noshade>

October 4, 2021 <p>We have reviewed your submission. Please see attached.

<p>If you have any questions, please contact the lead reviewer

assigned to your submission, Michele Lee. <p> <p>*** This is a system-generated email notification ***[attachment

"K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin

Mitchell/WIN/UK/AMS] <p>

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Hello (b)(4)

Yes, I was thinking 1:30pm EST on Wednesday 11/10.

Thanks,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D7D23F.548BA710]<http://www.fda.gov/>

[cid:image002.jpg@01D7D23F.548BA710]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D7D23F.548BA710] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7D23F.548BA710] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7D23F.548BA710] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D7D23F.548BA710]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: (b)(4)

Sent: Friday, November 5, 2021 11:57 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>; (b)(4); k211878@docs.fda.gov

Cc: (b)(4)

Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Michele:

Just confirming you are looking at 1:30 pm Eastern time.

(b)(4) That time would work for me; please confirm your availability.

(b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Sent: Friday, November 5, 2021 11:08 AM

To: (b)(4); k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Cc: (b)(4)

(b)(4)

Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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---

Hello (b)(4)

I have another meeting before that scheduled time. I can do a half hour earlier (6:30pm UTC+1) on Wednesday or a different time on another day next week?

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D7D23F.548BA710]<http://www.fda.gov/>

[cid:image002.jpg@01D7D23F.548BA710]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D7D23F.548BA710] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7D23F.548BA710] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7D23F.548BA710] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D7D23F.548BA710]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: (b)(4)

Sent: Friday, November 5, 2021 11:02 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Cc: (b)(4)
(b)(4)

Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Dear Michele,

many thanks for sending the invite.

I fear, IÂ´ve made a mistake, when communicating the time.

Could we schedule one hour earlier?

Kind regards.

(b)(4)

(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Sent: Freitag, 5. November 2021 15:59

To: (b)(4); k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Cc: (b)(4)
(b)(4)

Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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attachments

Hello (b)(4)

Sure, we can discuss via teleconference on 10 Nov 2021 at 7pm UTC+1/ 2pm EDT. I sent a ZoomGov invite via email and also copied the call-in information below.

[Image removed by sender.]<https://zoom.us/>

Hi there,

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov> is inviting you to a scheduled ZoomGov meeting.

Join Zoom

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Best Regards,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

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Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D7D23F.548BA710]<http://www.fda.gov/>

[cid:image002.jpg@01D7D23F.548BA710]<https://www.facebook.com/FDA>
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[cid:image004.jpg@01D7D23F.548BA710] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7D23F.548BA710] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D7D23F.548BA710]
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From: (b)(4)

Sent: Friday, November 5, 2021 10:10 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Cc: (b)(4)
(b)(4)
Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Dear Michele,

Many thanks for your message.

Martin, thank you for the connection.

Michele, would you be available next Wednesday, 10 November 2021, at 7 pm (UTC+1)?

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Then I would send an invitation.

Kind regards.

(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Sent: Freitag, 5. November 2021 14:33

To: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Cc: (b)(4)

(b)(4)

Subject: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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---

Hello all,

Thank you, Martin, for the connection.

(b)(4)

Best Regards,

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D7D23F.548BA710]<http://www.fda.gov/>

[cid:image002.jpg@01D7D23F.548BA710]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D7D23F.548BA710] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7D23F.548BA710] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7D23F.548BA710] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D7D23F.548BA710]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>
<Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Thursday, November 4, 2021 11:29 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>;
k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Cc: (b)(4)

(b)(4)

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

Regarding the recent deficiency question on our medical device submission which is currently under review with the FDA:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Hi Martin,

I received information that the FDA review timeline is strongly dependent on available review resources at the time that the q-submission is received. While the Agency is trying our best to meet review timeline goals, we are currently experiencing many delays due to lack of resources and unavailability of personnel to review. We encourage you to submit the SIR as early as you are able to try to get the feedback earlier. You may consider submitting multiple q-submissions if you are not able to compile all of the information in time.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov



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From: Lee, Michele
Sent: Thursday, December 2, 2021 10:31 AM
To: Martin.Mitchell@admedsol.com
Cc: k211878@docs.fda.gov
Subject: RE: [EXTERNAL] K211878 timeline - COVID-19

Hello Martin,

I have forwarded your question on to my management and will let you know when I receive their feedback.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov



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https://www.research.net/s/odrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Wednesday, December 1, 2021 12:05 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: k211878@docs.fda.gov
Subject: RE: [EXTERNAL] K211878 timeline - COVID-19

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Hi Michele

I have a further question regarding how COVID affects timelines below.

Knowing that FDA have are allowing a further 180 day timeline to respond to deficiencies due to COVID.... is there any scope or provision for timeline adjustments relating to a SIR review time?

More specifically, regarding an SIR submission i've seen in the guidance document that if the SIR is received before the 60 day timepoint after issuance of the deficiency letter, this would result in a 21 day FDA review time; whereas if we submit the SIR after this date this results in a 70 day FDA review time.

We have faced some delays in being able to meet the deadline of submitting an SIR before the 60 day timepoint. Where, we've spent some time liasing with yourselves through teleconference and email about the issues noted and covid has impacted our ability and our toxicologists ability to move quickly on these matters.

Therefore I'd like to enquire as to whether the FDA are allowing extensions to the time to receive an SIR (currently 60 days after issuance of the deficiency) where the SIR would still receive a 21 day FDA review time?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 16/11/2021 19:03
Subject: RE: [EXTERNAL] K211878 timeline - COVID-19

Hello Martin,

Thanks for the update and good to know this information. I also received your previous email with additional information about the test parameters of the degradation & extraction studies. I am still waiting on feedback from our consulting toxicologist but hope to have more information to provide you mid next week.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
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Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Monday, November 15, 2021 3:54 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Subject: Fw: [EXTERNAL] K211878 timeline - COVID-19

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Hi Michele

I got an update regarding timeline from the CCP email address.

FYI we are exploring a number of backup strategies to resolve the 510(k) deficiencies.... and some of these take us past the 180 day hold period.

As per the request below, I'll let you know closer to the time if we end up needing to request the additional 180 days.

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Tel: +44 (0) 1752 30 9360

----- Forwarded by Martin Mitchell/WIN/UK/AMS on 15/11/2021 08:31 -----

From: "CCP" <CCP@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Date: 12/11/2021 21:08
Subject: RE: [EXTERNAL] K211878 timeline - COVID-19

Good day to you Martin,

The extra 180 days for response are added as needed, and then only shortly before the original 180 days expires.

--
Happy trails,
~N els A nder son
Regulatory Systems & Data Management Staff
Center for Devices and Radiological Health | Office of Product Evaluation and Quality| Office of Regulatory Programs

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From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Friday, November 12, 2021 09:49
To: CCP <CCP@fda.hhs.gov>
Subject: [EXTERNAL] K211878 timeline - COVID-19

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Hello

Regarding the timeline showing for K211878 I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I (and the lead reviewer Michele Lee) were under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify that the 180 timeline in the customer collaboration portal won't trigger premature closure of the 510(k) before the actual 360 day timeline expires?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

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FDA deficiency:

(b)(4)

Applicant response:

(b)(4)

Supporting document
FDA teleconference meeting minutes (4th October 2021)

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CONFIDENTIAL
Toxicological risk assessment LIQUIBAND XL

Manufacturer:	Advanced Medical Solutions Ltd
Medical Device:	LIQUIBAND XL
Prepared by:	(b)(4)
Reviewed by:	(b)(4)
Date:	April 22nd, 2022

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(b)(4) Report

Report Information

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Processing Options

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(b)(4) Report

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Prediction Summary - Structure

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(b)(4) Report

Report Information

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Processing Options

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(b)(4) Report

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(b)(4)

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Hi Mr. Mitchell:

Please see attached for the labeling and 510kSummary with FDA edits.

(b)(4)

Please cc your response to K211878@docs.fda.gov.

Thx

Sam

Sam Arepalli, Ph.D.

FDA/CDRH/OPEQ/OHT4/PRSB2

Ph: 301 796 6434

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Tuesday, May 17, 2022 6:39 AM

To: Arepalli, Sambasiva <Sambasiva.Arepalli@fda.hhs.gov>

Subject: RE: [EXTERNAL] Re: K211878-s002

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Hi Sam

Just to be safe for the email trail.... so that your email has a response

The email with this information was send yesterday; however it is also provided again below:

Please find a response to the two points we discussed over the phone

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

As requested, the IFU has been revised with the updated warning

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov<mailto:Sambasiva.Arepalli@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Date: 17/05/2022 10:32

Subject: RE: [EXTERNAL] Re: K211878-s002

Hi Mr. Mitchell:

Can you please give an update on the revised labeling request? Could you please send the information cob today? Please give me a call when you have a minute.

Thx

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Sam

Sam Arepalli, Ph.D.

FDA/CDRH/OPEQ/OHT4/PRSB2

Ph: 301 796 6434

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From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com> <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Monday, May 16, 2022 12:06 PM

To: Arepalli, Sambasiva <Sambasiva.Arepalli@fda.hhs.gov<mailto:Sambasiva.Arepalli@fda.hhs.gov>>

Subject: [EXTERNAL] Re: K211878-s002

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Hi Sam

Just so you're aware it's 17:00 now so i'll be heading home; however i'll try to make myself available outside of hours so please don't hesitate to get in touch if you have any further questions.

Additionally i'll be working from home the next few days so I won't pick up calls from my office number you used previously.

If you have any further questions please email me or call me on my personal mobile number (b)(6)

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov<mailto:Sambasiva.Arepalli@fda.hhs.gov>>

Cc: "K211878@docs.fda.gov<mailto:K211878@docs.fda.gov>" <K211878@docs.fda.gov<mailto:K211878@docs.fda.gov>>, Rose Guang/WIN/UK/AMS@ams, Helen Topping/WIN/UK/AMS@ams

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Date: 16/05/2022 16:28

Subject: Re: K211878-s002

Hi Sam

Please find a response to the two points we discussed over the phone

(b)(4)

As requested, the IFU has been revised with the updated warning

[attachment "IFU.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov<mailto:Sambasiva.Arepalli@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "Arepalli, Sambasiva" <Sambasiva.Arepalli@fda.hhs.gov<mailto:Sambasiva.Arepalli@fda.hhs.gov>>, "K211878@docs.fda.gov<mailto:K211878@docs.fda.gov>" <K211878@docs.fda.gov<mailto:K211878@docs.fda.gov>>

Date: 16/05/2022 14:39

Subject: K211878-s002

Hi Mr. Martin:

Please address the following:

(b)(4)

Thx

Sam

Sam Arepalli, Ph.D.

FDA/CDRH/OPEQ/OHT4/PRSB2

Ph: 301 796 6434

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web.cisco.com/1z4ZIykl5rMf5xXkALZcFSaXARBHFfphXL5zOAOiOaFtvE8rdY5JYvsTpy63fXgD5KSI_rGj7-aHATeSlXNwVnAKJKnY7yVMWXr-0Es9pZT0ulTOx1cFfiAYC1I3nRCVxMJf8iskBHWn6Ug19jXGx8WmrkiOr81pVHaY4bJbZ9kqpmcpTLiLCOIEWQLe1hapZ/http%3A%2F%2Fwww.admedsol.com%2F>. This e-mail, including any attached files, is confidential and intended for the exclusive use of the addressee(s) only. If you are not the intended recipient, please notify the sender immediately and delete it from your mailbox or any other storage mechanism.

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RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your ResponseLee, Michele
to: Martin.Mitchell@admedsol.com 24/11/2021 18:00
Cc: "helen.topping@admedsol.com", "k211878@docs.fda.gov"
From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com"
<helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
History:This message has been replied to.

Hello Martin,

Please find the responses to your questions below in red font and revised meeting minutes attached. Hope this is helpful!

Best,
Michele

(b)(4)

(b)(4)

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov





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Hello Martin,

Thank you for the additional clarification requests. (b)(4)

(b)(4)

(b)(4) Thank you for bringing this report to my attention.

Best Regards,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

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<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Wednesday, July 7, 2021 11:19 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Subject: [EXTERNAL] Re: K211878 is on Hold Pending Your Response

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Michele

Nice to see we're working with you again.

I was a little surprised regarding the RTA decision as the level of information we've provided is the same as that which was provided in previous submissions, where we didn't receive an RTA from yourself. Therefore, I just wanted to reach out to you to ensure that I correctly answer the issue so as to avoid any further delays.

Regarding the RTA on question B.12(a)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Regarding the RTA on question F.28 and F.29

We require no clarification on this point and can provide the documents as requested.

Thanks in advance for your assistance

Best regards,

Martin Mitchell

Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.

Tel: +44 (0) 1752 30 9360

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov<mailto:michele.lee@fda.hhs.gov>>

To: <martin.mitchell@admedsol.com<mailto:martin.mitchell@admedsol.com>>

Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov<mailto:michele.lee@fda.hhs.gov>>

Date: 06/07/2021 20:49

Subject: K211878 is on Hold Pending Your Response

July 6, 2021Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your submission K211878. Our review indicates that your submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit one eCopy of your response, referencing your submission K211878, addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration

Center for Devices and Radiological Health

Document Control Center - WO66-G609

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

Your submission will remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist by 01/02/2022, we will consider this submission to be withdrawn, and we will delete it from our review system.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Upon receipt of the requested information, FDA will conduct another administrative review of your submission. We will contact you if we require any additional information during the course of our administrative review. FDA aims to apply the least burdensome principles<https://www.fda.gov/media/73188/download> when requesting additional information.

The lead reviewer assigned to your submission is me, Michele Lee. The file is being reviewed in Office of Health Technology 4, Division of Health Technology 4 B. The first line supervisor is the Assistant Director, Plastic Surgery Skin and Wound Devices. You may contact me at any point during the review if you have questions or concerns. You can provide valuable support for CDRH to continue to improve our programs by raising to the attention of management relevant issues that arise during the course of this review. If you feel there is an unresolved issue or a matter that requires additional attention, you should contact the Assistant Director. If your concern or issue is not addressed by the Assistant Director, you should contact the Division Director or OHT Director. The contact information for each management level can be found in the CDRH Management Directory<https://www.fda.gov/about-fda/cdrh-offices/cdrh-management-directory-organization>.

For additional information about the Refuse to Accept Policy for for 510(k)s please refer to the guidance document available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf.

If you have general questions about the review process for your submission, you should contact OPEQSubmissionSupport@fda.hhs.gov<mailto:OPEQSubmissionSupport@fda.hhs.gov>.

*** This is a system-generated email notification ***[attachment "K211878.RTAChecklist.RTA1.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

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Advanced Medical Solutions Ltd

Advanced Medical Solutions Limited
Western Wood Way,
Langage Science Park,
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Devon,
PL7 5BG,
United Kingdom
Tel: +44 (0) 1752 209955 Fax: +44 (0) 1752 209956
Web: www.admedsol.com
Registered in England 2666957 VAT No. GB 636 5551 27

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center (DCC) – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
USA

Dear FDA

In response to FDA's request for additional information letter (AI) received 4th October 2021, for K211878 please find the reply from Advanced Medical Solutions Ltd (AMS) to the deficiencies listed which support the subject device, LiquiBand® XL. FDA's deficiencies are in bold and are immediately followed by AMS' answers.

(b)(4)

This response is being submitted as the physical cover letter and an eCopy of the response on CD.

Should you require any additional data or clarification on the response provided, please do not hesitate to contact me using the details below.

(b)(6)

Sincerely,

Martin Mitchell
Regulatory Affairs Manager
Phone: +44 (0) 1752 30 9360
Email: Martin.Mitchell@admedsol.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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FDA deficiency:

(b)(4)

Applicant response:

(b)(4)

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APPENDIX B –LABELLING

Subject device labelling

The following proposed labelling for the subject device is provided in Appendix B:

Manufacturer	Advanced Medical Solutions Ltd

(b)(4)

Predicate Device IFU

The following IFU for the predicate devices are provided in Appendix B

(b)(4)

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Premarket Notification 510(k) Review

Post-Review Reminders

- ☐ Final Check: Ensure your documentation accurately reflects the final recommendation prior to signature (e.g., Review Summary, data in the Device Description section, the Labeling section, etc)
- ☐ Complete CTS: Procode, Clinical Trials, Combo Product, MR compatibility
- ☐ Ensure the content of the 510(k) Summary is accurate (N/A if a 510(k) Statement was provided instead).
- ☐ For SE Decisions: Upload SE Letter, and PDFs of IFU form and 510(k) Summary (if included) in DocMan.

To add reminders, type the reminder in the text field to the left then press the Tab key.

Date: May 19, 2022

Reviewer: Sam Arepalli

Subject: Traditional 510(k)# K211878/S002

Applicant: Advanced Medical Solutions Limited	**Device Trade Name:** LiquiBand XL
Contact Name: Martin Mitchell	**Contact Title:** Senior Regulatory Affairs Associate
Correspondent Firm: Advanced Medical Solutions Limited	**Phone:** **Email:** martin.mitchell@admedsol.com
Received Date: May 4, 2022	**Due Date:** May 24, 2022
Pro Code(s): OMD **Class:** II **Reg #:** 878.4011	**Reg Name:** Tissue Adhesive With Adjunct Wound Closure Device For Topical Approximation Of Skin

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K191461	OMD	Exofin Fusion Skin Closure System	Chemence Medical, Inc.
K183570	MPN	LiquiBand Plus	Advanced Medical Solutions Limited

Recommendation

(b)(5)

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(b)(5)

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(b)(5)

Digital Signature Concurrence Table (Doc ID: 04500.14.05)

This document represents a high-level summary of the Agency's determination on whether the applicant's device is substantially equivalent to a legally marketed predicate device. In determining whether the subject device is substantially equivalent to a predicate device, we carefully considered the relevant regulatory and statutory criteria for Agency decision-making under 21 CFR part 807 and section 513(i) of the Federal Food, Drug and Cosmetic Act (FD&C Act). We considered the burden that may be incurred by the applicant's attempt to follow the premarket notification process. The deficiencies provided in this review, if any, represent the required minimum information necessary to support a substantial equivalence determination. Therefore, we believe that we have considered the least burdensome requirements, under section 513(i)(1)(D) of the FD&C Act, for a 510(k) determination of substantial equivalence.

Reviewer Sign-Off	Sambasiva R. Arepalli -S Digitally signed by Sambasiva R. Arepalli -S Date: 2022.05.19 06:40:24 -04'00'

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Hi Michele

Please find the list of questions/clarifications

attached below.

I hope you have a good weekend. I'm

looking forwards to our discussion next week!

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions

Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From:

 "Lee, Michele"

<Michele.Lee@fda.hhs.gov>
To:

 "Martin.Mitchell@admedsol.com"

<Martin.Mitchell@admedsol.com>
Cc:

 "helen.topping@admedsol.com"

<helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date:

 13/10/2021 22:35
Subject:

   RE: [EXTERNAL]

Re: K211878/S001 is on Hold Pending Your Response
<hr noshade>

Hello Martin,

I have scheduled the teleconference for

next Tuesday October 19th at 9am EST/ 2pm BST. Per your request,

I can be on the call for 1 hour but our (b)(4) consultant/ team

management needs to drop off for another call at 9:30am. Please send me

the questions for discussion in advance of the meeting so that we can plan

to discuss (b)(4) questions first before the relevant

parties need to drop off. <p><table width=100% style="border-collapse:collapse;"><tr height=8><td colspan=2 bgcolor=white style="border-style:none none none none;border-color:#000000;border-width:0px 0px 0px 0px;padding:0px 0px;"><u>Join

Zoom Meeting</u> <tr

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

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(b)(4)

face="Calibri">

Thanks,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices

Team
DHT4B: Division of Infection Control and

Plastic Surgery Devices
OHT4: Office of Surgical and Infection

Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue

| Silver Spring, MD 20993
<u>Michele.Lee@fda.hhs.gov</u>

<img src=cid:_4_0D0E1B6C0D0E17F00057ED3D8025876F style="border:0px solid;">
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</u><img src=cid:_2_0D0E1FFC0D0E17F00057ED3D8025876F style="border:0px solid;"> <img src=cid:_2_0D0E24480D0E17F00057ED3D8025876F style="border:0px solid;"> <img src=cid:_2_0D0E28940D0E17F00057ED3D8025876F style="border:0px solid;"> <img src=cid:_2_0D0E2CE00D0E17F00057ED3D8025876F style="border:0px solid;"> <img src=cid:_2_0D0E312C0D0E17F00057ED3D8025876F style="border:0px solid;">
Excellent customer

service is important to us. Please take a moment to provide feedback

regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

From: Martin.Mitchell@admedsol.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

<Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 13, 2021 4:46 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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or open attachments unless you recognize the sender and know the content

is safe.

Apologies Michele, one final thing I missed

off my email... could you clarify how long the teleconference would be

by default? Could we request 1 hour just incase some of the points end

up taking longer to discuss?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: Martin

Mitchell/WIN/UK/AMS
To: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>
Cc: "<u>helen.topping@admedsol.com</u>"

<<u>helen.topping@admedsol.com</u>>,

"<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 13/10/2021

20:35
Subject: RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hi Michele

We're currently preparing our questions for the teleconference and will

send these through in due course, however to assist with scheduling the

relevant parties at FDA, I should let you know that we would definitely

like to discuss the questions related to (b)(4).

After discussion with the team we would like to request the teleconference

on the Tuesday 19th October

if that is possible? As we are based in

the UK, we would also like to request that this is arranged between the

hours of 2-5pm BST.

If this time slot is not available could you outline any alternative days/times

which would be possible?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: Martin

Mitchell/WIN/UK/AMS
To: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>
Cc: "<u>helen.topping@admedsol.com</u>"

<<u>helen.topping@admedsol.com</u>>,

"<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 08/10/2021

22:14
Subject: RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hi Michele

Thank you for the offer. I think after today's meeting we may need a little

more time to be better prepared for the teleconference.

We are reaching out to the **(b)(4)** for us as we

feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible

dates for you early next week.

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

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face="Arial">
From: <font size=1
face="Arial">"Lee,

Michele" <<font size=1 color=blue
face="Arial"><u>Michele.Lee@fda.hhs.gov</u><font size=1
face="Arial">>
To:
   "<a
href=mailto:Martin.Mitchell@admedsol.com><font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
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<<font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
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href=mailto:helen.topping@admedsol.com><font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
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face="Arial"><u>helen.topping@admedsol.com</u><font size=1
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"<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u>"

<<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u><font size=1
face="Arial">>
Date:
   06/10/2021

13:49
Subject:
 RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response<div
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Hello Martin,

If it makes it easier for your team, we
are able to extend the 10 day teleconference

deadline up to October 19th. Let me know if you would like to

select a date later than the 14thand I can check our management

schedules.

Regarding review timelines, we are still on the 90 day review cycle
and

are planning to complete the review of your response with the 20 calendar

days left on the clock. While we retain the right to add additional days,

we are doing our best with the resources that we have to avoid delaying

review timelines if possible.

Best,
Michele
 <font size=2
color=#0082bf face="Segoe UI">
Michele Lee, Ph.D.<font size=2
face="Segoe UI">
Lead Reviewer / Materials Engineer

Plastic Surgery
Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery
Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product
Evaluation and Quality

CDRH | Food and Drug Administration
White Oak |
10903 New Hampshire Avenue | Silver Spring, MD 20993<font size=2 color=blue
face="Calibri"><u>
</u><font size=2
color=blue face="Segoe UI"><u>Michele.Lee@fda.hhs.gov</u><font size=3
face="Segoe UI">
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to provide feedback regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

From: <u>Martin.Mitchell@admedsol.com</u><<u>Martin.Mitchell@admedsol.com</u>>

Sent: Wednesday, October 6, 2021 6:00 AM
To: Lee, Michele <<u>Michele.Lee@fda.hhs.gov</u>>
Cc: <u>helen.topping@admedsol.com</u>
Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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of the organization. Do not click links or open attachments unless you

recognize the sender and know the content is safe.

Hi Michele

Thank you again for your review. Our team are busy discussing the questions

and we would definitely like to have a teleconference with the FDA. We're

currently consolidating our understanding of the deficiencies and are determining

what our potential questions to you would be. I hope to get the questions

to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we

look to schedule a teleconference with the FDA on Wednesday 13th or Thursday

14th? As we're based in the UK we would appreciate a timeslot within our

working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines

for this project.... regarding the FDA timeline I can see on the CCP tracker

website that the FDA timeline is on day 70.
Will FDA be sticking to the 90 day target

and as a result only have 20 days left on the clock?<li>Or, due to the current situation with the

unprecedented resource limitations..... will you will assume 30 days to

review the response as standard? Or perhaps stick to the 20 days but retain

the right to add additional days?
Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From:

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
       "Michele

Lee [MICHELE.LEE]" <<u>michele.lee@fda.hhs.gov</u>>
To: <<u>martin.mitchell@admedsol.com</u>>,

<<u>helen.topping@admedsol.com</u>>
Cc: "Michele

Lee [MICHELE.LEE]" <<u>michele.lee@fda.hhs.gov</u>>
Date: 04/10/2021

21:44
Subject: K211878/S001

is on Hold Pending Your Response <hr noshade>

October 4, 2021 <p>We have reviewed your submission. Please see attached.

<p>If you have any questions, please contact the lead reviewer

assigned to your submission, Michele Lee. <p> <p>*** This is a system-generated email notification ***[attachment

"K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin

Mitchell/WIN/UK/AMS] <p>

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Hi Michele

I have a further question regarding

how COVID affects timelines below.

Knowing that FDA have are allowing a

further 180 day timeline to respond to deficiencies due to COVID.... is

there any scope or provision for timeline adjustments relating to a SIR

review time?

More specifically, regarding an SIR

submission i've seen in the guidance document that if the SIR is received

before the 60 day timepoint after issuance of the deficiency letter, this

would result in a 21 day FDA review time; whereas if we submit the SIR

after this date this results in a 70 day FDA review time.

We have faced some delays in being able

to meet the deadline of submitting an SIR before the 60 day timepoint.

Where, we've spent some time liasing with yourselves through teleconference

and email about the issues noted and covid has impacted our ability and

our toxicologists ability to move quickly on these matters.

Therefore I'd like to enquire as to

whether the FDA are allowing extensions to the time to receive an SIR (currently

60 days after issuance of the deficiency) where the SIR would still receive

a 21 day FDA review time?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions

Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From:

 "Lee, Michele"

<Michele.Lee@fda.hhs.gov>
To:

 "Martin.Mitchell@admedsol.com"

<Martin.Mitchell@admedsol.com>
Cc:

 "k211878@docs.fda.gov"

<k211878@docs.fda.gov>
Date:

 16/11/2021 19:03
Subject:

   RE: [EXTERNAL]

K211878 timeline - COVID-19
<hr noshade>

Hello Martin,

Thanks for the update and good to know

this information. I also received your previous email with additional information

about the test parameters of the degradation & extraction studies.

I am still waiting on feedback from our consulting toxicologist but hope

to have more information to provide you mid next week.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices

Team
DHT4B: Division of Infection Control and

Plastic Surgery Devices
OHT4: Office of Surgical and Infection

Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue

| Silver Spring, MD 20993
<u>Michele.Lee@fda.hhs.gov</u>

<img src=cid:_4_0B7F33C80B7F3068005DDFC98025879E style="border:0px solid;">
<u>
</u><img src=cid:_2_0B7F38580B7F3068005DDFC98025879E style="border:0px solid;"> <img src=cid:_2_0B7F3CA40B7F3068005DDFC98025879E style="border:0px solid;"> <img src=cid:_2_0B7F40F00B7F3068005DDFC98025879E style="border:0px solid;"> <img src=cid:_2_0B7F453C0B7F3068005DDFC98025879E style="border:0px solid;"> <img src=cid:_2_0B7F49880B7F3068005DDFC98025879E style="border:0px solid;">
Excellent customer

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regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

From: Martin.Mitchell@admedsol.com

<Martin.Mitchell@admedsol.com>
Sent: Monday, November 15, 2021 3:54 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Subject: Fw: [EXTERNAL] K211878 timeline - COVID-19

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is safe.

Hi Michele

I got an update regarding timeline from the CCP email address.

FYI we are exploring a number of backup strategies to resolve the 510(k)

deficiencies.... and some of these take us past the 180 day hold period.

As per the request below, I'll let you know closer to the time if we end

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up needing to request the additional 180 days. <font size=2
face="Calibri">

Best regards,

Martin
Mitchell
Regulatory Affairs Manager<font size=2
face="Calibri">

Advanced
Medical Solutions Ltd.
E-mail: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=2 color=#000080
face="Arial">
Tel: +44 (0) 1752 30 9360<font size=2
face="Calibri">

----- Forwarded
by Martin Mitchell/WIN/UK/AMS on 15/11/2021 08:31 -----<font size=2
face="Calibri">

From:
     "CCP"

<<font size=1 color=blue
face="Arial"><u>CCP@fda.hhs.gov</u><font size=1
face="Arial">>
To:
   "<a
href=mailto:Martin.Mitchell@admedsol.com><font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">>
Date:
   12/11/2021

21:08
Subject:
 RE:

[EXTERNAL] K211878 timeline - COVID-19 <hr
noshade>

<font size=2
face="Calibri">
Good day to you Martin,

The extra 180 days for response are
added as needed, and then only shortly

before the original 180 days expires.

--
Happy trails,
~Nels Anderson<font size=2
face="Calibri">
Regulatory Systems & Data Management Staff
Center for Devices
and Radiological Health | Office of Product Evaluation

and Quality| Office of Regulatory Programs

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or telephone.

From: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri"><<font size=2
color=blue face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri">>

Sent: Friday, November 12, 2021 09:49
To: CCP <<a
href=mailto:CCP@fda.hhs.gov><font size=2 color=blue
face="Calibri"><u>CCP@fda.hhs.gov</u><font size=2
face="Calibri">>
Subject: [EXTERNAL] K211878 timeline - COVID-19

CAUTION:<font size=2
face="Calibri">This email originated from outside

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face="Arial">
Hello

Regarding the timeline showing for K211878 I can see on the customer collaboration

portal that we have a 180 day hold period which ends on the 2nd of April

2022.

However, I (and the lead reviewer Michele Lee) were under the understanding

that the guidance document below was active which would provide us with

an additional 180 day hold period? <u>https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices</u>
Could you clarify that the 180 timeline in the customer collaboration portal

won't trigger premature closure of the 510(k) before the actual 360 day

timeline expires?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

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Hello Martin,

Thank you for the additional response- you may include it in your supplement response to RTA Checklist. Regarding the timeline, the clock resets to Day 1 being the day of the 510(k) acceptance notification for your supplement S001.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Thursday, July 15, 2021 10:37 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: k211878@docs.fda.gov; Helen.Topping@admedsol.com; Rose.Guang@admedsol.com
Subject: RE: [EXTERNAL] Re: K211878 is on Hold Pending Your Response

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Hello Michele

Thank you for your clarification; we have reviewed your feedback in line with the (b)(4) and we believe that this addresses your request:

(b)(4)

Could you provide a small clarification regarding the FDA timeline with regards the RTA issued

- I've read a statement in a MDFUA performance goals document which states *"FDA Days begin on the date of receipt of the submission or of the amendment to the submission that enables the submission to be accepted 510(k)"*
- Once the RTA is closed and the 510(k) is accepted.... would Day 1 of the FDA clock remain as the "acknowledgment" notification date (21st June 2021) or would now change to be the date of the 510(k) "acceptance" notification?

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 09/07/2021 20:12
Subject: RE: [EXTERNAL] Re: K211878 is on Hold Pending Your Response

---

Hello Martin,

Thank you for the additional clarification requests. (b)(4)

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(b)(4) Thank you for bringing this report to my attention.

Best Regards,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov

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https://www.research.net/s/odhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Wednesday, July 7, 2021 11:19 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Subject: [EXTERNAL] Re: K211878 is on Hold Pending Your Response

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Hi Michele

Nice to see we're working with you again.

I was a little surprised regarding the RTA decision as the level of information we've provided is the same as that which was provided in previous submissions, where we didn't receive an RTA from yourself. Therefore, I just wanted to reach out to you to ensure that I correctly answer the issue so as to avoid any further delays.

(b)(4)

Regarding the RTA on question F.28 and F.29

We require no clarification on this point and can provide the documents as requested.

Thanks in advance for your assistance

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate
Advanced Medical Solutions Ltd.
Tel: +44 (0) 1752 30 9360
E-mail: Martin.Mitchell@admedsol.com

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
To: <martin.mitchell@admedsol.com>
Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
Date: 06/07/2021 20:49
Subject: K211878 is on Hold Pending Your Response

July 6, 2021**Acceptance Review Notification - Refuse To Accept (RTA)**

We have completed the administrative acceptance review of your submission K211878. Our review indicates that your submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit one eCopy of your response, referencing your submission K211878, addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Your submission will remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist by 01/02/2022, we will consider this submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your submission. We will contact you if we require any additional information during the course of our administrative review. FDA aims to apply the least burdensome principles when requesting additional information.

The lead reviewer assigned to your submission is me, Michele Lee. The file is being reviewed in Office of Health Technology 4, Division of Health Tecl1nology 4 B. The first line supervisor is the Assistant Director, Plastic Surgery Skin and Wound Devices. You may contact me at any point during the review if you have questions or concerns. You can provide valuable support for CDRH to continue to improve our programs by raising to the attention of management relevant issues that arise during the course of this review. If you feel there is an unresolved issue or a matter that requires additional attention, you should contact the Assistant Director. If your concern or issue is not addressed by the Assistant Director, you should contact the Division Director or OHT Director. The contact information for each management level can be found in the CDRH Management Directory.

For additional information about the Refuse to Accept Policy for for 510(k)s please refer to the guidance document available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf.

If you have general questions about the review process for your submission, you should contact OPEQSubmissionSupport@fda.hhs.gov.

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Advanced Medical Solutions Ltd

Advanced Medical Solutions Limited
Western Wood Way,
Langage Science Park,
Plymouth,
Devon,
PL7 5BG,
United Kingdom
Tel: +44 (0) 1752 209955 **Fax:** +44 (0) 1752 209956
Web: www.admedsol.com
Registered in England 2666957 VAT No. GB 636 5551 27

510(k) Summary

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Dear both,

Yes, that would work for me as well.

Many thanks.

Kind regards.

(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov>

Sent: Freitag, 5. November 2021 17:19

To: (b)(4) (b)(4) ; k211878@docs.fda.gov

Cc: (b)(4)

Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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---

Hello (b)(4)

Yes, I was thinking 1:30pm EST on Wednesday 11/10.

Thanks,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Office of Product Evaluation and Quality

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D7D481.B78B0510]<http://www.fda.gov/>

[cid:image002.jpg@01D7D481.B78B0510]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D7D481.B78B0510] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7D481.B78B0510] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7D481.B78B0510] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D7D481.B78B0510]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: (b)(4)

Sent: Friday, November 5, 2021 11:57 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>; (b)(4)
(b)(4)
k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Cc: (b)(4)

Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Michele:

Just confirming you are looking at 1:30 pm Eastern time.

(b)(4) That time would work for me; please confirm your availability.

(b)(4)

_____

(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Sent: Friday, November 5, 2021 11:08 AM

To: (b)(4)
k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Cc: (b)(4)
(b)(4)

Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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---

Hello (b)(4)

I have another meeting before that scheduled time. I can do a half hour earlier (6:30pm UTC+1) on Wednesday or a different time on another day next week?

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D7D481.B78B0510]<http://www.fda.gov/>

[cid:image002.jpg@01D7D481.B78B0510]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D7D481.B78B0510] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7D481.B78B0510] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7D481.B78B0510] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D7D481.B78B0510]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: (b)(4)

Sent: Friday, November 5, 2021 11:02 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>;
k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Cc: (b)(4)
(b)(4)

Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Dear Michele,

many thanks for sending the invite.

I fear, IÂ´ve made a mistake, when communicating the time.

Could we schedule one hour earlier?

Kind regards.

(b)(4)

(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Sent: Freitag, 5. November 2021 15:59

To: (b)(4)
k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Cc: (b)(4)
(b)(4)

Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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---

(b)(4)

Sure, we can discuss via teleconference on 10 Nov 2021 at 7pm UTC+1/ 2pm EDT. I sent a ZoomGov invite via email and also copied the call-in information below.

[Image removed by sender.]<https://zoom.us/>

Hi there,

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov> is inviting you to a scheduled ZoomGov meeting.

Join Zoom

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

Best Regards,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D7D481.B78B0510]<http://www.fda.gov/>

[cid:image002.jpg@01D7D481.B78B0510]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D7D481.B78B0510] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7D481.B78B0510] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D7D481.B78B0510] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D7D481.B78B0510]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: (b)(4)

Sent: Friday, November 5, 2021 10:10 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>;
k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Cc: (b)(4)
(b)(4)
Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Michele,

Many thanks for your message.

Martin, thank you for the connection.

Michele, would you be available next Wednesday, 10 November 2021, at 7 pm (UTC+1)?

Then I would send an invitation.

Kind regards.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Sent: Freitag, 5. November 2021 14:33

To: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Cc: (b)(4)

(b)(4)

Subject: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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---

Hello all,

Thank you, Martin, for the connection.

(b)(4)

Best Regards,

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

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Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D7D481.B78B0510]<http://www.fda.gov/>

[cid:image002.jpg@01D7D481.B78B0510]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D7D481.B78B0510] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D7D481.B78B0510] <http://www.youtube.com/user/USFoodandDrugAdmin>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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[cid:image005.jpg@01D7D481.B78B0510] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D7D481.B78B0510]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>
<Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Thursday, November 4, 2021 11:29 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>;
k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Cc: (b)(4)

(b)(4)

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

Regarding the recent deficiency question on our medical device submission which is currently under review with the FDA:

(b)(4)

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211878

Device Name
LiquiBand® XL

Indications for Use *(Describe)*
The LiquiBand® XL is intended for topical application only to hold closed easily approximated skin edges of wounds from surgical incisions, including incisions from minimally invasive surgery, and simple, thoroughly cleansed, trauma-induced lacerations. The LiquiBand® XL should be used in conjunction with, but not in place of, deep dermal stitches. Additionally, the adjunct wound closure device component maintains temporary skin edge alignment along the length of the wound during application of the liquid adhesive.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

(b)(4)

Mon 5/23/2022 7:32 AM

To: k211878@docs.fda.gov <k211878@docs.fda.gov>;Arepalli, Sambasiva <Sambasiva.Arepalli@fda.hhs.gov>

Cc: (b)(4) ;Lee, Michele <Michele.Lee@fda.hhs.gov>

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Sambasiva:

I was asked to (re)send the following information regarding a 510(K) filing with the FDA. This information was originally sent to Michele Lee, and my understanding is that you have taken over the lead reviewer responsibility for this application. (b)(4) (on copy) should be your main contact if there are any questions, but with his currently being out of the office, I am resending the document on his behalf.

(b)(4)

(b)(4)

From: (b)(4)
Sent: Friday, November 12, 2021 4:39 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>; k211878@docs.fda.gov
Cc: (b)(4) >
Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Dear Michele,

Many thanks for taking the time talking to us on Wednesday.

As discussed, I am sharing the (b)(4) Deficiencies

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Thank you for keeping this confidential and not releasing information regarding proprietary formulations, including to the 510(k) submission holder.

Wish you a great weekend.
Best regards.

(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov>
Sent: Montag, 8. November 2021 15:03
To: (b)(4) k211878@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello (b)(4)

Ok, I have changed the Zoom call time to 1:30pm EST on Wednesday. The call in information should still be the same.

Thanks,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
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Michele.Lee@fda.hhs.gov





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From: (b)(4)
Sent: Monday, November 8, 2021 3:19 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>; (b)(4); k211878@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Dear both,

Yes, that would work for me as well.
Many thanks.

Kind regards.

(b)(4)

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(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov>
Sent: Freitag, 5. November 2021 17:19
To: (b)(4); k211878@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Mike,

Yes, I was thinking 1:30pm EST on Wednesday 11/10.

Thanks,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
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Michele.Lee@fda.hhs.gov

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From: (b)(4)
Sent: Friday, November 5, 2021 11:57 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>; (b)(4); k211878@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Michele:

Just confirming you are looking at 1:30 pm Eastern time.

(b)(4) That time would work for me; please confirm your availability.

(b)(4)

(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov>
Sent: Friday, November 5, 2021 11:08 AM
To: (b)(4); k211878@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello (b)(4)

I have another meeting before that scheduled time. I can do a half hour earlier (6:30pm UTC+1) on Wednesday or a different time on another day next week?

Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
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Michele.Lee@fda.hhs.gov





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From: (b)(4)
Sent: Friday, November 5, 2021 11:02 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>; k211878@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Dear Michele,

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many thanks for sending the invite.

I fear, I´ve made a mistake, when communicating the time.
Could we schedule one hour earlier?

Kind regards.

(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov>
Sent: Freitag, 5. November 2021 15:59
To: (b)(4); k211878@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello (b)(4)

Sure, we can discuss via teleconference on 10 Nov 2021 at 7pm UTC+1/ 2pm EDT. I sent a ZoomGov invite via email and also copied the call-in information below.

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Hi there,

Michele.Lee@fda.hhs.gov is inviting you to a scheduled ZoomGov meeting.

Join Zoom Meeting

One tap mobile:

Meeting URL:

Meeting ID:
Passcode:

(b)(4)

Join by Telephone

For higher quality, dial a number based on your current location.
Dial:

Meeting ID:

Passcode:

(b)(4)

International numbers

Join from an H.323/SIP room system

H.323:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Meeting ID: (b)(4)
Passcode:
SIP:
Passcode:

Best Regards,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov





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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: (b)(4)
Sent: Friday, November 5, 2021 10:10 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>; k211878@docs.fda.gov
Cc: (b)(4); Martin.Mitchell@admedsol.com
Subject: RE: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Dear Michele,

Many thanks for your message.
Martin, thank you for the connection.

Michele, would you be available next Wednesday, 10 November 2021, at 7 pm (UTC+1)?
Then I would send an invitation.

Kind regards.

(b)(4)

From: Lee, Michele <Michele.Lee@fda.hhs.gov>
Sent: Freitag, 5. November 2021 14:33
To: Martin.Mitchell@admedsol.com; k211878@docs.fda.gov
Cc: (b)(4)
Subject: [EXT] RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello all,

Thank you, Martin, for the connection.

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To the (b)(4) please feel free to ask any questions about our request for the (b)(4). Please be assured that any correspondence sent directly to FDA will be kept confidential and no information regarding proprietary formulations will be released, including to the 510(k) submission holder.

Best Regards,

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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Michele.Lee@fda.hhs.gov





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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Thursday, November 4, 2021 11:29 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>; k211878@docs.fda.gov
Cc: (b)(4)
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

Regarding the recent deficiency question on our medical device submission which is currently under review with the FDA:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

I have discussed this request with the supplier of the (b)(4) who are on copy in this email.

As they have not received such a request from the FDA before, they have a few of questions regarding the level of information you require and how best to supply it to you.

(b)(4) to continue the email conversation with their questions.

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

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(b)(4)

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eConsult Cover Sheet

Consult Number:	CON2211118
Document Number:	K211878/S002
Applicant:	Advanced Medical Solutions Limited
Trade Name:	LiquiBand XL
Consult Type:	Chemistry
Requestor:	Sam Arepalli [SRA]
	sambasiva.arepalli@fda.hhs.gov ; 301-796-6434
Requestor Home:	CDRH\ OHT4\ DHT4B\ THT4B4
Requested Consultant:	
Gatekeeper / Consultant:	Joshua Young [JOSHUA.YOUNG]
	joshua.young@fda.hhs.gov ; 3013481839
Consultant Home:	CDRH\ OSEL\ DBCMS\ DBCMS
Date Requested:	May 12, 2022
Due Date:	May 16, 2022
Instructions:	Hi Josh: Thx for accepting this consult. Please work with Diego. Thx Sam

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(5)

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(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(5)

Joshua Young -S Digitally signed by Joshua Young -S
Date: 2022.05.15 23:56:01 -04'00'

Joshua A. Young, Ph.D.

Staff Fellow, Division of Biology, Chemistry, and Materials Science; CDRH\OSEL

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Hello Martin,

I am sorry to hear about the (b)(4) I hope all is able to be resolved soon.

Thank you for the update. I am actually working in a different division within FDA and no longer the primary contact for this submission. I believe that the 180 days is automatically granted for responses to AINN hold but you can also confirm with the 510(k) Program staff (510k_Program@fda.hhs.gov, telephone: 301-796-5640) to make sure.

Best,
Michele

Michele Lee, Ph.D. *(she/her/hers)*
Regulatory Science Program Manager
Partnerships to Advance Innovation and Regulatory Science (PAIRS)

Center for Devices and Radiological Health
Office of Strategic Partnerships and Technology Innovation
Division of All Hazards Response, Science, and Strategic Partnerships
U.S. Food and Drug Administration
michele.lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Friday, March 25, 2022 11:28 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Michele

I'd like to provide an update on our progress with responding to the deficiencies raised on K211878

We were on track to have a deficiency response submitted to the FDA by the 180 day hold period deadline of 2nd April 2022.

However, the organisation performing the (b)(4) have been affected by (b)(4). As a result, they were unable to complete the testing by our targeted timeline.

Therefore, I just want to confirm that we are still intending to respond to the deficiencies, but we would need to use the second 180 day hold period granted to us through the COVID-19 situation.

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 08/11/2021 22:05
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

Thanks for your message. I'll need some time to review the teleconference minutes with my team and also obtain some feedback from our consulting toxicologist about the follow up questions. But I wanted to let you know I received your email and you may feel free to check in again next week.

I do have a clarification question about Follow Up (b)(4)

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(b)(4)

Regarding the timeline clarification- I am also under the understanding that the COVID-19 guidance document you cited was still active and that would allow you an additional 180 days for the hold period. I have reached out to the 510(k) Staff multiple times to confirm and am still waiting on their response. Is there a customer service contact email for the customer collaboration portal specifically? You may try contacting them as well to have the date corrected on your end.

Thank you,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov



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https://www.research.net/s/odhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>
Sent: Friday, November 5, 2021 12:07 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

I hope you had a nice holiday!

Following on from the teleconference we had a few actions to complete and get back to you with.

1) Teleconference minutes

Please find a draft of the the teleconference minutes below. Could you review and confirm if you require any changes made?

2) Follow-up questions on the teleconference discussion

As suggested during the teleconference there was the opportunity for a followup email clarification on a few minor points.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

3) Timeline clarification as per previous email

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Thank you again for your assistance

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>, "Liu, Lixin" <Lixin.Liu@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 20/10/2021 22:43
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Michele

Thank you for the prompt response to the clarifications! We'll take your points on board regarding future shelf life studies.

I do have a minor clarification question regarding our response timeline

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 20/10/2021 14:55
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

Thank you to you and your team for attending the teleconference yesterday. I wanted to follow up on two things I was discussing with my team:

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(b)(4)

I will be on leave for the next two weeks and you may contact our team management (Lixin.Liu@fda.hhs.gov) if you have questions during that time.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov



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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Lee, Michele
Sent: Friday, October 15, 2021 4:47 PM
To: Martin.Mitchell@admedsol.com
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you for providing your questions in advance of the meeting. We look forward to discussing our responses with you next week.

Have a good weekend,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Friday, October 15, 2021 12:00 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Please find the list of questions/clarifications attached below.

I hope you have a good weekend. I'm looking forwards to our discussion next week!

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 13/10/2021 22:35
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

I have scheduled the teleconference for next Tuesday October 19th at 9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour but our biocompatibility consultant/ team management needs to drop off for another call at 9:30am. Please send me the questions for discussion in advance of the meeting so that we can plan to discuss biocompatibility/ regulatory questions first before the relevant parties need to drop off.

Join Zoom Meeting
One tap mobile:
Meeting URL:
Meeting ID:
Passcode:
(b)(4)

Join by Telephone
For higher quality, dial a number based on your current location.
Dial:

Meeting ID:
Passcode:
(b)(4)
International numbers

Join from an H.323/SIP room system
H.323:

Meeting ID:
Passcode:
SIP:
Passcode:
(b)(4)

Thanks,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov



* * * * *
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 13, 2021 4:46 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com; k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Apologies Michele, one final thing I missed off my email... could you clarify how long the teleconference would be by default? Could we request 1 hour just incase some of the points end up taking longer to discuss?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 13/10/2021 20:35
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hi Michele

We're currently preparing our questions for the teleconference and will send these through in due course, however to assist with scheduling the relevant parties at FDA, I should let you know that we would definitely like to discuss the questions related to biocompatibility.

After discussion with the team we would like to request the teleconference on the Tuesday 19th October if that is possible? As we are based in the UK, we would also like to request that this is arranged between the hours of 2-5pm BST.

If this time slot is not available could you outline any alternative days/times which would be possible?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS
To: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 08/10/2021 22:14
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hi Michele

Thank you for the offer. I think after today's meeting we may need a little more time to be better prepared for the teleconference.

We are reaching out to the **(b)(4)** for us as we feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible dates for you early next week.

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>
To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>
Cc: "helen.topping@admedsol.com" <helen.topping@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>
Date: 06/10/2021 13:49
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

If it makes it easier for your team, we are able to extend the 10 day teleconference deadline up to October 19th. Let me know if you would like to select a date later than the 14th and I can check our management schedules.

Regarding review timelines, we are still on the 90 day review cycle and are planning to complete the review of your response with the 20 calendar days left on the clock. While we retain the right to add additional days, we are doing our best with the resources that we have to avoid delaying review timelines if possible.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Michele.Lee@fda.hhs.gov



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https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

From: Martin.Mitchell@admedsol.com<Martin.Mitchell@admedsol.com>
Sent: Wednesday, October 6, 2021 6:00 AM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: helen.topping@admedsol.com
Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Thank you again for your review. Our team are busy discussing the questions and we would definitely like to have a teleconference with the FDA. We're currently consolidating our understanding of the deficiencies and are determining what our potential questions to you would be. I hope to get the questions to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we look to schedule a teleconference with the FDA on Wednesday 13th or Thursday 14th? As we're based in the UK we would appreciate a timeslot within our working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines for this project.... regarding the FDA timeline I can see on the CCP tracker website that the FDA timeline is on day 70.

- Will FDA be sticking to the 90 day target and as a result only have 20 days left on the clock?
- Or, due to the current situation with the unprecedented resource limitations..... will you will assume 30 days to review the response as standard? Or perhaps stick to the 20 days but retain the right to add additional days?

Best regards,

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
To: <martin.mitchell@admedsol.com>, <helen.topping@admedsol.com>
Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov>
Date: 04/10/2021 21:44
Subject: K211878/S001 is on Hold Pending Your Response

October 4, 2021

We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Michele Lee.

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*** This is a system-generated email notification ***[attachment "K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hi Sam

I'll call you today at 6am (11am UK

time); we thought it would be better to send you the updated documents

to help aid the discussion during the call.

The IFU has been updated with your comments

(and as per our modifications we suggest below). I've provided a redlined

and clean copy of this:

The 510(k) summary has been updated

with your comments

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions

Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From:

 Martin Mitchell/WIN/UK/AMS
To:

 "Arepalli, Sambasiva"

<Sambasiva.Arepalli@fda.hhs.gov>
Cc:

 "K211878@docs.fda.gov"

<K211878@docs.fda.gov>, Rose Guang/WIN/UK/AMS@ams
Date:

 18/05/2022 22:37
Subject:

   RE: [EXTERNAL]

Re: K211878-s002
<hr noshade>

Hi Sam

Firstly, thank you for staying late

to continue to work with us on in the final stages of this submission.

It is much appreciated.

Please find attached the IFU with updated

comments from ourselves

[attachment "K211878-S002 - Revised

labeling received on 5-16-2022.jam.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

For most of the proposed updates we

will accept to make the changes. However there are two points we would

wish to clarify
Regarding the comment on

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

serif">As discussed I'll call you tomorrow

to discuss your email below

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions

Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From:

 "Arepalli, Sambasiva"

<Sambasiva.Arepalli@fda.hhs.gov>
To:

 "Martin.Mitchell@admedsol.com"

<Martin.Mitchell@admedsol.com>
Cc:

 "Arepalli, Sambasiva"

<Sambasiva.Arepalli@fda.hhs.gov>, "K211878@docs.fda.gov"

<K211878@docs.fda.gov>
Date:

 18/05/2022 20:39
Subject:

   RE: [EXTERNAL]

Re: K211878-s002
<hr noshade>

Hi Mr. Mitchell:
Please see attached for the labeling and

510kSummary with FDA edits.

Please address these edits and send me

both the edited versions and clean copies of the labeling and the 510kSummary

by COB tomorrow (5-19-2022).

Please cc your response to K211878@docs.fda.gov.

Thx
Sam

Sam Arepalli,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Ph.D.
FDA/CDRH/OPEQ/OHT4/PRSB2
Ph: 301 796 6434

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regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u><u></u>

From: Martin.Mitchell@admedsol.com

<Martin.Mitchell@admedsol.com>
Sent: Tuesday, May 17, 2022 6:39 AM
To: Arepalli, Sambasiva <Sambasiva.Arepalli@fda.hhs.gov>
Subject: RE: [EXTERNAL] Re: K211878-s002

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or open attachments unless you recognize the sender and know the content

is safe.

Hi Sam

Just to be safe for the email trail.... so that your email has a response

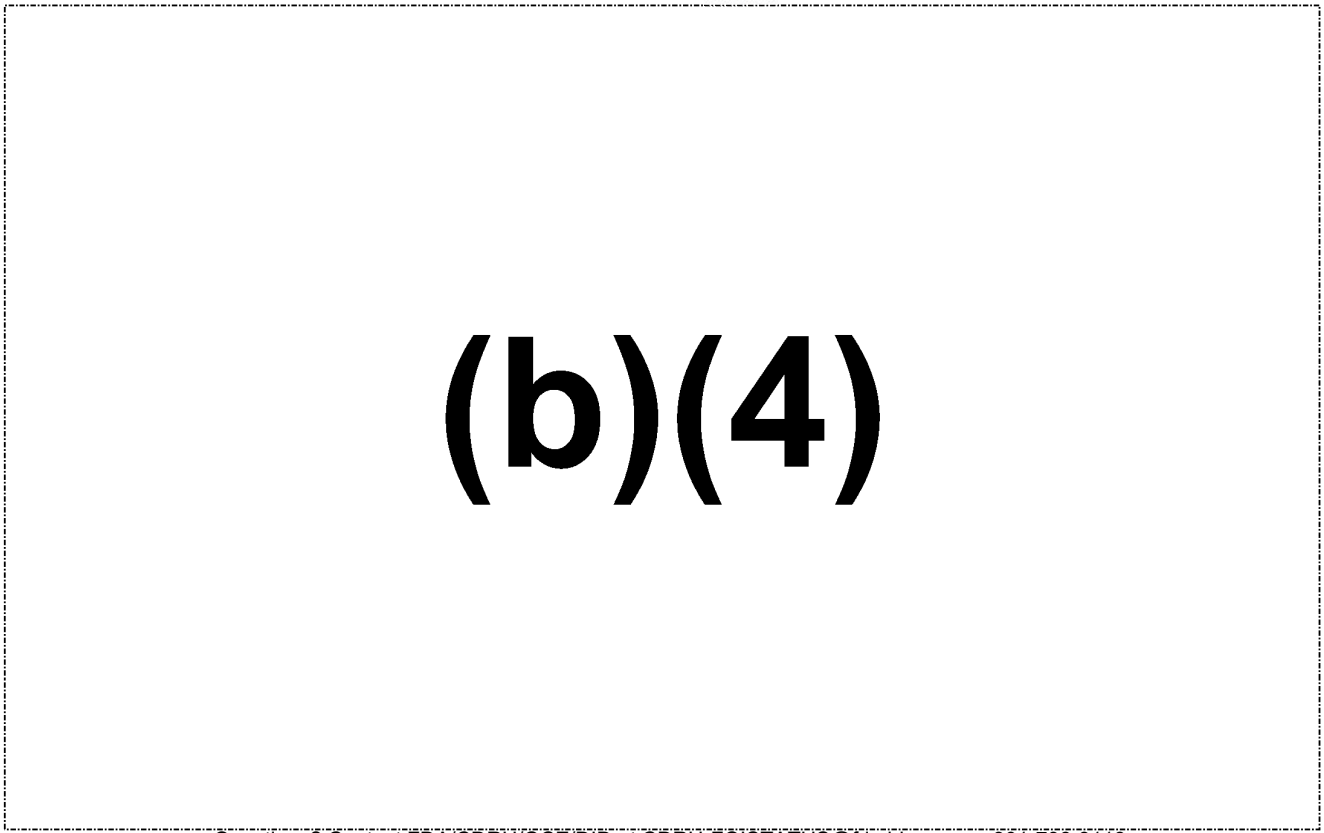
The email with this information was send yesterday; however it is also

provided again below:

Please find a response to the two points we discussed over the phone

FDA deficiency 13

(b)(4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

patient."
As requested, the IFU has been revised with the updated warning

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Arepalli,

Sambasiva" <<u>Sambasiva.Arepalli@fda.hhs.gov</u>>
To: "<u>Martin.Mitchell@admedsol.com</u>"

<<u>Martin.Mitchell@admedsol.com</u>>
Date: 17/05/2022

10:32
Subject: RE:

[EXTERNAL] Re: K211878-s002 <hr noshade>

Hi Mr. Mitchell:
Can you please give an update on the revised labeling request? Could you

please send the information cob today? Please give me a call when you have

a minute.
Thx
Sam

Sam Arepalli, Ph.D.
FDA/CDRH/OPEQ/OHT4/PRSB2
Ph: 301 796 6434

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to provide feedback regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u></f

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

ont>

From: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri"><<font size=2
color=blue face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri">>

Sent: Monday, May 16, 2022 12:06 PM
To: Arepalli, Sambasiva
<<font size=2 color=blue
face="Calibri"><u>Sambasiva.Arepalli@fda.hhs.gov</u><font size=2
face="Calibri">>
Subject: [EXTERNAL] Re: K211878-s002

CAUTION:This
email originated from outside

of the organization. Do not click links or open attachments unless you

recognize the sender and know the content is safe.
 <font size=2
face="Arial">
Hi Sam

Just so you're aware it's 17:00 now so i'll be heading
home; however i'll

try to make myself available outside of hours so please don't hesitate

to get in touch if you have any further questions.

Additionally i'll be working
from home the next few days so I won't pick

up calls from my office number you used previously.

If you have any further
questions please email me or call me on my personal

mobile number (b)(6)

Best regards,<font size=2
color=#000080 face="Arial">

Martin Mitchell
Regulatory Affairs
Manager

Advanced Medical Solutions Ltd.
E-mail: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=2 color=#000080
face="Arial">
Tel: +44 (0) 1752 30 9360<font size=2
face="Calibri">

From:
       Martin

Mitchell/WIN/UK/AMS
To:
   "Arepalli,

Sambasiva" <<font size=1
color=blue face="Arial"><u>Sambasiva.Arepalli@fda.hhs.gov</u><font size=1
face="Arial">>
Cc:
   "<a
href=mailto:K211878@docs.fda.gov><font size=1 color=blue
face="Arial"><u>K211878@docs.fda.gov</u>"

<<font size=1 color=blue
face="Arial"><u>K211878@docs.fda.gov</u>>,

Rose Guang/WIN/UK/AMS@ams, Helen Topping/WIN/UK/AMS@ams<font size=1
color=#5f5f5f face="Arial">
Date: <font size=1
face="Arial">16/05/2022

16:28
Subject:
 Re:

K211878-s002 <hr
noshade>

<font size=2
face="Arial">

Hi Sam

Please find a response to the two points we
discussed over the phone

 (b)(4)

(b)(4)

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

=2

patient."
As requested, the IFU has been revised with the updated warning

[attachment "IFU.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Arepalli,

Sambasiva" <<u>Sambasiva.Arepalli@fda.hhs.gov</u>>
To: "<u>Martin.Mitchell@admedsol.com</u>"

<<u>Martin.Mitchell@admedsol.com</u>>
Cc: "Arepalli,

Sambasiva" <<u>Sambasiva.Arepalli@fda.hhs.gov</u>>,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

"<u>K211878@docs.fda.gov</u>"

<<u>K211878@docs.fda.gov</u>>
Date: 16/05/2022

14:39
Subject: K211878-s002 <hr noshade>

Hi Mr. Martin:
Please address the following:
Please revise the product labeling to say:
â€œLiquiband XL is not safety tested to support use of the product on multiple

wounds of less than 20cm in a single patientâ€

Thx
Sam

Sam Arepalli, Ph.D.
FDA/CDRH/OPEQ/OHT4/PRSB2
Ph: 301 796 6434

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Revised labeling received on 5-16-2022.jam.pdf" deleted by Martin

Mitchell/WIN/UK/AMS] [attachment "K211878.510kSummary(Final).jam.pdf"

deleted by Martin Mitchell/WIN/UK/AMS]

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Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

May 23, 2022

Advanced Medical Solutions Limited
Martin Mitchell
Senior Regulatory Affairs Associate
Western Wood Way , Langage Science Park
Plymouth, Devon PL7 5BG
United Kingdom

Re: K211878
Trade/Device Name: LiquiBand® XL
Regulation Number: 21 CFR 878.4011
Regulation Name: Tissue Adhesive With Adjunct Wound Closure Device For Topical Approximation Of Skin
Regulatory Class: Class II
Product Code: OMD
Dated: May 4, 2022
Received: May 4, 2022

Dear Martin Mitchell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Julie A. Morabito -S

Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211878

Device Name
LiquiBand® XL

Indications for Use *(Describe)*
LiquiBand® XL is intended for topical application only to hold closed easily approximated skin edges of wounds from surgical incisions, including incisions from minimally invasive surgery, and simple, thoroughly cleansed, trauma-induced lacerations. LiquiBand® XL should be used in conjunction with, but not in place of, deep dermal stitches. Additionally, the adjunct wound closure device component maintains temporary skin edge alignment along the length of the wound during application of the liquid adhesive.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Advanced Medical Solutions Ltd

Advanced Medical Solutions Limited
Western Wood Way,
Langage Science Park,
Plymouth,
Devon,
PL7 5BG,
United Kingdom
Tel: +44 (0) 1752 209955 **Fax:** +44 (0) 1752 209956
Web: www.admedsol.com
Registered in England 2666957 VAT No. GB 636 5551 27

510(k) Summary

Submitted by: Advanced Medical Solutions Limited
Western Wood Way
Langage Science Park
Plymouth, Devon
PL7 5BG
United Kingdom
Tel: +44 (0)1752 209955
Fax: +44 (0) 1752 209956

Contact Person: Martin Mitchell
Regulatory Affairs Manager

Date of Summary: 19th May 2022

Device Name: LiquiBand® XL

Common Name: Cutaneous Tissue Adhesive With Mesh

Classification Name: Tissue adhesive with adjunct wound closure device for topical approximation of skin

Regulatory Number: 21 CFR 878.4011

Device Class: Class II

Product Code: OMD

Predicate Device
Device Name: Exofin Fusion Skin Closure System
510(k) Clearance: K191461

Reference Device
Device Name: LiquiBand® Plus
510(k) Clearance: K183570

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Advanced Medical Solutions Ltd

Advanced Medical Solutions Limited
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Registered in England 2666957 VAT No. GB 636 5551 27

Device Description

LiquiBand® XL is a sterile, liquid topical skin adhesive containing a monomeric (2-octyl cyanoacrylate) formulation and the colorant D & C Violet No. 2. It is provided in a single-use applicator. As applied to skin, the liquid topical skin adhesive is slightly more viscous than water and polymerizes within minutes.

In vitro studies have shown that LiquiBand® XL acts as a barrier to microbial penetration as long as the adhesive film remains intact. Clinical studies were not conducted to demonstrate microbial barrier properties.

LiquiBand® XL also incorporates a self-adhering mesh that is applied to the approximated skin edges to provide temporary skin edge alignment to an incision until the liquid adhesive is applied to achieve skin closure.

Indications for Use

LiquiBand® XL is intended for topical application only to hold closed easily approximated skin edges of wounds from surgical incisions, including incisions from minimally invasive surgery, and simple, thoroughly cleansed, trauma-induced lacerations. LiquiBand® XL should be used in conjunction with, but not in place of, deep dermal stitches. Additionally, the adjunct wound closure device component maintains temporary skin edge alignment along the length of the wound during application of the liquid adhesive.

Comparison of Technological Characteristics with the Predicate Device

The technological characteristics of the LiquiBand® XL and the predicate device are similar, in that they both contain the same technological characteristics:

Device	Subject device: LiquiBand® XL	Predicate device: Exofin Fusion Skin Closure System	Comparison
Adhesive	2-octyl cyanoacrylate adhesive with D&C Violet #2 colorant	2-octyl cyanoacrylate adhesive with D&C Violet #2 colorant	Same
Accelerant	Quaternary ammonium salt	Quaternary ammonium salt	Same
Applicator	Sterile single use applicator; comprising of a glass ampoule (containing the adhesive) within a plastic applicator body with a porous block (containing the accelerant) with a foam applicator tip	Sterile single use applicator; comprised of an aluminum tube (containing the adhesive) with a porous disk (containing the accelerant) with an applicator tip	Equivalent
Mesh	Polyester mesh with pressure sensitive adhesive	Polyester mesh with pressure sensitive adhesive	Same

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Advanced Medical Solutions Ltd

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United Kingdom
Tel: +44 (0) 1752 209955 **Fax:** +44 (0) 1752 209956
Web: www.admedsol.com
Registered in England 2666957 VAT No. GB 636 5551 27

Performance Data

Testing was performed in accordance with the FDA special controls guidance document for "Tissue Adhesive with Adjunct Wound Closure Device Intended for the Topical Approximation of Skin"

Performance Testing

The following tests were performed on the LiquiBand® XL to demonstrate substantial equivalence to the predicate device:

- Peel Adhesion of Pressure-Sensitive Tape (ASTM D3330/D3330M-04)
- Shear Adhesion of Pressure-Sensitive Tapes (ASTM D3654/D3654M-06)
- Tensile Properties of Thin Plastic Sheeting (ASTM D882-12)
- Lap-shear strength (ASTM F2255-05)
- T-peel adhesion strength (ASTM F2256-05)
- Adhesive strength in tension (ASTM F2258-05)
- Wound closure strength (ASTM F2458-05)
- Adhesive degradation study
- Heat of polymerization
- Force to actuate and express
- Viscosity
- Polymerization set time
- Microbial barrier testing
- Quality of adhesive film on mesh
- Accelerant degradation study
- Animal wound healing study

Biocompatibility

The biological evaluation of the LiquiBand® XL was performed in accordance with FDA guidance on the use of ISO 10993-1. The following test reports were provided in this submission:

- Cytotoxicity
- Sensitization
- Irritation
- Material mediated pyrogenicity
- Acute systemic toxicity
- Chemical characterization and toxicological risk assessment

Clinical Testing

- No clinical testing has been submitted, referenced, or relied upon for determining substantial equivalence.

Conclusions

Based on the intended use, technological characteristics, safety and performance testing, LiquiBand® XL has been demonstrated to be substantially equivalent to the predicate device, Exofin Fusion Skin Closure System.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Sumpter, Melanie * [Melanie.Sumpter@fda.hhs.gov]
Sent: 7/26/2021 6:21:53 PM
To: martin.mitchell@admedsol.com
Subject: K211878/S001 Acknowledgment Notification
Attachments: K211878.S001 Letter.pdf

Sincerely,
Melanie N. Sumpter
Technical Information Specialist - 510(k) Staff
CDRH Document Control Center
Melanie.Sumpter@fda.hhs.gov

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Acknowledgment Letter

7/26/2021

Martin Mitchell, Senior Regulatory Affairs Associate
Advanced Medical Solutions Limited
Western Wood Way , Langage Science Park
Plymouth, Devon PL7 5BG
UNITED KINGDOM

Dear Martin Mitchell:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the address listed below. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please contact the Office of Product Evaluation and Quality (OPEQ) submission support at (301) 796-5640 or OPEQSubmissionSupport@fda.hhs.gov.

Submission Number: K211878/S001
Received: 7/26/2021
Applicant: Advanced Medical Solutions Limited
Device: LiquiBand XL

We will notify you when the review of this document has been completed or if any additional information is required. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hello Martin,

Please find the responses to your questions below in red font and revised meeting minutes attached. Hope this is helpful!

Best,

Michele

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

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[cid:image005.jpg@01D7E130.5AD24B10] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D7E130.5AD24B10]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Friday, November 12, 2021 10:15 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>

Cc: helen.topping@admedsol.com; k211878@docs.fda.gov

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Regarding the timeline clarification i've taken a look on the customer collaboration portal but there was only an email to provide feedback on the portal. Nevertheless i've emailed as i'm a little concerned about what may happen if the portal shows that the 180 day hold periods has expired and we haven't yet submitted our response..... is there a risk that the 510(k) may be inadvertently withdrawn?

We have prepared our response to your question below which I hope you find helpful.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 08/11/2021 22:05

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

Thanks for your message. Iâ€™ll need some time to review the teleconference minutes with my team and also obtain some feedback from our consulting toxicologist about the follow up questions. But I wanted to let you know I received your email and you may feel free to check in again next week.

I do have a clarification question about Follow Up (b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Regarding the timeline clarification- I am also under the understanding that the COVID-19 guidance document you cited was still active and that would allow you an additional 180 days for the hold period. I have reached out to the 510(k) Staff multiple times to confirm and am still waiting on their response. Is there a customer service contact email for the customer collaboration portal specifically? You may try contacting them as well to have the date corrected on your end.

Thank you,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

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From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>
<Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Friday, November 5, 2021 12:07 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>;
k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

I hope you had a nice holiday!

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Following on from the teleconference we had a few actions to complete and get back to you with.

1) Teleconference minutes

Please find a draft of the the teleconference minutes below. Could you review and confirm if you require any changes made?

2) Follow-up questions on the teleconference discussion

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

The supporting information which provides further clarity on the questions above has been attached if required.

3) Timeline clarification as per previous email

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Thank you again for your assistance

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>, "Liu, Lixin" <Lixin.Liu@fda.hhs.gov<mailto:Lixin.Liu@fda.hhs.gov>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 20/10/2021 22:43

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Michele

Thank you for the prompt response to the clarifications! We'll take your points on board regarding future shelf life studies.

I do have a minor clarification question regarding our response timeline

I can see on the customer collaboration portal that we have a 180 day hold period which

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 20/10/2021 14:55

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

Thank you to you and your team for attending the teleconference yesterday. I wanted to follow up on two things I was discussing with my team:

(b)(4)

I will be on leave for the next two weeks and you may contact our team management (Lixin.Liu@fda.hhs.gov<mailto:Lixin.Liu@fda.hhs.gov>) if you have questions during that time.

Best,

Michele

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

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From: Lee, Michele

Sent: Friday, October 15, 2021 4:47 PM

To: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you for providing your questions in advance of the meeting. We look forward to discussing our responses with you next week.

Have a good weekend,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

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Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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[cid:image002.jpg@01D7E130.5AD24B10]<https://www.facebook.com/FDA>[cid:image003.jpg@01D7E130.5AD24B10]<https://twitter.com/US_FDA> [cid:image004.jpg@01D7E130.5AD24B10]<http://www.youtube.com/user/USFoodandDrugAdmin> [cid:image005.jpg@01D7E130.5AD24B10]<http://www.flickr.com/photos/fdaphotos/> [cid:image006.jpg@01D7E130.5AD24B10]<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Friday, October 15, 2021 12:00 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Please find the list of questions/clarifications attached below.

I hope you have a good weekend. I'm looking forwards to our discussion next week!

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 13/10/2021 22:35

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

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Hello Martin,

I have scheduled the teleconference for next Tuesday October 19that 9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour but our biocompatibility consultant/ team management needs to drop off for another call at 9:30am. Please send me the questions for discussion in advance of the meeting so that we can plan to discuss biocompatibility/ regulatory questions first before the relevant parties need to drop off.

Join Zoom

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Thanks,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

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From:
Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Wednesday, October 13, 2021 4:46 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Apologies Michele, one final thing I missed off my email... could you clarify how long the teleconference would be by default? Could we request 1 hour just incase some of the points end up taking longer to discuss?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

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From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 13/10/2021 20:35

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hi Michele

We're currently preparing our questions for the teleconference and will send these through in due course, however to assist with scheduling the relevant parties at FDA, I should let you know that we would definitely like to discuss the questions related to biocompatibility.

After discussion with the team we would like to request the teleconference on the Tuesday 19th October if that is possible? As we are based in the UK, we would also like to request that this is arranged between the hours of 2-5pm BST.

If this time slot is not available could you outline any alternative days/times which would be possible?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 08/10/2021 22:14

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hi Michele

Thank you for the offer. I think after today's meeting we may need a little more time to be better prepared for the teleconference.

We are reaching out to the (b)(4) for us as we feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible dates for you early next week.

Best regards,

Martin Mitchell

Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 06/10/2021 13:49

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference deadline up to October 19th. Let me know if you would like to select a date later than the 14thand I can check our management schedules.

Regarding review timelines, we are still on the 90 day review cycle and are planning to complete the review of your response with the 20 calendar days left on the clock. While we retain the right to add additional days, we are doing our best with the resources that we have to avoid delaying review timelines if possible.

Best,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

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Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

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From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Wednesday, October 6, 2021 6:00 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>

Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Thank you again for your review. Our team are busy discussing the questions and we would definitely like to have a teleconference with the FDA. We're currently consolidating our understanding of the deficiencies and are determining what our potential questions to you would be. I hope to get the questions to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we look to schedule a teleconference with the FDA on Wednesday 13th or Thursday 14th? As we're based in the UK we would appreciate a timeslot within our working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines for this project.... regarding the FDA timeline I can see on the CCP tracker website that the FDA timeline is on day 70.

* Will FDA be sticking to the 90 day target and as a result only have 20 days left on the clock?

* Or, due to the current situation with the unprecedented resource limitations..... will you will assume 30 days to review the response as standard? Or perhaps stick to the 20 days but retain the right to add additional days?

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Best regards,

Martin Mitchell

Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov<mailto:michele.lee@fda.hhs.gov>>

To: <martin.mitchell@admedsol.com<mailto:martin.mitchell@admedsol.com>>, <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>

Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov<mailto:michele.lee@fda.hhs.gov>>

Date: 04/10/2021 21:44

Subject: K211878/S001 is on Hold Pending Your Response

October 4, 2021

We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Michele Lee.

*** This is a system-generated email notification ***[attachment "K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Hi Michele

(b)(4)

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov>

To: "Martin.Mitchell@admedsol.com" <Martin.Mitchell@admedsol.com>, "k211878@docs.fda.gov" <k211878@docs.fda.gov>

Cc: (b)(4)

(b)(4)

Date: 05/11/2021 13:34

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello all,

Thank you, Martin, for the connection.

(b)(4)

Best Regards,

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Michele.Lee@fda.hhs.gov

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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Thursday, November 4, 2021 11:29 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov>; k211878@docs.fda.gov

Cc: (b)(4)

(b)(4)

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

Regarding the recent deficiency question on our medical device submission which is currently under review with the FDA:

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com

Tel: +44 (0) 1752 30 9360

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Hello Martin,

Thanks for reaching out. Iâ€™ll be glad to assist in answering your questions.

* Will there be any delays in assigning a new reviewer?

We do not anticipate a delay in assigning a new reviewer.

* Are there still resource constraints at the FDA?

Speaking regarding our team, we are still working through resource constraints and doing our best to meet deadlines.

* Would a new reviewer who is not familiar with the product/deficiencies require a longer period of time to perform the review?

We will do our best to align the new reviewer that is familiar and experienced with the review product, to limit delay to the extent possible.

I hope this is helpful, but please let me know if youâ€™d like to discuss further.

Best,

Julie

Julie Morabito, PhD, RAC (she/her/hers)

Assistant Director

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

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Ph: (240) 402-3839 | Cell: (b)(6)

julie.morabito@fda.hhs.gov<mailto:julie.morabito@fda.hhs.gov>

Formerly:

Assistant Director, Outreach and Partnerships Team 2 (MedSun)

DCEA1: Division of Clinical Science and Quality | OCEA: Office of Clinical Evidence and Analysis

Office of Product Evaluation and Quality

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[cid:image003.jpg@01D84F65.16C833A0] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D84F65.16C833A0] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D84F65.16C833A0] <http://www.flickr.com/photos/fdaphotos/>
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From: Martin.Mitchell@admedsol.com <Martin.Mitchell@admedsol.com>

Sent: Wednesday, April 13, 2022 3:32 PM

To: Morabito, Julie <Julie.Morabito@fda.hhs.gov>

Cc: Helen.Topping@admedsol.com; k211878@docs.fda.gov; Rose.Guang@admedsol.com; Lee, Michele <Michele.Lee@fda.hhs.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele and Julie

Thank you Michele for providing further clarification on the matter regarding maintenance of a lead reviewer. We are sad to lose you as our lead reviewer and wish you the best in your new role within the FDA.

During the initial review of the 510(k) it was flagged that the FDA had resource challenges which resulted in the review taking 70 days instead of the targeted 60 days....When we discussed this previously it was stated that when we submit our deficiency response the FDA would still target to complete the review within the remaining 20 days, however.... it was also flagged that if resource constraints still existed this could take longer than 20 days.

To keep the FDA informed about our progress we are planning to submit our response to the deficiency questions in around 3 weeks time. We would like to enquire about FDA's ability to complete the review within 20 days?

* Will there be any delays in assigning a new reviewer?

* Are there still resource constraints at the FDA?

* Would a new reviewer who is not familiar with the product/deficiencies require a longer period of time to perform the review?

The timely completion of your review would be massively appreciated as the large wound market is critical to urgent patient demand, AMS and our partners who are very keen to provide the improved product to hospitals across the United States.

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>, "Rose.Guang@admedsol.com<mailto:Rose.Guang@admedsol.com>" <Rose.Guang@admedsol.com<mailto:Rose.Guang@admedsol.com>>,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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"Helen.Topping@admedsol.com<mailto:Helen.Topping@admedsol.com>"
<Helen.Topping@admedsol.com<mailto:Helen.Topping@admedsol.com>>, "Morabito, Julie"
<Julie.Morabito@fda.hhs.gov<mailto:Julie.Morabito@fda.hhs.gov>>

Date: 05/04/2022 14:47

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

Unfortunately, it is not possible for me to take on lead review of this submission. As previously mentioned, I am currently working in another Office within FDA and do not conduct premarket reviews of medical devices in my current role.

It is not uncommon for new lead reviewers to be assigned to submissions returning from hold. The internal documentation serves as a complete record of the previous interactions during prior review of a submission. If you have further questions regarding the review process for your submission, you may contact the Assistant Director for the Plastic Surgery Skin & Wound Devices Team, Dr. Julie Morabito (Julie.Morabito@fda.hhs.gov<mailto:Julie.Morabito@fda.hhs.gov>).

Best,

Michele

Michele Lee, Ph.D.(she/her/hers)

Regulatory Science Program Manager

Partnerships to Advance Innovation and Regulatory Science (PAIRS)

Center for Devices and Radiological Health

Office of Strategic Partnerships and Technology Innovation

Division of All Hazards Response, Science, and Strategic Partnerships

U.S. Food and Drug Administration

michele.lee@fda.hhs.gov<mailto:michele.lee@fda.hhs.gov>

[cid:image001.png@01D84F65.16C833A0]<http://www.fda.gov/>

[cid:image002.jpg@01D84F65.16C833A0]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D84F65.16C833A0] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D84F65.16C833A0] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D84F65.16C833A0] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D84F65.16C833A0]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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https://www.research.net/s/cdrhcustomerservice?ID=7013&S=E.

From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>
<Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Tuesday, April 5, 2022 8:31 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Cc: k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>;
Rose.Guang@admedsol.com<mailto:Rose.Guang@admedsol.com>;
Helen.Topping@admedsol.com<mailto:Helen.Topping@admedsol.com>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele,

We have been pleased to have you as the lead reviewer for RTA review, technical review, and responses to deficiency discussions since July 2021, as well as having you for the review for our previous 510(k) submission of the same product.

(b)(4)

* Jun 2021 - We submitted K211878 in response the (b)(4)
(b)(4)
* Oct 2021 - Further deficiencies were raised on the new K211878 submission

We currently have only 20 days of FDA review time left on our product and have been advised that we will now be assigned a new reviewer. As you can imagine this causing us a high level of concern given you have a detailed knowledge of our submissions and of the current outstanding questions. Our concern being that a new reviewer will not have the same detailed knowledge of our submission or of the outstanding questions and hence this may cause unnecessary further delay.

We have been very satisfied with the support we have received from yourself and we would ask that you remain on our file for the final 20 days if at all possible, or an explanation of why this is not possible with some reassurances that a new assessor will not cause unnecessary delays whilst they gain detailed knowledge of our file.

Your expedited response to this request would be appreciated.

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Date: 25/03/2022 16:47

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Martin,

A new lead reviewer will not be assigned until a follow up submission is received. So there is currently not a primary contact unless there is an active submission under FDA review. All of our correspondence and the prior related review have been documented internally, so you can be assured that the history of the prior review and contact is available to the future lead reviewer.

Best,

Michele

From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Friday, March 25, 2022 12:21 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

I've seen on the FDA customer collaboration portal that the time has automatically been added, but just thought it would be prudent to also inform you of the situation.

Could I ask who the primary contact is now? Will you be assisting or have any involvement with the review of our response?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

Date: 25/03/2022 15:59

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

I am sorry to hear about the (b)(4). I hope all is able to be resolved soon.

Thank you for the update. I am actually working in a different division within FDA and no longer the primary contact for this submission. I believe that the 180 days is automatically granted for responses to AINN hold but you can also confirm with the 510(k) Program staff (510k_Program@fda.hhs.gov<mailto:510k_Program@fda.hhs.gov>, telephone: 301-796-5640) to make sure.

Best,

Michele

Michele Lee, Ph.D.(she/her/hers)

Regulatory Science Program Manager

Partnerships to Advance Innovation and Regulatory Science (PAIRS)

Center for Devices and Radiological Health

Office of Strategic Partnerships and Technology Innovation

Division of All Hazards Response, Science, and Strategic Partnerships

U.S. Food and Drug Administration

michele.lee@fda.hhs.gov<mailto:michele.lee@fda.hhs.gov>

[cid:image001.png@01D84F65.16C833A0]<http://www.fda.gov/>

[cid:image002.jpg@01D84F65.16C833A0]<https://www.facebook.com/FDA>[cid:image003.jpg@01D84F65.16C833A0]<https://twitter.com/US_FDA>[cid:image004.jpg@01D84F65.16C833A0]<http://www.youtube.com/user/USFoodandDrugAdmin>[cid:image005.jpg@01D84F65.16C833A0]<http://www.flickr.com/photos/fdaphotos/> [cid:image006.jpg@01D84F65.16C833A0]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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https://www.research.net/s/cdrhcustomerservice?ID=7013&S=E.

From:
Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Friday, March 25, 2022 11:28 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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open attachments unless you recognize the sender and know the content is safe.

Hi Michele

I'd like to provide an update on our progress with responding to the deficiencies raised on K211878

We were on track to have a deficiency response submitted to the FDA by the 180 day hold period deadline of 2nd April 2022.

However, the organisation performing the (b)(4) (b)(4) have been affected by (b)(4). As a result, they were unable to complete the testing by our targeted timeline.

Therefore, I just want to confirm that we are still intending to respond to the deficiencies, but we would need to use the second 180 day hold period granted to us through the COVID-19 situation.

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 08/11/2021 22:05

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

Thanks for your message. Iâ€™ll need some time to review the teleconference minutes with my team and also obtain some feedback from our consulting toxicologist about the follow up questions. But I wanted to let you know I received your email and you may feel free to check in again next week.

I do have a clarification question about Follow Up (b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Regarding the timeline clarification- I am also under the understanding that the COVID-19 guidance document you cited was still active and that would allow you an additional 180 days for the hold period. I have reached out to the 510(k) Staff multiple times to confirm and am still waiting on their response. Is there a customer service contact email for the customer collaboration portal specifically? You may try contacting them as well to have the date corrected on your end.

Thank you,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D84F65.16C833A0]<http://www.fda.gov/>

[cid:image002.jpg@01D84F65.16C833A0]<https://www.facebook.com/FDA>[cid:image003.jpg@01D84F65.16C833A0]<https://twitter.com/US_FDA>[cid:image004.jpg@01D84F65.16C833A0]<http://www.youtube.com/user/USFoodandDrugAdmin>[cid:image005.jpg@01D84F65.16C833A0]<http://www.flickr.com/photos/fdaphotos/>[cid:image006.jpg@01D84F65.16C833A0]<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Friday, November 5, 2021 12:07 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hello Michele

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I hope you had a nice holiday!

Following on from the teleconference we had a few actions to complete and get back to you with.

1) Teleconference minutes

Please find a draft of the the teleconference minutes below. Could you review and confirm if you require any changes made?

2) Follow-up questions on the teleconference discussion

As suggested during the teleconference there was the opportunity for a followup email clarification on a few minor points.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

The supporting information which provides further clarity on the questions above has been attached if required.

3) Timeline clarification as per previous email

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Thank you again for your assistance

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>, "Liu, Lixin" <Lixin.Liu@fda.hhs.gov<mailto:Lixin.Liu@fda.hhs.gov>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 20/10/2021 22:43

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Michele

Thank you for the prompt response to the clarifications! We'll take your points on board regarding future shelf life studies.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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I do have a minor clarification question regarding our response timeline

I can see on the customer collaboration portal that we have a 180 day hold period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below was active which would provide us with an additional 180 day hold period?

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 20/10/2021 14:55

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

Thank you to you and your team for attending the teleconference yesterday. I wanted to follow up on two things I was discussing with my team:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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I will be on leave for the next two weeks and you may contact our team management (Lixin.Liu@fda.hhs.gov<mailto:Lixin.Liu@fda.hhs.gov>) if you have questions during that time.

Best,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

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[cid:image002.jpg@01D84F65.16C833A0]<https://www.facebook.com/FDA>[cid:image003.jpg@01D84F65.16C833A0]<https://twitter.com/US_FDA>[cid:image004.jpg@01D84F65.16C833A0]<http://www.youtube.com/user/USFoodandDrugAdmin>[cid:image005.jpg@01D84F65.16C833A0]<http://www.flickr.com/photos/fdaphotos/>[cid:image006.jpg@01D84F65.16C833A0]<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: Lee, Michele

Sent: Friday, October 15, 2021 4:47 PM

To: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you for providing your questions in advance of the meeting. We look forward to discussing our responses with you next week.

Have a good weekend,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D84F65.16C833A0]<http://www.fda.gov/>

[cid:image002.jpg@01D84F65.16C833A0]<https://www.facebook.com/FDA>[cid:image003.jpg@01D84F65.16C833A0]<https://twitter.com/US_FDA>[cid:image004.jpg@01D84F65.16C833A0]<http://www.youtube.com/user/USFoodandDrugAdmin>[cid:image005.jpg@01D84F65.16C833A0]<http://www.flickr.com/photos/fdaphotos/>[cid:image006.jpg@01D84F65.16C833A0]<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Friday, October 15, 2021 12:00 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Please find the list of questions/clarifications attached below.

I hope you have a good weekend. I'm looking forwards to our discussion next week!

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>" <Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>"

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
<k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 13/10/2021 22:35

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

I have scheduled the teleconference for next Tuesday October 19that 9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour but our biocompatibility consultant/ team management needs to drop off for another call at 9:30am. Please send me the questions for discussion in advance of the meeting so that we can plan to discuss biocompatibility/ regulatory questions first before the relevant parties need to drop off.

Join Zoom

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Thanks,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

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Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

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[cid:image002.jpg@01D84F65.16C833A0]<https://www.facebook.com/FDA>[cid:image003.jpg@01D84F65.16C833A0]<https://twitter.com/US_FDA>[cid:image004.jpg@01D84F65.16C833A0]<http://www.youtube.com/user/USFoodandDrugAdmin>[cid:image005.jpg@01D84F65.16C833A0]<http://www.flickr.com/photos/fdaphotos/>[cid:image006.jpg@01D84F65.16C833A0]<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Wednesday, October 13, 2021 4:46 PM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>; k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Apologies Michele, one final thing I missed off my email... could you clarify how long the teleconference would be by default? Could we request 1 hour just incase some of the points end up taking longer to discuss?

Best regards,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>" <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>, "k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>" <k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 13/10/2021 20:35

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hi Michele

We're currently preparing our questions for the teleconference and will send these through in due course, however to assist with scheduling the relevant parties at FDA, I should let you know that we would definitely like to discuss the questions related to biocompatibility.

After discussion with the team we would like to request the teleconference on the Tuesday 19th October if that is possible? As we are based in the UK, we would also like to request that this is arranged between the hours of 2-5pm BST.

If this time slot is not available could you outline any alternative days/times which would be possible?

Best regards,

Martin Mitchell

Regulatory Affairs Manager

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: Martin Mitchell/WIN/UK/AMS

To: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>"

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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<helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>,
"k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>"
<k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 08/10/2021 22:14

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hi Michele

Thank you for the offer. I think after today's meeting we may need a little more time to be better prepared for the teleconference.

We are reaching out to the (b)(4) for us as we feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible dates for you early next week.

Best regards,

Martin Mitchell

Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Lee, Michele" <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

To: "Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>"
<Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Cc: "helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>"
<helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>,
"k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>"
<k211878@docs.fda.gov<mailto:k211878@docs.fda.gov>>

Date: 06/10/2021 13:49

Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

---

Hello Martin,

If it makes it easier for your team, we are able to extend the 10 day teleconference

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

deadline up to October 19th. Let me know if you would like to select a date later than the 14thand I can check our management schedules.

Regarding review timelines, we are still on the 90 day review cycle and are planning to complete the review of your response with the 20 calendar days left on the clock. While we retain the right to add additional days, we are doing our best with the resources that we have to avoid delaying review timelines if possible.

Best,

Michele

Michele Lee, Ph.D.

Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>

[cid:image001.png@01D84F65.16C833A0]<http://www.fda.gov/>

[cid:image002.jpg@01D84F65.16C833A0]<https://www.facebook.com/FDA>[cid:image003.jpg@01D84F65.16C833A0]<https://twitter.com/US_FDA>[cid:image004.jpg@01D84F65.16C833A0]<http://www.youtube.com/user/USFoodandDrugAdmin>[cid:image005.jpg@01D84F65.16C833A0]<http://www.flickr.com/photos/fdaphotos/>[cid:image006.jpg@01D84F65.16C833A0]<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com><Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>>

Sent: Wednesday, October 6, 2021 6:00 AM

To: Lee, Michele <Michele.Lee@fda.hhs.gov<mailto:Michele.Lee@fda.hhs.gov>>

Cc: helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>

Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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Hi Michele

Thank you again for your review. Our team are busy discussing the questions and we would definitely like to have a teleconference with the FDA. We're currently consolidating our understanding of the deficiencies and are determining what our potential questions to you would be. I hope to get the questions to you by Monday 11th at the latest.

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Therefore, with the 10 day teleconference deadline in mind.... could we look to schedule a teleconference with the FDA on Wednesday 13th or Thursday 14th? As we're based in the UK we would appreciate a timeslot within our working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines for this project.... regarding the FDA timeline I can see on the CCP tracker website that the FDA timeline is on day 70.

* Will FDA be sticking to the 90 day target and as a result only have 20 days left on the clock?

* Or, due to the current situation with the unprecedented resource limitations..... will you will assume 30 days to review the response as standard? Or perhaps stick to the 20 days but retain the right to add additional days?

Best regards,

Martin Mitchell

Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.

E-mail: Martin.Mitchell@admedsol.com<mailto:Martin.Mitchell@admedsol.com>

Tel: +44 (0) 1752 30 9360

From: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov<mailto:michele.lee@fda.hhs.gov>>

To: <martin.mitchell@admedsol.com<mailto:martin.mitchell@admedsol.com>>, <helen.topping@admedsol.com<mailto:helen.topping@admedsol.com>>

Cc: "Michele Lee [MICHELE.LEE]" <michele.lee@fda.hhs.gov<mailto:michele.lee@fda.hhs.gov>>

Date: 04/10/2021 21:44

Subject: K211878/S001 is on Hold Pending Your Response

October 4, 2021

We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Michele Lee.

*** This is a system-generated email notification ***[attachment "K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin Mitchell/WIN/UK/AMS]

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From: DCCLetters@fda.hhs.gov [DCCLetters@fda.hhs.gov]
Sent: 5/4/2022 4:31:51 PM
To: martin.mitchell@admedsol.com
CC: DCCLetters@fda.hhs.gov
Subject: K211878/S002 Acknowledgement Letter
Attachments: K211878-S002-Acknowlegement Letter.pdf

May 4, 2022

Thank you for your submission. We have attached your acknowledgement letter for your records. If you have any questions about your acknowledgement letter, please contact us at DCCmailroom@fda.hhs.gov. Please do not reply to this email.

*** This is a system-generated email notification ***

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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U.S. FOOD & DRUG ADMINISTRATION

Acknowlegement Letter

05/04/2022

Martin Mitchell, Senior Regulatory Affairs Associate
Advanced Medical Solutions Limited
Western Wood Way , Langage Science Park
Plymouth,
Devon PL7 5BG UNITED KINGDOM

Dear Martin Mitchell:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the address listed below. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please contact the Office of Product Evaluation and Quality (OPEQ) submission support at (301) 796-5640 or OPEQSubmissionSupport@fda.hhs.gov .

Submision Number: K211878/S002
Received: 05/04/2022
Applicant: Advanced Medical Solutions Limited
Device: LiquiBand XL

We will notify you when the review of this submission document has been completed or if any additional information is required.If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm .

Sincerely yours,

Center for Devices and Radiological Health

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Advanced Medical Solutions Ltd
Western Wood Way,
Langage Science Park,
Plympton, Plymouth,
Devon, PL7 5BG, UK
Tel : +44 (0)1752 209955 **Fax :** +44 (0)1752 209956
Web : www.admedsol.com

Advanced Medical Solutions Ltd

Meeting Minutes

Submission Number:	K211878 / S001
Submission Type:	510(k)
Product Name:	LiquiBand XL
Submitter:	Martin Mitchell
Meeting Date / Time:	14:00 BST on the 19th of October 2021
Meeting Format:	Teleconference via Zoom
Date FDA feedback was Sent:	4th October 2021

FDA attendees:

- Dr. Michele Lee, Lead Reviewer
- Dr. Lixin Liu, Acting Assistant Director, Plastic Surgery Skin & Wound Devices Team
- Dr. Diego Rua, Toxicology Consultant

Advanced Medical Solutions attendees:

- Martin Mitchell, RA Manager

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hello Michele,

We have been pleased to have you as

the lead reviewer for RTA review, technical review, and responses to deficiency

discussions since July 2021, as well as having you for the review for our

previous 510(k) submission of the same product.

(b)(4)

(b)(4)

(b)(4)<li>Jun 2021 - We submitted K211878 in response

(b)(4)<li>Oct 2021 - Further deficiencies were

raised on the new K211878 submission
 We currently have only 20 days

of FDA review time left on our product and have been advised that we will

now be assigned a new reviewer. As you can imagine this causing us

a high level of concern given you have a detailed knowledge of our

submissions and of the current outstanding questions. Our concern being

that a new reviewer will not have the same detailed knowledge of our submission

or of the outstanding questions and hence this may cause unnecessary further

delay.

We have been very satisfied with the

support we have received from yourself and we would ask that you

remain on our file for the final 20 days if at all possible, or an explanation

of why this is not possible with some reassurances that a new assessor

will not cause unnecessary delays whilst they gain detailed knowledge of

our file.

Your expedited response to this request

would be appreciated.

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions

Ltd.
E-mail: Martin.Mitchell@admedsol.com
Tel: +44 (0) 1752 30 9360

From:

 "Lee, Michele"

<Michele.Lee@fda.hhs.gov>
To:

 "Martin.Mitchell@admedsol.com"

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

<Martin.Mitchell@admedsol.com>
Cc:

 "k211878@docs.fda.gov"

<k211878@docs.fda.gov>
Date:

 25/03/2022 16:47
Subject:

   RE: [EXTERNAL]

Re: K211878/S001 is on Hold Pending Your Response
<hr noshade>

Hello Martin,

A new lead reviewer will not be assigned

until a follow up submission is received. So there is currently not a primary

contact unless there is an active submission under FDA review. All of our

correspondence and the prior related review have been documented internally,

so you can be assured that the history of the prior review and contact

is available to the future lead reviewer.

Best,
Michele

From: Martin.Mitchell@admedsol.com

<Martin.Mitchell@admedsol.com>
Sent: Friday, March 25, 2022 12:21 PM
To: Lee, Michele <Michele.Lee@fda.hhs.gov>
Cc: k211878@docs.fda.gov
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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or open attachments unless you recognize the sender and know the content

is safe.

Hi Michele

I've seen on the FDA customer collaboration portal that the time has automatically

been added, but just thought it would be prudent to also inform you of

the situation.

Could I ask who the primary contact is now? Will you be assisting or have

any involvement with the review of our response?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>
To: "<u>Martin.Mitchell@admedsol.com</u>"

<<u>Martin.Mitchell@admedsol.com</u>>
Cc: "<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 25/03/2022

15:59
Subject: RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hello Martin,

I am sorry to hear about the (b)(4) (b)(4). I hope all is able to be resolved

soon.

Thank you for the update. I am actually working in a different division

within FDA and no longer the primary contact for this submission. I believe

that the 180 days is automatically granted for responses to AINN hold but

you can also confirm with the 510(k) Program staff (<u>510k_Program@fda.hhs.gov</u>,

telephone: 301-796-5640) to make sure.

Best,
Michele

Michele Lee, Ph.D.(she/her/hers)
Regulatory Science Program Manager
Partnerships to Advance Innovation and Regulatory Science (PAIRS)

Center for Devices and Radiological Health
Office of Strategic Partnerships and Technology Innovation
Division of All Hazards Response, Science, and Strategic Partnerships
U.S. Food and Drug Administration<u>
</u><u>michele.lee@fda.hhs.gov</u>

 <u>
</u><img src=cid:_4_0B99A9B40B999D0C0044BE718025881B width=192 height=43 style="border:0px solid;"><u>
</u><u>
</u><img src=cid:_2_0B99AE440B999D0C0044BE718025881B style="border:0px solid;"><img src=cid:_2_0B99B2900B999D0C0044BE718025881B style="border:0px solid;"> <img src=cid:_2_0B99B6DC0B999D0C0044BE718025881B style="border:0px solid;"><img src=cid:_2_0B99BB280B999D0C0044BE718025881B style="border:0px solid;"> <img src=cid:_2_0B99BF740B999D0C0044BE718025881B style="border:0px solid;">

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provide feedback regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=7013&S=E</u>.

From: <u>Martin.Mitchell@admedsol.com</u><<font size=2

color=blue face="Calibri"><u>Martin.Mitchell@admedsol.com</u>>

Sent: Friday, March 25, 2022 11:28 AM
To: Lee, Michele <<u>Michele.Lee@fda.hhs.gov</u>>
Cc: <u>k211878@docs.fda.gov</u>
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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recognize the sender and know the content is safe.

Hi Michele

I'd like to provide an update on our progress with responding to the deficiencies

raised on K211878

We were on track to have a deficiency response submitted to the FDA by

the 180 day hold period deadline of 2nd April 2022.

However, the organisation performing the (b)(4) (b)(4) have been affected by (b)(4).

As a result, they were unable to complete the testing by our targeted timeline.

Therefore, I just want to confirm that we are still intending to respond

to the deficiencies, but we would need to use the second 180 day hold period

granted to us through the COVID-19 situation.

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>
To: "<u>Martin.Mitchell@admedsol.com</u>"

<<u>Martin.Mitchell@admedsol.com</u>>
Cc: "<u>helen.topping@admedsol.com</u>"

<<u>helen.topping@admedsol.com</u>>,

"<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 08/11/2021

22:05
Subject:

 RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hello Martin,

Thanks for your message. Iâ€™ll need some time to review the teleconference

minutes with my team and also obtain some feedback from our consulting

toxicologist about the follow up questions. But I wanted to let you know

I received your email and you may feel free to check in again next week.

I do have a clarification question about Follow Up (b)(4)

(b)(4)

(b)(4).

Regarding the timeline clarification- I am also under the understanding

that the COVID-19 guidance document you cited was still active and that

would allow you an additional 180 days for the hold period. I have reached

out to the 510(k) Staff multiple times to confirm and am still waiting

on their response. Is there a customer service contact email for the customer

collaboration portal specifically? You may try contacting them as well

to have the date corrected on your end.

Thank you,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993<u>
</u><u>Michele.Lee@fda.hhs.gov</u><u>
</u><u>
</u><img src=cid:_4_0B99FEAC0B99EF200044BE718025881B width=192 height=43 style="border:0px solid;"><u>
</u><u>
</u><img src=cid:_2_0B9A033C0B99EF200044BE718025881B style="border:0px solid;"><img src=cid:_2_0B9A07700B99EF200044BE718025881B style="border:0px solid;"><img src=cid:_2_0B9FCED40B99EF200044BE718025881B style="border:0px solid;"><a

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

href=http://www.flickr.com/photos/fdaphotos/><img
src=cid:_2_0B9FD3080B99EF200044BE718025881B style="border:0px solid;"><font size=1
color=#4f4f4f face="Arial"> <a
href=http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm><img
src=cid:_2_0B9FD7540B99EF200044BE718025881B style="border:0px solid;"><font size=2
color=#4f4f4f face="Calibri">
Excellent customer service is important to us.
 Please take a moment

to provide feedback regarding the customer service you have received: <a
href="https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E"
target=_blank><font size=2 color=#0082bf face="sans-
serif"><u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

From: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri"><<font size=2
color=blue face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri">>

Sent: Friday, November 5, 2021 12:07 PM
To: Lee, Michele
<<font size=2 color=blue
face="Calibri"><u>Michele.Lee@fda.hhs.gov</u><font size=2
face="Calibri">>
Cc: <a
href=mailto:helen.topping@admedsol.com><font size=2 color=blue
face="Calibri"><u>helen.topping@admedsol.com</u><font size=2
face="Calibri">;

<font size=2 color=blue
face="Calibri"><u>k211878@docs.fda.gov</u><font size=2
face="Calibri">
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending
Your Response<font size=2 color=#806210
face="Calibri">

CAUTION:This email originated
from outside

of the organization. Do not click links or open attachments unless you

recognize the sender and know the content is safe.<font size=2
face="Arial">

Hello Michele

I hope you had a nice
holiday!

Following on from the teleconference we had a few actions to complete
and

get back to you with.

1) Teleconference minutes

Please find a
draft of the the teleconference minutes below. Could you

review and confirm if you require any changes made?<font size=2
face="Calibri">

2) Follow-up
questions on the teleconference discussion

As suggested during the
teleconference there was the opportunity for a

followup email clarification on a few minor points.
1.   In
alignment with FDA recommendation, (b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

(b)(4)

(b)(4)

The supporting information which provides further clarity on the questions

above has been attached if required.
<font

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
size=2 face="Arial">

3) Timeline clarification as per previous email

I can see on the customer collaboration portal that we have a 180 day hold

period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below

was active which would provide us with an additional 180 day hold period?
<u>https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices</u>
Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Thank you again for your assistance

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: Martin

Mitchell/WIN/UK/AMS
To: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>,

"Liu, Lixin" <<u>Lixin.Liu@fda.hhs.gov</u>>
Cc: "<u>helen.topping@admedsol.com</u>"

<<u>helen.topping@admedsol.com</u>>,

"<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 20/10/2021

22:43
Subject: RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hello Michele

Thank you for the prompt response to the clarifications! We'll take your

points on board regarding future shelf life studies.

I do have a minor clarification question regarding our response timeline

I can see on the customer collaboration portal that we have a 180 day hold

period which ends on the 2nd of April 2022.

However, I was under the understanding that the guidance document below

was active which would provide us with an additional 180 day hold period?<u>
</u><u>
</u><u>https://www.fda.gov/regulatory-information/search-fda-guidance-</u>
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024

documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices</u>

Could you clarify if we have 180 days or 360 days to respond to the deficiencies?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>
To: "<u>Martin.Mitchell@admedsol.com</u>"

<<u>Martin.Mitchell@admedsol.com</u>>
Cc: "<u>helen.topping@admedsol.com</u>"

<<u>helen.topping@admedsol.com</u>>,

"<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 20/10/2021

14:55
Subject: RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hello Martin,

Thank you to you and your team for attending the teleconference yesterday.

I wanted to follow up on two things I was discussing with my team:
1.   (b)(4)

(b)(4)

(b)(4)

.

I will be on leave for the next two

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

weeks and you may contact our team

management (<u>Lixin.Liu@fda.hhs.gov</u>)

if you have questions during that time.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993<u>
</u><u>Michele.Lee@fda.hhs.gov</u><u>
</u><u>
</u><img src=cid:_4_0C770A800C76FB4C0044BE718025881B style="border:0px solid;"><u>
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Excellent customer service is important to us. Please take a moment

to provide feedback regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

From: Lee, Michele
Sent: Friday, October 15, 2021 4:47 PM
To: <u>Martin.Mitchell@admedsol.com</u>
Cc: <u>helen.topping@admedsol.com</u>;

<u>k211878@docs.fda.gov</u>
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

Hello Martin,

Thank you for providing your questions in advance of the meeting. We look

forward to discussing our responses with you next week.

Have a good weekend,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993<u>
</u><u>Michele.Lee@fda.hhs.gov</u><u>
</u><u>
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href=http://www.youtube.com/user/USFoodandDrugAdmin><img
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href=http://www.flickr.com/photos/fdaphotos/><img
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color=#4f4f4f face="Arial"><a
href=http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm><img
src=cid:_2_0C774AF80C76FB4C0044BE718025881B style="border:0px solid;"><font size=2
color=#4f4f4f face="Calibri">
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to provide feedback regarding the customer service you have received: <a
href="https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E"
target=_blank><font size=2 color=#0082bf face="sans-
serif"><u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

From: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri"><<font size=2
color=blue face="Calibri"><u>Martin.Mitchell@admedsol.com</u><font size=2
face="Calibri">>

Sent: Friday, October 15, 2021 12:00 PM
To: Lee, Michele
<<font size=2 color=blue
face="Calibri"><u>Michele.Lee@fda.hhs.gov</u><font size=2
face="Calibri">>
Cc: <a
href=mailto:helen.topping@admedsol.com><font size=2 color=blue
face="Calibri"><u>helen.topping@admedsol.com</u><font size=2
face="Calibri">;

<font size=2 color=blue
face="Calibri"><u>k211878@docs.fda.gov</u><font size=2
face="Calibri">
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending
Your Response<font size=2 color=#806210
face="Calibri">

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of the organization. Do not click links or open attachments unless you

recognize the sender and know the content is safe.<font size=2
face="Arial">

Hi Michele

Please find the list of questions/clarifications
attached below.

I hope you have a good weekend. I'm looking forwards to our
discussion

next week!

Best regards,<font size=2 color=#000080
face="Arial">

Martin Mitchell
Regulatory Affairs
Manager

Advanced Medical Solutions Ltd.
E-mail: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=2 color=#000080
face="Arial">
Tel: +44 (0) 1752 30 9360<font size=2
face="Calibri">

From:
       "Lee,

Michele" <<font size=1 color=blue
face="Arial"><u>Michele.Lee@fda.hhs.gov</u><font size=1
face="Arial">>
To:
   "<a
href=mailto:Martin.Mitchell@admedsol.com><font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">>
Cc:
   "<a
href=mailto:helen.topping@admedsol.com><font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue

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face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">>,

"<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u>"

<<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u><font size=1
face="Arial">>
Date:
   13/10/2021

22:35
Subject:
 RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response<font size=2
face="Calibri"> <hr noshade>
<font size=2
face="Calibri">

Hello Martin,

I have scheduled the
teleconference for next Tuesday October 19that

9am EST/ 2pm BST. Per your request, I can be on the call for 1 hour but

our biocompatibility consultant/ team management needs to drop off for

another call at 9:30am. Please send me the questions for discussion in

advance of the meeting so that we can plan to discuss biocompatibility/

regulatory questions first before the relevant parties need to drop off.

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color:#000000;border-width:0px 0px 0px 0px;padding:0px 0px;"><a
href="https://fda.zoomgov.com/j/1609831829?pwd=Mk16N1pXYnUrY2h2TFoyQTRaUCt5QT09"
target=_blank><u>Join

Zoom Meeting</u> <tr

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993<u>
</u><u>Michele.Lee@fda.hhs.gov</u><u>

</u><img src=cid:_4_0F4EA8880C97F4B40044BE718025881B style="border:0px solid;"><u>

</u><img src=cid:_2_0F4EACD40C97F4B40044BE718025881B style="border:0px solid;"><img src=cid:_2_0F4EB1080C97F4B40044BE718025881B style="border:0px solid;"><img src=cid:_2_0F4EB53C0C97F4B40044BE718025881B style="border:0px solid;"><img src=cid:_2_0F4EB9700C97F4B40044BE718025881B style="border:0px solid;"><img src=cid:_2_0F4EBDA40C97F4B40044BE718025881B style="border:0px solid;">
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From: <u>Martin.Mitchell@admedsol.com</u><<u>Martin.Mitchell@admedsol.com</u>>

Sent: Wednesday, October 13, 2021 4:46 PM
To: Lee, Michele <<u>Michele.Lee@fda.hhs.gov</u>>
Cc: <u>helen.topping@admedsol.com</u>;

<u>k211878@docs.fda.gov</u>
Subject: RE: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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and know the content is safe.

Apologies Michele, one final thing I missed off my email... could you clarify

how long the teleconference would be by default? Could we request 1 hour

just incase some of the points end up taking longer to discuss?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: Martin

Mitchell/WIN/UK/AMS
To: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>
Cc: "<u>helen.topping@admedsol.com</u><font size=1

face="Arial">"

<<u>helen.topping@admedsol.com</u>>,

"<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 13/10/2021

20:35
Subject: RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response <hr noshade>

Hi Michele

We're currently preparing our questions for the teleconference and will

send these through in due course, however to assist with scheduling the

relevant parties at FDA, I should let you know that we would definitely

like to discuss the questions related to biocompatibility.

After discussion with the team we would like to request the teleconference

on the Tuesday 19th October

if that is possible? As we are based in

the UK, we would also like to request that this is arranged between the

hours of 2-5pm BST.

If this time slot is not available could you outline any alternative days/times

which would be possible?

Best regards,

Martin Mitchell
Regulatory Affairs Manager

Advanced Medical Solutions Ltd.
E-mail: <u>Martin.Mitchell@admedsol.com</u>
Tel: +44 (0) 1752 30 9360

From: Martin

Mitchell/WIN/UK/AMS
To: "Lee,

Michele" <<u>Michele.Lee@fda.hhs.gov</u>>
Cc: "<u>helen.topping@admedsol.com</u>"

<<u>helen.topping@admedsol.com</u>>,

"<u>k211878@docs.fda.gov</u>"

<<u>k211878@docs.fda.gov</u>>
Date: 08/10/2021

22:14
Subject:
 RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response<font size=2
face="Calibri"> <hr noshade>
<font size=2
face="Calibri">

Hi
Michele

Thank you for the offer. I think after today's meeting we may need a
little

more time to be better prepared for the teleconference.

We are reaching out to
the (b)(4) for us as we

feel that it may be beneficial to have them join us on the teleconference.

As such we need to check their availability. I hope to have list of possible

dates for you early next week.

Best regards,<font size=2 color=#000080
face="Arial">

Martin Mitchell
Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.
E-mail: <a
href=mailto:Martin.Mitchell@admedsol.com><font size=2 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=2 color=#000080
face="Arial">
Tel: +44 (0) 1752 30 9360<font size=2
face="Calibri">
<font size=1 color=#5f5f5f
face="Arial">

From: <font size=1
face="Arial">"Lee,

Michele" <<font size=1 color=blue
face="Arial"><u>Michele.Lee@fda.hhs.gov</u><font size=1
face="Arial">>
To:
   "<a
href=mailto:Martin.Mitchell@admedsol.com><font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">"

<<font size=1 color=blue
face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=1
face="Arial">>
Cc:
   "<a
href=mailto:helen.topping@admedsol.com><font size=1 color=blue
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">"

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face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">>,

"<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u>"

<<font size=1 color=blue
face="Arial"><u>k211878@docs.fda.gov</u><font size=1
face="Arial">>
Date:
   06/10/2021

13:49
Subject:
 RE:

[EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response<font size=2
face="Calibri"> <hr noshade>
<font size=2
face="Calibri">

Hello Martin,

If it makes it easier
for your team, we are able to extend the 10 day teleconference

deadline up to October 19th. Let me know if you would like to

select a date later than the 14thand I can check our management

schedules.

Regarding review timelines, we are still on the 90 day review cycle
and

are planning to complete the review of your response with the 20 calendar

days left on the clock. While we retain the right to add additional days,

we are doing our best with the resources that we have to avoid delaying

review timelines if possible.

Best,
Michele

Michele Lee, Ph.D.
Lead Reviewer / Materials Engineer

Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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White Oak | 10903 New Hampshire Avenue | Silver Spring, MD 20993<u>
</u><u>Michele.Lee@fda.hhs.gov</u><u>
</u><u>
</u><img src=cid:_4_0F33F61C0F33EAB80044BE718025881B style="border:0px solid;"><u>
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</u><img src=cid:_2_0F33FAAC0F33EAB80044BE718025881B style="border:0px solid;"><img src=cid:_2_0F33FEE00F33EAB80044BE718025881B style="border:0px solid;"><img src=cid:_2_0F3403140F33EAB80044BE718025881B style="border:0px solid;"><img src=cid:_2_0F3407480F33EAB80044BE718025881B style="border:0px solid;"><img src=cid:_2_0F340B7C0F33EAB80044BE718025881B style="border:0px solid;">
Excellent customer service is important to us. Please take a moment

to provide feedback regarding the customer service you have received: <u>https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E</u>

From: <u>Martin.Mitchell@admedsol.com</u><<u>Martin.Mitchell@admedsol.com</u>>

Sent: Wednesday, October 6, 2021 6:00 AM
To: Lee, Michele <<u>Michele.Lee@fda.hhs.gov</u>>
Cc: <u>helen.topping@admedsol.com</u>
Subject: [EXTERNAL] Re: K211878/S001 is on Hold Pending Your Response

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of the organization. Do not click links or open attachments unless you

recognize the sender and know the content is safe.

Hi Michele

Thank you again for your review. Our team are busy discussing the questions

and we would definitely like to have a teleconference with the FDA. We're

currently consolidating our understanding of the deficiencies and are determining

what our potential questions to you would be. I hope to get the questions

to you by Monday 11th at the latest.

Therefore, with the 10 day teleconference deadline in mind.... could we

look to schedule a teleconference with the FDA on Wednesday 13th or Thursday

14th? As we're based in the UK we would appreciate a timeslot within our

working hours which finish at 17:00 BST.

Additionally, I have a small question to allow us to predict timelines

Records processed under FOIA Request 2023-7342; Released by CDRH on 04-11-2024
for this project.... regarding the FDA timeline I can see on the CCP tracker

website that the FDA timeline is on day 70.<font size=2
face="Calibri">
Will FDA be sticking to the 90
day target

and as a result only have 20 days left on the clock?
<font size=2
face="Arial">Or, due to the current situation with the

unprecedented resource limitations..... will you will assume 30 days to

review the response as standard? Or perhaps stick to the 20 days but retain

the right to add additional days?
Best
regards,

Martin Mitchell

Senior Regulatory Affairs Associate

Advanced Medical Solutions Ltd.

E-mail: <font size=2
color=#0082bf face="Arial"><u>Martin.Mitchell@admedsol.com</u><font size=2
color=#000080 face="Arial">
Tel: +44 (0) 1752 30 9360<font size=1
color=#5f5f5f face="Arial">

From:
 "Michele

Lee [MICHELE.LEE]" <<font size=1
color=#0082bf face="Arial"><u>michele.lee@fda.hhs.gov</u><font size=1
face="Arial">>
To:
   <<a
href=mailto:martin.mitchell@admedsol.com><font size=1 color=#0082bf
face="Arial"><u>martin.mitchell@admedsol.com</u><font size=1
face="Arial">>,

<<font size=1 color=#0082bf
face="Arial"><u>helen.topping@admedsol.com</u><font size=1
face="Arial">>
Cc:
   "Michele

Lee [MICHELE.LEE]" <<font size=1
color=#0082bf face="Arial"><u>michele.lee@fda.hhs.gov</u><font size=1
face="Arial">>
Date:
   04/10/2021

21:44
Subject:
 K211878/S001

is on Hold Pending Your Response <div
align=center><hr noshade>

October 4, 2021<font size=2
face="Calibri"> <p>We have reviewed your submission. Please see
attached.

<p>If you have any questions, please contact the lead reviewer

assigned to your submission, Michele Lee. <p> <p>*** This is a system-generated email notification ***[attachment

"K211878-S001.AdditionalInformation.AINN.pdf" deleted by Martin

Mitchell/WIN/UK/AMS] <p>

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color=#0082bf><u>http://www.admedsol.com</u>.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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