

Hi Allan,

I have received your message. I am reviewing your questions with the subject matter expert and will provide a response by tomorrow, 10/7 as requested.

Thank you.

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Thursday, October 06, 2022 11:22 AM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] K222578 3M Ioban CHG Incise Drape

Hi Hilary,

We are reviewing your 510(k) submission for the 3M Ioban CHG Incise Drape. At this time, please address the following regarding your

(b)(4)

(b)(4)

We kindly request your response by tomorrow, 10/7.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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U.S. FOOD & DRUG
ADMINISTRATION

Food and Drug Administration
CDRH/OPEQ/OHTIV/DHTIVB
WO66 RM4535
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-2851

Premarket Notification 510(k) Review

Date: May 18, 2023

Reviewer: Allan Guan

510(k)# K222578/S001 **Subject:** Traditional

Applicant: 3M Company

Contact Name: Hilary Hovde

Correspondent Firm: 3M Company

Received Date: April 14, 2023

Pro Code(s): KKK **Class:** II **Reg #:** 878.4370

Device Trade Name: 3M™ Ioban™ CHG
Chlorhexidine Gluconate Incise Drape (contains 2%
w/w CHG)

Contact Title: Regulatory Affairs Specialist

Phone: (651) 736-0364 **Email:**
hbhovde@mmm.com

Due Date: May 18, 2023

Reg Name: Surgical Drape And Drape Accessories

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K140250	KKX	3m Steri-drape Chg Antimicrobial Incise Drape	3m Health Care

Recommendation

(b)(5)

(b)(5)

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(b)(5)

Thanks Allan,

I appreciate it.
I have accepted the invite and understand it is subject to change.

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, May 15, 2023 6:55 PM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov; Brad Bagley <bdbagley@mmm.com>; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hi Hilary,

Sure, I'll try to find a time for a call tomorrow with our (b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection 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
White Oak, Bldg. 66 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



♦ < x > ♦
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Hilary Hovde <hbhovde@mmm.com>
Sent: Monday, May 15, 2023 6:34 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brad Bagley <bdbagley@mmm.com>; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review
Importance: High

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Hi Allan,

I have shared your request for additional information in regard to the (b)(4)

(b)(4)

I have copied Brad and Brendan (3M Regulatory Affairs Director and my direct manager) on this note as I would like to include them on the future call if you are able to accommodate this request.

Thank you for your guidance.

Best,

Hilary



Hilary B. Hovde | Regulatory Affairs Specialist -- HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
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Office: 651 736 0364 | Fax: 651 737 5320
bhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, May 15, 2023 4:29 PM
To: Hilary Hovde <bhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Thank you, Hilary.

Please see below for additional deficiency regarding the (b)(4)

(b)(4)

Please email me your response by COB tomorrow, 5/16.

Best regards,
Allan

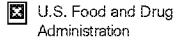
Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: Hilary Hovde <hbhovde@mmm.com>
Sent: Monday, May 15, 2023 3:13 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,
Hilary



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hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, May 15, 2023 8:56 AM
To: Hilary Hovde <hhhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

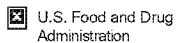
Please provide your response as soon as possible.

Best regards,
Allan

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Biomedical Engineer / Team Lead

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Allan.Guan@fda.hhs.gov



* * * * *

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From: Guan, Allan
Sent: Tuesday, April 25, 2023 5:04 PM
To: 'Hilary Hovde' <hhhovde@mmm.com>
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

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* * * * *

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From: Hilary Hovde <hhhovde@mmm.com>
Sent: Tuesday, April 25, 2023 4:04 PM
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Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

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

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call ([REDACTED]) at your convenience as needed.

Thanks so much.

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
bhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, April 24, 2023 2:25 PM
To: Hilary Hovde <bhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

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Hi Hilary,

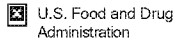
Thank you for providing your rationale and the prior Q-Sub feedback.

Best regards,
Allan

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Allan.Guan@fda.hhs.gov



Excellent customer service is important to us. *Please take a moment to provide feedback regarding the customer service you have received.*

From: Hilary Hovde <hbhovde@mmm.com>
Sent: Wednesday, May 17, 2023 3:10 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>
Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hello Allan,

Thank you to you and the FDA team for the call today to discuss

(b)(4)

(b)(4)

Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist -- HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group

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

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Hi Allan,

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(b)(4)

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Hilary



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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,
Allan

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Biomedical Engineer / Team Lead

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Sent: Tuesday, April 25, 2023 4:04 PM
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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call ((b)(6)) at your convenience as needed.

Thanks so much.

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

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
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Office: 651 736 0264 | Fax: 651 737 5320
hbhovde@mmm.com



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Sent: Monday, April 24, 2023 2:25 PM
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Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

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(b)(4)

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Best regards,
Allan

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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) 3M CO 3M CENTER BLDG 0275 05 W 06 ST PAUL MN 55144-1000 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****7775	2. CONTACT NAME Hilary Hovde 2.1 E-MAIL ADDRESS hbhovde@mmm.com 2.2 TELEPHONE NUMBER (include Area code) 651-736-0364 2.3 FACSIMILE (FAX) NUMBER (Include Area code)
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) <u>Select an application type:</u>	
☒ Premarket notification(510(k)); except for third party ☐ 513(g) Request for Information ☐ Biologics License Application (BLA) ☐ Premarket Approval Application (PMA) ☐ Modular PMA ☐ Product Development Protocol (PDP) ☐ Premarket Report (PMR) ☐ 30-Day Notice ☐ De Novo Request	3.1 Select a center ☒ CDRH ☐ CBER 3.2 Select one of the types below ☒ Original Application <u>Supplement Types:</u> ☐ Efficacy (BLA) ☐ Panel Track (PMA, PMR, PDP) ☐ Real-Time (PMA, PMR, PDP) ☐ 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 ☒ 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? ☒ 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 ☐ This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	☐ The sole purpose of the application is to support conditions of use for a pediatric population ☐ 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 ☒ 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. Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118	

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

[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)

13-Jan-2022

Form FDA 3601 (08/19)

"Close Window" Print Cover sheet

GLP REPORT

TEST FACILITY

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SPONSOR

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3M EHS
Product Stewardship - Product Safety
3M Center, Building 225-1N-11
Saint Paul, Minnesota 55144

CONFIDENTIAL

STUDY TITLE

ASTM Hemolysis Study - Extract Method

TEST ARTICLE NAME

(b)(4)

TEST ARTICLE IDENTIFICATION

(b)(4)

3M STUDY NUMBER

(b)(4)

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GLP PROTOCOL

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TEST FACILITY

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ASTM Hemolysis Study - Extract Method

TEST ARTICLE

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TEST ARTICLE IDENTIFICATION

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3M STUDY NUMBER

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GLP PROTOCOL AMENDMENT 1

SPONSOR:

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3M EHS
Product Stewardship – Product Safety
3M Center, Building 225-1N-11
Saint Paul, Minnesota 55144

TEST FACILITY:

(b)(4)

STUDY TITLE:

ASTM Hemolysis Study - Extract Method

(b)(4)

GLP PROTOCOL AMENDMENT 2

SPONSOR:

(b)(4)

3M EHS
Product Stewardship – Product Safety
3M Center, Building 225-1N-11
Saint Paul, Minnesota 55144

TEST FACILITY:

(b)(4)

STUDY TITLE:

ASTM Hemolysis Study - Extract Method

(b)(4)

(b)(4)

(b)(4)



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ADMINISTRATION**

(b)(4)

3M Health Care
Hilary Hovde

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- Hilary Hovde

Page 3

This notification is being sent in lieu of a formal written letter. If you have any questions, please contact Ramesh K Panguluri at 301-796-6303 or Ramesh.Panguluri@fda.hhs.gov.

Yes, I am available.



Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 735 8364 | Fax: 651 737 5320
hbhovde@mmm.com



-
-

From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Thursday, May 18, 2023 4:39 PM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: RE: RE: K222578/S001 interactive review

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Hi Hilary,

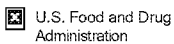
Are you available for a quick call at 5:45 or 6 pm ET?

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



• < x > x
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From: Guan, Allan
Sent: Thursday, May 18, 2023 3:46 PM
To: 'Hilary Hovde' <hbhovde@mmm.com>
Cc: 'K222578@docs.fda.gov' <K222578@docs.fda.gov>; 'Brendan Casey' <bcasey@mmm.com>
Subject: RE: [EXTERNAL] RE: RE: RE: RE: RE: K222578/S001 interactive review

Thank you, Hilary.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection 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, Bldg. 66 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



x > x > x

From: Hilary Hovde <hbhovde@mmm.com>
Sent: Thursday, May 18, 2023 3:34 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: RE: RE: RE: RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Best,
Hilary

Hilary B. Hovde | Regulatory Affairs Specialist - HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com

From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Thursday, May 18, 2023 1:36 PM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Thank you, Hilary. Yes, that's correct regarding the

(b)(4)

(b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
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Allan.Guan@fda.hhs.gov

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To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
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Hi Allan,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI@FDA.HHS.GOV or 301-796-8118

(b)(4)

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Thursday, May 18, 2023 10:10 AM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: Hilary Hovde <hbhovde@mmm.com>
Sent: Thursday, May 18, 2023 10:20 AM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hello Allan,

(b)(4)

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000

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

Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



-
-

From: Hilary Hovde
Sent: Thursday, May 18, 2023 8:33 AM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

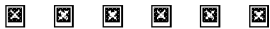
Good Morning Allan,

(b)(4)

Thanks,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Thursday, May 18, 2023 8:18 AM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Good morning Hilary,

(b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Guan, Allan
Sent: Wednesday, May 17, 2023 3:36 PM
To: 'Hilary Hovde' <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Hi Hilary,

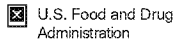
Thank you for providing your rationale and the prior Q-Sub feedback.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: Hilary Hovde <hbhovde@mmm.com>
Sent: Wednesday, May 17, 2023 3:10 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>
Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hello Allan,

Thank you to you and the FDA team for the call today to discuss: (b)(4)

(b)(4)

Best Regards,
Hilary



Hilary S. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Hilary Hovde
Sent: Monday, May 15, 2023 2:13 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist -- HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, May 15, 2023 8:56 AM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

(b)(4)

Please provide your response as soon as possible.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



x x x x x
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From: Guan, Allan
Sent: Tuesday, April 25, 2023 5:04 PM
To: 'Hilary Hovde' <hbhovde@mmm.com>
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



x x x x x
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Hilary Hovde <hbhovde@mmm.com>
Sent: Tuesday, April 25, 2023 4:04 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call ((b)(4)) at your convenience as needed.

Thanks so much.

Best,

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

Hilary



Hilary B. Hovde | Regulatory Affairs Specialist -- HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, April 24, 2023 2:25 PM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
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Good morning Hilary,

This is to confirm the meeting today at 9am ET.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection 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, Bldg. 66 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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From: Hilary Hovde <hbhovde@mmm.com>

Sent: Monday, May 15, 2023 9:22 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov>

Cc: K222578@docs.fda.gov; Brad Bagley <bdbagley@mmm.com>; Brendan Casey <bcasey@mmm.com>

Subject: [EXTERNAL] RE: RE: RE: RE: K222578/S001 interactive review

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Thanks Allan,

I appreciate it.

I have accepted the invite and understand it is subject to change.

Best,

Hilary

[cid:image014.gif@01D987D0.B7FD04E0]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, May 15, 2023 6:55 PM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brad Bagley
<bdbagley@mmm.com<mailto:bdbagley@mmm.com>>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hi Hilary,

Sure, I'll try to find a time for a call tomorrow with our (b)(4)

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of
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Office of Product Evaluation and Quality

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Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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

From: Hilary Hovde <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

Sent: Monday, May 15, 2023 6:34 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<<mailto:Allan.Guan@fda.hhs.gov>>>

Cc: K222578@docs.fda.gov<<mailto:K222578@docs.fda.gov>>; Brad Bagley
<bdbagley@mmm.com<<mailto:bdbagley@mmm.com>>>; Brendan Casey
<bcasey@mmm.com<<mailto:bcasey@mmm.com>>>

Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hi Allan,

I have shared your request for additional information in regard to the (b)(4)

(b)(4)

I have copied Brad and Brendan (3M Regulatory Affairs Director and my direct manager)
on this note as I would like to include them on the future call if you are able to
accommodate this request.

Thank you for your guidance.

Best,

Hilary

[cid:image014.gif@01D987D0.B7FD04E0]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<<mailto:Allan.Guan@fda.hhs.gov>>>

Sent: Monday, May 15, 2023 4:29 PM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Thank you, Hilary.

Please see below for additional deficiency regarding the (b)(4)

(b)(4)

(b)(4)

Please email me your response by COB tomorrow, 5/16.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Monday, May 15, 2023 3:13 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

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

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,

Hilary

[cid:image014.gif@01D987D0.B7FD04E0]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com<mailto:hbhovde@mmm.com>

[cid:image015.png@01D987D0.B7FD04E0]<https://twitter.com/3m>[cid:image016.png@01D987D0.B7FD04E0]<https://www.linkedin.com/company/3m>[cid:image017.png@01D987D0.B7FD04E0]<http

s://www.facebook.com/3MCorporate>[cid:image018.png@01D987D0.B7FD04E0]<https://instagram.com/3m/>[cid:image019.png@01D987D0.B7FD04E0]<https://www.youtube.com/3m>[cid:image021.png@01D987D0.B7FD04E0]<http://www.3m.com/>

From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, May 15, 2023 8:56 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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

From: Guan, Allan

Sent: Tuesday, April 25, 2023 5:04 PM

To: 'Hilary Hovde' <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Tuesday, April 25, 2023 4:04 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,

Hilary

[cid:image014.gif@01D987D0.B7FD04E0]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com<mailto:hbhovde@mmm.com>

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, April 24, 2023 2:25 PM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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electronic Submission Template And Resource (eSTAR)

For non-In Vitro Diagnostic Medical Devices

Version 2.0 (2022-06-06)

STATUS: eSTAR COMPLETE

Introduction

This template is intended for use in both constructing a non-*in vitro* diagnostic medical device premarket application/ submission, and in being a resource of non-*in vitro* medical device premarket regulations. It contains regulatory information pulled from both International Medical Device Regulators Forum (IMDRF) documents, as well as regulatory documents (e.g., guidance documents).

This template is only used for constructing, not submitting, your application or submission. Directions at the end of the template provide instructions on how to submit it.

Key

A **Red Bar** indicates the associated required question, or a required question in that section, wasn't answered.

A **Green Bar** indicates the associated required question, or all required questions in that section, was answered.

A **Grey Bar** indicates the associated question is optional. Green and Grey Bars act as left borders when present.

Blue Help Text Buttons when clicked display regulatory information pertaining to the question or section heading they immediately follow. Assistive Technology (AT) users including text to speech, will hear "Help Text Button." If activated, the help text windows will open, and can be closed by tabbing to the OK key and pressing return.

Hover Text Hover text displays information about your application, such as the date an attachment was attached, or, if the section corresponds to an IMDRF harmonized section, the hover text will display the chapter number of the IMDRF Table of Contents.

FAQ

Q: Where can I send questions, feedback, and/or bug reports?

A: Send questions and feedback to DICE@fda.hhs.gov and bug reports to eSubPilot@fda.hhs.gov.

Q: When I click on a bookmark, the view jumps to the beginning of eSTAR. Why did this happen?

A: The bookmarked section is not applicable based on your submission choices and therefore should be ignored.

Q: Is there an attachment type or size restriction?

A: eSTAR will prevent unacceptable attachment types from being added. We tested eSTAR submissions up to 1GB in size. If your eSTAR is greater than 1GB, file handling may be delayed. Large attachments will increase save times.

Q: If an eSTAR is signed, a message is displayed at the top saying changes were made after signing. Why?

Version History

A major version update will consist of policy changes, regulatory changes, or major changes to the template and will be denoted by a major version number increment (e.g., 1.2 to 2.0). A minor version update will consist of other changes and will be denoted by a minor version number increment (e.g., 1.2 to 1.3). eSTARs updated with policy or regulatory changes will be made available before the implementation date of those changes, and the previous eSTAR will be removed on the implementation date. **Be sure you submit using the major version that is currently implemented, otherwise you may receive additional information requests related to the changes.**

Version History

2.0 (2022-06-06): Bug fixed where clinical trials forms would incorrectly display if the user chose Traditional and

Application/Submission Type

If none of the attachments to a question are relevant to the question, or if an inaccurate response is provided to any question, the submission may be put on an early Technical Screening hold, which would request correction of these inadequacies. Examples of responses that would place the submission on a Technical Screening hold include: stating "0" wireless functions are used, but wireless functions are used by the device, improperly indicating device(s) changes are appropriate for a Special 510(k), improper citation of attachments or page numbers in text boxes, stating "N/A" in text boxes that are applicable. An example of an irrelevant attachment includes providing attachments to the software description question none of which contains a software description. FDA may also put the submission on hold if an English translation for any documentation provided is not included.

The content of this template complements the FDA reviewer's smart template used in reviewing submissions, and therefore this template will provide the reviewers what they are expecting. This may reduce the number of inconsistencies and omissions in your application/submission documents, and therefore the number of additional information requests the FDA may send to you.

Application Purpose

- ☒ Premarket Notification 510(k)
☐ De Novo
☐ Premarket Application PMA

?

Show Application Introduction

Application Type

(Choose Abbreviated if you are submitting a Safety & Performance based submission.)

- ☒ Traditional
☐ Abbreviated
☐ Special

Show Application Type Introduction

Application Sub-Type

(Modify the Original eSTAR when responding to Additional Information requests. See Help Text)

- ☒ New Application/Submission
☐ Additional Information

?

Cover Letter / Letters of Reference

Add Attachment

Attach your Cover Letter

?

Open Attachment

Cover Letter.pdf

Delete Attachment

Add Attachment

Attach any Letters of Reference

?

Applicant Information

?

Contact

Title

Ms.

Last Name

Hovde

First Name

Hilary

Email

hbhovde@mmm.com

Phone Number

651-736-0364

Occupation Title

Regulatory Affairs Specialist

Company

Company Name

3M Company

Address - Line 1

2510 Conway Ave.

Address - Line 2

Building 275-5W-06

City

St. Paul

State

MN

Zip

55144

Country/Region

United States

Add Correspondent/Consultant

Pre-Submission Correspondence & Previous Regulator Interaction

Are there prior related submissions or regulator interaction for the subject device(s)?

Yes

?

Add Submission

Please provide the submission number(s) of prior related submission(s) as defined above, regardless of outcome. If none, type "N/A."

(b)(4)

Delete Submission

Add Attachment

Please upload copies of prior regulatory feedback (e.g., letter, meeting minutes, submission feedback) regarding this device and/or data and/or information to support this submission. Please specify the location in the current submission where additional information requests in prior submissions were addressed, or provide a rationale for not responding to those additional information requests.

Open Attachment

(b)(4)

Delete Attachment

Open Attachment

Delete Attachment

Standards

?

Add Standard

Please list the standards used in your submission (if any). If only certain sections were used, or there were deviations, cite these in an attachment. The recognition number is only applicable to certain regulators, see help text. Instead of typing in information, some regulators use drop-downs populated with their recognized Standards.

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

ISO	10993-1 Fifth edition 2018-08	2-258	Delete Standard
Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process			
Are you using this standard for general use, or are you declaring conformity to it?		General Use	?
Add Attachment	Standards Details / Supplemental Documentation per ISO/IEC 17050-2		
Add Standard			
ISO	10993-5 Third edition 2009-06-01	2-245	Delete Standard
Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity			
Are you using this standard for general use, or are you declaring conformity to it?		General Use	?
Add Attachment	Standards Details / Supplemental Documentation per ISO/IEC 17050-2		
Add Standard			
ISO	10993-10 Third Edition 2010-08-01	2-174	Delete Standard
Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization			
Are you using this standard for general use, or are you declaring conformity to it?		General Use	?
Add Attachment	Standards Details / Supplemental Documentation per ISO/IEC 17050-2		
Add Standard			
ISO	10993-11 Third edition 2017-09	2-255	Delete Standard
Biological evaluation of medical devices - Part 11: Tests for systemic toxicity			
Are you using this standard for general use, or are you declaring conformity to it?		General Use	?
Add Attachment	Standards Details / Supplemental Documentation per ISO/IEC 17050-2		
Add Standard			
ISO	10993-12 Fourth edition 2012-07-01	2-191	Delete Standard
Biological evaluation of medical devices - Part 12: Sample preparation and reference materials			
Are you using this standard for general use, or are you declaring conformity to it?		General Use	?
Add Attachment	Standards Details / Supplemental Documentation per ISO/IEC 17050-2		
Add Standard			
ISO	11135 Second edition 2014-07-15	14-529	Delete Standard
Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine c			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI@FDA.HHS.gov or 301-796-8118

Are you using this standard for general use, or are you declaring conformity to it?

General Use

Add Attachment

Standards Details / Supplemental Documentation per ISO/IEC 17050-2

Add Standard

ISO

11737-1 Third edition 2018-01

14-514

Delete Standard

Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms

Are you using this standard for general use, or are you declaring conformity to it?

General Use

Add Attachment

Standards Details / Supplemental Documentation per ISO/IEC 17050-2

Add Standard

ISO

11737-2 Third edition 2019-12

14-540

Delete Standard

Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition validation

Are you using this standard for general use, or are you declaring conformity to it?

General Use

Add Attachment

Standards Details / Supplemental Documentation per ISO/IEC 17050-2

Add Standard

ISO

10993-17 First edition 2002-12-01

2-237

Delete Standard

Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances

Are you using this standard for general use, or are you declaring conformity to it?

General Use

Add Attachment

Standards Details / Supplemental Documentation per ISO/IEC 17050-2

Add Standard

ISO

21387 2020

Recognition #

Delete Standard

Sterilization of medical devices - Guidance on the requirements for the validation and routine processing of ethylene oxide

Are you using this standard for general use, or are you declaring conformity to it?

General Use

Add Attachment

Standards Details / Supplemental Documentation per ISO/IEC 17050-2

Add Standard

AAMI

TIR 28:2016

Recognition #

Delete Standard

Product adoption and process equivalence for ethylene oxide sterilization

Are you using this standard for general use, or are you declaring conformity to it?

General Use

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

[Add Attachment](#)[Standards Details / Supplemental Documentation per ISO/IEC 17050-2](#)

?

[Add Standard](#)

AAMI

TIR 16:2017

Recognition #

[Delete Standard](#)

Process Development and Performance Qualification for Ethylene Oxide Sterilization - Microbiological Aspects

Are you using this standard for general use, or are you declaring conformity to it?

General Use

?

[Add Attachment](#)[Standards Details / Supplemental Documentation per ISO/IEC 17050-2](#)

?

[Add Standard](#)

AAMI

TIR 14:2016

Recognition #

[Delete Standard](#)

Contract Sterilization for Ethylene Oxide

Are you using this standard for general use, or are you declaring conformity to it?

General Use

?

[Add Attachment](#)[Standards Details / Supplemental Documentation per ISO/IEC 17050-2](#)

?

[Add Standard](#)

ASTM

F2096-11 (Reapproved 2019)

14-359

[Delete Standard](#)

Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)

Are you using this standard for general use, or are you declaring conformity to it?

General Use

?

[Add Attachment](#)[Standards Details / Supplemental Documentation per ISO/IEC 17050-2](#)

?

[Add Standard](#)

ANSI AAMI

PB70:2012

6-296

[Delete Standard](#)

Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities

Are you using this standard for general use, or are you declaring conformity to it?

General Use

?

[Add Attachment](#)[Standards Details / Supplemental Documentation per ISO/IEC 17050-2](#)

?

[Add Standard](#)

ASTM

F1670/F1670M-17

6-402

[Delete Standard](#)

Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood

Are you using this standard for general use, or are you declaring conformity to it?

General Use

?

[Add Attachment](#)[Standards Details / Supplemental Documentation per ISO/IEC 17050-2](#)

?

[Questions? Contact FDA/CDRH/OCE/DART at \[CDRH.DART@fda.hhs.gov\]\(mailto:CDRH.DART@fda.hhs.gov\) or 301-796-8118](#)

ASTM	E2315-16	Records processed under FOIA Request 2024-1745; Released by CDRH on 08/22/2024	Recognition #	Delete Standard
Standard Guide for Assessment of Antimicrobial Activity Using a Time-Kill Procedure				
Are you using this standard for general use, or are you declaring conformity to it?			General Use	?
Add Attachment	Standards Details / Supplemental Documentation per ISO/IEC 17050-2			?
Add Standard				

Device Description

Listing of Device(s)

Add Device

Provide the Product Trade Name and (optionally) Model Number/Name

3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)

8840EZ, 8850EZ, 8851EZ

Delete Device

General Device Characteristics

Is the device life-supporting or life-sustaining?

No

?

Are there any direct or indirect tissue contacting components?

Yes

?

• Is the device or a component an implant?

No

?

Does the device use software/firmware?

No

?

Is the device or a component packaged as sterile?

Yes

The device/system uses or is... (choose all that apply)

☒ a single use device(s), non-sterile or packaged as sterile☐ a single use device(s), terminal/end user sterilized☐ a reusable single patient use device(s)☐ a reusable multi-patient use device(s)

?

The environment of use of the device/system includes... (choose all that apply)

☒ Professional Healthcare Facility☐ Home Environment☐ Magnetic Resonance (MR) Environment☐ Transport (Ambulatory) Environment☐ Other Environment

?

Is the device a combination product?

Yes

?

• If a Request for Designation (RFD) number exists, please provide the RFD number that established that the device or combination product being submitted here was assigned to CDRH.

?

• Does the combination product contain as a constituent part an approved drug as defined in section 503(g)(5)(B) of the FD&C Act?

Yes

?

Add Attachment

Please include appropriate patent statement or certification and a statement that the applicant will give notice to the patent related owner and holder, as applicable.

?

Open Attachment

Patent Statement.pdf

Delete Attachment

Is the device electrical (battery or wall powered)?

No, the device is not electrical

?

Please check the attributes that are applicable to your device. If none apply, keep all unchecked.

☐ Medical Counter Measures Device☐ Nanotechnology☐ Reprocessed Single Use Device☐ Animal-Derived Material(s)

?

Description

Please provide a Device Description Summary below, and ensure it includes an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as device design, material used, and physical properties.

?

Records processed under FOIA Request 2024-1745, Released by CDRH on 08-26-2024

If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), you must provide this device description information in the textbox below, in accordance with 21 CFR 807.92(a)(4). The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE DEVICE DESCRIPTION SUMMARY TEXTBOX BELOW. CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).

The 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG) is a sterile adhesive film that is applied pre-operatively to skin. It adheres and conforms to body contours, providing a sterile surface on top of the skin prior to surgery. The surgeon incises through the adhesive film and skin, ensuring a sterile film barrier all the way to the edge of the incision. The Chlorhexidine Gluconate (CHG) contained in the adhesive provides antibacterial activity to help reduce the risk of bacterial contamination in the surgical wound.

The drape consists of a transparent, conformable, breathable, barrier film coated with an acrylic adhesive containing 2% w/w CHG. The adhesive drape is delivered on a release liner that is discarded after application.

Add Attachment	Comprehensive Device Description and Principles of Operation Documentation	?
Open Attachment	Device Description.pdf	Delete Attachment
Add Attachment	Device Pictures, Illustrations, Schematics, and/or Diagrams. Attach a justification if the device does not have a physical form.	
Open Attachment	Device Picture.pdf	Delete Attachment
Open Attachment	Device Construction Schematic.pdf	Delete Attachment
Add Attachment	Description of Device Packaging	?
Open Attachment	Device Packaging Description.pdf	Delete Attachment

Accessories

Is the device intended to be marketed with accessories?

No

?

Guidance and Special Controls Adherence

Please cite the attachment(s) and page number(s) of any information you provided demonstrating special controls or device specific guidance adherence in this section. Please use the primary product code you will provide in the Classification section below to determine whether a device specific guidance or special controls exists for your device. Type "N/A" if no device specific guidance or special controls exist for your device type. If you type "N/A," and special controls or a device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

Primary Product Code KXX and parts of the Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes, August 1993 which is written more generally for surgical drapes rather than incise drapes that incorporate an antibacterial agent.

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls, please provide a rationale for this alternative approach below.

Indications for Use

Submission Number (if known)

Device Name

3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)

Indications for Use (Describe)

3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG) is indicated for use as an incise drape with continuous antibacterial activity based on in vitro time kill data out to 90 minutes. It is intended for external use only.

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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"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."

Classification

Add a primary product code and any associated product codes below. You may type in the primary product code directly (only the product code field is required) or you may filter down by choosing first a medical specialty, regulation, then product code. If a device specific guidance is available for the product code, the guidance name and web link will be displayed. Use the Product Classification Website resource in the help text to obtain information about your product code and check the regulation text for any special controls that need to be considered (e.g, PAE and 21 CFR 890.3450).

Medical Specialty

Regulation

Product Code

The primary product code of your device indicates a device specific guidance document is available to aid you in preparing a comprehensive submission. The document entitled "Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes" is available at the link below. If you have any questions about applicability of this guidance, please contact the CDRH review Office.

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-premarket-notification-510k-submissions-surgical-gowns-and-surgical-drapes>

Associated Product Code(s)

Predicate and Reference Devices

Primary Predicate

Is this a Preamendments or Exempt device without a submission number?

No

Predicate Submission Number (e.g., K210001)

K140250

Predicate Device Trade Name

3M™ Steri-Drape™CHG Antimicrobial Incise Drape

Predicate Device Primary Product Code

Medical Specialty General & Plastic Surgery

Regulation 878.4370 - Surgical drape and drape accessories

Product Code KXX (Class 2) - Drape, Surgical

Add Predicate/Reference Device

Delete Predicate/Reference Device

Substantial Equivalence Comparison

If the device has different indications for use in comparison to the predicate device(s), describe why the differences do not constitute a new intended use. If the indications for use are the same, state this in the text box below.

If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), and the Indications are different in comparison to your predicate device(s), you must include the information from 21 CFR 807.92(a)(5) in this rationale. The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE RATIONALE TEXTBOX BELOW. CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).

Both the subject and predicate devices are intended to be used as surgical incise drape. The CHG contained in the adhesive of both devices provides antimicrobial/antibacterial activity to help reduce the risk of bacterial contamination in the surgical wound. Minor differences in indications for use do not alter the fundamental intended use of these devices as surgical incise drapes containing CHG to help reduce the risk of contamination at the surgical site and do not raise new questions of safety and effectiveness.

If the device has the same technological characteristics (i.e., design, material, chemical composition, principle of operation, energy source, etc.) as the predicate device(s) identified above, include a summary in the memo box below of the technological characteristics of the new device in comparison to those of the predicate device(s). Or, if the device has different technological characteristics from the predicate device(s), include a summary of how the technological characteristics of the device compare to a legally marketed device(s) identified above.

If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), you must include the information from 21 CFR 807.92(a)(6) in this rationale. The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE DESCRIPTION TEXTBOX BELOW. CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).

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

Record processed under FOIA request 2024-11745, Release by CDC on 02/28/2024

The submission and predicate device have differences in technological characteristic such as differences in materials and design. However these differences do not raise new or different questions of safety and effectiveness and were evaluated through biocompatibility and performance testing. The performance testing completed was in alignment with the predicate device. The performance data demonstrated substantial equivalence.

Add Attachment	Please attach your Substantial Equivalence Comparison in tabular format. Please ensure the table(s) includes a comparison of the Indications for Use as well as a comparison of the pertinent technology characteristics of your device and your predicate device(s). If your submission is intended for the safety and performance pathway, then you should satisfy the Substantial Equivalence comparison as outlined in the relevant guidance. Please open the link in the help text for more information.	?
Open Attachment	Substantial Equivalence.pdf	Delete Attachment

Labeling

You must submit proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. Where applicable, photographs or engineering drawings should be supplied (21 CFR 807.87(e)). We also strongly recommend you consult standard AAMI ANSI ES60601-1 Section 7 for applicable labeling that may be important for your device if it is electrical (consult ISO 14708-1 instead for implantable components).

General Labeling

If a symbols glossary was used, please specifically cite the attachment and page number where it is located in the labeling (type "N/A" if not used). Be aware that if a glossary was not used, the symbols should be described in adjacent text (if applicable, see Help Text).

Please refer to attachment under Package Insert/Instructions for Use labeled IFU_3M Ioban CHG Drape.pdf

What is the Magnetic Resonance (MR) safety status for the device(s) in the submission?

Not Needed

Package Labeling

Add Attachment

Please attach copies of packaging that demonstrate the labeling of any applicable packaging used in the transportation of the device. This includes, but is not limited to, the device packaging and sterile packaging.

Open Attachment

Device Pouch_8840EZ.pdf

Delete Attachment

Open Attachment

Device Pouch_8850EZ.pdf

Delete Attachment

Open Attachment

Device Pouch_8851EZ.pdf

Delete Attachment

Open Attachment

Primary Carton_all models.pdf

Delete Attachment

Open Attachment

Primary Carton Label_8840EZ.pdf

Delete Attachment

Open Attachment

Primary Carton Label_8850EZ.pdf

Delete Attachment

Open Attachment

Primary Carton Label_8851EZ.pdf

Delete Attachment

Package Insert / Instructions for Use

Add Attachment

Please attach copies of the User Instructions, Inserts, Directions for Use and/or Instructions for Use that are intended for use with your device. This includes instructions that may be downloaded or viewed on a website.

Open Attachment

(b)(4)

Delete Attachment

Other Labeling

Add Attachment

Choose the attachment type in the dropdown for each attachment. Click the help text button to the right for an explanation of each option.

Other Labeling and Promotional Material

Open Attachment

Printing on Drape Film_all models.pdf

Delete Attachment

Other Labeling and Promotional Material

Open Attachment

Printed Drape Handle_all models.pdf

Delete Attachment

Questions? Contact FDA CDRH at CDRLH@FDA.GOV or FOIA STATUS@FDA.HHS.GOV or 301-796-8118

Open Attachment

Printing on Drape Liner_all models.pdf

Delete Attachment

Other Labeling and Promotional Material

Open Attachment

Printing on Drape Wrapper_all models.pdf

Delete Attachment

Specific Labeling

Please specifically cite the attachment and page number where the prescription statement or "Rx only" exists in the labeling.	"Rx only" is on the device pouch and the primary carton label. +	?
Please specifically cite the attachment and page number where the Indications for Use exists in the labeling.	Please refer to attachments under Package Insert/Instructions for Use +	
Please specifically cite the attachment and page number where the name and place of business of the manufacturer, packer, or distributor is located.	The name and place of business of the manufacturer is located on the device pouch, the primary carton +	?

Guidance and Special Controls Adherence

Please cite the attachment(s) and page number(s) of any information you provided demonstrating special controls or device specific guidance adherence in this section. Please use the primary product code you listed in the Classification section above to determine whether a device specific guidance or special controls exists for your device. Type "N/A" if no device specific guidance or special controls exist for your device type. If you type "N/A," and special controls or a device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes, August 1993, Section II, Part C, pages 6-7

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls, please provide a rationale for this alternative approach below.

Reprocessing, Sterility, and Shelf-Life

Based on the answers provided in the Device Description section, sterility information, but no reprocessing information, is needed.

Sterility

How many sterilization methods are there (maximum of 4)?

1

Sterilization Method 1

Identify the device(s) / accessory(ies) / component(s) that is sterilized.

3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape in a sterile barrier pouch.

What is the Sterilization Method?

Ethylene Oxide (EO, EtO) (Est A)

What are the maximum levels of sterilant residuals that remain on the device?

(b)(4)

What standard(s) were used for validation?

ISO 11135:2014/A+ 2019: Sterilization of healthcare products – Ethylene Oxide - Requirements for development, validation, and routine control of a sterilization process for medical devices.
ANSI/AAMI/ISO 11737-1:2018: Sterilization of Medical Devices – Microbiological Methods – Part 1: Estimation of population of microorganisms on products.
ANSI/AAMI/ISO 11737-2:2019: Sterilization of Medical Devices – Microbiological Methods – Part 2: Tests of sterility performed in the validation of a sterilization process.
ISO 10993-7:2008/FDAM 1:2019: Biological evaluation of medical devices Part 7: Ethylene oxide sterilization residuals.
ISO 10993-17:2002. Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances.
ISO 21387: 2020 Sterilization of medical devices – Guidance on the requirements for the validation and routine processing of ethylene oxide sterilization processes using parametric release.
AAMI TIR 28:2016: Product adoption and process equivalence for ethylene oxide sterilization
AAMI TIR 16:2017: Process Development and Performance Qualification for Ethylene Oxide Sterilization
AAMI TIR 14:2016: Contract Sterilization for Ethylene Oxide

What validation method was used for the sterilization cycle?

(b)(4)

What is the Sterility Assurance Level (SAL)?

10⁻⁶

If a device within the submission should be "Non-Pyrogenic," or if you are asserting a device is "Non-Pyrogenic," what is the pyrogenicity test method?

Not labeled nor required to be "Non-Pyrogenic"

Please provide a description of the packaging, the materials used, and a description of the package test methods.

The packaging consists of polyester film/uncoated Tyvek pouch.

Please cite the attachment(s) and page number(s) of any information you provided demonstrating special controls or device specific guidance adherence for reprocessing or sterility. Please use the primary product code you listed in the Classification section above to determine whether a device specific guidance or special controls exists for your device. Type "N/A" if no device specific guidance or special controls exist for your device type. If you type "N/A," and special controls or a device specific guidance exists that requests information covered by these review sections, the time-line for review of your file may be affected.

Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes, August 1993, Section II, Part H, pages 10-11

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls regarding reprocessing or sterility, provide a rationale for this alternative approach below.

Shelf-Life

Does your device have a shelf-life?

Yes

?

What is the proposed shelf-life?

(b)(4)

Please include a summary of the methods used to support the sterility and performance of the device over its proposed shelf-life. Alternatively, please provide a rationale for why testing to establish shelf-life is not applicable.

In order to support a shelf claim for the 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape, a shelf life study was initiated to evaluate both package integrity and key performance characteristics are maintained throughout the labeled shelf life of the device. As presented in the Shelf Life Summary and Reports, the CHG drape currently has (b)(4)

(b)(4)

Please refer to the Shelf Life Summary and Reports in the attachments under Reprocessing, Sterility, and Shelf Life Documents for additional details.

Reprocessing, Sterility, and Shelf-Life Documents

Add Attachment

Please attach any Sterility, Cleaning, Shelf-Life and Reuse documentation that you believe is pertinent to the review of your device. Choose the attachment type in the dropdown for each attachment.

?

Manufacturer Sterilization

Open Attachment

Sterilization Validation Protocol and Report.pdf

Delete Attachment

Product Stability

Open Attachment

Shelf Life Summary.pdf

Delete Attachment

Product Stability

Open Attachment

Bubble Leak Test Report.pdf

Delete Attachment

Product Stability

Open Attachment

Peelable Package Report.pdf

Delete Attachment

Product Stability

Open Attachment

Seal Strength Report.pdf

Delete Attachment

Product Stability

Open Attachment

Force at 25 pct Elongation Report .pdf

Delete Attachment

Product Stability

Open Attachment

Adhesion to Steel Report.pdf

Delete Attachment

Product Stability

Open Attachment

CHG_PCA Content Report.pdf

Delete Attachment

Product Stability

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

Open Attachment

Time Kill Report.pdf

Records processed under FOIA Request 2024-1745; Released by CDRH on 08-26-2024

Delete Attachment

Biocompatibility

Based on the answer provided in the Device Description section, biocompatibility information is needed.

Tissue Contacting Products/Components/Materials

How many tissue contacting products/components/materials are there?
(See Help Text if multiple materials share the same justification for no testing.)

1

Tissue Contacting Material 1

Identify the device(s) / accessory(ies) / component(s) that directly or indirectly contacts the tissue.

CHG Incise Drape final finished sterilized device

(b)(4)

Please state the exact name and any identifiable information for the particular material used.

(b)(4)

If color additives are included, please identify them here.

Choose intended contact of the particular material.

Direct

Please provide the FDA submission number (e.g., K210001) if you are aware of a previously submitted device using the same material with similar nature of contact.

K140250

If you are aware of a previously submitted device using the same material with similar nature of contact, please provide any pertinent information to compare your device to the device/test article in the previously submitted biocompatibility assessment. Any changes in formulation, processing, sterilization, geometry (including surface characteristics) and the addition of other chemicals (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents) should be addressed to support use of the previous biocompatibility assessment (e.g., no additional biocompatibility testing is necessary).

The predicate device submission (K140250) used a similar material and nature of contact. The adhesive formulation of the predicate device was similar but contained

(b)(4)

(b)(4)

Is there a potential for repeat exposure?

No

Choose the type of tissue contact of your tissue contacting material.

Surface Device: Breached or Compromised Surfaces

Duration of Contact

< 24 hours

The type of tissue contact and duration of contact will determine the types of Biocompatibility endpoints that we recommend be assessed, based on the Biocompatibility Guidance Document. These endpoints will display as tabs below, and FDA recommends that complete test reports be provided for biocompatibility tests performed for these endpoints. If you used an alternative test method than the options provided, or

you did not conduct the test, please provide an explanation or justification (e.g., the device component is identical in materials/formulation and processing to a legally marketed device) in the Comments section for each test method. **If you select an item that includes a star (*) in any of the drop down menus below, provide supporting evidence or justification for the selection in the comments box at the bottom of each test.** A starred (*) selection within the Accreditation Scheme for Conformity Assessment (ASCA) Pilot indicates a deviation. Per the ASCA guidance, for ASCA testing, the complete test report should be provided in addition to the ASCA summary test report.

Cytotoxicity	Sensitization	Irritation	Acute Systemic & Pyrogenicity
Cytotoxicity Testing			
What type of cytotoxicity testing was conducted?	Extraction Method (MEM Elution) ?		
Identify the test article used in testing.	CHG Incise Drape, final sterilized device (b)(4)		

Extraction Conditions

(b)(4)

Conclusion

(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, cell abnormalities, etc, below.

Close Tab

Sensitization Testing

What type of sensitization testing was conducted? Guinea Pig Maximization Test (GPMT)

?

Identify the test article used in testing (e.g., final sterilized device, component of final sterilized device, other with description).

CHG Incise Drape, final sterilized device (3X EO)

Extraction Conditions

(b)(4)

(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, animal deaths, etc, below.

Close Tab

Irritation Testing

What type of irritation testing was conducted?	* Dermal Irritation Test	?
Identify the test article used in testing.	CHG Incise Drape, final sterilized device (b)(4)	

Sample Preparation

(b)(4)

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

(b)(4)

Close Tab

Acute Systemic Toxicity Testing & Material Mediated Pyrogenicity Testing

Acute Systemic Toxicity Testing

Was Acute Systemic Toxicity testing conducted? ?

Material Mediated Pyrogenicity Testing

Was Material Mediated Pyrogenicity testing conducted? ?

Specific questions for these tests do not exist yet in this template or the FDA reviewer's Smart Templates. We recommend Acute Systemic Toxicity and and Material Mediated Pyrogenicity be assessed. If testing is performed, we recommend it be conducted per ISO 10993-11 for Acute Systemic Toxicity and per ISO 10993-12 for Material Mediated Pyrogenicity.

10993-11 and USP <151> for Material Mediated Pyrogenicity. You may also like to consult the [FDA supplemental information sheet](#) for this testing. Please provide a test report in an attachment in the Biocompatibility Reports and Documentation section below, or provide a justification for why testing was not conducted in the Comments below.

Comments

Please summarize justifications, why testing was not conducted, etc, below.

(b)(4)

Close Tab

Biocompatibility Reports and Documentation

Add Attachment	Please attach any documentation (e.g., test reports) pertaining to the biocompatibility of your device. If no test reports were attached, please attach a rationale explaining why testing is not necessary.	
Open Attachment	Cytotoxicity Report.pdf	Delete Attachment
Open Attachment	Sensitization Report.pdf	Delete Attachment
Open Attachment	Irritation Report.pdf	Delete Attachment
Open Attachment	Acute Systemic Toxicity Report.pdf	Delete Attachment
Open Attachment	Pyrogenicity Report.pdf	Delete Attachment

Software/Firmware & Cybersecurity/Interoperability

Records processed under FOIA Request 2024-1745. Released by CDRH on 08-26-2024.

Based on the answers provided in the Device Description section, no software, cybersecurity, or interoperability information is needed.

Based on the answers provided in the Device Description section, no EMC or wireless technology information is needed.

Electrical, Mechanical, and Thermal Summary

Please summarize the Electrical, Mechanical and Thermal Testing of your device, or summarize why testing was not needed. Please ensure any standards cited here are also cited in the Standards subsection within the first part of this template (located after Applicant, Correspondent, and Pre-Submission Correspondence).

The submission device is not electromechanical in nature therefore no testing is provided in this submission.

EMC, Wireless, & EMT Documentation

Add Attachment

Please attach the documentation pertaining to the Electromagnetic Compatibility Testing (e.g., EMC test reports/summaries), Safeguards, Wireless Testing, and Electrical, Mechanical and Thermal Testing of your device.

Performance Testing

Was Bench Testing used in order to support this submission?

Yes

Was Animal Testing used in order to support this submission?

No

Was Clinical Testing used in order to support this submission?

No

If the determination of substantial equivalence is also based on an assessment of performance data, we recommend you fill out the text boxes below. If no testing was necessary, state this in the respective field below. If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), you must include this information, in accordance with 21 CFR 807.92(b). The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

THEREFORE, ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE SUMMARY TEXTBOXES BELOW.

Provide a brief discussion of the nonclinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence. If any guidance documents or FDA recognized consensus standards were used/referenced for testing, cite these here.

Bench testing was performed to demonstrate substantial equivalence as recommended by the FDA Guidance on Premarket Notification [510(k)] Submission for Surgical Gowns and Surgical Drapes, August 1993 and in alignment with the predicate device.

Performance Testing includes:

- Barrier performance per AAMI PB70:2012 using ASTM F1670 Resistance to Synthetic Blood Penetration
- Force at 25% Elongation
- Flammability testing per 16 CFR 1610
- Moisture Vapor Transmission Rate
- in vitro Direct Time Kill
- Minimum Effective Concentration
- CHG Release Kinetics

Provide a summary discussion of the clinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence. Refer to the help text for a list of the details we recommend be included regarding the subjects and clinical evidence. If no clinical data were necessary, please type "Not Applicable." (There should not be any patient identifier information in the summary.)

Not applicable

State the conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified above.

In alignment with the predicate device, testing of the submission device was completed to evaluate the same performance characteristics; barrier performance, force at 25% elongation, flammability, moisture vapor transmission rate, in vitro direct time kill, minimum effective concentration, and CHG release kinetics. The submission device met the requirements of each performance test. Therefore, the performance testing

demonstrates that the 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG) is substantially equivalent to the predicate device. There are no new questions of safety and effectiveness.

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Bench Testing

Provide the predicate device submission number (e.g., K180001) that is the best comparator for the testing attached below.

K140250

Add Attachment

Please attach documentation that includes details of the bench testing performed with your device (test report, characterization, etc). A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre- defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test support this submission.

Other Non-Clinical Evidence

Open Attachment

Bench Testing Overview.pdf

Delete Attachment

Other Non-Clinical Evidence

Open Attachment

Synthetic Blood Penetration Report.pdf

Delete Attachment

Other Non-Clinical Evidence

Open Attachment

Force at 25 pct Elongation Report.pdf

Delete Attachment

Other Non-Clinical Evidence

Open Attachment

Flammability Testing Report.pdf

Delete Attachment

Other Non-Clinical Evidence

Open Attachment

MVTR Testing Report.pdf

Delete Attachment

Other Non-Clinical Evidence

Open Attachment

in vitro Time Kill Report.pdf

Delete Attachment

Other Non-Clinical Evidence

Open Attachment

MEC Report.pdf

Delete Attachment

Other Non-Clinical Evidence

Open Attachment

CHG Kinetic Release Testing Report.pdf

Delete Attachment

Guidance and Special Controls Adherence

Please cite the attachment(s) and page number(s) of any information you provided demonstrating special controls or device specific guidance adherence in this section. Please use the primary product code you listed in the Classification section above to determine whether a device specific guidance or special controls exists for your device. Type "N/A" if no device specific guidance or special controls exist for your device type. If you type "N/A," and special controls or a device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

Primary Product Code KKK and FDA Guidance on Premarket Notification [510(k)] Submission for Surgical Gowns and Surgical Drapes, August 1993

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls, please provide a rationale for this alternative approach below.

Questions? Contact FDA CDRH POC/DID at CDRH-FOI@FDA.HHS.gov or 1-800-796-8118

References

Is literature referenced in the submission?

No

?

Administrative Documentation

Add Attachment

General Summary of Submission/Executive Summary

Open Attachment

Executive Summary.pdf

Delete Attachment

The Truthful and Accurate Statement is required for all 510(k) types (21 CFR 807.87(k)). It is a legally binding statement that provides additional assurance that the data submitted in the 510(k) is truthful and accurate and that no material fact has been omitted. This statement must be signed by a responsible person of the applicant company; it cannot be signed by a consultant to the applicant. If you are a responsible party of the 510(k) owner, this statement will be automatically produced and signed with your electronic signature (click the Administrative Documentation help text above to learn how to obtain an electronic signature). Ensure the signature you use to sign this application is for the owner of the 510(k), or, if you are not a responsible party of the 510(k) owner, attach a Truthful and Accurate statement below.

Weblink: [Truthful and Accurate Statement](#)

Are you a responsible party of the owner for this 510(k) Premarket Notification, and will you be electronically signing this application for submission? If you are unable to sign PDF documents with a valid electronic signature, choose No.

Would you like to attach a 510(k) Statement or Summary? If you do not attach a 510(k) Statement or Summary, and you provided all of the data necessary to produce a 510(k) Summary, then a 510(k) Summary will be produced by this form. If you choose to submit a 510(k) Summary instead of a 510(k) Statement, be aware that the data provided in the 510(k) Summary will be publicly available if your 510(k) is cleared. As a result, be sure no confidential information is included in the 510(k) Summary. If you choose to submit a 510(k) Statement, be aware that you must provide summary information to anyone who requests it.

Add Attachment

510(k) Summary or Statement

Open Attachment

510k Summary.pdf

Delete Attachment

Add Attachment

Please attach your User Fee form here. Please be sure to submit your user fee payment at least three (3) business days before submitting, to ensure the payment is processed and your submission is not placed on user fee hold.

Open Attachment

MDUFMA Cover Sheet.pdf

Delete Attachment

Please enter in the User Fee Payment Identification Number.

[Show User Fee Introduction](#)

Truthful & Accurate Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Regulatory Affairs Specialist of 3M Company, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(b)(6)

2022.08.25 11:58:40 -05'00'

Date Signed: 2022-08-25

510(k)#:

For a new submission, leave the 510(k) number blank.

Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].

Verification

The following sections are complete:

- Application/Submission Type
- Cover Letter / Letters of Reference
- Administrative Information
- Device Description
- Indications for Use
- Classification
- Predicates and Substantial Equivalence
- Labeling
- Reprocessing, Sterility, and Shelf-Life
- Biocompatibility
- Software/Firmware & Cybersecurity/Interoperability
- EMC, Wireless, Electrical, Mechanical, and Thermal Safety
- Performance Testing
- References
- Administrative Documentation

Export Data	If you want to save the data in this eSTAR in XML format, you can click the Export Data button to the left. Attachments will not be included in the generated XML file.
Import Data	You can import the XML data of another eSTAR into this eSTAR by clicking the Import Data button to the left, and choosing the XML file. Attachments will not be imported.

Registration and Listing

Owners or operators of places of business (also called establishments or facilities) that are involved in the production and distribution of medical devices intended for use in the United States (U.S.) are required to register annually with the FDA. This process is known as establishment registration.

Congress has authorized FDA to collect an annual establishment registration fee for device establishment registrations. A detailed list of all those establishment types that have to pay the registration fee can be found at the [Who Must Register, List and Pay the Fee](#) website. There are no reductions in annual establishment registration fees for small businesses or any other group.

Most establishments that are required to register with the FDA are also required to list the devices that are made there and the activities that are performed on those devices. If a device requires premarket approval or notification before being marketed in the U.S., then the owner/operator should also submit the FDA premarket submission number (510(k), De Novo, PMA, PDP, HDE). The owner/operator cannot list the device until the premarket submission has been cleared, granted, or approved to market in the United States.

Registration and listing provides FDA with the location of medical device establishments and the devices manufactured at those establishments. Knowing where devices are made increases the nation's ability to prepare for and respond to public health emergencies.

For details about registering and listing your device, please see the [Device Registration and Listing](#) website. If you encounter an issue or wish to contact us regarding the Electronic Registration and Listing System known as the FDA Unified Registration and Listing System (FURLS)/Device Registration and Listing Module (DRLM), please send an email to reglist@cdrh.fda.gov.

Delivery Directions

You only need to mail this eSTAR PDF with embedded attachments on a CD, DVD, or USB Drive (SD cards are not accepted) with a printed cover letter to our Document Control Center. As an example, an

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acceptable submission package would consist of a printed cover letter accompanying a USB drive with only this eSTAR PDF on it. **The submission does not need to be eCopy compliant, nor does the eSTAR PDF need to be zipped and placed in a MISC FILES folder.**

**R & D Supporting
Document**

(b)(4)

Version: (b)(4)

Status: Release

Release Date: 07/01/2022 12:26:35 PM
CDT

Document Name:

(b)(4)

Document Title:

Results of CHG Drape Verification Testing for Force at 25% Elongation

Released Date:

07/01/2022 12:26:35 PM CDT

Superseded Date:

Owner:

(b)(4)

Location:

(b)(4)

Approvals optional for this document

SIGNERS:

(b)(4)

Results of CHG Drape Verification Testing for Force at 25% Elongation
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(b)(4)

(b)(4)

**R & D Supporting
Document**

(b)(4)

Version: (b)(4)

Status: Release

Release Date: 03/10/2022 07:54:02 AM
CST

Document Name:

(b)(4)

Document Title:

Results of CHG Drape Verification Testing for Flammability

Released Date:

03/10/2022 07:54:02 AM CST

Superseded Date:

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(b)(4)

Location:

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SIGNERS:

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Results of CHG Drape Verification Testing for Flammability

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Version: (b)(4)
Status: Release

Release Date: 06/29/2022 10:16:03 AM
CDT

Document Name:

(b)(4)

Document Title:
Rate

Results of CHG Drape Verification Testing for Moisture Vapor Transmission

Released Date:

06/29/2022 10:16:03 AM CDT

Superseded Date:

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Results of CHG Drape Verification Testing for Moisture Vapor Transmission Rate

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Version (b)(4)

Status: Release

Release Date: 06/30/2022 11:40:38 AM
CDT

Document Name:

(b)(4)

Document Title:

Results of CHG Drape Verification Testing for Time Kill

Released Date:

06/30/2022 11:40:38 AM CDT

Superseded Date:

Owner:

(b)(4)

Location:

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Results of CHG Drape Verification Testing for Time Kill

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**R & D Supporting
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(b)(4)

Status: Release

Release Date: 06/30/2022 11:41:27 AM
CDT

Document Name:

(b)(4)

Document Title:

Results of Time Kill Testing for CHG Drape Stability

Released Date:

06/30/2022 11:41:27 AM CDT

Superseded Date:

Owner:

Location:

(b)(4)

Approvals optional for this document

SIGNERS:

(b)(4)

Results of Time Kill Testing for CHG Drape Stability

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

(b)(4)

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(b)(4)

Substantial Equivalence Discussion

Predicate Device

The legally marketed predicate device is the 3M™ Steri-Drape™ CHG Antimicrobial Incise Drape cleared per K140250.

Intended Use and Indications for Use

Both the predicate device and the submission device are intended to be used as an incise drape. The CHG contained in the adhesive of both devices provides antimicrobial/antibacterial activity to help reduce the risk of bacterial contamination in the surgical wound. Both the predicate device and the submission device have the same intended use.

Indications for Use:

3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG) is indicated for use as an incise drape with continuous antibacterial activity based on in vitro time kill data out to 90 minutes. It is intended for external use only.

Technological Characteristics:

(b)(4)

(b)(4)

Substantial Equivalence Comparison Table

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Methods and Performance Data:

Bench testing was performed to demonstrate substantial equivalence as recommended by the *FDA Guidance on Premarket Notification [510(k)] Submission for Surgical Gowns and Surgical Drapes*, August 1993 and in alignment with the predicate device. Performance Testing included:

- Barrier performance per AAMI PB70:2012 using ASTM F1670 Resistance to Synthetic Blood Penetration
- Force at 25% Elongation
- Flammability testing per 16 CFR 1610
- Moisture Vapor Transmission Rate
- in vitro Direct Time Kill
- Minimum Effective Concentration
- CHG Release Kinetics

In alignment with the predicate device, these tests demonstrate the performance of the 3M™ Ioban™ CHG Incise Drape and raise no new or different questions of safety and effectiveness

Substantial Equivalence as Demonstrated by the Performance Data:

Testing of the submission device was completed in alignment with the testing that was completed in support of the predicate device submission. As summarized in the Bench Testing Overview and the attached testing reports in the Performance Testing section of this 510(k), the submission device met the requirements of each test. Therefore, the performance testing demonstrates that the 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG) is substantially equivalent to the predicate device. There are no new questions of safety and effectiveness.

Executive Summary

Device Name:

3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)

The common or usual names for this type of product:

Surgical drape

The classification name for this device:

Surgical drape and drape accessories (21 CFR § 878.4370, KXX)

Establishment Registration Number

This 510(k) Premarket Notification is submitted by:

3M Company
2510 Conway Avenue
St. Paul, MN 55144-1000
FDA Establishment Registration Number: 2110898

Manufacturing Information

3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)
is manufactured by:

3M Company
601 22nd Ave. South
Brookings, SD 57006 USA
FDA Establishment Registration Number: 1717046

The class in which the device is classified under section 513 of the act and, if known, its appropriate classification panel

Surgical drape and drape accessories (21 CFR § 878.4370)
Product Code: KXX
The appropriate classification panel is General Hospital

Performance Standards

There are no mandatory performance standards under section 514 of the Act to which this device is subject.

Concise Description of Device

3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG) is a sterile adhesive film that is applied pre-operatively to skin. It adheres and conforms to

body contours, providing a sterile surface on top of the skin prior to surgery. The surgeon incises through the adhesive film and skin, ensuring a sterile film barrier all the way to the edge of the incision. The Chlorhexidine Gluconate (CHG) contained in the adhesive provides antibacterial activity to help reduce the risk of bacterial contamination in the surgical wound. The drape consists of a transparent, conformable, breathable, barrier film coated with an acrylic adhesive containing 2% w/w CHG. The adhesive drape is delivered on a release liner that is discarded after application.

Indications for Use:

3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG) is indicated for use as an incise drape with continuous antibacterial activity based on in vitro time kill data out to 90 minutes. It is intended for external use only.

Technological Characteristics:

(b)(4)

(b)(4)

Substantial Equivalence Comparison Table

(b)(4)

(b)(4)

(b)(4)

The 3M™ Ioban™ CHG Incise Drape has the same intended use as the predicate device, 3M™ Steri-Drape™ CHG Antimicrobial Incise Drape. Although there are some differences in technological characteristics between the submission and predicate devices, these differences do not raise new or different questions of safety and effectiveness. The biocompatibility and performance data demonstrates substantial equivalence.

Concise Summary of Performance Testing

There are no mandatory performance standards under section 514 of the Act to which this device is subject.

Bench testing was performed to demonstrate substantial equivalence as recommended by the *FDA Guidance on Premarket Notification [510(k)] Submission for Surgical Gowns and Surgical Drapes*, August 1993 and in alignment with the predicate device.

Performance Testing included:

- Barrier performance per AAMI PB70:2012 using ASTM F1670 Resistance to Synthetic Blood Penetration
- Force at 25% Elongation
- Flammability testing per 16 CFR 1610
- Moisture Vapor Transmission Rate
- in vitro Direct Time Kill
- Minimum Effective Concentration
- CHG Release Kinetics

In alignment with the predicate device, these tests demonstrate the performance of the 3M™ Ioban™ CHG Incise Drape and raise no new or different questions of safety and effectiveness.

As summarized in the Bench Testing Overview and the attached testing reports in the Performance Testing section of this 510(k), the submission device met the requirements of each test. Therefore, the performance testing demonstrates that the 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG) is substantially equivalent to the predicate device. There are no new questions of safety and effectiveness.

3M

Ioban™ CHG

Chlorhexidine Gluconate Incise Drape
(contains 2% w/w CHG)



REF 8840EZ

13 in x 13 in
34 cm x 35 cm



Made in USA with Globally
Sourced Materials.
3M Company
2510 Conway Ave.
St. Paul, MN 55114 USA
1-800-228-3957 (USA only)
34-8722-8077-0

Level 4 barrier per AAMI/ANSI PB70.

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Rx Only

3M

Ioban™ CHG

Chlorhexidine Gluconate Incise Drape
(contains 2% w/w CHG)



REF 8850EZ

22 in x 17 in
56 cm x 45 cm



Made in USA with Globally
Sourced Materials.

3M Company
2510 Conway Ave.
St. Paul, MN 55114 USA
1-800-228-3957 (USA only)
34-8722-8321-2

Level 4 barrier per AAMI/ANSI PB70.

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Rx Only

3M

Ioban™ CHG

Chlorhexidine Gluconate Incise Drape
(contains 2% w/w CHG)



REF 8851EZ

22 in x 33 in
56 cm x 85 cm



Made in USA with Globally
Sourced Materials.

3M Company
2510 Conway Ave.
St. Paul, MN 55114 USA
1-800-228-3957 (USA only)
34-8722-8322-0

Level 4 barrier per AAMI/ANSI PB70.

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(b)(4)

From: Guan, Allan
To: hbhoyde@mmm.com
Cc: K222578@docs.fda.gov
Subject: K222578/S001 interactive review
Date: Monday, April 24, 2023 3:22:00 PM
Attachments: [image001.png](#)

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: Guan, Allan
To: "Hilary Hovde"
Cc: K222578@docs.fda.gov; Brendan Casey
Subject: RE: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review
Date: Thursday, May 18, 2023 2:34:00 PM
Attachments: [image008.png](#)
[image016.png](#)
[image017.png](#)
[image018.png](#)
[image019.png](#)
[image020.png](#)
[image021.png](#)
[image022.png](#)

Thank you, Hilary. Yes, that's correct regarding the (b)(4)

(b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: Hilary Hovde <hbhovde@mmm.com>
Sent: Thursday, May 18, 2023 1:45 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>

Sent: Thursday, May 18, 2023 10:10 AM

To: Hilary Hovde <hbhovde@mmm.com>

Cc: k222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: Hilary Hovde <hbhovde@mmm.com>
Sent: Thursday, May 18, 2023 10:20 AM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hello Allan,

(b)(4)

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist -- HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Hilary Hovde
Sent: Thursday, May 18, 2023 8:33 AM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Good Morning Allan,

(b)(4)

Thanks,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Thursday, May 18, 2023 8:18 AM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Good morning Hilary,

(b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control
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Allan.Guan@fda.hhs.gov



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From: Guan, Allan
Sent: Wednesday, May 17, 2023 3:36 PM
To: 'Hilary Hovde' <hbhovde@mmrn.com>
Cc: K222578@docs.fda.gov; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Hi Hilary,

Thank you for providing your rationale and the prior Q-Sub feedback.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Hilary Hovde <hbhovde@mmm.com>

Sent: Wednesday, May 17, 2023 3:10 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov>

Cc: K222578@docs.fda.gov; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>

Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hello Allan,

Thank you to you and the FDA team for the call today to discuss

(b)(4)

(b)(4)

(b)(4)

Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com



3M.com

From: Hilary Hovde

Sent: Monday, May 15, 2023 2:13 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov>

Cc: K222578@docs.fda.gov

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>

Sent: Monday, May 15, 2023 8:56 AM

To: Hilary Hovde <hbhovde@mmm.com>

Cc: K222578@docs.fda.gov

Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov



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From: Guan, Allan
Sent: Tuesday, April 25, 2023 5:04 PM
To: 'Hilary Hovde' <hbhgovde@mmm.com>
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Hilary Hovde <hbhgovde@mmm.com>
Sent: Tuesday, April 25, 2023 4:04 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call
(b)(6) at your convenience as needed.

Thanks so much.

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist -- HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, April 24, 2023 2:25 PM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: Guan, Allan
To: "Hilary Hovde"
Cc: "K222578@docs.fda.gov"; "Brendan Casey"
Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review
Date: Thursday, May 18, 2023 11:08:00 AM
Attachments: [image008.png](#)
[image016.png](#)
[image017.png](#)
[image018.png](#)
[image019.png](#)
[image020.png](#)
[image021.png](#)
[image022.png](#)
[510k Summary.aq.pdf](#)

Hi Hilary,

(b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: Hilary Hovde <hbhovde@mmm.com>
Sent: Thursday, May 18, 2023 10:20 AM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hello Allan,

(b)(4)

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



-
-

From: Hilary Hovde
Sent: Thursday, May 18, 2023 8:33 AM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Good Morning Allan,

(b)(4)

Thanks,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>

Sent: Thursday, May 18, 2023 8:18 AM

To: Hilary Hovde <hbhovde@mmm.com>

Cc: K222578@docs.fda.gov

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Good morning Hilary,

(b)(4)

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Guan, Allan

Sent: Wednesday, May 17, 2023 3:36 PM

To: 'Hilary Hovde' <hbhovde@mmm.com>

Cc: K222578@docs.fda.gov; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>

Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Hi Hilary,

Thank you for providing your rationale and the prior Q-Sub feedback.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

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From: Hilary Hovde <hbhovde@mmm.com>
Sent: Wednesday, May 17, 2023 3:10 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>
Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hello Allan,

Thank you to you and the FDA team for the call today to discuss (b)(4)

(b)(4)

(b)(4)

Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com



From: Hilary Hovde

Sent: Monday, May 15, 2023 2:13 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov>

Cc: K222578@docs.fda.gov

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,
Hilary



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hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>

Sent: Monday, May 15, 2023 8:56 AM

To: Hilary Hovde <hbhovde@mmm.com>

Cc: K222578@docs.fda.gov

Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

(b)(4)

Please provide your response as soon as possible.

Best regards,
Allan

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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: Guan, Allan
Sent: Tuesday, April 25, 2023 5:04 PM
To: 'Hilary Hovde' <hbhovde@mmm.com>
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

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Best regards,
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From: Hilary Hovde <hbhovde@mmm.com>
Sent: Tuesday, April 25, 2023 4:04 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call
(b)(6) at your convenience as needed.

Thanks so much.

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist -- HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
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hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, April 24, 2023 2:25 PM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: k222578@docs.fda.gov
Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,
Allan

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From: Guan, Allan
To: "Hilary Hovde"
Cc: K222578@docs.fda.gov
Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review
Date: Monday, May 15, 2023 5:27:00 PM
Attachments: [image002.png](#)
[image015.png](#)
[image017.png](#)
[image018.png](#)
[image019.png](#)
[image020.png](#)
[image021.png](#)
[image022.png](#)

Thank you, Hilary.

Please see below for additional deficiency regarding the (b)(4)

(b)(4)

(b)(4)

Please email me your response by COB tomorrow, 5/16.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

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Hi Allan,

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(b)(4)

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,
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hbhovde@mmm.com



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Hi Hilary,

(b)(4)

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

(b)(4)

Please provide your response as soon as possible.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

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Hi Allan,

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Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,
Hilary



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hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, April 24, 2023 2:25 PM
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Cc: k222578@docs.fda.gov
Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

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From: Guan, Allan
To: "Hilary Hovde"
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review
Date: Tuesday, April 25, 2023 5:03:00 PM
Attachments: [image001.png](#)
[image008.png](#)
[image009.png](#)
[image010.png](#)
[image011.png](#)
[image012.png](#)
[image013.png](#)

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Best regards,
Allan

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Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

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

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call

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Thanks so much.

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>

Sent: Monday, April 24, 2023 2:25 PM

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Cc: K222578@docs.fda.gov

Subject: [EXTERNAL] K222578/S001 interactive review

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(b)(4)

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Best regards,
Allan

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From: Guan, Allan
To: "Hilary Hovde"
Cc: "K222578@docs.fda.gov"
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review
Date: Monday, May 15, 2023 9:55:00 AM
Attachments: [image001.png](#)
[image008.png](#)
[image009.png](#)
[image010.png](#)
[image011.png](#)
[image012.png](#)
[image013.png](#)

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(b)(4)

Please provide your response as soon as possible.

Best regards,
Allan

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Thanks so much.

Best,
Hilary



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3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
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hbhovde@mmm.com



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From: [Hilary Hovde](#)
To: [Guan, Allan](#)
Cc: K222578@docs.fda.gov; [Brendan Casey](#)
Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review
Date: Thursday, May 18, 2023 1:46:39 PM
Attachments: [image002.png](#)
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[image006.png](#)
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[image008.png](#)
[image014.png](#)
[K222578_510k_Summary_revised_05182023.docx](#)

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Hi Allan,

(b)(4)

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist -- HCBG Regulatory Affairs Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>

Sent: Thursday, May 18, 2023 10:10 AM

To: Hilary Hovde <hbhovde@mmm.com>

Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Best regards,
Allan

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Biomedical Engineer / Team Lead

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From: Hilary Hovde <hbhovde@mmm.com>
Sent: Thursday, May 18, 2023 10:20 AM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hello Allan,

(b)(4)

Best,
Hilary



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hbhovde@mmm.com



-
-

From: Hilary Hovde
Sent: Thursday, May 18, 2023 8:33 AM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: k222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Good Morning Allan,

(b)(4)

Thanks,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
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U.S. FOOD & DRUG
ADMINISTRATION



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Sent: Wednesday, May 17, 2023 3:36 PM

To: 'Hilary Hovde' <hbhovde@mmm.com>

Cc: K222578@docs.fda.gov; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>

Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Hi Hilary,

Thank you for providing your rationale and the prior Q-Sub feedback.

Best regards,

Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Hilary Hovde <hbhovde@mnm.com>
Sent: Wednesday, May 17, 2023 3:10 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>
Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hello Allan,

Thank you to you and the FDA team for the call today to discuss (b)(4)

(b)(4)

(b)(4)

Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com



From: Hilary Hovde

Sent: Monday, May 15, 2023 2:13 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov>

Cc: K222578@docs.fda.gov

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, May 15, 2023 8:56 AM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: k222578@docs.fda.gov
Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Guan, Allan
Sent: Tuesday, April 25, 2023 5:04 PM
To: 'Hilary Hovde' <hbhovde@mmm.com>
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

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From: Hilary Hovde <hbhovde@mmm.com>
Sent: Tuesday, April 25, 2023 4:04 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov

Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call

(b)(6) at your convenience as needed.

Thanks so much.

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>

Sent: Monday, April 24, 2023 2:25 PM

To: Hilary Hovde <hbhovde@mmm.com>

Cc: K222578@docs.fda.gov

Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Allan.Guan@fda.hhs.gov



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From: [Hilary Hovde](#)
To: [Guan, Allan](#)
Cc: K222578@docs.fda.gov; [Brendan Casey](#)
Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review
Date: Thursday, May 18, 2023 10:22:15 AM
Attachments: [image002.png](#)
[image003.png](#)
[image004.png](#)
[image005.png](#)
[image006.png](#)
[image007.png](#)
[image008.png](#)
[image014.png](#)
[K222578 Indications for Use Form.pdf](#)

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Hello Allan,

(b)(4)

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



-
-

From: Hilary Hovde
Sent: Thursday, May 18, 2023 8:33 AM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Good Morning Allan,

(b)(4)

Thanks,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist -- HCBG Regulatory Affairs Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>

Sent: Thursday, May 18, 2023 8:18 AM

To: Hilary Hovde <hbhovde@mmm.com>

Cc: K222578@docs.fda.gov

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Good morning Hilary,

(b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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From: Guan, Allan

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Cc: K222578@docs.fda.gov; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>

Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Hi Hilary,

Thank you for providing your rationale and the prior Q-Sub feedback.

Best regards,
Allan

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Biomedical Engineer / Team Lead

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Cc: K222578@docs.fda.gov; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Murray III, Clarence

<Clarence.Murray@fda.hhs.gov>

Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hello Allan,

Thank you to you and the FDA team for the call today to discuss (b)(4)

(b)(4)

(b)(4)

Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist -- HCBG Regulatory Affairs Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com



From: Hilary Hovde

Sent: Monday, May 15, 2023 2:13 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov>

Cc: K222578@docs.fda.gov

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com



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Sent: Monday, May 15, 2023 8:56 AM

To: Hilary Hovde <hbhovde@mmm.com>

Cc: k222578@docs.fda.gov

Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Allan.Guan@fda.hhs.gov



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From: Guan, Allan
Sent: Tuesday, April 25, 2023 5:04 PM
To: 'Hilary Hovde' <hbhovde@mmm.com>
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Allan.Guan@fda.hhs.gov



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From: Hilary Hovde <hbhovde@mmm.com>
Sent: Tuesday, April 25, 2023 4:04 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call

(b)(6)

at your convenience as needed.

Thanks so much.

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist -- HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651.736.0364 | Fax: 651.737.5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, April 24, 2023 2:25 PM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: k222578@docs.fda.gov
Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: Hilary Hovde
To: Guan, Allan
Cc: K222578@docs.fda.gov; Brendan Casey; Brad Bagley
Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review
Date: Wednesday, May 17, 2023 8:57:16 AM
Attachments: [image007.png](#)
[image008.png](#)
[image009.png](#)
[image010.png](#)
[image011.png](#)
[image012.png](#)
[image013.png](#)
[image021.png](#)

(b)(4)

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Hello Allan,

Based on our phone call yesterday, the (b)(4) has been updated to address the points below.
Please see the attached file: (b)(4) for the requested updates to the (b)(4)

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, May 15, 2023 4:29 PM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Thank you, Hilary.

Please see below for additional deficiency regarding the (b)(4)

(b)(4)

(b)(4)

Please email me your response by COB tomorrow, 5/16.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

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

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com



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From: Guan, Allan <Allan.Guan@fda.hhs.gov>

Sent: Monday, May 15, 2023 8:56 AM

To: Hilary Hovde <hbhovde@mmm.com>

Cc: K222578@docs.fda.gov

Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Allan.Guan@fda.hhs.gov



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Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

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Sent: Tuesday, April 25, 2023 4:04 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, April 24, 2023 2:25 PM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

(b)(4)

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Best regards,
Allan

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From: [Hilary Hovde](#)
To: [Guan, Allan](#)
Cc: K222578@docs.fda.gov; [Brendan Casey](#)
Subject: [EXTERNAL] RE: RE: RE: RE: RE: K222578/S001 interactive review
Date: Thursday, May 18, 2023 3:35:04 PM
Attachments: [image002.png](#)
[image003.png](#)
[image004.png](#)
[image005.png](#)
[image006.png](#)
[image007.png](#)
[image008.png](#)
[image014.png](#)
[K222578_510k_Summary_revised_05182023_v2.docx](#)

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Hi Allan,

(b)(4)

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy

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To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: RE: K222578/S001 interactive review

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Thank you, Hilary. Yes, that's correct regarding the

(b)(4)

(b)(4)

(b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Allan.Guan@fda.hhs.gov



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From: Hilary Hovde <hbhovde@mmm.com>
Sent: Thursday, May 18, 2023 1:45 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com



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-

-

From: Guan, Allan <Allan.Guan@fda.hhs.gov>

Sent: Thursday, May 18, 2023 10:10 AM

To: Hilary Hovde <hbhovde@mmm.com>

Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov



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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.

From: Hilary Hovde <hbhovde@mmm.com>
Sent: Thursday, May 18, 2023 10:20 AM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hello Allan,

(b)(4)

Best,
Hilary



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3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



-
-

From: Hilary Hovde
Sent: Thursday, May 18, 2023 8:33 AM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Good Morning Allan,

(b)(4)

Summary?

Thanks,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>

Sent: Thursday, May 18, 2023 8:18 AM

To: Hilary Hovde <hbhovde@mmm.com>

Cc: K222578@docs.fda.gov

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Good morning Hilary,

(b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov





Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Guan, Allan

Sent: Wednesday, May 17, 2023 3:36 PM

To: 'Hilary Hovde' <hbhovde@mmm.com>

Cc: K222578@docs.fda.gov; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>

Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Hi Hilary,

Thank you for providing your rationale and the prior Q-Sub feedback.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Hilary Hovde <hbhovde@mmm.com>

Sent: Wednesday, May 17, 2023 3:10 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov>

Cc: K222578@docs.fda.gov; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>

Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hello Allan,

Thank you to you and the FDA team for the call today to discuss

(b)(4)

(b)(4)

Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Hilary Hovde
Sent: Monday, May 15, 2023 2:13 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist -- HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, May 15, 2023 8:56 AM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,
Allan

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Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Guan, Allan
Sent: Tuesday, April 25, 2023 5:04 PM
To: 'Hilary Hovde' <hbhovde@mmm.com>
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

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Allan.Guan@fda.hhs.gov



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From: Hilary Hovde <hbhovde@mimm.com>
Sent: Tuesday, April 25, 2023 4:04 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call

(b)(6) at your convenience as needed.

Thanks so much.

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization

Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, April 24, 2023 2:25 PM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: Hilary Hovde
To: Guan, Allan
Cc: K222578@docs.fda.gov; Qian, Bifeng; Murray III, Clarence
Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review
Date: Wednesday, May 17, 2023 3:11:20 PM
Attachments: [image003.png](#)
[image004.png](#)
[image005.png](#)
[image006.png](#)
[image007.png](#)
[image008.png](#)
[image009.png](#)
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(b)(4)

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Hello Allan,

Thank you to you and the FDA team for the call today to discuss

(b)(4)

(b)(4)

(b)(4)

Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Hilary Hovde
Sent: Monday, May 15, 2023 2:13 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist -- HCBG Regulatory Affairs Commercialization

Strategy

3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651.736.0364 | Fax: 651.737.5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>

Sent: Monday, May 15, 2023 8:56 AM

To: Hilary Hovde <hbhovde@mmm.com>

Cc: k222578@docs.fda.gov

Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

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Please provide your response as soon as possible.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Guan, Allan

Sent: Tuesday, April 25, 2023 5:04 PM

To: 'Hilary Hovde' <hbhovde@mmm.com>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Hilary Hovde <hbhovde@mmm.com>

Sent: Tuesday, April 25, 2023 4:04 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov>

Cc: K222578@docs.fda.gov

Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call

(b)(6)

at your convenience as needed.

Thanks so much.

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>

Sent: Monday, April 24, 2023 2:25 PM

To: Hilary Hovde <hbhovde@mmm.com>

Cc: K222578@docs.fda.gov

Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,
Allan

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Biomedical Engineer / Team Lead

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3M Health Care

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(b)(4)

Page 4

This notification is being sent in lieu of a formal written letter. If you have any questions, please contact Ramesh K Panguluri at 301-796-6303 or Ramesh.Panguluri@fda.hhs.gov.

From: [Hilary Hovde](#)
To: [Guan, Allan](#)
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review
Date: Monday, May 15, 2023 3:14:12 PM
Attachments: [image008.png](#)
[image009.png](#)
[image010.png](#)
[image011.png](#)
[image012.png](#)
[image013.png](#)
[image014.png](#)
[image001.png](#)

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Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

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(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, May 15, 2023 8:56 AM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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(b)(4)

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Biomedical Engineer / Team Lead

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Allan.Guan@fda.hhs.gov



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From: Guan, Allan
Sent: Tuesday, April 25, 2023 5:04 PM
To: 'Hilary Hovde' <hbhovde@mmm.com>
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

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Allan

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From: Hilary Hovde <hbhovde@mmm.com>
Sent: Tuesday, April 25, 2023 4:04 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call

(b)(6) at your convenience as needed.

Thanks so much.

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist -- HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, April 24, 2023 2:25 PM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

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We kindly request your response by 4/27.

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From: [Hilary Hovde](#)
To: [Guan, Allan](#)
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review
Date: Monday, May 15, 2023 10:16:40 AM
Attachments: [image008.png](#)
[image009.png](#)
[image010.png](#)
[image011.png](#)
[image012.png](#)
[image013.png](#)
[image014.png](#)

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Hi Allan,

I have forwarded your note to the team and we are working on providing a response as soon as possible.

(b)(4)

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



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From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, May 15, 2023 8:56 AM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

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(b)(4)

Please provide your response as soon as possible.

Best regards,

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Sent: Tuesday, April 25, 2023 5:04 PM

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Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

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Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

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(b)(6) at your convenience as needed.

Thanks so much.

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group

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Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, April 24, 2023 2:25 PM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: k222578@docs.fda.gov
Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: [Hilary Hovde](#)
To: [Guan, Allan](#)
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: K222578/S001 interactive review
Date: Monday, April 24, 2023 4:57:26 PM
Attachments: [image008.png](#)
[image009.png](#)
[image010.png](#)
[image011.png](#)
[image012.png](#)
[image013.png](#)
[image014.png](#)

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Hi Allan,

I just wanted to acknowledge that I received this request for additional information.

I will provide a response to you by April 27th as requested.

Thanks,

Hilary



Hilary B. Hovde | Regulatory Affairs Specialist -- HCBG Regulatory Affairs Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>

Sent: Monday, April 24, 2023 2:25 PM

To: Hilary Hovde <hbhovde@mmm.com>

Cc: K222578@docs.fda.gov

Subject: [EXTERNAL] K222578/S001 interactive review

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(b)(4)

(b)(4)

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Allan

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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: [Hilary Hovde](#)
To: [Guan, Allan](#)
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: K222578/S001 interactive review
Date: Tuesday, April 25, 2023 4:05:04 PM
Attachments: [image008.png](#)
[image009.png](#)
[image010.png](#)
[image011.png](#)
[image012.png](#)
[image013.png](#)
[image014.png](#)
(b)(4)

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call

(b)(6) at your convenience as needed.

Thanks so much.

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



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Build Correspondence

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K222578

3M Company

Trade/Device Name: 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)

Contact Name: Hilary Hovde

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 K222578 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 K222578 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.

MAJOR DEFICIENCY LIST

The Agency has identified major deficiencies that if not adequately resolved, may preclude a favorable decision on the marketing application.

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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 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.

Consult Memorandum



Date: May 2, 2023

From: Jon Weeks, PhD.
Microbiologist
CDRH/OSEL/DBCMS

To: Allan Guan, PhD
Team Lead
CDRH/OHT4/DHT4B/THT4B2

Subject: K222578/S001
3M Ioban CHG Chlorhexidine Gluconate Incise Drape
3M Company

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(b)(5)

Digital Signature Concurrence Table (Doc ID: 04504.04.00)	
For each of the specific issues identified in the recommended requests to the applicant above, I have provided a statement of basis for the request(s); and either cited as part of it an available, applicable, and relevant final rule, statute, final guidance, or FDA-recognized consensus standard, or confirmed to the best of my ability that there is no final rule, statute, final guidance, or FDA-recognized consensus standard available, applicable, and relevant to the request(s).	
Reviewer Sign-Off	Digitally signed by Jon Weeks -S Date: 2023.05.02 23:43:52 -04'00'

(b)(4)

(b)(4)

Thank you, Hilary.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Hilary Hovde <hbhovde@mmm.com>
Sent: Thursday, May 18, 2023 3:34 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: RE: RE: RE: RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist -- HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Thursday, May 18, 2023 1:36 PM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: RE: K222578/S001 interactive review

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Thank you, Hilary. Yes, that's correct regarding the (b)(4)

(b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



x x x x x

Excellent customer service is important to us. [Please take a moment to provide feedback regarding the customer service you have received.](#)

From: Hilary Hovde <hbhovde@mmm.com>
Sent: Thursday, May 18, 2023 1:45 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Thursday, May 18, 2023 10:10 AM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Best regards,
Allan

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Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



x x x x x

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From: Hilary Hovde <hbhovde@mmm.com>
Sent: Thursday, May 18, 2023 10:20 AM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>

Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>

Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hello Allan,

(b)(4)

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Hilary Hovde
Sent: Thursday, May 18, 2023 8:33 AM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Good Morning Allan,

(b)(4)

Thanks,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Thursday, May 18, 2023 8:18 AM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Good morning Hilary,

(b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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

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CDRH | Food and Drug Administration
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



* * * * *

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Guan, Allan
Sent: Wednesday, May 17, 2023 3:36 PM
To: 'Hilary Hovde' <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Hi Hilary,

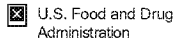
Thank you for providing your rationale and the prior Q-Sub feedback.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

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* * * * *

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From: Hilary Hovde <hbhovde@mmm.com>
Sent: Wednesday, May 17, 2023 3:10 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>
Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hello Allan,

Thank you to you and the FDA team for the call today to discuss:

(b)(4)

(b)(4)

(b)(4)

Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs Commercialization Strategy
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3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Hilary Hovde
Sent: Monday, May 15, 2023 2:13 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 735 0364 | Fax: 651 737 5320
hhhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, May 15, 2023 8:56 AM
To: Hilary Hovde <hhhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

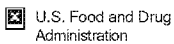
Please provide your response as soon as possible.

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Allan

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Biomedical Engineer / Team Lead

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Allan.Guan@fda.hhs.gov



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From: Guan, Allan
Sent: Tuesday, April 25, 2023 5:04 PM
To: 'Hilary Hovde' <hhhovde@mmm.com>
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,
Allan

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Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hhhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, April 24, 2023 2:25 PM
To: Hilary Hovde <hhhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] K222578/S001 interactive review

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(b)(4)

We kindly request your response by 4/27.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

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Thanks so much.

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
bhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, April 24, 2023 2:25 PM
To: Hilary Hovde <bhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

Good morning Hilary,

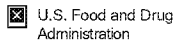
(b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



x > x x o
Excellent customer service is important to us. [Please take a moment to provide feedback regarding the customer service you have received.](#)

From: Guan, Allan
Sent: Wednesday, May 17, 2023 3:36 PM
To: 'Hilary Hovde' <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Hi Hilary,

Thank you for providing your rationale and the prior Q-Sub feedback.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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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.](#)

From: Hilary Hovde <hbhovde@mmm.com>
Sent: Wednesday, May 17, 2023 3:10 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>
Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hello Allan,

Thank you to you and the FDA team for the call today to discuss (b)(4)

(b)(4)

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

(b)(4)

Best Regards,
Hilary



Hilary M. Hovde | Regulatory Affairs Specialist – HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Hilary Hovde
Sent: Monday, May 15, 2023 2:13 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)



(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist - HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
bhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, May 15, 2023 8:56 AM
To: Hilary Hovde <bhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



x > < < <

Excellent customer service is important to us. *Please take a moment to provide feedback regarding the customer service you have received.*

From: Guan, Allan
Sent: Tuesday, April 25, 2023 5:04 PM
To: 'Hilary Hovde' <bhovde@mmm.com>
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

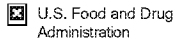
Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Hilary Hovde <hbhovde@mmm.com>
Sent: Tuesday, April 25, 2023 4:04 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,
Hilary



Hilary S. Hovde | Regulatory Affairs Specialist - HCSC Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



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To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

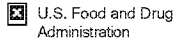
We kindly request your response by 4/27.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection 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
White Oak, Bldg. 66 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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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.

Hi Hilary,

(b)(4)

We kindly request your response by tomorrow, 10/7.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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

Yes, that should work.

Thanks so much.

Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Tuesday, May 16, 2023 7:51 AM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov; Brad Bagley <bdbagley@mmm.com>; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: RE: RE: K222578/S001 interactive review

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Hi Hilary,

Does 10:30am ET work?

Thanks,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection 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
White Oak, Bldg. 66 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



* * * * *

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Hilary Hovde <hbhovde@mmm.com>
Sent: Tuesday, May 16, 2023 8:41 AM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brad Bagley <bdbagley@mmm.com>; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: RE: RE: RE: RE: RE: K222578/S001 interactive review

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Hi Allan,

Would it at all be possible to move the meeting back one hour to 10:00 AM ET? We have a mandatory meeting on our side that was scheduled abruptly for 9:00 AM ET.

I apologize, but hope this will work.

Thanks,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 735 9364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Tuesday, May 16, 2023 7:32 AM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov; Brad Bagley <bdbagley@mmm.com>; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Good morning Hilary,

This is to confirm the meeting today at 9am ET.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Hilary Hovde <hbhovde@mmm.com>
Sent: Monday, May 15, 2023 9:22 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brad Bagley <bdbagley@mmm.com>; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Thanks Allan,

I appreciate it.
I have accepted the invite and understand it is subject to change.

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 735 9364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, May 15, 2023 6:55 PM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov; Brad Bagley <bdbagley@mmm.com>; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hi Hilary,

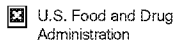
Sure, I'll try to find a time for a call tomorrow with our (b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection 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
White Oak, Bldg. 66 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Hilary Hovde <hhhovde@mmm.com>
Sent: Monday, May 15, 2023 6:34 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brad Bagley <bdbagley@mmm.com>; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review
Importance: High

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Hi Allan,

I have shared your request for additional information in regard to the (b)(4)

(b)(4)

I have copied Brad and Brendan (3M Regulatory Affairs Director and my direct manager) on this note as I would like to include them on the future call if you are able to accommodate this request.

Thank you for your guidance.

Best,
Hilary



Hilary H. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hhhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, May 15, 2023 4:29 PM
To: Hilary Hovde <hhhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Thank you, Hilary.

Please see below for additional deficiency regarding the (b)(4)

(b)(4)

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

(b)(4)

Please email me your response by COB tomorrow, 5/16.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: Hilary Hovde <[hhbhovde@mmm.com](mailto:hbhovde@mmm.com)>
Sent: Monday, May 15, 2023 3:13 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

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

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

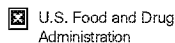
Best regards,
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Biomedical Engineer / Team Lead

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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



* * * * *

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From: Guan, Allan
Sent: Tuesday, April 25, 2023 5:04 PM
To: 'Hilary Hovde' <hbhovde@mmm.com>
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



* * * * *

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Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 735 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, April 24, 2023 2:25 PM

To: Hilary Hovde <hhhovde@mmm.com>

Cc: K222578@docs.fda.gov

Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices

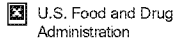
Office of Product Evaluation and Quality

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White Oak, Bldg. 66 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov



U.S. Food and Drug
Administration

Excellent customer service is important to us. *Please take a moment to provide feedback regarding the customer service you have received.*

TRADITIONAL PREMARKET NOTIFICATION [510(k)]
3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)

510(k) Summary for
3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape
(contains 2% w/w CHG)

K222578

3M Company
3M Health Care
2510 Conway Ave.
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144-1000

Contact: Hilary B. Hovde
Regulatory Affairs Specialist
hbhovdc@mmm.com

Submission Date: May 18, 2023

TRADITIONAL PREMARKET NOTIFICATION [510(k)]
3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)

Device Name and Classification

Trade Name:	3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)
Common/Usual Name:	Surgical drape
Device Classification:	Class II
Classification Name:	Surgical drape and drape accessories [21 CFR § 878.4370, KKK]

Predicate Device

3M™ Steri-Drape™ CHG Antimicrobial Incise Drape, K140250

Indications for Use

3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG) is indicated for use as an incise drape with continuous antibacterial activity based on in vitro time kill data out to 90 minutes. It is intended for external use only.

Description of Device

3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG) is a sterile adhesive film that is applied pre-operatively to skin. It adheres and conforms to body contours, providing a sterile surface on top of the skin prior to surgery. The surgeon incises through the adhesive film and skin, ensuring a sterile film barrier all the way to the edge of the incision. The Chlorhexidine Gluconate (CHG) contained in the adhesive provides antibacterial activity to help reduce the risk of bacterial contamination in the surgical wound.

The drape consists of a transparent, conformable, breathable, barrier film coated with an acrylic adhesive containing 2% w/w CHG. The adhesive drape is delivered on a release liner that is discarded after application.

TRADITIONAL PREMARKET NOTIFICATION [510(k)]
3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)**Comparison of Technological Characteristics with the Predicate Device**

Feature	Submission Device: 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)	Predicate Device (K140250): 3M™ Steri-Drape™ CHG Antimicrobial Incise Drape	Comparison
Classification Name	Surgical drape and drape accessories	Surgical drape and drape accessories	Identical
Regulation	21 CFR 878.4370	21 CFR 878.4370	Identical
Product Code	KKX	KKX	Identical
Classification	Class II	Class II	Identical
Committee	General Hospital	General Hospital	Identical
Indications for use	3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG) is indicated for use as an incise drape with continuous antibacterial activity based on in vitro time kill data out to 90 minutes. It is intended for external use only.	3M™ Steri-Drape™ CHG Antimicrobial Incise Drape is indicated for use as an incise drape with continuous antimicrobial activity based on in vitro time kill data out to 90 minutes. It is intended for external use only.	Similar Both the submission and predicate devices are intended to be used as an incise drape. The testing of the submission device supports that the drape is antibacterial rather than antimicrobial.
Design/Materials	Antibacterial impregnated adhesive coated on breathable film with silicone-coated release liner.	Antimicrobial impregnated adhesive coated on breathable film with silicone-coated release liner.	Similar Some minor modifications were made to the adhesive formulation, adhesive coat weight, and film of the submission device as compared to the predicate device.
Active Ingredient	Chlorhexidine Gluconate (2% w/w CHG)	Chlorhexidine Gluconate (2% w/w CHG)	Identical
Sterilization	Modality: Ethylene Oxide SAL: 10 ⁻⁶	Modality: Ethylene Oxide	Identical

TRADITIONAL PREMARKET NOTIFICATION [510(k)]**3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)**

Feature	Submission Device: 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)	Predicate Device (K140250): 3M™ Steri-Drape™ CHG Antimicrobial Incise Drape	Comparison
	Residuals meet ISO 10993-7: 2008; Amd 1: 2019 requirements	SAL: 10 ⁻⁶ Residuals meet ISO 10993-7 (R) 2012 requirements	
Packaging	Film/Tyvek pouch	Film/Tyvek pouch	Identical
Principles of Operation	The 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG) is considered a non-invasive device containing an antimicrobial/antibacterial agent (chlorhexidine gluconate) in the adhesive. The primary mode of action of this device is to provide a sterile barrier during surgical procedures. The secondary mode of action, based on the CHG containing adhesive, is to provide continuous antibacterial activity and to reduce the risk of surgical site contamination due to skin flora. Surgical incisions can be made directly through the Ioban incise film which creates a sterile surface all the way to the wound edge.	The 3M™ Steri-Drape™ CHG Antimicrobial Drape is a sterile adhesive film that is applied pre-operatively to skin. The film adheres and conforms to the body contours, providing a sterile surface on top of the skin prior to surgery. The surgeon incises through the adhesive film and skin, ensuring a sterile film barrier all the way to the edge of the incision. The CHG contained in the adhesive provides additional antimicrobial activity to reduce the risk of microbial contamination of the surgical wound.	Identical
Performance Characteristics	- Barrier performance per AAMI PB70:2012 using ASTM 1670 <i>Resistance to Synthetic Blood Penetration</i> - Force at 25% Elongation - Assessment of Tear Resistance	Barrier performance per AAMI PB70:2012 using ASTM 1670 <i>Resistance to Synthetic Blood Penetration</i>	The same testing was completed to assess the barrier, mechanical and antimicrobial properties of the subject device in

TRADITIONAL PREMARKET NOTIFICATION [510(k)]**3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)**

Feature	Submission Device: 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)	Predicate Device (K140250): 3M™ Steri-Drape™ CHG Antimicrobial Incise Drape	Comparison
	• Flammability testing per 16 CFR 1610 • Moisture Vapor Transmission Rate • <i>In vitro</i> Direct Time Kill • Minimum Effective Concentration • CHG Release Kinetics	• Tensile and Elongation • Flammability testing per 16 CFR 1610 • Moisture Vapor Transmission Rate • <i>In vitro</i> Direct Time Kill • Minimum Effective Concentration • CHG Release Kinetics	addition to an assessment of tear resistance.
Biocompatibility	Not cytotoxic, slight irritant, not a potential skin sensitizer, not pyrogenic, not acutely systemically toxic, non-hemolytic	Non cytotoxic, slight irritant, not a potential skin sensitizer	Duration and type of contact are identical. Additional endpoints tested are in alignment with updates to ISO 10993.
Clinical Testing	None provided	Adhesion to skin study	No clinical testing was provided to support substantial equivalence since this was a minor change. Adhesion was assessed through bench testing.

TRADITIONAL PREMARKET NOTIFICATION [510(k)]
3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)**Summary of Non-Clinical Testing**

Bench Testing and biocompatibility testing were completed to demonstrate substantial equivalence of the submission device, the 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG), to the predicate device.

The device performance was verified through the following tests:

Test	Test Method Description	Acceptance Criteria	Results
Barrier Performance	AAMI PB70:2012 using ASTM F1670 <i>Resistance to Synthetic Blood Penetration</i>	Level 4	PASS
Force at 25% Elongation	Based on PSTC-131, ASTM D882, ASTM D3759	< 425 g/in	PASS
Assessment of Tear Resistance	N/A	Rationalization Provided	PASS
Flammability	16 CFR 1610	Class I (Normal)	PASS
Moisture Vapor Transmission Rate	Based on ASTM E96	> 400 g/m ² /24 hours	PASS
<i>in vitro</i> Direct Time Kill and Minimum Effective Concentration	Based on ASTM E2315	> 4 log reduction at 90 minutes	PASS
CHG Release Kinetics	3M CHG Kinetic Release Test Method	> 0.0% after 90 minute extraction	PASS
Ethylene Oxide Residuals	ISO 10993-7: 2008; Amd 1: 2019	Per ISO 10993-7: 2008; Amd 1: 2019	PASS

TRADITIONAL PREMARKET NOTIFICATION [510(k)]
3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)

Device samples passed the following biocompatibility tests performed in accordance with ISO 10993-1, *Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process* as recognized by FDA. The 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG) is categorized as a surface contacting device, with breached or compromised skin contact of limited duration in accordance with ISO 10993-1 and FDA Guidance, *Use of International Standard ISO 10993-1, “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process.”* The battery of tests included the following:

- Chemical Characterization and Toxicology Risk Assessment of Extractables
- Hemolysis
- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Material-Mediated Pyrogenicity

Summary of Clinical Testing

Clinical testing was not provided to support substantial equivalence.

Conclusion

The conclusions drawn from the non-clinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K140250.

From: DCCLetters@fda.hhs.gov [DCCLetters@fda.hhs.gov]
Sent: 4/14/2023 5:50:26 PM
To: hbhovde@mmm.com
CC: DCCLetters@fda.hhs.gov
Subject: K222578/S001 Acknowledgement Letter
Attachments: K222578-S001-Acknowledgement Letter.pdf

April 14, 2023

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ADMINISTRATION**

Acknowledgement Letter

04/14/2023

Hilary Hovde, Regulatory Affairs Specialist
3M Company
2510 Conway Ave. Building 275-5W-06
St. Paul, MN 55144
UNITED STATES

Dear Hilary Hovde:

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: K222578/S001

Received: 04/14/2023

Applicant: 3M Company

Device: 3M Ioban CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)

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

Hello Allan,

(b)(4)

I am standing by.

Thanks,

Hilary

[cid:image001.gif@01D989BB.43888390]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

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From: Hilary Hovde

Sent: Thursday, May 18, 2023 2:34 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov>

Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>

Subject: RE: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: K222578/s001 interactive review

Hi Allan,

(b)(4)

Best,

Hilary

[cid:image001.gif@01D989BB.43888390]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Thursday, May 18, 2023 1:36 PM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

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Thank you, Hilary. Yes, that's correct regarding the (b)(4) section.

(b)(4)

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Thursday, May 18, 2023 1:45 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

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Hi Allan,

(b)(4)

Best,
Hilary

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Thursday, May 18, 2023 10:10 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

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Hi Hilary,

(b)(4)

Best regards,
Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

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

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Office of Product Evaluation and Quality

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White Oak, Bldg. 66 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Thursday, May 18, 2023 10:20 AM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey <bcasey@mmm.com<mailto:bcasey@mmm.com>>

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Hello Allan,

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Best,

Hilary

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From: Hilary Hovde

Sent: Thursday, May 18, 2023 8:33 AM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey <bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Good Morning Allan,

(b)(4)

Thanks,

Hilary

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Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Thursday, May 18, 2023 8:18 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Good morning Hilary,

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Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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From: Guan, Allan

Sent: Wednesday, May 17, 2023 3:36 PM

To: 'Hilary Hovde' <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Qian, Bifeng
<Bifeng.Qian@fda.hhs.gov<mailto:Bifeng.Qian@fda.hhs.gov>>; Murray III, Clarence
<Clarence.Murray@fda.hhs.gov<mailto:Clarence.Murray@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Hi Hilary,

Thank you for providing your rationale and the prior Q-Sub feedback.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of

Records processed under FOIA Request 2024-1745; Released by CDRH on 08-26-2024
Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Wednesday, May 17, 2023 3:10 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Qian, Bifeng
<Bifeng.Qian@fda.hhs.gov<mailto:Bifeng.Qian@fda.hhs.gov>>; Murray III, Clarence
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Hello Allan,

Thank you to you and the FDA team for the call today to discuss

(b)(4)

(b)(4)

(b)(4)

Best Regards,

Hilary

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Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

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Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com<mailto:hbhovde@mmm.com>

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From: Hilary Hovde

Sent: Monday, May 15, 2023 2:13 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,

Hilary

[cid:image001.gif@01D989BB.43888390]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

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Office: 651 736 0364 | Fax: 651 737 5320

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, May 15, 2023 8:56 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices

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Ph: (301) 796-2851

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From: Guan, Allan

Sent: Tuesday, April 25, 2023 5:04 PM

To: 'Hilary Hovde' <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Tuesday, April 25, 2023 4:04 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,

Hilary

[cid:image001.gif@01D989BB.43888390]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, April 24, 2023 2:25 PM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

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Hi Hilary,

Sure, I'll try to find a time for a call tomorrow with our (b)(4)

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

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From: Hilary Hovde <hbhovde@mmm.com>

Sent: Monday, May 15, 2023 6:34 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov>

Cc: K222578@docs.fda.gov; Brad Bagley <bdbagley@mmm.com>; Brendan Casey <bcasey@mmm.com>

Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

Importance: High

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Hi Allan,

I have shared your request for additional information in regard to the (b)(4)

(b)(4)

(b)(4)

I have copied Brad and Brendan (3M Regulatory Affairs Director and my direct manager) on this note as I would like to include them on the future call if you are able to accommodate this request.

Thank you for your guidance.

Best,
Hilary

[cid:image014.gif@01D98766.FD63F260]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

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3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, May 15, 2023 4:29 PM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Thank you, Hilary.

Please see below for additional deficiency regarding the

(b)(4)

(b)(4)

(b)(4)

Please email me your response by COB tomorrow, 5/16.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Monday, May 15, 2023 3:13 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

(b)(4)

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,

Hilary

[cid:image014.gif@01D98766.FD63F260]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, May 15, 2023 8:56 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

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

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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From: Guan, Allan

Sent: Tuesday, April 25, 2023 5:04 PM

To: 'Hilary Hovde' <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

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From: Hilary Hovde <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

Sent: Tuesday, April 25, 2023 4:04 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<<mailto:Allan.Guan@fda.hhs.gov>>>

Cc: K222578@docs.fda.gov<<mailto:K222578@docs.fda.gov>>

Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,

Hilary

[cid:image014.gif@01D98766.FD63F260]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
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png@01D98766.FD63F260]<<http://www.3m.com/>>

From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, April 24, 2023 2:25 PM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,

Hilary

[cid:image007.gif@01D97786.BA51B420]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
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From: Guan, Allan <Allan.Guan@fda.hhs.gov>

Sent: Monday, April 24, 2023 2:25 PM

To: Hilary Hovde <hbhovde@mmm.com>

Cc: K222578@docs.fda.gov

Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

(b)(4)

We kindly request your response by 4/27.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

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Friday, April 14, 2023

FDA/CDRH/DCC

Dr. Allan Guan, Ph.D.
Biomedical Engineer/ Team Lead
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation [510(K)]
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

APR 14 2023

RECEIVED

K222578/S001

Re: K222578s1 510(k) for the 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)

Dear Dr. Guan,

As requested in your letter dated October 20, 2022, please find enclosed 3M's written responses to your questions related to K222578, the 510(k) Premarket Notification for 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG). In alignment with the *eCopy Program for Medical Device Submissions, Guidance for Industry and Food and Drug Administration Staff*, issued April 27, 2020, only the eCopy has been provided in this submission.

Please contact me at the email below if you should have any questions concerning this submission.

Sincerely,

(b)(6)

Hilary B. Hovde

Regulatory Affairs Specialist
3M Company, 3M Health Care
2510 Conway Avenue, Bldg. 275-5W-06
St. Paul, MN 55144-1000 USA
hbhovde@mmm.com

Hi Allan,

I have forwarded your note to the team and we are working on providing a response as soon as possible.

(b)(4)

Best,

Hilary

[cid:image007.gif@01D9870D.DAD09E50]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com<mailto:hbhovde@mmm.com>

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From: Guan, Allan <Allan.Guan@fda.hhs.gov>

Sent: Monday, May 15, 2023 8:56 AM

To: Hilary Hovde <hbhovde@mmm.com>

Cc: K222578@docs.fda.gov

Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

WARNING: This email is not from 3M. If you are not expecting an email from this sender, do not click on links or open attachments and report it using the Report Phish button.

Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-2851

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From: Guan, Allan

Sent: Tuesday, April 25, 2023 5:04 PM

To: 'Hilary Hovde' <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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From: Hilary Hovde <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

Sent: Tuesday, April 25, 2023 4:04 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<<mailto:Allan.Guan@fda.hhs.gov>>>

Cc: K222578@docs.fda.gov<<mailto:K222578@docs.fda.gov>>

Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,

Hilary

[cid:image007.gif@01D9870D.DAD09E50]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<<mailto:Allan.Guan@fda.hhs.gov>>>

Sent: Monday, April 24, 2023 2:25 PM

To: Hilary Hovde <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

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

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices

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Hi Allan,

(b)(4)

Please contact me if further clarification is needed.

Thank you.

Best Regards,

Hilary

[cid:image007.gif@01D8D9A1.6F7A07A0]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

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From: Guan, Allan <Allan.Guan@fda.hhs.gov>

Sent: Thursday, October 06, 2022 11:22 AM

To: Hilary Hovde <hbhovde@mmm.com>

Cc: K222578@docs.fda.gov

Subject: [EXTERNAL] K222578 3M Ioban CHG Incise Drape

Hi Hilary,

(b)(4)

We kindly request your response by tomorrow, 10/7.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices

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Ph: (301) 796-2851

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TRADITIONAL PREMARKET NOTIFICATION [510(k)]
3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)

510(k) Summary for
3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape
(contains 2% w/w CHG)

K222578

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3M Corporate Toxicology & Environmental Science
3M Center, Bldg. 220-6E-03
Saint Paul, Minnesota 55144

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USP Rabbit Pyrogen Study, Material Mediated

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(b)(4)

TEST ARTICLE IDENTIFICATION

(b)(4)

3M STUDY NUMBER

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(b)(4)

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3M Corporate Toxicology & Environmental Science
3M Center, Bldg. 220-6E-03
St. Paul, Minnesota 55144

STUDY TITLE

USP Rabbit Pyrogen Study, Material Mediated

TEST ARTICLE NAME

(b)(4)

TEST ARTICLE IDENTIFICATION

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3M STUDY NUMBER

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U.S. FOOD & DRUG
ADMINISTRATION

May 18, 2023

3M Company
Hilary Hovde
Regulatory Affairs Specialist
2510 Conway Ave.
Building 275-5W-06
St. Paul, Minnesota 55144

Re: K222578

Trade/Device Name: 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)

Regulation Number: 21 CFR 878.4370

Regulation Name: Surgical Drape And Drape Accessories

Regulatory Class: Class II

Product Code: KKKX

Dated: April 14, 2023

Received: April 14, 2023

Dear Hilary Hovde:

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 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,

Bifeng Qian -S

Bifeng Qian, M.D., 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

Indications for Use

510(k) Number (if known)
K222578

Device Name
3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)

Indications for Use (Describe)

3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG) is indicated for use as an incise drape with continuous antibacterial activity based on in vitro time kill data out to 90 minutes. It is intended for external use only.

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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TRADITIONAL PREMARKET NOTIFICATION [510(k)]
3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)

510(k) Summary for
3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape
(contains 2% w/w CHG)

K222578

3M Company
3M Health Care
2510 Conway Ave.
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144-1000

Contact: Hilary B. Hovde
Regulatory Affairs Specialist
hbhovdc@mmm.com

Submission Date: May 18, 2023

TRADITIONAL PREMARKET NOTIFICATION [510(k)]
3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)

Device Name and Classification

Trade Name:	3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)
Common/Usual Name:	Surgical drape
Device Classification:	Class II
Classification Name:	Surgical drape and drape accessories [21 CFR § 878.4370, KXX]

Predicate Device

3M™ Steri-Drape™ CHG Antimicrobial Incise Drape, K140250

Indications for Use

3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG) is indicated for use as an incise drape with continuous antibacterial activity based on in vitro time kill data out to 90 minutes. It is intended for external use only.

Description of Device

3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG) is a sterile adhesive film that is applied pre-operatively to skin. It adheres and conforms to body contours, providing a sterile surface on top of the skin prior to surgery. The surgeon incises through the adhesive film and skin, ensuring a sterile film barrier all the way to the edge of the incision. The Chlorhexidine Gluconate (CHG) contained in the adhesive provides antibacterial activity to help reduce the risk of bacterial contamination in the surgical wound.

The drape consists of a transparent, conformable, breathable, barrier film coated with an acrylic adhesive containing 2% w/w CHG. The adhesive drape is delivered on a release liner that is discarded after application.

TRADITIONAL PREMARKET NOTIFICATION [510(k)]**3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)****Comparison of Technological Characteristics with the Predicate Device**

Feature	Submission Device: 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)	Predicate Device (K140250): 3M™ Steri-Drape™ CHG Antimicrobial Incise Drape	Comparison
Classification Name	Surgical drape and drape accessories	Surgical drape and drape accessories	Identical
Regulation	21 CFR 878.4370	21 CFR 878.4370	Identical
Product Code	KKX	KKX	Identical
Classification	Class II	Class II	Identical
Committee	General Hospital	General Hospital	Identical
Indications for use	3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG) is indicated for use as an incise drape with continuous antibacterial activity based on in vitro time kill data out to 90 minutes. It is intended for external use only.	3M™ Steri-Drape™ CHG Antimicrobial Incise Drape is indicated for use as an incise drape with continuous antimicrobial activity based on in vitro time kill data out to 90 minutes. It is intended for external use only.	Similar Both the submission and predicate devices are intended to be used as an incise drape. The testing of the submission device supports that the drape is antibacterial rather than antimicrobial.
Design/Materials	Antibacterial impregnated adhesive coated on breathable film with silicone-coated release liner.	Antimicrobial impregnated adhesive coated on breathable film with silicone-coated release liner.	Similar Some minor modifications were made to the adhesive formulation, adhesive coat weight, and film of the submission device as compared to the predicate device.
Active Ingredient	Chlorhexidine Gluconate (2% w/w CHG)	Chlorhexidine Gluconate (2% w/w CHG)	Identical
Sterilization	Modality: Ethylene Oxide SAL: 10 ⁻⁶	Modality: Ethylene Oxide	Identical

TRADITIONAL PREMARKET NOTIFICATION [510(k)]**3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)**

Feature	Submission Device: 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)	Predicate Device (K140250): 3M™ Steri-Drape™ CHG Antimicrobial Incise Drape	Comparison
	Residuals meet ISO 10993-7: 2008; Amd 1: 2019 requirements	SAL: 10 ⁻⁶ Residuals meet ISO 10993-7 (R) 2012 requirements	
Packaging	Film/Tyvek pouch	Film/Tyvek pouch	Identical
Principles of Operation	The 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG) is considered a non-invasive device containing an antimicrobial/antibacterial agent (chlorhexidine gluconate) in the adhesive. The primary mode of action of this device is to provide a sterile barrier during surgical procedures. The secondary mode of action, based on the CHG containing adhesive, is to provide continuous antibacterial activity and to reduce the risk of surgical site contamination due to skin flora. Surgical incisions can be made directly through the Ioban incise film which creates a sterile surface all the way to the wound edge.	The 3M™ Steri-Drape™ CHG Antimicrobial Drape is a sterile adhesive film that is applied pre-operatively to skin. The film adheres and conforms to the body contours, providing a sterile surface on top of the skin prior to surgery. The surgeon incises through the adhesive film and skin, ensuring a sterile film barrier all the way to the edge of the incision. The CHG contained in the adhesive provides additional antimicrobial activity to reduce the risk of microbial contamination of the surgical wound.	Identical
Performance Characteristics	- Barrier performance per AAMI PB70:2012 using ASTM 1670 <i>Resistance to Synthetic Blood Penetration</i> - Force at 25% Elongation - Assessment of Tear Resistance	Barrier performance per AAMI PB70:2012 using ASTM 1670 <i>Resistance to Synthetic Blood Penetration</i>	The same testing was completed to assess the barrier, mechanical and antimicrobial properties of the subject device in

TRADITIONAL PREMARKET NOTIFICATION [510(k)]**3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)**

Feature	Submission Device: 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)	Predicate Device (K140250): 3M™ Steri-Drape™ CHG Antimicrobial Incise Drape	Comparison
	• Flammability testing per 16 CFR 1610 • Moisture Vapor Transmission Rate • <i>In vitro</i> Direct Time Kill • Minimum Effective Concentration • CHG Release Kinetics	• Tensile and Elongation • Flammability testing per 16 CFR 1610 • Moisture Vapor Transmission Rate • <i>In vitro</i> Direct Time Kill • Minimum Effective Concentration • CHG Release Kinetics	addition to an assessment of tear resistance.
Biocompatibility	Not cytotoxic, slight irritant, not a potential skin sensitizer, not pyrogenic, not acutely systemically toxic, non-hemolytic	Non cytotoxic, slight irritant, not a potential skin sensitizer	Duration and type of contact are identical. Additional endpoints tested are in alignment with updates to ISO 10993.
Clinical Testing	None provided	Adhesion to skin study	No clinical testing was provided to support substantial equivalence since this was a minor change. Adhesion was assessed through bench testing.

TRADITIONAL PREMARKET NOTIFICATION [510(k)]
3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)**Summary of Non-Clinical Testing**

Bench Testing and biocompatibility testing were completed to demonstrate substantial equivalence of the submission device, the 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG), to the predicate device.

The device performance was verified through the following tests:

Test	Test Method Description	Acceptance Criteria	Results
Barrier Performance	AAMI PB70:2012 using ASTM F1670 <i>Resistance to Synthetic Blood Penetration</i>	Level 4	PASS
Force at 25% Elongation	Based on PSTC-131, ASTM D882, ASTM D3759	< 425 g/in	PASS
Assessment of Tear Resistance	N/A	Rationalization Provided	PASS
Flammability	16 CFR 1610	Class I (Normal)	PASS
Moisture Vapor Transmission Rate	Based on ASTM E96	> 400 g/m ² /24 hours	PASS
<i>in vitro</i> Direct Time Kill and Minimum Effective Concentration	Based on ASTM E2315	> 4 log reduction at 90 minutes	PASS
CHG Release Kinetics	3M CHG Kinetic Release Test Method	> 0.0% after 90 minute extraction	PASS
Ethylene Oxide Residuals	ISO 10993-7: 2008; Amd 1: 2019	Per ISO 10993-7: 2008; Amd 1: 2019	PASS

TRADITIONAL PREMARKET NOTIFICATION [510(k)]
3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)

Device samples passed the following biocompatibility tests performed in accordance with ISO 10993-1, *Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process* as recognized by FDA. The 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG) is categorized as a surface contacting device, with breached or compromised skin contact of limited duration in accordance with ISO 10993-1 and FDA Guidance, *Use of International Standard ISO 10993-1, “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process.”* The battery of tests included the following:

- Chemical Characterization and Toxicology Risk Assessment of Extractables
- Hemolysis
- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Material-Mediated Pyrogenicity

Summary of Clinical Testing

Clinical testing was not provided to support substantial equivalence.

Conclusion

The conclusions drawn from the non-clinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K140250.



Friday, April 14, 2023

Dr. Allan Guan, Ph.D.
Biomedical Engineer/ Team Lead
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation [510(K)]
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: K222578s1 510(k) for the 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)

Dear Dr. Guan,

As requested in your letter dated October 20, 2022, please find enclosed 3M's written responses to your questions related to K222578, the 510(k) Premarket Notification for 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG). In alignment with the *eCopy Program for Medical Device Submissions, Guidance for Industry and Food and Drug Administration Staff*, issued April 27, 2020, only the eCopy has been provided in this submission.

Please contact me at the email below if you should have any questions concerning this submission.

Sincerely,

(b)(4)

Hilary B. Hovde

Regulatory Affairs Specialist
3M Company, 3M Health Care
2510 Conway Avenue, Bldg. 275-5W-06
St. Paul, MN 55144-1000 USA
hbhovde@mmm.com

Thank you, Hilary, for your prompt response. This is to acknowledge receipt.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-2851

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From: Hilary Hovde <hbhovde@mmm.com>

Sent: Thursday, October 6, 2022 6:02 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov>

Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>

Subject: [EXTERNAL] RE: K222578 3M Ioban CHG Incise Drape

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Hi Allan,

(b)(4)

(b)(4)

Please contact me if further clarification is needed.

Thank you.

Best Regards,

Hilary

[cid:image007.gif@01D8D9AF.F7862EE0]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com<mailto:hbhovde@mmm.com>

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Thursday, October 06, 2022 11:22 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] K222578 3M Ioban CHG Incise Drape

Hi Hilary,

(b)(4)

We kindly request your response by tomorrow, 10/7.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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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Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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Hi Allan,

Thank you.

That is acceptable to me.

Thanks Again,

Hilary

[cid:image001.gif@01D989C1.CF677E60]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
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From: Guan, Allan <Allan.Guan@fda.hhs.gov>

Sent: Thursday, May 18, 2023 7:46 PM

To: Hilary Hovde <hbhovde@mmm.com>

Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: RE: RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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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Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Thursday, May 18, 2023 8:18 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey <bcasey@mmm.com<mailto:bcasey@mmm.com>>; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov<mailto:Bifeng.Qian@fda.hhs.gov>>

Subject: [EXTERNAL] RE: RE: RE: RE: RE: K222578/S001 interactive review

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Hello Allan,

(b)(4)

I am standing by.

Thanks,

Hilary

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From: Hilary Hovde

Sent: Thursday, May 18, 2023 2:34 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: RE: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: RE: K222578/S001 interactive review

Hi Allan,

(b)(4)

Best,

Hilary

[cid:image001.gif@01D989C1.CF677E60]

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Thursday, May 18, 2023 1:36 PM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

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Thank you, Hilary. Yes, that's correct regarding the **(b)(4)** section.

(b)(4)

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Thursday, May 18, 2023 1:45 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey <bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: RE: RE: RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Best,

Hilary

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Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
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3M Medical Solutions Division, Health Care Business Group

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Thursday, May 18, 2023 10:10 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey <bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices

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Ph: (301) 796-2851

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Thursday, May 18, 2023 10:20 AM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hello Allan,

(b)(4)

Best,

Hilary

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Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

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From: Hilary Hovde

Sent: Thursday, May 18, 2023 8:33 AM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Good Morning Allan,

(b)(4)

Thanks,

Hilary

[cid:image001.gif@01D989C1.CF677E60]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

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Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com<mailto:hbhovde@mmm.com>

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Thursday, May 18, 2023 8:18 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Good morning Hilary,

(b)(4)

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

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From: Guan, Allan

Sent: Wednesday, May 17, 2023 3:36 PM

To: 'Hilary Hovde' <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

Cc: K222578@docs.fda.gov<<mailto:K222578@docs.fda.gov>>; Qian, Bifeng
<Bifeng.Qian@fda.hhs.gov<<mailto:Bifeng.Qian@fda.hhs.gov>>>; Murray III, Clarence
<Clarence.Murray@fda.hhs.gov<<mailto:Clarence.Murray@fda.hhs.gov>>>

Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Hi Hilary,

Thank you for providing your rationale and the prior Q-Sub feedback.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices

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Ph: (301) 796-2851

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From: Hilary Hovde <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

Sent: Wednesday, May 17, 2023 3:10 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<<mailto:Allan.Guan@fda.hhs.gov>>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Qian, Bifeng
<Bifeng.Qian@fda.hhs.gov<mailto:Bifeng.Qian@fda.hhs.gov>>; Murray III, Clarence
<Clarence.Murray@fda.hhs.gov<mailto:Clarence.Murray@fda.hhs.gov>>

Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hello Allan,

Thank you to you and the FDA team for the call today to discuss

(b)(4)

(b)(4)

Best Regards,

Hilary

[cid:image001.gif@01D989C1.CF677E60]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

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Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com<mailto:hbhovde@mmm.com>

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From: Hilary Hovde

Sent: Monday, May 15, 2023 2:13 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,

Hilary

[cid:image001.gif@01D989C1.CF677E60]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, May 15, 2023 8:56 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

(b)(4)

Please provide your response as soon as possible.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices

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From: Guan, Allan

Sent: Tuesday, April 25, 2023 5:04 PM

To: 'Hilary Hovde' <hbhovde@mmm.com><mailto:hbhovde@mmm.com>>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Office of Product Evaluation and Quality

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Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Tuesday, April 25, 2023 4:04 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,

Hilary

[cid:image001.gif@01D989C1.CF677E60]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

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Office: 651 736 0364 | Fax: 651 737 5320

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<<mailto:Allan.Guan@fda.hhs.gov>>>

Sent: Monday, April 24, 2023 2:25 PM

To: Hilary Hovde <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

Cc: K222578@docs.fda.gov<<mailto:K222578@docs.fda.gov>>

Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices

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Ph: (301) 796-2851

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Yes, that should work.

Thanks so much.

Hilary

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Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
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From: Guan, Allan <Allan.Guan@fda.hhs.gov>

Sent: Tuesday, May 16, 2023 7:51 AM

To: Hilary Hovde <hbhovde@mmm.com>

Cc: K222578@docs.fda.gov; Brad Bagley <bdbagley@mmm.com>; Brendan Casey <bcasey@mmm.com>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: RE: RE: K222578/S001 interactive review

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Hi Hilary,

Does 10:30am ET work?

Thanks,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Tuesday, May 16, 2023 8:41 AM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brad Bagley
<bdbagley@mmm.com<mailto:bdbagley@mmm.com>>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: RE: RE: RE: RE: RE: K222578/S001 interactive review

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Hi Allan,

Would it at all be possible to move the meeting back one hour to 10:00 AM ET? We have a mandatory meeting on our side that was scheduled abruptly for 9:00 AM ET.

I apologize, but hope this will work.

Thanks,

Hilary

[cid:image001.gif@01D987CB.DF3DF230]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
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Office: 651 736 0364 | Fax: 651 737 5320

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Tuesday, May 16, 2023 7:32 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brad Bagley
<bdbagley@mmm.com<mailto:bdbagley@mmm.com>>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: RE: K222578/S001 interactive review

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Good morning Hilary,

This is to confirm the meeting today at 9am ET.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Monday, May 15, 2023 9:22 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brad Bagley
<bdbagley@mmm.com<mailto:bdbagley@mmm.com>>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: RE: RE: RE: K222578/S001 interactive review

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Thanks Allan,

I appreciate it.

I have accepted the invite and understand it is subject to change.

Best,

Hilary

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Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, May 15, 2023 6:55 PM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brad Bagley
<bdbagley@mmm.com<mailto:bdbagley@mmm.com>>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hi Hilary,

Sure, I'll try to find a time for a call tomorrow with our

(b)(4)

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Monday, May 15, 2023 6:34 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brad Bagley
<bdbagley@mmm.com<mailto:bdbagley@mmm.com>>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hi Allan,

I have shared your request for additional information in regard to the

(b)(4)

(b)(4)

I have copied Brad and Brendan (3M Regulatory Affairs Director and my direct manager) on this note as I would like to include them on the future call if you are able to accommodate this request.

Thank you for your guidance.

Best,

Hilary

[cid:image001.gif@01D987CB.DF3DF230]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, May 15, 2023 4:29 PM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

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Thank you, Hilary.

Please see below for additional deficiency regarding the (b)(4)

(b)(4)

(b)(4)

Please email me your response by COB tomorrow, 5/16.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Monday, May 15, 2023 3:13 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,

Hilary

[cid:image001.gif@01D987CB.DF3DF230]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, May 15, 2023 8:56 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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From: Guan, Allan

Sent: Tuesday, April 25, 2023 5:04 PM

To: 'Hilary Hovde' <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Tuesday, April 25, 2023 4:04 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,

Hilary

[cid:image001.gif@01D987CB.DF3DF230]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, April 24, 2023 2:25 PM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)
Questions? Contact FDA/CDRH/OCE/NID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

We kindly request your response by 4/27.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices

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Ph: (301) 796-2851

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Hi Hilary,

We are reviewing your 510(k) submission for the 3M Ioban CHG Incise Drape. At this time, please address the following regarding your

(b)(4)

(b)(4)

We kindly request your response by tomorrow, 10/7.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
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Hi Hilary,

Are you available for a quick call at 5:45 or 6 pm ET?

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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From: Guan, Allan

Sent: Thursday, May 18, 2023 3:46 PM

To: 'Hilary Hovde' <hbhovde@mmm.com>

Cc: 'K222578@docs.fda.gov' <K222578@docs.fda.gov>; 'Brendan Casey' <bcasey@mmm.com>

Subject: RE: [EXTERNAL] RE: RE: RE: RE: RE: K222578/S001 interactive review

Thank you, Hilary.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Thursday, May 18, 2023 3:34 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: RE: RE: RE: RE: RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Best,

Hilary

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Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

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Office: 651 736 0364 | Fax: 651 737 5320

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Thursday, May 18, 2023 1:36 PM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Thank you, Hilary. Yes, that's correct regarding the

(b)(4)

(b)(4)

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Thursday, May 18, 2023 1:45 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

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Hi Allan,

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Best,
Hilary

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Thursday, May 18, 2023 10:10 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey
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Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hi Hilary,

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Best regards,
Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Thursday, May 18, 2023 10:20 AM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hello Allan,

(b)(4)

Best,

Hilary

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Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
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Office: 651 736 0364 | Fax: 651 737 5320

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From: Hilary Hovde

Sent: Thursday, May 18, 2023 8:33 AM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Good Morning Allan,

(b)(4)

Thanks,

Hilary

[cid:image007.gif@01D989AE.FD3E8CB0]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Thursday, May 18, 2023 8:18 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Good morning Hilary,

(b)(4)

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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From: Guan, Allan

Sent: Wednesday, May 17, 2023 3:36 PM

To: 'Hilary Hovde' <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Qian, Bifeng
<Bifeng.Qian@fda.hhs.gov<mailto:Bifeng.Qian@fda.hhs.gov>>; Murray III, Clarence
<Clarence.Murray@fda.hhs.gov<mailto:Clarence.Murray@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Hi Hilary,

Thank you for providing your rationale and the prior Q-Sub feedback.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection 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

White Oak, Bldg. 66 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Wednesday, May 17, 2023 3:10 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Qian, Bifeng
<Bifeng.Qian@fda.hhs.gov<mailto:Bifeng.Qian@fda.hhs.gov>>; Murray III, Clarence
<Clarence.Murray@fda.hhs.gov<mailto:Clarence.Murray@fda.hhs.gov>>

Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hello Allan,

Thank you to you and the FDA team for the call today to discuss

(b)(4)

(b)(4)

(b)(4)

Best Regards,

Hilary

[cid:image007.gif@01D989AE.FD3E8CB0]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com<mailto:hbhovde@mmm.com>

[cid:image008.png@01D989AE.FD3E8CB0]<https://twitter.com/3m>[cid:image009.png@01D989AE.FD3E8CB0]<https://www.linkedin.com/company/3m>[cid:image010.png@01D989AE.FD3E8CB0]<https://www.facebook.com/3MCorporate>[cid:image011.png@01D989AE.FD3E8CB0]<https://instagram.com/3m/>[cid:image012.png@01D989AE.FD3E8CB0]<https://www.youtube.com/3m>[cid:image013.png@01D989AE.FD3E8CB0]<http://www.3m.com/>

From: Hilary Hovde

Sent: Monday, May 15, 2023 2:13 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,

Hilary

[cid:image007.gif@01D989AE.FD3E8CB0]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

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hbhovde@mmm.com<mailto:hbhovde@mmm.com>

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, May 15, 2023 8:56 AM

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

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

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From: Guan, Allan

Sent: Tuesday, April 25, 2023 5:04 PM

To: 'Hilary Hovde' <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

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

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Office of Product Evaluation and Quality

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Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Tuesday, April 25, 2023 4:04 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call { (b)(6) } at your convenience as needed.

Thanks so much.

Best,
Hilary

[cid:image007.gif@01D989AE.FD3E8CB0]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com<mailto:hbhovde@mmm.com>

[cid:image008.png@01D989AE.FD3E8CB0]<https://twitter.com/3m>[cid:image009.png@01D989AE.FD3E8CB0]<https://www.linkedin.com/company/3m>[cid:image010.png@01D989AE.FD3E8CB0]<https://www.facebook.com/3MCorporate>[cid:image011.png@01D989AE.FD3E8CB0]<https://instagram.com/3m/>[cid:image012.png@01D989AE.FD3E8CB0]<https://www.youtube.com/3m>[cid:image013.png@01D989AE.FD3E8CB0]<http://www.3m.com/>

From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, April 24, 2023 2:25 PM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,
Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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WO66 RM4535
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Silver Spring, MD 20993-0002
301-796-2851

Premarket Notification 510(k) Review

Date: May 18, 2023

Reviewer: Allan Guan

510(k)# K222578/S001 **Subject:** Traditional

Applicant: 3M Company

Contact Name: Hilary Hovde

Correspondent Firm: 3M Company

Received Date: April 14, 2023

Pro Code(s): KKK **Class:** II **Reg #:** 878.4370

Device Trade Name: 3M™ Ioban™ CHG
Chlorhexidine Gluconate Incise Drape (contains 2%
w/w CHG)

Contact Title: Regulatory Affairs Specialist

Phone: (651) 736-0364 **Email:**
hbhovde@mmm.com

Due Date: May 18, 2023

Reg Name: Surgical Drape And Drape Accessories

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K140250	KKX	3m Steri-drape Chg Antimicrobial Incise Drape	3m Health Care

(b)(5)

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(b)(5)

(b)(5)

Hi Hilary,

Are you available for a quick call at 5:45 or 6 pm ET?

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: Guan, Allan
Sent: Thursday, May 18, 2023 3:46 PM
To: 'Hilary Hovde' <hbhovde@mmm.com>
Cc: 'K222578@docs.fda.gov' <K222578@docs.fda.gov>; 'Brendan Casey' <bcasey@mmm.com>
Subject: RE: [EXTERNAL] RE: RE: RE: RE: RE: K222578/S001 interactive review

Thank you, Hilary.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: Hilary Hovde <hbhovde@mmm.com>
Sent: Thursday, May 18, 2023 3:34 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: RE: RE: RE: RE: RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist - HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320

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

hbhove@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Thursday, May 18, 2023 1:36 PM
To: Hilary Hovde <hbhove@mmm.com>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Thank you, Hilary. Yes, that's correct regarding the

(b)(4)

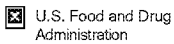
(b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: Hilary Hovde <hbhove@mmm.com>
Sent: Thursday, May 18, 2023 1:45 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: RE: RE: RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Best,
Hilary



Hilary S. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 735 0364 | Fax: 651 737 5320
hbhove@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Thursday, May 18, 2023 10:10 AM
To: Hilary Hovde <hbhove@mmm.com>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: Hilary Hovde <hbhovde@mmm.com>
Sent: Thursday, May 18, 2023 10:20 AM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hello Allan,

(b)(4)

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist - HCEG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Hilary Hovde
Sent: Thursday, May 18, 2023 8:33 AM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Good Morning Allan,

(b)(4)

Thanks,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 735 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Thursday, May 18, 2023 8:18 AM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Good morning Hilary,

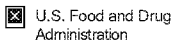
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Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



x > * > *

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From: Guan, Allan
Sent: Wednesday, May 17, 2023 3:36 PM
To: 'Hilary Hovde' <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Hilary,

Thank you for providing your rationale and the prior Q-Sub feedback.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



* x x x x

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From: Hilary Hovde <hbhovde@mmm.com>
Sent: Wednesday, May 17, 2023 3:10 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov>

Cc: K222578@docs.fda.gov; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>

Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hello Allan,

Thank you to you and the FDA team for the call today to discuss:

(b)(4)

(b)(4)

Best Regards,
Hilary



Hilary S. Hovde | Regulatory Affairs Specialist - HCSG Regulatory Affairs Commercialization Strategy
JM Medical Solutions Division, Health Care Business Group
JM Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hhhovde@mmm.com



From: Hilary Hovde
Sent: Monday, May 15, 2023 2:13 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

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

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, May 15, 2023 8:56 AM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



Excellent customer service is important to us. [Please take a moment to provide feedback regarding the customer service you have received.](#)

From: Guan, Allan
Sent: Tuesday, April 25, 2023 5:04 PM
To: 'Hilary Hovde' <hbhovde@mmm.com>
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

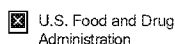
Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



x x x x x
Excellent customer service is important to us. [Please take a moment to provide feedback regarding the customer service you have received.](#)

From: Hilary Hovde <hbhovde@mmm.com>
Sent: Tuesday, April 25, 2023 4:04 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call ((b)(6)) at your convenience as needed.

Thanks so much.

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, April 24, 2023 2:25 PM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

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

(b)(4)

We kindly request your response by 4/27.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
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Allan.Guan@fda.hhs.gov

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GLP REPORT

TEST FACILITY

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SPONSOR

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3M Corporate Toxicology & Environmental Science
3M Center, Bldg. 220-6E-03
Saint Paul, Minnesota 55144

CONFIDENTIAL

STUDY TITLE

ISO Guinea Pig Maximization Sensitization Test

TEST ARTICLE NAME

(b)(4)

TEST ARTICLE IDENTIFICATION

(b)(4)

3M STUDY NUMBER

(b)(4)

(b)(4)

(b)(4)

(b)(4)

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GLP PROTOCOL

TEST FACILITY

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3M Corporate Toxicology & Environmental Science
3M Center, Bldg. 220-6E-03
St. Paul, Minnesota 55144

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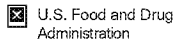
Thank you, Hilary, for your prompt response. This is to acknowledge receipt.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Hilary Hovde <hhhovde@mmm.com>
Sent: Thursday, October 6, 2022 6:02 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: K222578 3M Ioban CHG Incise Drape

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Hi Allan,

(b)(4)

Please contact me if further clarification is needed.
Thank you.

Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hhhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Thursday, October 06, 2022 11:22 AM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] K222578 3M loban CHG Incise Drape

Hi Hilary,

We are reviewing your 510(k) submission for the 3M loban CHG Incise Drape. At this time, please address the following regarding your

(b)(4)

(b)(4)

We kindly request your response by tomorrow, 10/7.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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Records processed under FOIA Request 2024-1745; Released by CDRH on 08-26-2024

Sponsor:

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3M Company

3M Center, Bldg. 270-4N-04

Saint Paul, MN 55144

ASTM Method F 1670 Synthetic Blood Penetration GLP Report

(b)(4)

(b)(4)

(b)(4)

Hi Hilary,

Does 10:30am ET work?

Thanks,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Hilary Hovde <hbhovde@mmm.com>
Sent: Tuesday, May 16, 2023 8:41 AM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brad Bagley <bdbagley@mmm.com>; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: RE: RE: RE: RE: K222578/S001 interactive review

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Hi Allan,

Would it at all be possible to move the meeting back one hour to 10:00 AM ET? We have a mandatory meeting on our side that was scheduled abruptly for 9:00 AM ET.

I apologize, but hope this will work.

Thanks,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 735 0364 | Fax: 651 737 5320
hbhovde@mmm.com



-
-

From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Tuesday, May 16, 2023 7:32 AM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov; Brad Bagley <bdbagley@mmm.com>; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Good morning Hilary,

This is to confirm the meeting today at 9am ET.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



* * * * *

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Hilary Hovde <hbhovde@mmm.com>
Sent: Monday, May 15, 2023 9:22 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brad Bagley <bdbagley@mmm.com>; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Thanks Allan,

I appreciate it.
I have accepted the invite and understand it is subject to change.

Best,
Hilary



Hilary S. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, May 15, 2023 6:55 PM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov; Brad Bagley <bdbagley@mmm.com>; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hi Hilary,

Sure, I'll try to find a time for a call tomorrow with our (b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection 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
White Oak, Bldg. 66 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



* * * * *

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Hilary Hovde <hbhovde@mmm.com>
Sent: Monday, May 15, 2023 6:34 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>

Cc: K222578@docs.fda.gov; Brad Bagley <bdbagley@mmm.com>; Brendan Casey <bcasey@mmm.com>

Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

Importance: High

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Hi Allan,

I have shared your request for additional information in regard to the

(b)(4)

(b)(4)

I have copied Brad and Brendan (3M Regulatory Affairs Director and my direct manager) on this note as I would like to include them on the future call if you are able to accommodate this request.

Thank you for your guidance.

Best,
Hilary



Hilary S. Hovde | Regulatory Affairs Specialist - HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hhhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>

Sent: Monday, May 15, 2023 4:29 PM

To: Hilary Hovde <hhhovde@mmm.com>

Cc: K222578@docs.fda.gov

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Thank you, Hilary.

Please see below for additional deficiency regarding the

(b)(4)

(b)(4)

(b)(4)

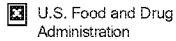
Please email me your response by COB tomorrow, 5/16.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
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Allan.Guan@fda.hhs.gov



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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.

From: Hilary Hovde <hbhovde@mmm.com>
Sent: Monday, May 15, 2023 3:13 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
bhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, May 15, 2023 8:56 AM
To: Hilary Hovde <bhovde@mmm.com>
Cc: K222578@fda.hhs.gov
Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



Excellent customer service is important to us. *Please take a moment to provide feedback regarding the customer service you have received.*

From: Guan, Allan
Sent: Tuesday, April 25, 2023 5:04 PM
To: 'Hilary Hovde' <bhovde@mmm.com>
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

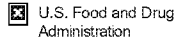
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Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: Hilary Hovde <hhhovde@mmm.com>
Sent: Tuesday, April 25, 2023 4:04 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,
Hilary



Hilary S. Hovde | Regulatory Affairs Specialist - HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 738 0364 | Fax: 651 737 5320
hhhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, April 24, 2023 2:25 PM
To: Hilary Hovde <hhhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

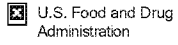
We kindly request your response by 4/27.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

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Allan.Guan@fda.hhs.gov



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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.

Hello Allan,

Thank you to you and the FDA team for the call today to discuss (b)(4)

(b)(4)

Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 735 0366 | Fax: 651 737 5320
hhhovde@mmm.com



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To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
bhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, May 15, 2023 8:56 AM
To: Hilary Hovde <bhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: Guan, Allan
Sent: Tuesday, April 25, 2023 5:04 PM

To: 'Hilary Hovde' <hhhovde@mmm.com>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

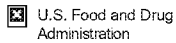
Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: Hilary Hovde <hhhovde@mmm.com>

Sent: Tuesday, April 25, 2023 4:04 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov>

Cc: K222578@docs.fda.gov

Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,
Hilary



Hilary S. Hovde | Regulatory Affairs Specialist - HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hhhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>

Sent: Monday, April 24, 2023 2:25 PM

To: Hilary Hovde <hhhovde@mmm.com>

Cc: K222578@docs.fda.gov

Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

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

(b)(4)

We kindly request your response by 4/27.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov

 U.S. Food and Drug
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Hello Allan,

(b)(4)

Best,
Hilary

[cid:image001.gif@01D98969.EB4F6280]

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Commercialization Strategy

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From: Hilary Hovde

Sent: Thursday, May 18, 2023 8:33 AM

To: Guan, Allan <Allan.Guan@fda.hhs.gov>

Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>

Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Good Morning Allan,

(b)(4)

Thanks,
Hilary

[cid:image001.gif@01D98969.EB4F6280]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com<mailto:hbhovde@mmm.com>

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Thursday, May 18, 2023 8:18 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Good morning Hilary,

(b)(4)

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices

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Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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From: Guan, Allan

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

Sent: Wednesday, May 17, 2023 3:36 PM

To: 'Hilary Hovde' <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Qian, Bifeng
<Bifeng.Qian@fda.hhs.gov<mailto:Bifeng.Qian@fda.hhs.gov>>; Murray III, Clarence
<Clarence.Murray@fda.hhs.gov<mailto:Clarence.Murray@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Hi Hilary,

Thank you for providing your rationale and the prior Q-Sub feedback.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of
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Ph: (301) 796-2851

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Wednesday, May 17, 2023 3:10 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Qian, Bifeng
<Bifeng.Qian@fda.hhs.gov<mailto:Bifeng.Qian@fda.hhs.gov>>; Murray III, Clarence
<Clarence.Murray@fda.hhs.gov<mailto:Clarence.Murray@fda.hhs.gov>>

Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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open attachments unless you recognize the sender and know the content is safe.

Hello Allan,

Thank you to you and the FDA team for the call today to discuss

(b)(4)

(b)(4)

Best Regards,

Hilary

[cid:image001.gif@01D98969.EB4F6280]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

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3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

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From: Hilary Hovde

Sent: Monday, May 15, 2023 2:13 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Allan,

(b)(4)

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,

Hilary

[cid:image001.gif@01D98969.EB4F6280]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, May 15, 2023 8:56 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

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

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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From: Guan, Allan

Sent: Tuesday, April 25, 2023 5:04 PM

To: 'Hilary Hovde' <hbhovde@mmm.com><mailto:hbhovde@mmm.com>>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

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From: Hilary Hovde <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

Sent: Tuesday, April 25, 2023 4:04 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<<mailto:Allan.Guan@fda.hhs.gov>>>

Cc: K222578@docs.fda.gov<<mailto:K222578@docs.fda.gov>>

Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,

Hilary

[cid:image001.gif@01D98969.EB4F6280]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<<mailto:Allan.Guan@fda.hhs.gov>>>

Sent: Monday, April 24, 2023 2:25 PM

To: Hilary Hovde <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

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Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,

Hilary

[cid:image007.gif@01D98712.5AB59130]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

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hbhovde@mmm.com<mailto:hbhovde@mmm.com>

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From: Guan, Allan <Allan.Guan@fda.hhs.gov>

Sent: Monday, May 15, 2023 8:56 AM

To: Hilary Hovde <hbhovde@mmm.com>

Cc: K222578@docs.fda.gov

Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

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From: Guan, Allan

Sent: Tuesday, April 25, 2023 5:04 PM

To: 'Hilary Hovde' <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

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From: Hilary Hovde <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

Sent: Tuesday, April 25, 2023 4:04 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<<mailto:Allan.Guan@fda.hhs.gov>>>

Cc: K222578@docs.fda.gov<<mailto:K222578@docs.fda.gov>>

Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,

Hilary

[cid:image007.gif@01D98712.5AB59130]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com<mailto:hbhovde@mmm.com>

[cid:image008.png@01D98712.5AB59130]<https://twitter.com/3m>[cid:image009.png@01D98712.5AB59130]<https://www.linkedin.com/company/3m>[cid:image010.png@01D98712.5AB59130]<https://www.facebook.com/3MCorporate>[cid:image011.png@01D98712.5AB59130]<https://instagram.com/3m/>[cid:image012.png@01D98712.5AB59130]<https://www.youtube.com/3m>[cid:image013.png@01D98712.5AB59130]<http://www.3m.com/>

From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, April 24, 2023 2:25 PM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

(b)(4)

We kindly request your response by 4/27.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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Best Regards,
Hilary



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3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
bhovde@mmm.com



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Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Please provide your response as soon as possible.

Best regards,

Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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* * * * *

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To: 'Hilary Hovde' <hbhovde@mmm.com>
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

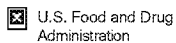
Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,
Allan

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Biomedical Engineer / Team Lead

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* * * * *

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Thanks so much.

Best,
Hilary



Hilary S. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320

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

hbhovde@mmm.com



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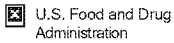
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Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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CDRH | Food and Drug Administration
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Test Method

(b)(4)

Test method to assess antimicrobial activity - Time Kill
Version: 1.0
Status: Release
Release Date: 08/28/2020 04:12:00 PM CDT

Document Name:

(b)(4)

Document Title:

Test method to assess antimicrobial activity - Time Kill

Released Date:

08/28/2020 04:12:00 PM CDT

Superseded Date:

Owner:

(b)(4)

Location Name	Description
3M MAPLEWOOD-3MUS-MN 3M HEADQUARTERS - 01J9C020	3M MAPLEWOOD-3MUS-MN 3M HEADQUARTERS - 01J9C020: 3M CENTER, MAPLEWOOD, MN, US

Operation Name	Description

(b)(4)

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 Medical Solutions Division	Records processed under FOIA Request 2024-1745; Released by CDRH on 08-26-2024	(b)(4)
	Toxicology Assessment	Revision: (b)(4) Status: Release Release Date: 05/17/2023 07:45:48 AM CDT Page 1 of 79
Title: Toxicology Risk Assessment for 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)		

Document Name:

(b)(4)

Document Title: Toxicology Risk Assessment for 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)

Effective From: 05/17/2023 07:45:48 AM CDT **To:**

Owner :

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SIGNERS:

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Document Name:

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Thanks Allan. Working on it right now.

Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Thursday, May 18, 2023 10:10 AM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: Hilary Hovde <hbhovde@mmm.com>
Sent: Thursday, May 18, 2023 10:20 AM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hello Allan,

(b)(4)

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Hilary Hovde
Sent: Thursday, May 18, 2023 8:33 AM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Good Morning Allan,

(b)(4)

Thanks,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Thursday, May 18, 2023 8:18 AM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Good morning Hilary,

(b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: Guan, Allan
Sent: Wednesday, May 17, 2023 3:36 PM
To: 'Hilary Hovde' <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Hi Hilary,

Thank you for providing your rationale and the prior Q-Sub feedback.

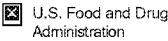
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Cc: K222578@fda.gov; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>
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Hello Allan,

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3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Hilary Hovde
Sent: Monday, May 15, 2023 2:13 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

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(b)(4)

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hhhovde@mmm.com



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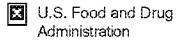
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Thanks so much.

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
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Office: 651 735 0364 | Fax: 651 737 5320
hbhovde@mmm.com



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Sent: Monday, April 24, 2023 2:25 PM
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**R & D Supporting
Document**

(b)(4)

Version: (b)(4)

Status: Release

Release Date: 03/10/2022 07:59:56 AM
CST

Document Name:

(b)(4)

Document Title:

Results of CHG Drape Verification Testing for Kinetic Release

Released Date:

03/10/2022 07:59:56 AM CST

Superseded Date:

Owner:

(b)(4)

Location:

Approvals optional for this document

SIGNERS:

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Results of CHG Drape Verification Testing for Kinetic Release

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Indications for Use

510(k) Number (if known)
K222578

Device Name
3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)

Indications for Use (Describe)

3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG) is indicated for use as an incise drape with continuous antibacterial activity based on in vitro time kill data out to 90 minutes. It is intended for external use only.

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)

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Hi Allan,

I just wanted to acknowledge that I received this request for additional information.
I will provide a response to you by April 27th as requested.

Thanks,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



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Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Hi Allan,

I just wanted to acknowledge that I received this request for additional information. I will provide a response to you by April 27th as requested.

Thanks,

Hilary

[cid:image007.gif@01D976C5.40D66E90]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com<mailto:hbhovde@mmm.com>

[cid:image008.png@01D976C5.40D66E90]<https://twitter.com/3m>[cid:image009.png@01D976C5.40D66E90]<https://www.linkedin.com/company/3m>[cid:image010.png@01D976C5.40D66E90]<https://www.facebook.com/3MCorporate>[cid:image011.png@01D976C5.40D66E90]<https://instagram.com/3m/>[cid:image012.png@01D976C5.40D66E90]<https://www.youtube.com/3m>[cid:image013.png@01D976C5.40D66E90]<http://www.3m.com/>

From: Guan, Allan <Allan.Guan@fda.hhs.gov>

Sent: Monday, April 24, 2023 2:25 PM

To: Hilary Hovde <hbhovde@mmm.com>

Cc: K222578@docs.fda.gov

Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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Version: (b)(4)

Status: Release

Page 1 of 7

Release Date: 02/10/2016 08:21:24 AM
CST

Document Name: (b)(4)

Document Title: Peelable Package Openability

Released Date: 02/10/2016 08:21:24 AM CST

Superseded Date:

Owner: (b)(4)

Approvers:

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(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Hi Allan,

I have forwarded your note to the team and we are working on providing a response as soon as possible.

(b)(4)

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 735 0364 | Fax: 651 737 5320
hbhovde@mmm.com



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Sent: Monday, May 15, 2023 8:56 AM
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Cc: K222578@docs.fda.gov
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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,
Allan

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Biomedical Engineer / Team Lead

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From: Guan, Allan
Sent: Tuesday, April 25, 2023 5:04 PM
To: 'Hilary Hovde' <hbhovde@mmm.com>
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

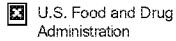
Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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• • • • •

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Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,
Hilary



Hilary S. Hovde | Regulatory Affairs Specialist - HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 738 0364 | Fax: 651 737 5320
hbhovde@mmm.com



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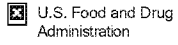
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Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

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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.

Hi Allan,

Thank you.
That is acceptable to me.

Thanks Again,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist -- HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Thursday, May 18, 2023 7:46 PM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: RE: RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

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From: Hilary Hovde <hbhovde@mmm.com>
Sent: Thursday, May 18, 2023 8:18 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>
Subject: [EXTERNAL] RE: RE: RE: RE: RE: RE: K222578/S001 interactive review

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Hello Allan,

(b)(4)

I am standing by.

Thanks,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist -- HCBG Regulatory Affairs Commercialization Strategy

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

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3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Hilary Hovde
Sent: Thursday, May 18, 2023 2:34 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: RE: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

Hi Allan,

(b)(4)

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Thursday, May 18, 2023 1:36 PM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Thank you, Hilary. Yes, that's correct regarding the (b)(4)

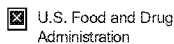
(b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: Hilary Hovde <hbhovde@mmm.com>
Sent: Thursday, May 18, 2023 1:45 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

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

(b)(4)

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
bhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Thursday, May 18, 2023 10:10 AM
To: Hilary Hovde <bhovde@mmm.com>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: Hilary Hovde <bhovde@mmm.com>
Sent: Thursday, May 18, 2023 10:20 AM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hello Allan,

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Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCSG Regulatory Affairs Commercialization Strategy
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3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Hilary Hovde
Sent: Thursday, May 18, 2023 8:33 AM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Good Morning Allan,

(b)(4)

Thanks,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



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Sent: Thursday, May 18, 2023 8:18 AM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Good morning Hilary,

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Best regards,
Allan

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Sent: Wednesday, May 17, 2023 3:36 PM
To: 'Hilary Hovde' <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Hi Hilary,

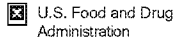
Thank you for providing your rationale and the prior Q-Sub feedback.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

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Sent: Wednesday, May 17, 2023 3:10 PM
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Cc: K222578@docs.fda.gov; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>
Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hello Allan,

Thank you to you and the FDA team for the call today to discuss

(b)(4)

(b)(4)

Best Regards,
Hilary



Hilary S. Hovde | Regulatory Affairs Specialist - HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

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hbhoyde@mmm.com



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To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,
Hilary



Hilary S. Hovde | Regulatory Affairs Specialist - HCSG Regulatory Affairs Commercialization Strategy
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Allan

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Allan

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Thanks so much.

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Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
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We kindly request your response by 4/27.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



Excellent customer service is important to us. [Please take a moment to provide feedback regarding the customer service you have received.](#)

Hello Allan,

(b)(4)

I am standing by.

Thanks,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Hilary Hovde
Sent: Thursday, May 18, 2023 2:34 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: RE: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

Hi Allan,

(b)(4)

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Thursday, May 18, 2023 1:36 PM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Thank you, Hilary. Yes, that's correct regarding the

(b)(4)

(b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection 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

From: Hilary Hovde <hhhovde@mmm.com>
Sent: Thursday, May 18, 2023 1:45 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Best,
Hilary



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Office: 651 736 0364 | Fax: 651 737 5320
hhhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Thursday, May 18, 2023 10:10 AM
To: Hilary Hovde <hhhovde@mmm.com>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
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Hi Hilary,

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Best regards,
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(b)(4)

Best,
Hilary



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hbhovde@mmm.com



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Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Good Morning Allan,

(b)(4)

Thanks,
Hilary



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* * * * *

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Cc: K222578@docs.fda.gov; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Hi Hilary,

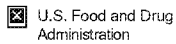
Thank you for providing your rationale and the prior Q-Sub feedback.

Best regards,
Allan

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Hello Allan,

Thank you to you and the FDA team for the call today to discuss

(b)(4)

(b)(4)

(b)(4)

Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
bhovde@mmm.com



From: Hilary Hovde
Sent: Monday, May 15, 2023 2:13 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
bhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, May 15, 2023 8:56 AM
To: Hilary Hovde <hhhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

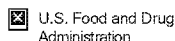
Please provide your response as soon as possible.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



Excellent customer service is important to us. *Please take a moment to provide feedback regarding the customer service you have received.*

From: Guan, Allan
Sent: Tuesday, April 25, 2023 5:04 PM
To: 'Hilary Hovde' <hhhovde@mmm.com>
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

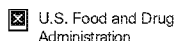
Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Sent: Tuesday, April 25, 2023 4:04 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call ((b)(6)) at your convenience as needed.

Thanks so much.

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 735 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, April 24, 2023 2:25 PM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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Hi Allan,

(b)(4)

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
bhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Thursday, May 18, 2023 10:10 AM
To: Hilary Hovde <bhovde@mmm.com>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Allan.Guan@fda.hhs.gov



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From: Hilary Hovde <bhovde@mmm.com>
Sent: Thursday, May 18, 2023 10:20 AM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hello Allan,

(b)(4)

Best,
Hilary



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3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
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hbhovde@mmm.com



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Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Good Morning Allan,

(b)(4)

Thanks,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
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Good morning Hilary,

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Best regards,
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Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Hi Hilary,

Thank you for providing your rationale and the prior Q-Sub feedback.

Best regards,

Allan

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Hello Allan,

Thank you to you and the FDA team for the call today to discuss (b)(4)

(b)(4)

Best Regards,

Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
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Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,
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Hi Hilary,

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Please provide your response as soon as possible.

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(b)(4)

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Thanks so much.

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCSG Regulatory Affairs Commercialization Strategy
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Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] K222578/S001 interactive review

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(b)(4)

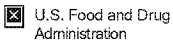
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Hi Allan,

Would it at all be possible to move the meeting back one hour to 10:00 AM ET? We have a mandatory meeting on our side that was scheduled abruptly for 9:00 AM ET.

I apologize, but hope this will work.

Thanks,
Hilary



Hilary S. Hovde | Regulatory Affairs Specialist - HCEG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 735 8364 | Fax: 651 737 5320
hbhovde@mmm.com



-
-

From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Tuesday, May 16, 2023 7:32 AM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov; Brad Bagley <bdbagley@mmm.com>; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Good morning Hilary,

This is to confirm the meeting today at 9am ET.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



* * * * *

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Hilary Hovde <hbhovde@mmm.com>
Sent: Monday, May 15, 2023 9:22 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brad Bagley <bdbagley@mmm.com>; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: RE: RE: RE: K222578/S001 interactive review

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Thanks Allan,

I appreciate it.
I have accepted the invite and understand it is subject to change.

Best,
Hilary



Hilary S. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hhhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, May 15, 2023 6:55 PM
To: Hilary Hovde <hhhovde@mmm.com>
Cc: K222578@dcfs.fda.gov; Brad Bagley <bdbagley@mmm.com>; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hi Hilary,

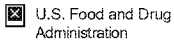
Sure, I'll try to find a time for a call tomorrow with our (b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review
Importance: High

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Hi Allan,

I have shared your request for additional information in regard to the (b)(4)

(b)(4)

I have copied Brad and Brendan (3M Regulatory Affairs Director and my direct manager) on this note as I would like to include them on the future call if you are able to accommodate this request.

Thank you for your guidance.

Best,
Hilary



Hilary S. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hhhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>

Sent: Monday, May 15, 2023 4:29 PM

To: Hilary Hovde <hhhovde@mmm.com>

Cc: K222578@docs.fda.gov

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Thank you, Hilary.

Please see below for additional deficiency regarding the (b)(4)

(b)(4)

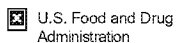
Please email me your response by COB tomorrow, 5/16.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Ph: (301) 796-2851
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• < x o x

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From: Hilary Hovde <hbhovde@mmm.com>
Sent: Monday, May 15, 2023 3:13 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,
Hilary



Hilary S. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 735 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, May 15, 2023 8:56 AM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Questions? Contact FD/CDRH/CEOID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

Please provide your response as soon as possible.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection 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, Bldg. 66 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



x > x x v

Excellent customer service is important to us. *Please take a moment to provide feedback regarding the customer service you have received.*

From: Guan, Allan
Sent: Tuesday, April 25, 2023 5:04 PM
To: 'Hilary Hovde' <hbhovde@mmm.com>
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

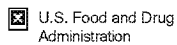
Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

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x x x x x

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From: Hilary Hovde <hbhovde@mmm.com>
Sent: Tuesday, April 25, 2023 4:04 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 735 0364 | Fax: 651 737 5320
hhhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, April 24, 2023 2:25 PM
To: Hilary Hovde <hhhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



* * * * *

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UPS

January 21, 2019

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

RE:

(b)(4)

To Whom It May Concern:

Per FDA Guidance, "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff, Document", issued on February 18, 2014, attached are the Meeting Minutes between FDA and 3M, held on August 9, 2018, for **(b)(4)** for the 3M™ Steri-Drape™ CHG Antimicrobial Incise Drape.

In accordance with section 745(A)(b) of the FD&C Act, this document is submitted in duplicate, with one paper copy and one eCopy. The eCopy is an exact duplicate of the paper copy.

Attachment 1 contains the PowerPoint slides presented to FDA for the purpose of this meeting.

3M considers the intent to market this device as confidential commercial information.

(b)(4)**(b)(4)**

and confidential commercial information under 21 CFR §20.61 and requests that the Food and Drug Administration not disclose this information either in response to a Freedom of Information Request or by any other means.

Please feel free to contact me if you have any questions or need additional information regarding this Pre-Submission Amendment – Meeting Minutes.

Sincerely,

Margaret DePuydt, RAC, M.Eng.

3M Center
2510 Conway Avenue, Bldg. 275-5W-06
St. Paul, MN 55144-1000 U.S.A.
Phone (651) 737-8730
mdepuydt@mmm.com

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(b)(4)

(b)(4)

Thanks Allan,

I appreciate it.

I have accepted the invite and understand it is subject to change.

Best,

Hilary

[cid:image001.gif@01D9876A.EAF9E8B0]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com<mailto:hbhovde@mmm.com>

[cid:image007.png@01D9876A.EAF9E8B0]<https://twitter.com/3m>[cid:image008.png@01D9876A.EAF9E8B0]<https://www.linkedin.com/company/3m>[cid:image009.png@01D9876A.EAF9E8B0]<https://www.facebook.com/3MCorporate>[cid:image010.png@01D9876A.EAF9E8B0]<https://instagram.com/3m/>[cid:image011.png@01D9876A.EAF9E8B0]<https://www.youtube.com/3m>[cid:image012.png@01D9876A.EAF9E8B0]<http://www.3m.com/>

From: Guan, Allan <Allan.Guan@fda.hhs.gov>

Sent: Monday, May 15, 2023 6:55 PM

To: Hilary Hovde <hbhovde@mmm.com>

Cc: K222578@docs.fda.gov; Brad Bagley <bdbagley@mmm.com>; Brendan Casey <bcasey@mmm.com>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hi Hilary,

Sure, I'll try to find a time for a call tomorrow with our

(b)(4)

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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CDRH | Food and Drug Administration

White Oak, Bldg. 66 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Monday, May 15, 2023 6:34 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brad Bagley
<bdbagley@mmm.com<mailto:bdbagley@mmm.com>>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

Importance: High

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Hi Allan,

I have shared your request for additional information in regard to the

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I have copied Brad and Brendan (3M Regulatory Affairs Director and my direct manager) on this note as I would like to include them on the future call if you are able to accommodate this request.

Thank you for your guidance.

Best,

Hilary

[cid:image001.gif@01D9876A.EAF9E8B0]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

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Thank you, Hilary.

Please see below for additional deficiency regarding the (b)(4)

(b)(4)

(b)(4)

Please email me your response by COB tomorrow, 5/16.

Best regards,

Allan

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Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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Sent: Monday, May 15, 2023 3:13 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

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

Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

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If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,

Hilary

[cid:image001.gif@01D9876A.EAF9E8B0]

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Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

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hbhovde@mmm.com<mailto:hbhovde@mmm.com>

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Sent: Monday, May 15, 2023 8:56 AM

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Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

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Please provide your response as soon as possible.

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From: Guan, Allan

Sent: Tuesday, April 25, 2023 5:04 PM

To: 'Hilary Hovde' <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

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From: Hilary Hovde <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

Sent: Tuesday, April 25, 2023 4:04 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<<mailto:Allan.Guan@fda.hhs.gov>>>

Cc: K222578@docs.fda.gov<<mailto:K222578@docs.fda.gov>>

Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,

Hilary

[cid:image001.gif@01D9876A.EAF9E8B0]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

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hbhovde@mmm.com<mailto:hbhovde@mmm.com>

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, April 24, 2023 2:25 PM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

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

(b)(4)

We kindly request your response by 4/27.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

TRADITIONAL PREMARKET NOTIFICATION [510(k)]
3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)

510(k) Summary for
3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape
(contains 2% w/w CHG)

K222578

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

TRADITIONAL PREMARKET NOTIFICATION [510(k)]
3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)

510(k) Summary for
3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape
(contains 2% w/w CHG)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)



U.S. FOOD & DRUG
ADMINISTRATION

K222578

3M Company

Trade/Device Name: 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)

Contact Name: Hilary Hovde

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 K222578 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 K222578 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.

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)

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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 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.



**U.S. FOOD & DRUG
ADMINISTRATION**

(b)(4)

3M Health Care
Hilary Hovde

(b)(4)

(b)(4)

(b)(4)

- Hilary Hovde

Page 3

This notification is being sent in lieu of a formal written letter. If you have any questions, please contact Ramesh K Panguluri at 301-796-6303 or Ramesh.Panguluri@fda.hhs.gov.

Hello Allan,

Based on our phone call yesterday, the (b)(4) has been updated to address the points below.
Please see the attached file (b)(4) for the requested updates to the (b)(4).

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
bhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, May 15, 2023 4:29 PM
To: Hilary Hovde <bhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Thank you, Hilary.

Please see below for additional deficiency regarding the (b)(4).

(b)(4)

Please email me your response by COB tomorrow, 5/16.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov

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From: Hilary Hovde <hbhovde@mmm.com>
Sent: Monday, May 15, 2023 3:13 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, May 15, 2023 8:56 AM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: Guan, Allan
Sent: Tuesday, April 25, 2023 5:04 PM
To: 'Hilary Hovde' <hbhovde@mmm.com>
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
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Allan.Guan@fda.hhs.gov



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From: Hilary Hovde <hbhovde@mmm.com>
Sent: Tuesday, April 25, 2023 4:04 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, April 24, 2023 2:25 PM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

Hi Hilary,

Thank you for updating the 510(k) Summary.

(b)(4)

(b)(4)

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices

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From: Hilary Hovde <hbhovde@mmm.com>

Sent: Thursday, May 18, 2023 8:18 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov>

Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>

Subject: [EXTERNAL] RE: RE: RE: RE: RE: RE: K222578/S001 interactive review

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Hello Allan,

(b)(4)

I am standing by.

Thanks,

Hilary

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

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From: Hilary Hovde

Sent: Thursday, May 18, 2023 2:34 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: RE: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: RE: K222578/S001 interactive review

Hi Allan,

(b)(4)

Best,

Hilary

[cid:image015.gif@01D989C8.CB0642F0]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

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hbhovde@mmm.com<mailto:hbhovde@mmm.com>

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Thursday, May 18, 2023 1:36 PM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: RE: K222578/S001 interactive review

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Thank you, Hilary. Yes, that's correct regarding the

(b)(4)

(b)(4)

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection 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, Bldg. 66 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Thursday, May 18, 2023 1:45 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey <bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: RE: RE: RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

(b)(4)

Best,
Hilary

[cid:image015.gif@01D989C8.CB0642F0]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com<mailto:hbhovde@mmm.com>

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Thursday, May 18, 2023 10:10 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Thursday, May 18, 2023 10:20 AM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hello Allan,

(b)(4)

Best,

Hilary

[cid:image015.gif@01D989C8.CB0642F0]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

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From: Hilary Hovde

Sent: Thursday, May 18, 2023 8:33 AM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Good Morning Allan,

(b)(4)

Thanks,

Hilary

[cid:image015.gif@01D989C8.CB0642F0]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Thursday, May 18, 2023 8:18 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Good morning Hilary,

(b)(4)

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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From: Guan, Allan

Sent: Wednesday, May 17, 2023 3:36 PM

To: 'Hilary Hovde' <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Qian, Bifeng
<Bifeng.Qian@fda.hhs.gov<mailto:Bifeng.Qian@fda.hhs.gov>>; Murray III, Clarence
<Clarence.Murray@fda.hhs.gov<mailto:Clarence.Murray@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Hi Hilary,

Thank you for providing your rationale and the prior Q-Sub feedback.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices

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Ph: (301) 796-2851

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From: Hilary Hovde <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

Sent: Wednesday, May 17, 2023 3:10 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<<mailto:Allan.Guan@fda.hhs.gov>>>

Cc: K222578@docs.fda.gov<<mailto:K222578@docs.fda.gov>>; Qian, Bifeng
<Bifeng.Qian@fda.hhs.gov<<mailto:Bifeng.Qian@fda.hhs.gov>>>; Murray III, Clarence
<Clarence.Murray@fda.hhs.gov<<mailto:Clarence.Murray@fda.hhs.gov>>>

Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hello Allan,

Thank you to you and the FDA team for the call today to discuss

(b)(4)

(b)(4)

(b)(4)

Best Regards,

Hilary

[cid:image015.gif@01D989C8.CB0642F0]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
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3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

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From: Hilary Hovde

Sent: Monday, May 15, 2023 2:13 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,

Hilary

[cid:image015.gif@01D989C8.CB0642F0]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, May 15, 2023 8:56 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices

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From: Guan, Allan

Sent: Tuesday, April 25, 2023 5:04 PM

To: 'Hilary Hovde' <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Tuesday, April 25, 2023 4:04 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call **(b)(6)** at your convenience as needed.

Thanks so much.

Best,

Hilary

[cid:image015.gif@01D989C8.CB0642F0]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com<mailto:hbhovde@mmm.com>

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, April 24, 2023 2:25 PM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection 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, Bldg. 66 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-2851

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Yes, I am available.

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From: Guan, Allan <Allan.Guan@fda.hhs.gov>

Sent: Thursday, May 18, 2023 4:39 PM

To: Hilary Hovde <hbhovde@mmm.com>

Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: RE: RE: K222578/S001 interactive review

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Hi Hilary,

Are you available for a quick call at 5:45 or 6 pm ET?

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices

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From: Guan, Allan

Sent: Thursday, May 18, 2023 3:46 PM

To: 'Hilary Hovde' <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

Cc: 'K222578@docs.fda.gov' <K222578@docs.fda.gov<<mailto:K222578@docs.fda.gov>>>;
'Brendan Casey' <bcasey@mmm.com<<mailto:bcasey@mmm.com>>>

Subject: RE: [EXTERNAL] RE: RE: RE: RE: RE: K222578/S001 interactive review

Thank you, Hilary.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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From: Hilary Hovde <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

Sent: Thursday, May 18, 2023 3:34 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<<mailto:Allan.Guan@fda.hhs.gov>>>

Cc: K222578@docs.fda.gov<<mailto:K222578@docs.fda.gov>>; Brendan Casey

<bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: RE: RE: RE: RE: RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Best,

Hilary

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Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com<mailto:hbhovde@mmm.com>

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Thursday, May 18, 2023 1:36 PM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: RE: K222578/S001 interactive review

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Thank you, Hilary. Yes, that's correct regarding the

(b)(4)

(b)(4)

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Thursday, May 18, 2023 1:45 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey <bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: RE: RE: RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Best,

Hilary

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Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Thursday, May 18, 2023 10:10 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey <bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Thursday, May 18, 2023 10:20 AM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hello Allan,

(b)(4)

Best,

Hilary

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Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
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Office: 651 736 0364 | Fax: 651 737 5320

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From: Hilary Hovde

Sent: Thursday, May 18, 2023 8:33 AM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Good Morning Allan,

(b)(4)

Thanks,

Hilary

[cid:image007.gif@01D989A7.6D161DD0]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

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Office: 651 736 0364 | Fax: 651 737 5320

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Thursday, May 18, 2023 8:18 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Good morning Hilary,

(b)(4)

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of
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From: Guan, Allan

Sent: Wednesday, May 17, 2023 3:36 PM

To: 'Hilary Hovde' <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

Cc: K222578@docs.fda.gov<<mailto:K222578@docs.fda.gov>>; Qian, Bifeng
<Bifeng.Qian@fda.hhs.gov<<mailto:Bifeng.Qian@fda.hhs.gov>>>; Murray III, Clarence
<Clarence.Murray@fda.hhs.gov<<mailto:Clarence.Murray@fda.hhs.gov>>>

Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Hi Hilary,

Thank you for providing your rationale and the prior Q-Sub feedback.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

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From: Hilary Hovde <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

Sent: Wednesday, May 17, 2023 3:10 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<<mailto:Allan.Guan@fda.hhs.gov>>>

Cc: K222578@docs.fda.gov<<mailto:K222578@docs.fda.gov>>; Qian, Bifeng

<Bifeng.Qian@fda.hhs.gov<mailto:Bifeng.Qian@fda.hhs.gov>>; Murray III, Clarence
<Clarence.Murray@fda.hhs.gov<mailto:Clarence.Murray@fda.hhs.gov>>

Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hello Allan,

Thank you to you and the FDA team for the call today to discuss

(b)(4)

(b)(4)

Best Regards,

Hilary

[cid:image007.gif@01D989A7.6D161DD0]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
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From: Hilary Hovde

Sent: Monday, May 15, 2023 2:13 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,

Hilary

[cid:image007.gif@01D989A7.6D161DD0]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, May 15, 2023 8:56 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices

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From: Guan, Allan

Sent: Tuesday, April 25, 2023 5:04 PM

To: 'Hilary Hovde' <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Tuesday, April 25, 2023 4:04 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,

Hilary

[cid:image007.gif@01D989A7.6D161DD0]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<<mailto:Allan.Guan@fda.hhs.gov>>>

Sent: Monday, April 24, 2023 2:25 PM

To: Hilary Hovde <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

Cc: K222578@docs.fda.gov<<mailto:K222578@docs.fda.gov>>

Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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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Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<<mailto:Allan.Guan@fda.hhs.gov>>

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Good Morning Allan,

(b)(4)

Thanks,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist - HCEG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 735 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Thursday, May 18, 2023 8:18 AM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Good morning Hilary,

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Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Allan.Guan@fda.hhs.gov



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From: Guan, Allan
Sent: Wednesday, May 17, 2023 3:36 PM
To: 'Hilary Hovde' <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Hilary,

Thank you for providing your rationale and the prior Q-Sub feedback.

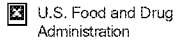
Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: Hilary Hovde <hbhovde@mmm.com>
Sent: Wednesday, May 17, 2023 3:10 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>
Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hello Allan,

(b)(4)

Best Regards,
Hilary



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3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Hilary Hovde
Sent: Monday, May 15, 2023 2:13 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,
Hilary



Hilary S. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 735 0364 | Fax: 651 737 5320
hhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, May 15, 2023 8:56 AM
To: Hilary Hovde <hhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



* * * * *

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From: Guan, Allan
Sent: Tuesday, April 25, 2023 5:04 PM
To: 'Hilary Hovde' <hbhovde@mmm.com>
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



* * * * *

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From: Hilary Hovde <hbhovde@mmm.com>
Sent: Tuesday, April 25, 2023 4:04 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>

Sent: Monday, April 24, 2023 2:25 PM

To: Hilary Hovde <hhhovde@mmm.com>

Cc: K222578@docs.fda.gov

Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
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Thank you, Hilary.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices

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Ph: (301) 796-2851

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From: Hilary Hovde <hbhovde@mmm.com>

Sent: Thursday, May 18, 2023 3:34 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov>

Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>

Subject: [EXTERNAL] RE: RE: RE: RE: RE: RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Best,

Hilary

[cid:image015.gif@01D9899F.AD28D500]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Thursday, May 18, 2023 1:36 PM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey <bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: RE: K222578/S001 interactive review

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Thank you, Hilary. Yes, that's correct regarding the

(b)(4)

(b)(4)

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

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From: Hilary Hovde <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

Sent: Thursday, May 18, 2023 1:45 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<<mailto:Allan.Guan@fda.hhs.gov>>>

Cc: K222578@docs.fda.gov<<mailto:K222578@docs.fda.gov>>; Brendan Casey <bcasey@mmm.com<<mailto:bcasey@mmm.com>>>

Subject: [EXTERNAL] RE: RE: RE: RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Best,

Hilary

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Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
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From: Guan, Allan <Allan.Guan@fda.hhs.gov<<mailto:Allan.Guan@fda.hhs.gov>>>

Sent: Thursday, May 18, 2023 10:10 AM

To: Hilary Hovde <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

Cc: K222578@docs.fda.gov<<mailto:K222578@docs.fda.gov>>; Brendan Casey <bcasey@mmm.com<<mailto:bcasey@mmm.com>>>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Thursday, May 18, 2023 10:20 AM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey <bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hello Allan,

(b)(4)

Best,

Hilary

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Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

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From: Hilary Hovde

Sent: Thursday, May 18, 2023 8:33 AM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Good Morning Allan,

(b)(4)

Thanks,

Hilary

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Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

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

Sent: Thursday, May 18, 2023 8:18 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Good morning Hilary,

(b)(4)

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection 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, Bldg. 66 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-2851

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From: Guan, Allan

Sent: Wednesday, May 17, 2023 3:36 PM

To: 'Hilary Hovde' <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Qian, Bifeng
<Bifeng.Qian@fda.hhs.gov<mailto:Bifeng.Qian@fda.hhs.gov>>; Murray III, Clarence
<Clarence.Murray@fda.hhs.gov<mailto:Clarence.Murray@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Hi Hilary,

Thank you for providing your rationale and the prior Q-Sub feedback.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Wednesday, May 17, 2023 3:10 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Qian, Bifeng
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<Clarence.Murray@fda.hhs.gov<mailto:Clarence.Murray@fda.hhs.gov>>

Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hello Allan,

Thank you to you and the FDA team for the call today to discuss

(b)(4)

(b)(4)

(b)(4)

Best Regards,

Hilary

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Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
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From: Hilary Hovde

Sent: Monday, May 15, 2023 2:13 PM

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

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,

Hilary

[cid:image015.gif@01D9899F.AD28D500]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, May 15, 2023 8:56 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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From: Guan, Allan

Sent: Tuesday, April 25, 2023 5:04 PM

To: 'Hilary Hovde' <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<<mailto:Allan.Guan@fda.hhs.gov>>

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From: Hilary Hovde <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

Sent: Tuesday, April 25, 2023 4:04 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<<mailto:Allan.Guan@fda.hhs.gov>>>

Cc: K222578@docs.fda.gov<<mailto:K222578@docs.fda.gov>>

Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,

Hilary

[cid:image015.gif@01D9899F.AD28D500]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com<mailto:hbhovde@mmm.com>

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, April 24, 2023 2:25 PM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

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

(b)(4)

We kindly request your response by 4/27.

Best regards,

Allan

Allan Guan, Ph.D.

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Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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Good morning Hilary,

This is to confirm the meeting today at 9am ET.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: Hilary Hovde <hbhovde@mmm.com>
Sent: Monday, May 15, 2023 9:22 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brad Bagley <bdbagley@mmm.com>; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Thanks Allan,

I appreciate it.
I have accepted the invite and understand it is subject to change.

Best,
Hilary



Hilary S. Hovde | Regulatory Affairs Specialist - HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, May 15, 2023 6:55 PM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov; Brad Bagley <bdbagley@mmm.com>; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hi Hilary,

Sure, I'll try to find a time for a call tomorrow with our (b)(4)

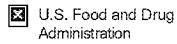
Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov



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From: Hilary Hovde <hhhovde@mmm.com>
Sent: Monday, May 15, 2023 6:34 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brad Bagley <bdbagley@mmm.com>; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review
Importance: High

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Hi Allan,

I have shared your request for additional information in regard to the (b)(4)

(b)(4)

I have copied Brad and Brendan (3M Regulatory Affairs Director and my direct manager) on this note as I would like to include them on the future call if you are able to accommodate this request.

Thank you for your guidance.

Best,
Hilary



Hilary M. Hovde | Regulatory Affairs Specialist – HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hhhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, May 15, 2023 4:29 PM
To: Hilary Hovde <hhhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Thank you, Hilary.

Please see below for additional deficiency regarding the (b)(4)

(b)(4)

(b)(4)

Please email me your response by COB tomorrow, 5/16.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Allan.Guan@fda.hhs.gov

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From: Hilary Hovde <hbhovde@mmm.com>
Sent: Monday, May 15, 2023 3:13 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
bhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, May 15, 2023 8:56 AM
To: Hilary Hovde <bhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Allan.Guan@fda.hhs.gov



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From: Guan, Allan
Sent: Tuesday, April 25, 2023 5:04 PM
To: 'Hilary Hovde' <bhovde@mmm.com>
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

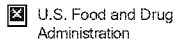
Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,
Allan

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Hi Allan,

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Thanks so much.

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 735 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, April 24, 2023 2:25 PM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Hi Hilary,

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Please provide your response as soon as possible.

Best regards,

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Biomedical Engineer / Team Lead

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Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

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Sent: Tuesday, April 25, 2023 4:04 PM

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Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

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(b)(4)

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Thanks so much.

Best,

Hilary

[cid:image007.gif@01D98711.B7196970]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, April 24, 2023 2:25 PM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

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We kindly request your response by 4/27.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

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Toxicology Assessment

(b)(4)

Revision: (b)(4)

Status: Release

Release Date: 04/10/2023

04:18:25 PM CDT

Page 1 of 59

Title: Toxicology Risk Assessment for 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise
Drape (contains 2% w/w CHG)

Document Name:

(b)(4)

Document Title: Toxicology Risk Assessment for 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise
Drape (contains 2% w/w CHG)

Effective From: 04/10/2023 04:18:25 PM CDT To:

(b)(4)

Document Name:

(b)(4)

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

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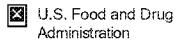
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Best regards,
Allan

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Biomedical Engineer / Team Lead

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Food and Drug Administration
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Silver Spring, MD 20993-0002
301-796-2851

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: October 19, 2022

Reviewer: Allan Guan

510(k)# K222578 Subject: Traditional

Applicant: 3M Company

Device Trade Name: 3M™ Ioban™ CHG
Chlorhexidine Gluconate Incise Drape (contains 2%
w/w CHG)

Contact Name: Hilary Hovde

Contact Title: Regulatory Affairs Specialist

Correspondent Firm: 3M Company

Phone: (651) 736-0364 **Email:**
hbhovde@mmm.com

Received Date: August 25, 2022

Due Date: November 23, 2022

Pro Code(s): KKK **Class:** II **Reg #:** 878.4370

Reg Name: Surgical Drape And Drape Accessories

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K140250	KKX	3m Steri-drape Chg Antimicrobial Incise Drape	3m Health Care

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Device Packaging Description

The 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape is a sterile, single use device that is individually packaged in a printed polyester pouch. A quantity of individually pouched devices and a copy of the Instructions for Use will be placed inside a printed paper cardstock primary carton. A quantity of primary cartons will be placed inside of a corrugated shipper with a shipping label. Please refer to the Labeling section of this 510(k) for images of the individual device pouch, the primary carton label, and the instructions for use.

The printing on the device is also provided in the Labeling section under “Other Labeling.” This includes printing on the drape film, the printed paper handle, the printed drape liner, and a printed paper drape wrapper that is discarded before use.

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Subject Matter Expert (SME) Review

Date: May 10, 2023

SME Reviewer: Keaton Nahan

Expertise: Chemical Characterization

Applicable Review Guide (if used): [Choose Review Guide]

Submission # K222578/S001

Applicant: 3M Company

Device Trade Name: 3M™
Ioban™ CHG Chlorhexidine
Gluconate Incise Drape (contains
2% w/w CHG)

Optional Classification Information:

Pro Code(s): KXX, PLY **Class:** II **Reg #:**
878.4370

Reg Name: Surgical Drape And
Drape Accessories

Rx/OTC: [Choose Option]

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Shelf Life

In order to support a shelf claim for the 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG), a shelf life study was initiated to evaluate both package integrity and critical performance characteristics to ensure that they are maintained throughout the labeled shelf life of the device as established by the predicate device. As presented in the Shelf Life Summary and Stability Reports, the 3M™ Ioban™ CHG Incise Drape currently has

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Study Information

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Overview of Shelf Life Testing

At each pull point, tests were completed to evaluate both package integrity and critical performance characteristics to ensure that they are maintained throughout the labeled shelf of the device as established by the predicate device. The following table summarizes the stability plan for the 3M™ Ioban™ CHG Incise Drape.

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Conclusion

The stability testing demonstrates that both the package integrity and the critical performance characteristics of the 3M™ Ioban™ CHG Incise Drape are maintained

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Hello Allan,

(b)(4)

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 735 0364 | Fax: 651 737 5320
hbhovde@mmm.com



-
-

From: Hilary Hovde
Sent: Thursday, May 18, 2023 8:33 AM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Good Morning Allan,

(b)(4)

Thanks,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 735 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Thursday, May 18, 2023 8:18 AM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Good morning Hilary,

(b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

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

Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



* * * * *

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From: Guan, Allan
Sent: Wednesday, May 17, 2023 3:36 PM
To: 'Hilary Hovde' <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Hi Hilary,

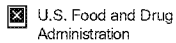
Thank you for providing your rationale and the prior Q-Sub feedback.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



* * * * *

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From: Hilary Hovde <hbhovde@mmm.com>
Sent: Wednesday, May 17, 2023 3:10 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>
Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hello Allan,

Thank you to you and the FDA team for the call today to discuss (b)(4)

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Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
bhovde@mmm.com



From: Hilary Hovde
Sent: Monday, May 15, 2023 2:13 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

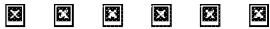
Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000

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

Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, May 15, 2023 8:56 AM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: Guan, Allan
Sent: Tuesday, April 25, 2023 5:04 PM
To: 'Hilary Hovde' <hbhovde@mmm.com>
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

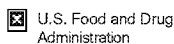
Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Ph: (301) 796-2851
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From: Hilary Hovde <hbhovde@mmm.com>
Sent: Tuesday, April 25, 2023 4:04 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov

Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call (b)(4) at your convenience as needed.

Thanks so much.

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist - HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
bhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, April 24, 2023 2:25 PM
To: Hilary Hovde <bhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

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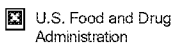
We kindly request your response by 4/27.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Document**

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Version: (b)(4)

Status: Release

Release Date: 06/30/2022 04:22:56 PM
CDT

Document Name:

(b)(4)

Document Title:

Results of Whole Package Integrity Testing for CHG Drape Stability

Released Date:

06/30/2022 04:22:56 PM CDT

Superseded Date:

Owner:

(b)(4)

Location:

3M MAPLEWOOD-3MUS-MN 3M HEADQUARTERS - 01J9C020

Approvals optional for this document

SIGNERS:

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Results of Whole Package Integrity Testing for CHG Drape Stability

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Thank you, Hilary.

Please see below for additional deficiency regarding the (b)(4)

(b)(4)

Please email me your response by COB tomorrow, 5/16.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Allan.Guan@fda.hhs.gov

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From: Hilary Hovde <hbhovde@mmm.com>
Sent: Monday, May 15, 2023 3:13 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,
Hilary



Hilary M. Hovde | Regulatory Affairs Specialist – HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hhovde@mmm.com



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Hi Hilary,

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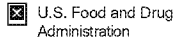
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Best regards,
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To: 'Hilary Hovde' <hbhovde@mmm.com>
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

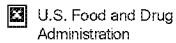
Thank you, Hilary. I will let you know if we have any additional questions.

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Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

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

Office: 651 736 0364 | Fax: 651 737 5320
hbhoyde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, April 24, 2023 2:25 PM
To: Hilary Hovde <hbhoyde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
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Allan.Guan@fda.hhs.gov



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3M Corporate Toxicology & Environmental Science
3M Center, Bldg. 220-6E-03
Saint Paul, Minnesota 55144

CONFIDENTIAL

STUDY TITLE

ISO Skin Irritation Study in Rabbits

TEST ARTICLE NAME

(b)(4)

TEST ARTICLE IDENTIFICATION

(b)(4)

3M STUDY NUMBER

(b)(4)

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GLP PROTOCOL

TEST FACILITY

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3M Corporate Toxicology & Environmental Science
3M Center, Bldg. 220-6E-03
St. Paul, Minnesota 55144

STUDY TITLE

ISO Skin Irritation Study in Rabbits

TEST ARTICLE

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TEST ARTICLE IDENTIFICATION

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3M STUDY NUMBER

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Page 1 of 4

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**R & D Supporting
Document**

(b)(4)

Version: (b)(4)

Status: Release

Release Date: 06/30/2022 04:32:17 PM
CDT

Document Name:

(b)(4)

Document Title:

Results of Fluid Penetration for CHG Drape Stability

Released Date:

06/30/2022 04:32:17 PM CDT

Superseded Date:

Owner:

Location:

(b)(4)

Approvals optional for this document

SIGNERS:

(b)(4)

Results of Fluid Penetration for CHG Drape Stability

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

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3M
Confidential**EtO Sterilization Validation
Protocol & Report****(b)(4)**Version: **(b)(4)**

Status: Release

Page 1 of 39

Release Date: 06/22/2022 11:30:27 AM
CDT

Document Name:

(b)(4)

Document Title:

3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (Contains 2% CHG):

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Released Date:

06/22/2022 11:30:27 AM CDT

Superseded Date:

Owner:

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Location:

Location Name	Description
(b)(4)	

Approvers:

SIGNERS:

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3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (Contains 2% CHG): Product Adoption into

(b)(4)**(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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TRADITIONAL PREMARKET NOTIFICATION [510(k)]
3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)

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U.S. FOOD & DRUG
ADMINISTRATION

May 18, 2023

3M Company
Hilary Hovde
Regulatory Affairs Specialist
2510 Conway Ave.
Building 275-5W-06
St. Paul, Minnesota 55144

Re: K222578

Trade/Device Name: 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)

Regulation Number: 21 CFR 878.4370

Regulation Name: Surgical Drape And Drape Accessories

Regulatory Class: Class II

Product Code: KKKX

Dated: April 14, 2023

Received: April 14, 2023

Dear Hilary Hovde:

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 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,


Bifeng Qian -S

Bifeng Qian, M.D., 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

Good Morning Allan,

(b)(4)

Thanks,

Hilary

[cid:image007.gif@01D98963.67E615C0]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

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From: Guan, Allan <Allan.Guan@fda.hhs.gov>

Sent: Thursday, May 18, 2023 8:18 AM

To: Hilary Hovde <hbhovde@mmm.com>

Cc: K222578@docs.fda.gov

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Good morning Hilary,

(b)(4)

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of
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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, Bldg. 66 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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From: Guan, Allan

Sent: Wednesday, May 17, 2023 3:36 PM

To: 'Hilary Hovde' <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Qian, Bifeng
<Bifeng.Qian@fda.hhs.gov<mailto:Bifeng.Qian@fda.hhs.gov>>; Murray III, Clarence
<Clarence.Murray@fda.hhs.gov<mailto:Clarence.Murray@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Hi Hilary,

Thank you for providing your rationale and the prior Q-Sub feedback.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Wednesday, May 17, 2023 3:10 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov<mailto:Bifeng.Qian@fda.hhs.gov>>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov<mailto:Clarence.Murray@fda.hhs.gov>>

Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hello Allan,

Thank you to you and the FDA team for the call today to discuss

(b)(4)

(b)(4)

(b)(4)

Best Regards,

Hilary

[cid:image007.gif@01D98963.67E615C0]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

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hbhovde@mmm.com<mailto:hbhovde@mmm.com>

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From: Hilary Hovde

Sent: Monday, May 15, 2023 2:13 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,

Hilary

[cid:image007.gif@01D98963.67E615C0]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, May 15, 2023 8:56 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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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Ph: (301) 796-2851

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From: Guan, Allan

Sent: Tuesday, April 25, 2023 5:04 PM

To: 'Hilary Hovde' <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Tuesday, April 25, 2023 4:04 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a
quick call **(b)(6)** at your convenience as needed.

Thanks so much.

Best,

Hilary

[cid:image007.gif@01D98963.67E615C0]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, April 24, 2023 2:25 PM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of
Surgical and Infection Control Devices

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Ph: (301) 796-2851

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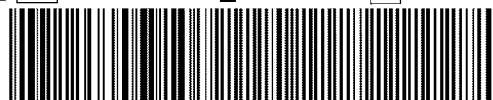
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an Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)

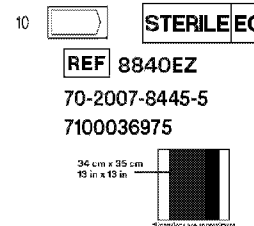
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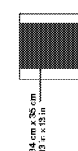
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Version: (b)(4)

Status: Release

Release Date: 07/01/2022 12:43:22 PM
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Document Name:

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Document Title:

Results of Adhesion to Steel Testing for CHG Drape Stability

Released Date:

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Results of Adhesion to Steel Testing for CHG Drape Stability

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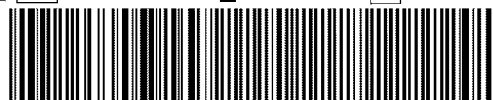
3M | Ioban™ CHG

an Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)

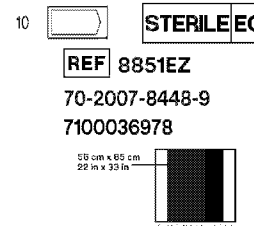
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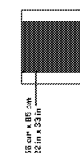
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(01)30707387771493(11)000000(17)000000(10)0000000000



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BIOCOMPATIBILITY REVIEW OF K222578, 3M COMPANY

To: Allan Guan, CDRH/OPEQ/OHT4/OHT4B2

From: Sojan Abraham, CDRH/OPEQ/OHT4/OHT4B1

Through: Clarence Murray III, Assistant Director, CDRH/OPEQ/OHT4/OHT4B1

Consult Type: Biocompatibility

Consult : CON2220198

Submission : K222578

Device Name: 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape

Sponsor: 3M Company

Date: 10/13/2022

(b)(5)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Sojan Abraham-S

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Version (b)(4)

Status: Release

Release Date: 07/01/2022 12:46:02 PM
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Document Name:

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Document Title:

Results of CHG and PCA content for CHG Drape Stability

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Results of CHG and PCA content for CHG Drape Stability

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Hi Hilary,

Does 10:30am ET work?

Thanks,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

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From: Hilary Hovde <hbhovde@mmm.com>

Sent: Tuesday, May 16, 2023 8:41 AM

To: Guan, Allan <Allan.Guan@fda.hhs.gov>

Cc: K222578@docs.fda.gov; Brad Bagley <bdbagley@mmm.com>; Brendan Casey <bcasey@mmm.com>

Subject: [EXTERNAL] RE: RE: RE: RE: RE: RE: K222578/S001 interactive review

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Hi Allan,

Would it at all be possible to move the meeting back one hour to 10:00 AM ET? We have a mandatory meeting on our side that was scheduled abruptly for 9:00 AM ET.

I apologize, but hope this will work.

Thanks,

Hilary

[cid:image014.gif@01D987D3.5021EC70]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com<mailto:hbhovde@mmm.com>

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Tuesday, May 16, 2023 7:32 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brad Bagley
<bdbagley@mmm.com<mailto:bdbagley@mmm.com>>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Good morning Hilary,

This is to confirm the meeting today at 9am ET.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of
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From: Hilary Hovde <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

Sent: Monday, May 15, 2023 9:22 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<<mailto:Allan.Guan@fda.hhs.gov>>>

Cc: K222578@docs.fda.gov<<mailto:K222578@docs.fda.gov>>; Brad Bagley
<bdbagley@mmm.com<<mailto:bdbagley@mmm.com>>>; Brendan Casey
<bcasey@mmm.com<<mailto:bcasey@mmm.com>>>

Subject: [EXTERNAL] RE: RE: RE: RE: K222578/S001 interactive review

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Thanks Allan,

I appreciate it.

I have accepted the invite and understand it is subject to change.

Best,

Hilary

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Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
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From: Guan, Allan <Allan.Guan@fda.hhs.gov<<mailto:Allan.Guan@fda.hhs.gov>>>

Sent: Monday, May 15, 2023 6:55 PM

To: Hilary Hovde <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

Cc: K222578@docs.fda.gov<<mailto:K222578@docs.fda.gov>>; Brad Bagley
<bdbagley@mmm.com<<mailto:bdbagley@mmm.com>>>; Brendan Casey
<bcasey@mmm.com<<mailto:bcasey@mmm.com>>>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hi Hilary,

Sure, I'll try to find a time for a call tomorrow with our

(b)(4)

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Monday, May 15, 2023 6:34 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brad Bagley <bdbagley@mmm.com<mailto:bdbagley@mmm.com>>; Brendan Casey <bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

Importance: High

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Hi Allan,

I have shared your request for additional information in regard to the

(b)(4)

(b)(4)

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

(b)(4)

I have copied Brad and Brendan (3M Regulatory Affairs Director and my direct manager) on this note as I would like to include them on the future call if you are able to accommodate this request.

Thank you for your guidance.

Best,
Hilary

[cid:image014.gif@01D987D3.5021EC70]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, May 15, 2023 4:29 PM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Thank you, Hilary.

Please see below for additional deficiency regarding the (b)(4)

(b)(4)

(b)(4)

Please email me your response by COB tomorrow, 5/16.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Monday, May 15, 2023 3:13 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,

Hilary

[cid:image014.gif@01D987D3.5021EC70]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, May 15, 2023 8:56 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

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

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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From: Guan, Allan

Sent: Tuesday, April 25, 2023 5:04 PM

To: 'Hilary Hovde' <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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From: Hilary Hovde <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

Sent: Tuesday, April 25, 2023 4:04 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<<mailto:Allan.Guan@fda.hhs.gov>>>

Cc: K222578@docs.fda.gov<<mailto:K222578@docs.fda.gov>>

Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,

Hilary

[cid:image014.gif@01D987D3.5021EC70]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, April 24, 2023 2:25 PM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices

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Version:

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Document Title:
Concentration

Results of CHG Drape Verification Testing for Minimum Effective

Released Date:

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(b)(4)

Hello Allan,

Based on our phone call yesterday, the

(b)(4)

(b)(4)

Please see the attached file

(b)(4)

(b)(4)

Best,

Hilary

[cid:image001.gif@01D98894.534E7B90]

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From: Guan, Allan <Allan.Guan@fda.hhs.gov>

Sent: Monday, May 15, 2023 4:29 PM

To: Hilary Hovde <hbhovde@mmm.com>

Cc: K222578@docs.fda.gov

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Thank you, Hilary.

Please see below for additional deficiency regarding the

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(b)(4)

(b)(4)

Please email me your response by COB tomorrow, 5/16.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Monday, May 15, 2023 3:13 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,

Hilary

[cid:image001.gif@01D98894.534E7B90]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, May 15, 2023 8:56 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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From: Guan, Allan

Sent: Tuesday, April 25, 2023 5:04 PM

To: 'Hilary Hovde' <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices

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Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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From: Hilary Hovde <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

Sent: Tuesday, April 25, 2023 4:04 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<<mailto:Allan.Guan@fda.hhs.gov>>>

Cc: K222578@docs.fda.gov<<mailto:K222578@docs.fda.gov>>

Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,

Hilary

[cid:image001.gif@01D98894.534E7B90]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>

[cid:image007.png@01D98894.534E7B90]<<https://twitter.com/3m>>[cid:image008.png@01D98894.534E7B90]<<https://www.linkedin.com/company/3m>>[cid:image009.png@01D98894.534E7B90]<<https://www.facebook.com/3MCorporate>>[cid:image010.png@01D98894.534E7B90]<<https://instagram.com/3m/>>[cid:image011.png@01D98894.534E7B90]<<https://www.youtube.com/3m>>[cid:image012.

From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, April 24, 2023 2:25 PM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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Records processed under FOIA Request 2024-1745; Released by CDRH on 08-26-2024
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TRADITIONAL PREMARKET NOTIFICATION [510(k)]
3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)

510(k) Summary for
3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape
(contains 2% w/w CHG)

K222578

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)



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ADMINISTRATION

Build Correspondence

Convert to PDF

April 2, 2024

3M Company
Hilary Hovde
Regulatory Affairs Specialist
2510 Conway Ave.
Building 275-5W-06
St. Paul, Minnesota 55144

Re: K222578

Trade/Device Name: 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)

Regulation Number: 21 CFR 878.4370

Regulation Name: Surgical Drape And Drape Accessories

Regulatory Class: Class II

Product Code: KKK

Dated: April 14, 2023

Received: April 14, 2023

Dear Hilary Hovde:

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 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.**

Bifeng Qian, M.D., 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



electronic Submission Template And Resource (eSTAR)

For non-In Vitro Diagnostic Medical Devices

Version 2.0 (2022-06-06)

STATUS: eSTAR COMPLETE

Introduction

This template is intended for use in both constructing a non-*in vitro* diagnostic medical device premarket application/submission, and in being a resource of non-*in vitro* medical device premarket regulations. It contains regulatory information pulled from both International Medical Device Regulators Forum (IMDRF) documents, as well as regulatory documents (e.g., guidance documents).

This template is only used for constructing, not submitting, your application or submission. Directions at the end of the template provide instructions on how to submit it.

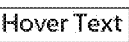
Key

A Red Bar indicates the associated required question, or a required question in that section, wasn't answered.

A Green Bar indicates the associated required question, or all required questions in that section, was answered.

A Grey Bar indicates the associated question is optional. Green and Grey Bars act as left borders when present.

 Blue Help Text Buttons when clicked display regulatory information pertaining to the question or section heading they immediately follow. Assistive Technology (AT) users including text to speech, will hear "Help Text Button." If activated, the help text windows will open, and can be closed by tabbing to the OK key and pressing return.

 Hover text displays information about your application, such as the date an attachment was attached, or, if the section corresponds to an [IMDRF](#) harmonized section, the hover text will display the chapter number of the [IMDRF Table of Contents](#).

FAQ

Q: Where can I send questions, feedback, and/or bug reports?

A: Send questions and feedback to DICE@fda.hhs.gov and bug reports to eSubPilot@fda.hhs.gov.

Q: When I click on a bookmark, the view jumps to the beginning of eSTAR. Why did this happen?

A: The bookmarked section is not applicable based on your submission choices and therefore should be ignored.

Q: Is there an attachment type or size restriction?

A: eSTAR will prevent unacceptable attachment types from being added. We tested eSTAR submissions up to 1GB in size. If your eSTAR is greater than 1GB, file handling may be delayed. Large attachments will increase save times.

Q: If an eSTAR is signed, a message is displayed at the top saying changes were made after signing. Why?

Version History

A major version update will consist of policy changes, regulatory changes, or major changes to the template and will be denoted by a major version number increment (e.g., 1.2 to 2.0). A minor version update will consist of other changes and will be denoted by a minor version number increment (e.g., 1.2 to 1.3). eSTARs updated with policy or regulatory changes will be made available before the implementation date of those changes, and the previous eSTAR will be removed on the implementation date. **Be sure you submit using the major version that is currently implemented, otherwise you may receive additional information requests related to the changes.**

Version History

2.0 (2022-06-06): Bug fixed where clinical trials forms would incorrectly display if the user chose Traditional and

Application/Submission Type

If none of the attachments to a question are relevant to the question, or if an inaccurate response is provided to any question, the submission may be put on an early Technical Screening hold, which would request correction of these inadequacies. Examples of responses that would place the submission on a Technical Screening hold include: stating "0" wireless functions are used, but wireless functions are used by the device, improperly indicating device(s) changes are appropriate for a Special 510(k), improper citation of attachments or page numbers in text boxes, stating "N/A" in text boxes that are applicable. An example of an irrelevant attachment includes providing attachments to the software description question none of which contains a software description. FDA may also put the submission on hold if an English translation for any documentation provided is not included.

The content of this template complements the FDA reviewer's smart template used in reviewing submissions, and therefore this template will provide the reviewers what they are expecting. This may reduce the number of inconsistencies and omissions in your application/submission documents, and therefore the number of additional information requests the FDA may send to you.

Application Purpose	☒ Premarket Notification 510(k) ☐ De Novo ☐ Premarket Application PMA	?
Show Application Introduction		
Application Type (Choose Abbreviated if you are submitting a Safety & Performance based submission.)	☒ Traditional ☐ Abbreviated ☐ Special	
Show Application Type Introduction		
Application Sub-Type (Modify the Original eSTAR when responding to Additional Information requests. See Help Text)	☒ New Application/Submission ☐ Additional Information	?

Cover Letter / Letters of Reference

Add Attachment Attach your Cover Letter ?
Open Attachment Cover Letter.pdf Delete Attachment
Add Attachment Attach any Letters of Reference ?

Applicant Information

Contact

Title Ms. Last Name Hovde First Name Hilary
Email hbhovde@mmm.com Phone Number 651-736-0364
Occupation Title Regulatory Affairs Specialist

Company

Company Name 3M Company
Address - Line 1 2510 Conway Ave.
Address - Line 2 Building 275-5W-06
City St. Paul State MN Zip 55144 Country/Region United States

Add Correspondent/Consultant

Pre-Submission Correspondence & Previous Regulator Interaction

Are there prior related submissions or regulator interaction for the subject device(s)? Yes ?

Add Submission Please provide the submission number(s) of prior related submission(s) as defined above, regardless of outcome. If none, type "N/A."

(b)(4)

Delete Submission

Add Attachment

Please upload copies of prior regulatory feedback (e.g., letter, meeting minutes, submission feedback) regarding this device and/or data and/or information to support this submission. Please specify the location in the current submission where additional information requests in prior submissions were addressed, or provide a rationale for not responding to those additional information requests.

Open Attachment

(b)(4)

Delete Attachment

Open Attachment

Delete Attachment

Standards

Add Standard

Please list the standards used in your submission (if any). If only certain sections were used, or there were deviations, cite these in an attachment. The recognition number is only applicable to certain regulators, see help text. Instead of typing in information, some regulators use drop-downs populated with their recognized Standards.

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

ISO	10993-1 Fifth edition 2010-08-01	2-258	Delete Standard
Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process			
Are you using this standard for general use, or are you declaring conformity to it?		General Use	?
Add Attachment	Standards Details / Supplemental Documentation per ISO/IEC 17050-2		?
Add Standard			
ISO	10993-5 Third edition 2009-06-01	2-245	Delete Standard
Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity			
Are you using this standard for general use, or are you declaring conformity to it?		General Use	?
Add Attachment	Standards Details / Supplemental Documentation per ISO/IEC 17050-2		?
Add Standard			
ISO	10993-10 Third Edition 2010-08-01	2-174	Delete Standard
Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization			
Are you using this standard for general use, or are you declaring conformity to it?		General Use	?
Add Attachment	Standards Details / Supplemental Documentation per ISO/IEC 17050-2		?
Add Standard			
ISO	10993-11 Third edition 2017-09	2-255	Delete Standard
Biological evaluation of medical devices - Part 11: Tests for systemic toxicity			
Are you using this standard for general use, or are you declaring conformity to it?		General Use	?
Add Attachment	Standards Details / Supplemental Documentation per ISO/IEC 17050-2		?
Add Standard			
ISO	10993-12 Fourth edition 2012-07-01	2-191	Delete Standard
Biological evaluation of medical devices - Part 12: Sample preparation and reference materials			
Are you using this standard for general use, or are you declaring conformity to it?		General Use	?
Add Attachment	Standards Details / Supplemental Documentation per ISO/IEC 17050-2		?
Add Standard			
ISO	11135 Second edition 2014-07-15	14-529	Delete Standard
Sterilization of health-care products - Ethylene oxide - Requirements for the development validation and routine c			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI@FDA.HHS.gov or 301-796-8118

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General Use

Add Attachment

Standards Details / Supplemental Documentation per ISO/IEC 17050-2

Add Standard

ISO

11737-1 Third edition 2018-01

14-514

Delete Standard

Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms

Are you using this standard for general use, or are you declaring conformity to it?

General Use

Add Attachment

Standards Details / Supplemental Documentation per ISO/IEC 17050-2

Add Standard

ISO

11737-2 Third edition 2019-12

14-540

Delete Standard

Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition validation

Are you using this standard for general use, or are you declaring conformity to it?

General Use

Add Attachment

Standards Details / Supplemental Documentation per ISO/IEC 17050-2

Add Standard

ISO

10993-17 First edition 2002-12-01

2-237

Delete Standard

Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances

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General Use

Add Attachment

Standards Details / Supplemental Documentation per ISO/IEC 17050-2

Add Standard

ISO

21387 2020

Recognition #

Delete Standard

Sterilization of medical devices - Guidance on the requirements for the validation and routine processing of ethylene oxide

Are you using this standard for general use, or are you declaring conformity to it?

General Use

Add Attachment

Standards Details / Supplemental Documentation per ISO/IEC 17050-2

Add Standard

AAMI

TIR 28:2016

Recognition #

Delete Standard

Product adoption and process equivalence for ethylene oxide sterilization

Are you using this standard for general use, or are you declaring conformity to it?

General Use

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

[Add Attachment](#)[Standards Details / Supplemental Documentation per ISO/IEC 17050-2](#)

?

[Add Standard](#)

AAMI

TIR 16:2017

Recognition #

[Delete Standard](#)

Process Development and Performance Qualification for Ethylene Oxide Sterilization - Microbiological Aspects

Are you using this standard for general use, or are you declaring conformity to it?

General Use

?

[Add Attachment](#)[Standards Details / Supplemental Documentation per ISO/IEC 17050-2](#)

?

[Add Standard](#)

AAMI

TIR 14:2016

Recognition #

[Delete Standard](#)

Contract Sterilization for Ethylene Oxide

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General Use

?

[Add Attachment](#)[Standards Details / Supplemental Documentation per ISO/IEC 17050-2](#)

?

[Add Standard](#)

ASTM

F2096-11 (Reapproved 2019)

14-359

[Delete Standard](#)

Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)

Are you using this standard for general use, or are you declaring conformity to it?

General Use

?

[Add Attachment](#)[Standards Details / Supplemental Documentation per ISO/IEC 17050-2](#)

?

[Add Standard](#)

ANSI AAMI

PB70:2012

6-296

[Delete Standard](#)

Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities

Are you using this standard for general use, or are you declaring conformity to it?

General Use

?

[Add Attachment](#)[Standards Details / Supplemental Documentation per ISO/IEC 17050-2](#)

?

[Add Standard](#)

ASTM

F1670/F1670M-17

6-402

[Delete Standard](#)

Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood

Are you using this standard for general use, or are you declaring conformity to it?

General Use

?

[Add Attachment](#)[Standards Details / Supplemental Documentation per ISO/IEC 17050-2](#)

?

[Questions? Contact FDA/CDRH/OCE/DATUS at \[fdacus@fda.hhs.gov\]\(mailto:fdacus@fda.hhs.gov\) or 301-796-8118](#)

ASTM	E2315-16	Records processed under FOIA Request 2024-1745; Released by CDRH on 08/26/2024	Recognition #	Delete Standard
Standard Guide for Assessment of Antimicrobial Activity Using a Time-Kill Procedure				
Are you using this standard for general use, or are you declaring conformity to it?			General Use	?
Add Attachment	Standards Details / Supplemental Documentation per ISO/IEC 17050-2			?
Add Standard				

Device Description

Listing of Device(s)

Add Device

Provide the Product Trade Name and (optionally) Model Number/Name

3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)

8840EZ, 8850EZ, 8851EZ

Delete Device

General Device Characteristics

Is the device life-supporting or life-sustaining?

No

Are there any direct or indirect tissue contacting components?

Yes

• Is the device or a component an implant?

No

Does the device use software/firmware?

No

Is the device or a component packaged as sterile?

Yes

The device/system uses or is... (choose all that apply)

- ☒ a single use device(s), non-sterile or packaged as sterile
☐ a single use device(s), terminal/end user sterilized
☐ a reusable single patient use device(s)
☐ a reusable multi-patient use device(s)

The environment of use of the device/system includes... (choose all that apply)

- ☒ Professional Healthcare Facility
☐ Home Environment
☐ Magnetic Resonance (MR) Environment
☐ Transport (Ambulatory) Environment
☐ Other Environment

Is the device a combination product?

Yes

• If a Request for Designation (RFD) number exists, please provide the RFD number that established that the device or combination product being submitted here was assigned to CDRH.

• Does the combination product contain as a constituent part an approved drug as defined in section 503(g)(5)(B) of the FD&C Act?

Yes

Add Attachment

Please include appropriate patent statement or certification and a statement that the applicant will give notice to the patent related owner and holder, as applicable.

Open Attachment

Patent Statement.pdf

Delete Attachment

Is the device electrical (battery or wall powered)?

No, the device is not electrical

Please check the attributes that are applicable to your device. If none apply, keep all unchecked.

- ☐ Medical Counter Measures Device
☐ Nanotechnology
☐ Reprocessed Single Use Device
☐ Animal-Derived Material(s)

Description

Please provide a Device Description Summary below, and ensure it includes an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as device design, material used, and physical properties.

If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), you must provide this device description information in the textbox below, in accordance with 21 CFR 807.92(a)(4). The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE DEVICE DESCRIPTION SUMMARY TEXTBOX BELOW. CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).

The 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG) is a sterile adhesive film that is applied pre-operatively to skin. It adheres and conforms to body contours, providing a sterile surface on top of the skin prior to surgery. The surgeon incises through the adhesive film and skin, ensuring a sterile film barrier all the way to the edge of the incision. The Chlorhexidine Gluconate (CHG) contained in the adhesive provides antibacterial activity to help reduce the risk of bacterial contamination in the surgical wound.

The drape consists of a transparent, conformable, breathable, barrier film coated with an acrylic adhesive containing 2% w/w CHG. The adhesive drape is delivered on a release liner that is discarded after application.

Add Attachment	Comprehensive Device Description and Principles of Operation Documentation	?
Open Attachment	Device Description.pdf	Delete Attachment
Add Attachment	Device Pictures, Illustrations, Schematics, and/or Diagrams. Attach a justification if the device does not have a physical form.	
Open Attachment	Device Picture.pdf	Delete Attachment
Open Attachment	Device Construction Schematic.pdf	Delete Attachment
Add Attachment	Description of Device Packaging	?
Open Attachment	Device Packaging Description.pdf	Delete Attachment

Accessories

Is the device intended to be marketed with accessories? ?

Guidance and Special Controls Adherence

Please cite the attachment(s) and page number(s) of any information you provided demonstrating special controls or device specific guidance adherence in this section. Please use the primary product code you will provide in the Classification section below to determine whether a device specific guidance or special controls exists for your device. Type "N/A" if no device specific guidance or special controls exist for your device type. If you type "N/A," and special controls or a device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

Primary Product Code KXX and parts of the Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes, August 1993 which is written more generally for surgical drapes rather than incise drapes that incorporate an antibacterial agent.

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls, please provide a rationale for this alternative approach below.

Indications for Use

Submission Number (if known)

Device Name

3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)

Indications for Use (Describe)

3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG) is indicated for use as an incise drape with continuous antibacterial activity based on in vitro time kill data out to 90 minutes. It is intended for external use only.

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
PRASStaff@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."

Classification

Add a primary product code and any associated product codes below. You may type in the primary product code directly (only the product code field is required) or you may filter down by choosing first a medical specialty, regulation, then product code. If a device specific guidance is available for the product code, the guidance name and web link will be displayed. Use the Product Classification Website resource in the help text to obtain information about your product code and check the regulation text for any special controls that need to be considered (e.g, PAE and 21 CFR 890.3450).

Medical Specialty

Regulation

Product Code

The primary product code of your device indicates a device specific guidance document is available to aid you in preparing a comprehensive submission. The document entitled "Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes" is available at the link below. If you have any questions about applicability of this guidance, please contact the CDRH review Office.

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-premarket-notification-510k-submissions-surgical-gowns-and-surgical-drapes>

Associated Product Code(s)

Predicates and Substantial Equivalence

Predicate and Reference Devices

Primary Predicate

Is this a Preamendments or Exempt device without a submission number?

No

Predicate Submission Number (e.g., K210001)

K140250

Predicate Device Trade Name

3M™ Steri-Drape™ CHG Antimicrobial Incise Drape

Predicate Device Primary Product Code

Medical Specialty General & Plastic Surgery

Regulation 878.4370 - Surgical drape and drape accessories

Product Code KXX (Class 2) - Drape, Surgical

Add Predicate/Reference Device

Delete Predicate/Reference Device

Substantial Equivalence Comparison

If the device has different indications for use in comparison to the predicate device(s), describe why the differences do not constitute a new intended use. If the indications for use are the same, state this in the text box below.

If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), and the Indications are different in comparison to your predicate device(s), you must include the information from 21 CFR 807.92(a)(5) in this rationale. The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

**ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE RATIONALE TEXTBOX BELOW.
CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).**

Both the subject and predicate devices are intended to be used as surgical incise drape. The CHG contained in the adhesive of both devices provides antimicrobial/antibacterial activity to help reduce the risk of bacterial contamination in the surgical wound. Minor differences in indications for use do not alter the fundamental intended use of these devices as surgical incise drapes containing CHG to help reduce the risk of contamination at the surgical site and do not raise new questions of safety and effectiveness.

If the device has the same technological characteristics (i.e., design, material, chemical composition, principle of operation, energy source, etc.) as the predicate device(s) identified above, include a summary in the memo box below of the technological characteristics of the new device in comparison to those of the predicate device(s). Or, if the device has different technological characteristics from the predicate device(s), include a summary of how the technological characteristics of the device compare to a legally marketed device(s) identified above.

If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), you must include the information from 21 CFR 807.92(a)(6) in this rationale. The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

**ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE DESCRIPTION TEXTBOX BELOW.
CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).**

Questions? Contact FDA CDRH FOIA at CDHR-FOIA@fda.hhs.gov or 800-735-0118

The submission and predicate device have differences in technological characteristic such as differences in materials and design. However these differences do not raise new or different questions of safety and effectiveness and were evaluated through biocompatibility and performance testing. The performance testing completed was in alignment with the predicate device. The performance data demonstrated substantial equivalence.

Add Attachment	Please attach your Substantial Equivalence Comparison in tabular format. Please ensure the table(s) includes a comparison of the Indications for Use as well as a comparison of the pertinent technology characteristics of your device and your predicate device(s). If your submission is intended for the safety and performance pathway, then you should satisfy the Substantial Equivalence comparison as outlined in the relevant guidance. Please open the link in the help text for more information.	?
Open Attachment	Substantial Equivalence.pdf	Delete Attachment

General Labeling	
If a symbols glossary was used, please specifically cite the attachment and page number where it is located in the labeling (type "N/A" if not used). Be aware that if a glossary was not used, the symbols should be described in adjacent text (if applicable, see Help Text).	Please refer to attachment under Package Insert/Instructions for Use labeled IFU_3M Ioban CHG Drape.pdf
What is the Magnetic Resonance (MR) safety status for the device(s) in the submission?	Not Needed

Add Attachment	Please attach copies of packaging that demonstrate the labeling of any applicable packaging used in the transportation of the device. This includes, but is not limited to, the device packaging and sterile packaging.	?
Open Attachment	Device Pouch_8840EZ.pdf	Delete Attachment
Open Attachment	Device Pouch_8850EZ.pdf	Delete Attachment
Open Attachment	Device Pouch_8851EZ.pdf	Delete Attachment
Open Attachment	Primary Carton_all models.pdf	Delete Attachment
Open Attachment	Primary Carton Label_8840EZ.pdf	Delete Attachment
Open Attachment	Primary Carton Label_8850EZ.pdf	Delete Attachment
Open Attachment	Primary Carton Label_8851EZ.pdf	Delete Attachment

Add Attachment	Please attach copies of the User Instructions, Inserts, Directions for Use and/or Instructions for Use that are intended for use with your device. This includes instructions that may be downloaded or viewed on a website.	?
Open Attachment	IFU_3M Ioban CHG Drape.pdf	Delete Attachment

Add Attachment Choose the attachment type in the dropdown for each attachment. Click the help text button to the right for an explanation of each option.

[Open Attachment](#) Printing on Drape Film_all models.pdf [Delete Attachment](#)

[Open Attachment](#)
[Printed Draper Handle all models.pdf](#)
[Questions - Contact FDA CDRH/CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118](#)
[Delete Attachment](#)

Open Attachment

Printing on Drape Liner_all models.pdf

Delete Attachment

Open Attachment

Printing on Drape Wrapper_all models.pdf

Delete Attachment

Specific Labeling		
Please specifically cite the attachment and page number where the prescription statement or "Rx only" exists in the labeling.	"Rx only" is on the device pouch and the primary carton label.	+ ?
Please specifically cite the attachment and page number where the Indications for Use exists in the labeling.	Please refer to attachments under Package Insert/Instructions for Use	+
Please specifically cite the attachment and page number where the name and place of business of the manufacturer, packer, or distributor is located.	The name and place of business of the manufacturer is located on the device pouch, the primary carton	+ ?

Guidance and Special Controls Adherence

Please cite the attachment(s) and page number(s) of any information you provided demonstrating special controls or device specific guidance adherence in this section. Please use the primary product code you listed in the Classification section above to determine whether a device specific guidance or special controls exists for your device. Type "N/A" if no device specific guidance or special controls exist for your device type. If you type "N/A," and special controls or a device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes, August 1993, Section II, Part C, pages 6-7

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls, please provide a rationale for this alternative approach below.

Reprocessing, Sterility, and Shelf-Life

Based on the answers provided in the Device Description section, sterility information, but no reprocessing information, is needed.

Sterility

How many sterilization methods are there (maximum of 4)?

1

Sterilization Method 1

Identify the device(s) / accessory(ies) / component(s) that is sterilized.

3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape in a sterile barrier pouch.

What is the Sterilization Method?

Ethylene Oxide (EO, EtO) (Est A)

What are the maximum levels of sterilant residuals that remain on the device?

(b)(4)

What standard(s) were used for validation?

ISO 11135:2014/A+ 2019: Sterilization of healthcare products – Ethylene Oxide - Requirements for development, validation, and routine control of a sterilization process for medical devices.
ANSI/AAMI/ISO 11737-1:2018: Sterilization of Medical Devices – Microbiological Methods – Part 1: Estimation of population of microorganisms on products.
ANSI/AAMI/ISO 11737-2:2019: Sterilization of Medical Devices – Microbiological Methods – Part 2: Tests of sterility performed in the validation of a sterilization process.
ISO 10993-7:2008/FDAM 1:2019: Biological evaluation of medical devices Part 7: Ethylene oxide sterilization residuals.
ISO 10993-17:2002. Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances.
ISO 21387: 2020 Sterilization of medical devices – Guidance on the requirements for the validation and routine processing of ethylene oxide sterilization processes using parametric release.
AAMI TIR 28:2016: Product adoption and process equivalence for ethylene oxide sterilization
AAMI TIR 16:2017: Process Development and Performance Qualification for Ethylene Oxide Sterilization
AAMI TIR 14:2016: Contract Sterilization for Ethylene Oxide

What validation method was used for the sterilization cycle?

(b)(4)

What is the Sterility Assurance Level (SAL)?

10⁻⁶

If a device within the submission should be "Non-Pyrogenic," or if you are asserting a device is "Non-Pyrogenic," what is the pyrogenicity test method?

(b)(4)

Please provide a description of the packaging, the materials used, and a description of the package test methods.

The packaging consists of polyester film/uncoated Tyvek pouch.

Please cite the attachment(s) and page number(s) of any information you provided demonstrating special controls or device specific guidance adherence for reprocessing or sterility. Please use the primary product code you listed in the Classification section above to determine whether a device specific guidance or special controls exists for your device. Type "N/A" if no device specific guidance or special controls exist for your device type. If you type "N/A," and special controls or a device specific guidance exists that requests information covered by these review sections, the time-line for review of your file may be affected.

Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes, August 1993, Section II, Part H, pages 10-11

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls regarding reprocessing or sterility, provide a rationale for this alternative approach below.

Shelf-Life

Does your device have a shelf-life?

Yes

?

What is the proposed shelf-life?

(b)(4)

Please include a summary of the methods used to support the sterility and performance of the device over its proposed shelf-life. Alternatively, please provide a rationale for why testing to establish shelf-life is not applicable.

In order to support a shelf claim for the 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape, a shelf life study was initiated to evaluate both package integrity and key performance characteristics are maintained throughout the labeled shelf life of the device. As presented in the Shelf Life Summary and Reports, the CHG drape (b)(4)

(b)(4)

Please refer to the Shelf Life Summary and Reports in the attachments under Reprocessing, Sterility, and Shelf Life Documents for additional details.

Reprocessing, Sterility, and Shelf-Life Documents

Add Attachment

Please attach any Sterility, Cleaning, Shelf-Life and Reuse documentation that you believe is pertinent to the review of your device. Choose the attachment type in the dropdown for each attachment.

?

Manufacturer Sterilization

Open Attachment

Sterilization Validation Protocol and Report.pdf

Delete Attachment

Product Stability

Open Attachment

Shelf Life Summary.pdf

Delete Attachment

Product Stability

Open Attachment

Bubble Leak Test Report.pdf

Delete Attachment

Product Stability

Open Attachment

Peelable Package Report.pdf

Delete Attachment

Product Stability

Open Attachment

Seal Strength Report.pdf

Delete Attachment

Product Stability

Open Attachment

Force at 25 pct Elongation Report .pdf

Delete Attachment

Product Stability

Open Attachment

Adhesion to Steel Report.pdf

Delete Attachment

Product Stability

Open Attachment

CHG_PCA Content Report.pdf

Delete Attachment

Product Stability

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

Open Attachment

Time Kill Report.pdf

Records processed under FOIA Request 2024-1745; Released by CDRH on 08-26-2024

Delete Attachment

2

1

2

1

(b)(4)

Direct

K140250

(b)(4)

(b)(4)

No

Surface Device: Breached or Compromised Surfaces

< 24 hours

at

you did not conduct the test, please provide an explanation or justification (e.g., the device component is identical in materials/formulation and processing to a legally marketed device) in the Comments section for each test method. **If you select an item that includes a star (*) in any of the drop down menus below, provide supporting evidence or justification for the selection in the comments box at the bottom of each test.** A starred (*) selection within the Accreditation Scheme for Conformity Assessment (ASCA) Pilot indicates a deviation. Per the ASCA guidance, for ASCA testing, the complete test report should be provided in addition to the ASCA summary test report.

Cytotoxicity	Sensitization	Irritation	Acute Systemic & Pyrogenicity
Cytotoxicity Testing			
What type of cytotoxicity testing was conducted?	Extraction Method (MEM Elution) ?		
Identify the test article used in testing.	CHG Incise Drape, final sterilized device (3X EO)		

(b)(4)

(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, cell abnormalities, etc, below.

Close Tab

Sensitization Testing

What type of sensitization testing was conducted?

Identify the test article used in testing (e.g., final sterilized device, component of final sterilized device, other with description).

(b)(4)

(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, animal deaths, etc, below.

Close Tab

Irritation Testing

What type of irritation testing was conducted?	* Dermal Irritation Test	?
Identify the test article used in testing.	CHG Incise Drape, final sterilized device (3X EO)	

Sample Preparation

(b)(4)

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

(b)(4)

Close Tab

Acute Systemic Toxicity Testing & Material Mediated Pyrogenicity Testing

Acute Systemic Toxicity Testing

Was Acute Systemic Toxicity testing conducted?

Yes

?

Material Mediated Pyrogenicity Testing

Was Material Mediated Pyrogenicity testing conducted?

Yes

?

Specific questions for these tests do not exist yet in this template or the FDA reviewer's Smart Templates. We recommend Acute Systemic Toxicity and and Material Mediated Pyrogenicity be assessed. If testing is performed, we recommend it be conducted per ISO 10993-11 for Acute Systemic Toxicity and per ISO 10993-12 for Material Mediated Pyrogenicity.

10993-11 and USP <151> for Material Mediated Pyrogenicity. You may also like to consult the [FDA supplemental information sheet](#) for this testing. Please provide a test report in an attachment in the Biocompatibility Reports and Documentation section below, or provide a justification for why testing was not conducted in the Comments below.

Comments

(b)(4)

Close Tab

Biocompatibility Reports and Documentation

Add Attachment	Please attach any documentation (e.g., test reports) pertaining to the biocompatibility of your device. If no test reports were attached, please attach a rationale explaining why testing is not necessary.	
Open Attachment	Cytotoxicity Report.pdf	Delete Attachment
Open Attachment	Sensitization Report.pdf	Delete Attachment
Open Attachment	Irritation Report.pdf	Delete Attachment
Open Attachment	Acute Systemic Toxicity Report.pdf	Delete Attachment
Open Attachment	Pyrogenicity Report.pdf	Delete Attachment

Software/Firmware & Cybersecurity/Interoperability

Based on the answers provided in the Device Description section, no software, cybersecurity, or interoperability information is needed.

EMC, Wireless, Electrical, Mechanical, and Thermal Safety

Records processed under FOIA Request ID: A745745 Released by GPOPR in 08/20/2024

Based on the answers provided in the Device Description section, no EMC or wireless technology information is needed.

Electrical, Mechanical, and Thermal Summary

Please summarize the Electrical, Mechanical and Thermal Testing of your device, or summarize why testing was not needed. Please ensure any standards cited here are also cited in the Standards subsection within the first part of this template (located after Applicant, Correspondent, and Pre-Submission Correspondence).

The submission device is not electromechanical in nature therefore no testing is provided in this submission.

EMC, Wireless, & EMT Documentation

Add Attachment

Please attach the documentation pertaining to the Electromagnetic Compatibility Testing (e.g., EMC test reports/summaries), Safeguards, Wireless Testing, and Electrical, Mechanical and Thermal Testing of your device.

Performance Testing

Was Bench Testing used in order to support this submission?

Yes

Was Animal Testing used in order to support this submission?

No

Was Clinical Testing used in order to support this submission?

No

If the determination of substantial equivalence is also based on an assessment of performance data, we recommend you fill out the text boxes below. If no testing was necessary, state this in the respective field below. If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), you must include this information, in accordance with 21 CFR 807.92(b). The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

THEREFORE, ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE SUMMARY TEXTBOXES BELOW.

Provide a brief discussion of the nonclinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence. If any guidance documents or FDA recognized consensus standards were used/referenced for testing, cite these here.

Bench testing was performed to demonstrate substantial equivalence as recommended by the FDA Guidance on Premarket Notification [510(k)] Submission for Surgical Gowns and Surgical Drapes, August 1993 and in alignment with the predicate device.

Performance Testing includes:

- Barrier performance per AAMI PB70:2012 using ASTM F1670 Resistance to Synthetic Blood Penetration
- Force at 25% Elongation
- Flammability testing per 16 CFR 1610
- Moisture Vapor Transmission Rate
- in vitro Direct Time Kill
- Minimum Effective Concentration
- CHG Release Kinetics

Provide a summary discussion of the clinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence. Refer to the help text for a list of the details we recommend be included regarding the subjects and clinical evidence. If no clinical data were necessary, please type "Not Applicable." (There should not be any patient identifier information in the summary.)

Not applicable

State the conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified above.

In alignment with the predicate device, testing of the submission device was completed to evaluate the same performance characteristics; barrier performance, force at 25% elongation, flammability, moisture vapor transmission rate, in vitro direct time kill, minimum effective concentration, and CHG release kinetics. The submission device met the requirements of each performance test. Therefore, the performance testing

demonstrates that the 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG) is substantially equivalent to the predicate device. There are no new questions of safety and effectiveness.

Records processed under FOIA Request 2024-1745; Released by CDRH on 08-26-2024

Bench Testing

Provide the predicate device submission number (e.g., K180001) that is the best comparator for the testing attached below.

K140250

Add Attachment

Please attach documentation that includes details of the bench testing performed with your device (test report, characterization, etc). A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre- defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test support this submission.

Other Non-Clinical Evidence

Open Attachment

Bench Testing Overview.pdf

Delete Attachment

Other Non-Clinical Evidence

Open Attachment

Synthetic Blood Penetration Report.pdf

Delete Attachment

Other Non-Clinical Evidence

Open Attachment

Force at 25 pct Elongation Report.pdf

Delete Attachment

Other Non-Clinical Evidence

Open Attachment

Flammability Testing Report.pdf

Delete Attachment

Other Non-Clinical Evidence

Open Attachment

MVTR Testing Report.pdf

Delete Attachment

Other Non-Clinical Evidence

Open Attachment

in vitro Time Kill Report.pdf

Delete Attachment

Other Non-Clinical Evidence

Open Attachment

MEC Report.pdf

Delete Attachment

Other Non-Clinical Evidence

Open Attachment

CHG Kinetic Release Testing Report.pdf

Delete Attachment

Guidance and Special Controls Adherence

Please cite the attachment(s) and page number(s) of any information you provided demonstrating special controls or device specific guidance adherence in this section. Please use the primary product code you listed in the Classification section above to determine whether a device specific guidance or special controls exists for your device. Type "N/A" if no device specific guidance or special controls exist for your device type. If you type "N/A," and special controls or a device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

Primary Product Code KXX and FDA Guidance on Premarket Notification [510(k)] Submission for Surgical Gowns and Surgical Drapes, August 1993

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls, please provide a rationale for this alternative approach below.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI@FDA.HHS.gov or 1-800-796-8118

References

Is literature referenced in the submission?

No

?

Administrative Documentation

Add Attachment

General Summary of Submission/Executive Summary

Open Attachment

Executive Summary.pdf

Delete Attachment

The Truthful and Accurate Statement is required for all 510(k) types (21 CFR 807.87(k)). It is a legally binding statement that provides additional assurance that the data submitted in the 510(k) is truthful and accurate and that no material fact has been omitted. This statement must be signed by a responsible person of the applicant company; it cannot be signed by a consultant to the applicant. If you are a responsible party of the 510(k) owner, this statement will be automatically produced and signed with your electronic signature (click the Administrative Documentation help text above to learn how to obtain an electronic signature). Ensure the signature you use to sign this application is for the owner of the 510(k), or, if you are not a responsible party of the 510(k) owner, attach a Truthful and Accurate statement below.

Weblink: [Truthful and Accurate Statement](#)

Are you a responsible party of the owner for this 510(k) Premarket Notification, and will you be electronically signing this application for submission? If you are unable to sign PDF documents with a valid electronic signature, choose No.

Yes

Would you like to attach a 510(k) Statement or Summary? If you do not attach a 510(k) Statement or Summary, and you provided all of the data necessary to produce a 510(k) Summary, then a 510(k) Summary will be produced by this form. If you choose to submit a 510(k) Summary instead of a 510(k) Statement, be aware that the data provided in the 510(k) Summary will be publicly available if your 510(k) is cleared. As a result, be sure no confidential information is included in the 510(k) Summary. If you choose to submit a 510(k) Statement, be aware that you must provide summary information to anyone who requests it.

Yes

Add Attachment

510(k) Summary or Statement

Open Attachment

510k Summary.pdf

Delete Attachment

Add Attachment

Please attach your User Fee form here. Please be sure to submit your user fee payment at least three (3) business days before submitting, to ensure the payment is processed and your submission is not placed on user fee hold.

Open Attachment

MDUFMA Cover Sheet.pdf

Delete Attachment

Please enter in the User Fee Payment Identification Number.

(b)(4)

Show User Fee Introduction

Truthful & Accurate Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Regulatory Affairs Specialist of 3M Company, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(b)(6)

2022.08.25 11:58:40 -05'00'

Date Signed: 2022-08-25

510(k)#: For a new submission, leave the 510(k) number blank.

Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].

Verification

The following sections are complete:

- Application/Submission Type
- Cover Letter / Letters of Reference
- Administrative Information
- Device Description
- Indications for Use
- Classification
- Predicates and Substantial Equivalence
- Labeling
- Reprocessing, Sterility, and Shelf-Life
- Biocompatibility
- Software/Firmware & Cybersecurity/Interoperability
- EMC, Wireless, Electrical, Mechanical, and Thermal Safety
- Performance Testing
- References
- Administrative Documentation

Export Data

If you want to save the data in this eSTAR in XML format, you can click the Export Data button to the left. Attachments will not be included in the generated XML file.

Import Data

You can import the XML data of another eSTAR into this eSTAR by clicking the Import Data button to the left, and choosing the XML file. Attachments will not be imported.

Registration and Listing

Owners or operators of places of business (also called establishments or facilities) that are involved in the production and distribution of medical devices intended for use in the United States (U.S.) are required to register annually with the FDA. This process is known as establishment registration.

Congress has authorized FDA to collect an annual establishment registration fee for device establishment registrations. A detailed list of all those establishment types that have to pay the registration fee can be found at the [Who Must Register, List and Pay the Fee](#) website. There are no reductions in annual establishment registration fees for small businesses or any other group.

Most establishments that are required to register with the FDA are also required to list the devices that are made there and the activities that are performed on those devices. If a device requires premarket approval or notification before being marketed in the U.S., then the owner/operator should also submit the FDA premarket submission number (510(k), De Novo, PMA, PDP, HDE). The owner/operator cannot list the device until the premarket submission has been cleared, granted, or approved to market in the United States.

Registration and listing provides FDA with the location of medical device establishments and the devices manufactured at those establishments. Knowing where devices are made increases the nation's ability to prepare for and respond to public health emergencies.

For details about registering and listing your device, please see the [Device Registration and Listing](#) website. If you encounter an issue or wish to contact us regarding the Electronic Registration and Listing System known as the FDA Unified Registration and Listing System (FURLS)/Device Registration and Listing Module (DRLM), please send an email to reglist@cdrh.fda.gov.

Delivery Directions

You only need to mail this eSTAR PDF with embedded attachments on a CD, DVD, or USB Drive (SD cards are not accepted) with a printed cover letter to our Document Control Center. As an example, an

acceptable submission package would consist of a printed cover letter accompanying a USB drive with only this eSTAR PDF on it. Records processed under FOIA Request 2024-1745; Released by CDRH on 08-26-2024 **The submission does not need to be eCopy compliant, nor does the eSTAR PDF need to be zipped and placed in a MISC FILES folder.**

Hi Allan,

(b)(4)

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCEG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
bhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Thursday, May 18, 2023 1:36 PM
To: Hilary Hovde <bhovde@mmm.com>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Thank you, Hilary. Yes, that's correct regarding the (b)(4)

(b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Hilary Hovde <bhovde@mmm.com>
Sent: Thursday, May 18, 2023 1:45 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: RE: RE: RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCEG Regulatory Affairs Commercialization Strategy
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Thursday, May 18, 2023 10:10 AM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



* * * * *

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From: Hilary Hovde <hbhovde@mmm.com>
Sent: Thursday, May 18, 2023 10:20 AM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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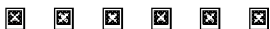
Hello Allan,

(b)(4)

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Hilary Hovde

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

Sent: Thursday, May 18, 2023 8:33 AM

To: Guan, Allan <Allan.Guan@fda.hhs.gov>

Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>

Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Good Morning Allan,

(b)(4)

Thanks,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 735 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>

Sent: Thursday, May 18, 2023 8:18 AM

To: Hilary Hovde <hbhovde@mmm.com>

Cc: K222578@docs.fda.gov

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Good morning Hilary,

(b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Allan.Guan@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Guan, Allan

Sent: Wednesday, May 17, 2023 3:36 PM

To: 'Hilary Hovde' <hbhovde@mmm.com>

Cc: K222578@docs.fda.gov; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>

Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Hi Hilary,

Thank you for providing your rationale and the prior Q-Sub feedback.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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* * * * *

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Cc: K222578@docs.fda.gov; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>
Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hello Allan,

Thank you to you and the FDA team for the call today to discuss: (b)(4)

(b)(4)

Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Hilary Hovde
Sent: Monday, May 15, 2023 2:13 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, May 15, 2023 8:56 AM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



* * * * *

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Guan, Allan
Sent: Tuesday, April 25, 2023 5:04 PM
To: 'Hilary Hovde' <hbhovde@mmm.com>
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Allan.Guan@fda.hhs.gov



* * * * *

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Hilary Hovde <hbhovde@mmm.com>
Sent: Tuesday, April 25, 2023 4:04 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call ((b)(6)) at your convenience as needed.

Thanks so much.

Best,
Hilary



Hilary S. Hovde | Regulatory Affairs Specialist - HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, April 24, 2023 2:25 PM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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x x x x x
Excellent customer service is important to us. [Please take a moment to provide feedback regarding the customer service you have received.](#)

Hi Hilary,

(b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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From: Hilary Hovde <hbhovde@mmm.com>
Sent: Thursday, May 18, 2023 8:18 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>
Subject: [EXTERNAL] RE: RE: RE: RE: RE: K222578/S001 interactive review

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Hello Allan,

(b)(4)

Thanks,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Hilary Hovde
Sent: Thursday, May 18, 2023 2:34 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: RE: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

Hi Allan,

(b)(4)

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Thursday, May 18, 2023 1:36 PM
To: Hilary Hovde <hhhovde@mmm.com>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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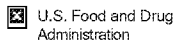
(b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Subject: [EXTERNAL] RE: RE: RE: RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hhhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Thursday, May 18, 2023 10:10 AM
To: Hilary Hovde <hhhovde@mmm.com>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hi Hilary,

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

(b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

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Allan.Guan@fda.hhs.gov

☒ U.S. Food and Drug
Administration

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Hello Allan,

(b)(4)

Best,
Hilary



Hilary S. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Hilary Hovde
Sent: Thursday, May 18, 2023 8:33 AM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Good Morning Allan,

(b)(4)

Thanks,
Hilary



Hilary S. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
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Good morning Hilary,

(b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

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Hi Hilary,

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Allan

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Subject: [EXTERNAL] RE: K222578/S001 interactive review

Hello Allan,

Thank you to you and the FDA team for the call today to discuss (b)(4)

(b)(4)

Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
bhovde@mmm.com



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Cc: K222578@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,
Allan

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Biomedical Engineer / Team Lead

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Allan.Guan@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Guan, Allan
Sent: Tuesday, April 25, 2023 5:04 PM

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

To: 'Hilary Hovde' <hhhovde@mmm.com>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

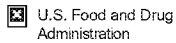
Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,
Allan

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From: Hilary Hovde <hhhovde@mmm.com>

Sent: Tuesday, April 25, 2023 4:04 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov>

Cc: K222578@docs.fda.gov

Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call ((b)(6)) at your convenience as needed.

Thanks so much.

Best,
Hilary



Hilary S. Hovde | Regulatory Affairs Specialist - HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hhhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>

Sent: Monday, April 24, 2023 2:25 PM

To: Hilary Hovde <hhhovde@mmm.com>

Cc: K222578@docs.fda.gov

Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

(b)(4)

We kindly request your response by 4/27.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov

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From: Guan, Allan
To: hbhoyde@mmm.com
Cc: K222578@docs.fda.gov
Subject: K222578 3M Ioban CHG Incise Drape
Date: Thursday, October 6, 2022 12:21:00 PM
Attachments: image001.png

Hi Hilary,

We are reviewing your 510(k) submission for the 3M Ioban CHG Incise Drape. At this time, please address the following regarding your (b)(4)

(b)(4)

We kindly request your response by tomorrow, 10/7.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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, Bldg. 66 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: [Hilary Hovde](#)
To: [Guan, Allan](#)
Cc: K222578@docs.fda.gov; [Brendan Casey](#)
Subject: [EXTERNAL] RE: K222578 3M Ioban CHG Incise Drape
Date: Thursday, October 6, 2022 6:06:27 PM
Attachments: [image008.png](#)
[image009.png](#)
[image010.png](#)
[image011.png](#)
[image012.png](#)
[image013.png](#)
[image014.png](#)

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Hi Allan,

Please see below for 3M's response to the question in regard to the (b)(4) provided in the 510(k) submission for the 3M Ioban™ CHG Incise Drape (K222578).

(b)(4)

(b)(4)

Please contact me if further clarification is needed.

Thank you.

Best Regards,

Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>

Sent: Thursday, October 06, 2022 11:22 AM

To: Hilary Hovde <hbhovde@mmm.com>

Cc: K222578@docs.fda.gov

Subject: [EXTERNAL] K222578 3M loban CHG Incise Drape

Hi Hilary,

We are reviewing your 510(k) submission for the 3M loban CHG Incise Drape. At this time, please address the following regarding you:

(b)(4)

(b)(4)

(b)(4)

We kindly request your response by tomorrow, 10/7.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control
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Allan.Guan@fda.hhs.gov



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September 6, 2022</br></br>

Review Assignment Notification

<p>I am the lead reviewer assigned to your submission K222578. Your file is being reviewed in Office of Health Technology 4, Division of Health Technology 4 B. The first line supervisor is the Assistant Director of Personal Protective Equipment, Reprocessing and Disinfection Devices. </p>

<p>I will contact you should any additional information be required during the course of the review of your submission. You may contact me at any point during the review if you have questions or concerns. FDA aims to apply the least burdensome principles when requesting additional information. </p>

<p>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. </p>

<p>If you have general questions about the review process for your submission, you should contact OPEQSubmissionSupport@fda.hhs.gov. </p>

<p>*** This is a system-generated email notification ***</p>

Hi Allan,

Would it at all be possible to move the meeting back one hour to 10:00 AM ET? We have a mandatory meeting on our side that was scheduled abruptly for 9:00 AM ET.

I apologize, but hope this will work.

Thanks,

Hilary

[cid:image001.gif@01D987C9.B753D0C0]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com<mailto:hbhovde@mmm.com>

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From: Guan, Allan <Allan.Guan@fda.hhs.gov>

Sent: Tuesday, May 16, 2023 7:32 AM

To: Hilary Hovde <hbhovde@mmm.com>

Cc: K222578@docs.fda.gov; Brad Bagley <bdbagley@mmm.com>; Brendan Casey <bcasey@mmm.com>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: RE: K222578/S001 interactive review

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Good morning Hilary,

This is to confirm the meeting today at 9am ET.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices

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Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Monday, May 15, 2023 9:22 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brad Bagley
<bdbagley@mmm.com<mailto:bdbagley@mmm.com>>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: RE: RE: RE: K222578/S001 interactive review

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Thanks Allan,

I appreciate it.

I have accepted the invite and understand it is subject to change.

Best,

Hilary

[cid:image001.gif@01D987C9.B753D0C0]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, May 15, 2023 6:55 PM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brad Bagley
<bdbagley@mmm.com<mailto:bdbagley@mmm.com>>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hi Hilary,

Sure, I'll try to find a time for a call tomorrow with our

(b)(4)

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Monday, May 15, 2023 6:34 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brad Bagley
<bdbagley@mmm.com<mailto:bdbagley@mmm.com>>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

Importance: High

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open attachments unless you recognize the sender and know the content is safe.

Hi Allan,

I have shared your request for additional information in regard to the

(b)(4)

(b)(4)

I have copied Brad and Brendan (3M Regulatory Affairs Director and my direct manager) on this note as I would like to include them on the future call if you are able to accommodate this request.

Thank you for your guidance.

Best,

Hilary

[cid:image001.gif@01D987C9.B753D0C0]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, May 15, 2023 4:29 PM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Thank you, Hilary.

Please see below for additional deficiency regarding the TRA:

(b)(4)

Questions? Contact FDA/CDRH/OE/DART at CDRH-FOI@FDA.HHS.gov or 301-796-8118

(b)(4)

Please email me your response by COB tomorrow, 5/16.

Best regards,

Allan

Allan Guan, Ph.D.

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

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Monday, May 15, 2023 3:13 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,

Hilary

[cid:image001.gif@01D987C9.B753D0C0]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

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Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com<mailto:hbhovde@mmm.com>

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, May 15, 2023 8:56 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

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

(b)(4)

Please provide your response as soon as possible.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

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From: Guan, Allan

Sent: Tuesday, April 25, 2023 5:04 PM

To: 'Hilary Hovde' <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Tuesday, April 25, 2023 4:04 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,

Hilary

[cid:image001.gif@01D987C9.B753D0C0]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com<mailto:hbhovde@mmm.com>

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, April 24, 2023 2:25 PM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

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Thank you, Hilary. Yes, that's correct regarding the

(b)(4)

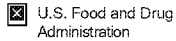
(b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: Hilary Hovde <hbhovde@mmm.com>
Sent: Thursday, May 18, 2023 1:45 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Thursday, May 18, 2023 10:10 AM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Best regards,
Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Allan.Guan@fda.hhs.gov

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From: Hilary Hovde <hbhovde@mmm.com>
Sent: Thursday, May 18, 2023 10:20 AM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hello Allan,

(b)(4)

Best,
Hilary



Hilary S. Hovde | Regulatory Affairs Specialist - HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Hilary Hovde
Sent: Thursday, May 18, 2023 8:33 AM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Good Morning Allan,

(b)(4)

Thanks,
Hilary



Hilary S. Hovde | Regulatory Affairs Specialist - HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>

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

Sent: Thursday, May 18, 2023 8:18 AM

To: Hilary Hovde <hhhovde@mmm.com>

Cc: K222578@docs.fda.gov

Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Good morning Hilary,

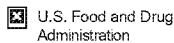
(b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: Guan, Allan
Sent: Wednesday, May 17, 2023 3:36 PM
To: 'Hilary Hovde' <hhhovde@mmm.com>
Cc: K222578@docs.fda.gov; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Hilary,

Thank you for providing your rationale and the prior Q-Sub feedback.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Hilary Hovde <hhhovde@mmm.com>
Sent: Wednesday, May 17, 2023 3:10 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>
Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hello Allan,

Thank you to you and the FDA team for the call today to discuss (b)(4)

(b)(4)

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

(b)(4)

Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist - HCEG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Hilary Hovde
Sent: Monday, May 15, 2023 2:13 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, May 15, 2023 8:56 AM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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, Bldg. 66 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Guan, Allan
Sent: Tuesday, April 25, 2023 5:04 PM
To: 'Hilary Hovde' <hbhovde@mmm.com>
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

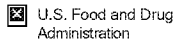
Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection 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, Bldg. 66 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Hilary Hovde <hbhovde@mmm.com>
Sent: Tuesday, April 25, 2023 4:04 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 735 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, April 24, 2023 2:25 PM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
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Ph: (301) 796-2851
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Thursday, August 25, 2022

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation [510(K)]
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Traditional 510(k) Premarket Notification for the 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)

Dear Sir or Madam:

In compliance with the Federal Food, Drug and Cosmetic Act (as amended) and as required in 21 CFR § 807, Subpart E, 3M Company, 3M Health Care submits this Premarket Notification for your review. This premarket submission is submitted online in eSTAR format via the FDA Customer Collaboration Portal (CCP).

The purpose of the submission is to notify the Agency of the intent of 3M to market the 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG) which will be shown to be substantially equivalent to the 3M™ Steri-Drape™ CHG Antimicrobial Incise Drape cleared per K140250.

We are identifying the 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG) as a combination device. The drug constituent part is Chlorhexidine gluconate (CHG). Paragraph I certification to NDA (b)(4). To the best of our knowledge no patent information has been submitted to the FDA.

Trade Name: 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape
(contains 2% w/w CHG)
Classification Name: Surgical drape and drape accessories
Device Classification: Class II, 21 CFR 878.4370
Product Code: KXX

The 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG) was reviewed by the Agency via the (b)(4).

3M considers the intent to market this device as confidential commercial information. Therefore, 3M considers the information provided under this submission to be a trade secret and confidential commercial information under 21 CFR §20.61 and requests that the Food and Drug Administration not disclose this information either in response to a Freedom of Information Request or by any other means.

3M Company

3M Health Care
Records processed under FOIA Request 2024-1745. Released by CDRH on 08-26-2024
2510 Conway Ave., Bldg. 275-5W-06
St. Paul, MN 55144 U.S.A.
651 733 1110

An electronic payment of (b)(4) was made to FDA on January 13, 2022 in support of this submission, and 3M's Medical Device User Fee Payment Identification Number for this submission is (b)(4). Should you have any questions regarding this submission, please contact me at the email listed below. In the event that I cannot be reached, please contact Brendan Casey at bcasey@mmm.com.

Sincerely,

(b)(6)

Hilary B. Hovde
Regulatory Affairs Specialist
3M Health Care, 3M Center
2510 Conway Avenue, Bldg. 275-5W-06
St. Paul, MN 55144-1000 USA
hbhovde@mmm.com

Hi Allan,

Please see below for 3M's response to the question in regard to the (b)(4) provided in the 510(k) submission for the 3M Ioban™ CHG Incise Drape (K222578).

(b)(4)

Please contact me if further clarification is needed.
Thank you.

Best Regards,
Hilary



Hilary S. Hovde | Regulatory Affairs Specialist - HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hhhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Thursday, October 06, 2022 11:22 AM
To: Hilary Hovde <hhhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] K222578 3M Ioban CHG Incise Drape

Hi Hilary,

We are reviewing your 510(k) submission for the 3M Ioban CHG Incise Drape. At this time, please address the following regarding your

(b)(4)

(b)(4)

We kindly request your response by tomorrow, 10/7.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov



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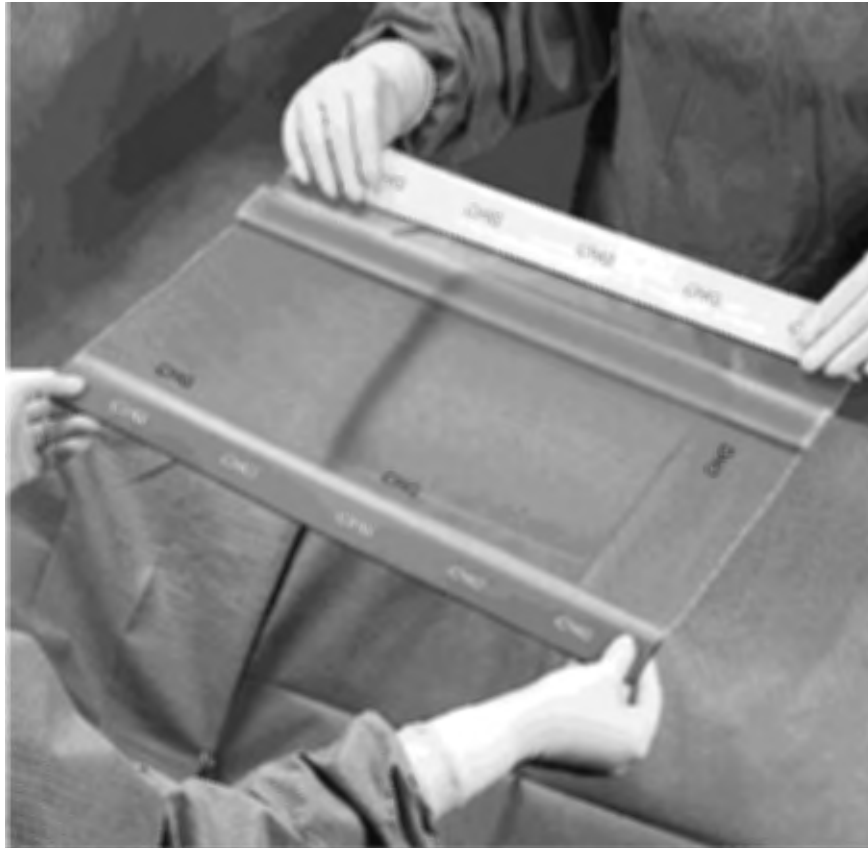
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**3M™ Ioban™ CHG
Incise Drape 510(k)**

Device Picture

**3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape
(contains 2% w/w CHG)**



Hi Allan,

I have received your message. I am reviewing your questions with the subject matter expert and will provide a response by tomorrow, 10/7 as requested.

Thank you.

Best,

Hilary

[cid:image007.gif@01D8D988.AB569EF0]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com<mailto:hbhovde@mmm.com>

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From: Guan, Allan <Allan.Guan@fda.hhs.gov>

Sent: Thursday, October 06, 2022 11:22 AM

To: Hilary Hovde <hbhovde@mmm.com>

Cc: K222578@docs.fda.gov

Subject: [EXTERNAL] K222578 3M Ioban CHG Incise Drape

Hi Hilary,

We are reviewing your 510(k) submission for the 3M Ioban CHG Incise Drape. At this time, please address the following regarding your (b)(4)

(b)(4)

We kindly request your response by tomorrow, 10/7.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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White Oak, Bldg. 66 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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Food and Drug Administration
CDRH/OPEQ/OHTIV/DHTIVB
WO66 RM4535
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-2851

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: October 19, 2022

Reviewer: Allan Guan

510(k)# K222578 **Subject:** Traditional

Applicant: 3M Company

Device Trade Name: 3M™ Ioban™ CHG
Chlorhexidine Gluconate Incise Drape (contains 2%
w/w CHG)

Contact Name: Hilary Hovde

Contact Title: Regulatory Affairs Specialist

Correspondent Firm: 3M Company

Phone: (651) 736-0364 **Email:**
hbhovde@mmm.com

Received Date: August 25, 2022

Due Date: November 23, 2022

Pro Code(s): KKK Class: II **Reg #:** 878.4370

Reg Name: Surgical Drape And Drape Accessories

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K140250	KKX	3m Steri-drape Chg Antimicrobial Incise Drape	3m Health Care

(b)(5)

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(b)(5)

Digital Signature Concurrence Table (Doc ID: 04500.15.00)

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

Allan Guan -S Digitally signed by Allan Guan -S
Date: 2022.10.20 13:42:45 -04'00'

GLP REPORT

TEST FACILITY

(b)(4)

SPONSOR

(b)(4)

3M Corporate Toxicology & Environmental Science
3M Center, Bldg. 220-6E-03
Saint Paul, Minnesota 55144

CONFIDENTIAL

STUDY TITLE

Cytotoxicity Study Using the ISO Elution Method

TEST ARTICLE NAME

(b)(4)

TEST ARTICLE IDENTIFICATION

(b)(4)

3M STUDY NUMBER

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

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GLP PROTOCOL

TEST FACILITY

(b)(4)

SPONSOR

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3M Corporate Toxicology & Environmental Science
3M Center, Bldg. 220-6E-03
St. Paul, Minnesota 55144

STUDY TITLE

Cytotoxicity Study Using the ISO Elution Method

TEST ARTICLE NAME

(b)(4)

TEST ARTICLE IDENTIFICATION

(b)(4)

3M STUDY NUMBER

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

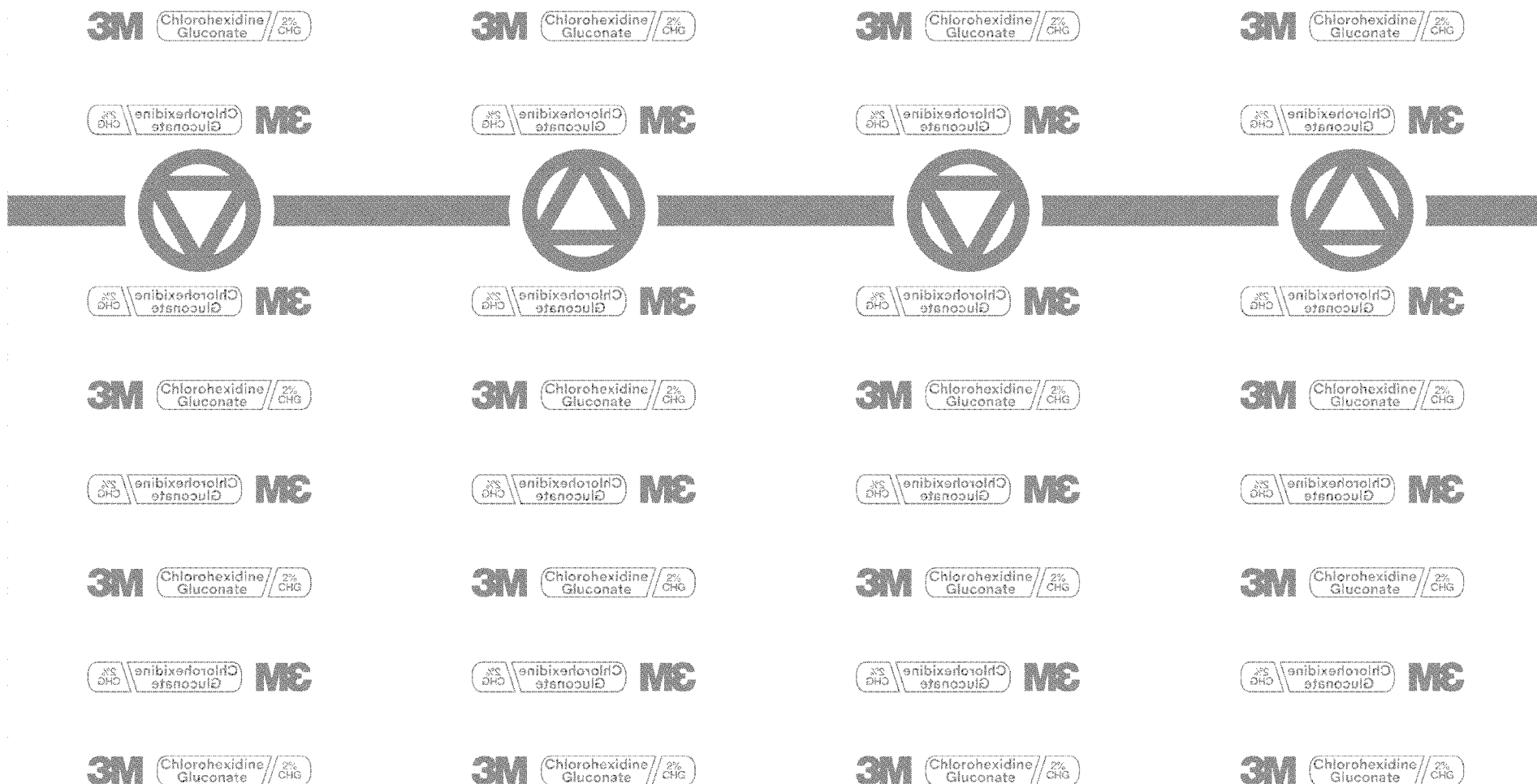
(b)(4)

(b)(4)

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(b)(4)



Hi Hilary,

(b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



Excellent customer service is important to us. *Please take a moment to provide feedback regarding the customer service you have received.*

From: Hilary Hovde <hbhovde@mmm.com>
Sent: Thursday, May 18, 2023 10:20 AM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hello Allan,

(b)(4)

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 735 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Hilary Hovde
Sent: Thursday, May 18, 2023 8:33 AM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Good Morning Allan,

(b)(4)

Thanks,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 8364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Thursday, May 18, 2023 8:18 AM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Good morning Hilary,

(b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: Guan, Allan
Sent: Wednesday, May 17, 2023 3:36 PM
To: 'Hilary Hovde' <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Hilary,

Thank you for providing your rationale and the prior Q-Sub feedback.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Sent: Wednesday, May 17, 2023 3:10 PM
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Cc: K222578@docs.fda.gov; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>
Subject: [EXTERNAL] RE: K222578/S001 interactive review
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hello Allan,

Thank you to you and the FDA team for the call today to discuss (b)(4)

(b)(4)

Best Regards,
Hilary



Hilary S. Hovde | Regulatory Affairs Specialist - HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hhhovde@mmm.com



From: Hilary Hovde
Sent: Monday, May 15, 2023 2:13 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs Commercialization Strategy
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hbhovde@mmm.com



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Cc: K222578@docs.fda.gov
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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: Guan, Allan
Sent: Tuesday, April 25, 2023 5:04 PM
To: 'Hilary Hovde' <hbhovde@mmm.com>
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

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Hi Allan,

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Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, April 24, 2023 2:25 PM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

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

(b)(4)

We kindly request your response by 4/27.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

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Performance Testing- Bench Testing

Overview

Bench testing was performed to demonstrate substantial equivalence as recommended by the *FDA Guidance on Premarket Notification [510(k)] Submission for Surgical Gowns and Surgical Drapes*, August 1993 and in alignment with the predicate device.

Performance Testing includes:

- Barrier performance per AAMI PB70:2012 using ASTM F1670 Resistance to Synthetic Blood Penetration
- Force at 25% Elongation
- Flammability testing per 16 CFR 1610
- Moisture Vapor Transmission Rate
- *in vitro* Direct Time Kill
- Minimum Effective Concentration
- CHG Release Kinetics

As summarized here and in the attached testing reports, the submission device met the requirements of each performance test.

Please refer to the attached performance testing reports for full details and results. The complete testing reports are provided as attachments to the Bench Testing section.

1.0 Barrier performance per AAMI PB70:2012 using ASTM F1670 *Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood*

(b)(4)

(b)(4)

2.0 Force at 25% Elongation

(b)(4)

(b)(4)

3.0 Flammability per 16 CFR 1610

(b)(4)

4.0 Moisture Vapor Transmission Rate (MVTR)

(b)(4)

5.0 *in vitro* Time Kill

(b)(4)

(b)(4)

(b)(4)

(b)(4)

6.0 Minimum Effective Concentration (MEC)

(b)(4)

(b)(4)

7.0 CHG Release Kinetics

(b)(4)

(b)(4)

Hi Allan,

I have shared your request for additional information in regard to the

(b)(4)

(b)(4)

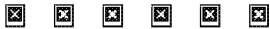
I have copied Brad and Brendan (3M Regulatory Affairs Director and my direct manager) on this note as I would like to include them on the future call if you are able to accommodate this request.

Thank you for your guidance.

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 735 0364 | Fax: 651 737 5320
bhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, May 15, 2023 4:29 PM
To: Hilary Hovde <bhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Thank you, Hilary.

Please see below for additional deficiency regarding the

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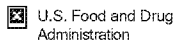
Please email me your response by COB tomorrow, 5/16.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Hi Allan,

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Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
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Office: 651 735 8364 | Fax: 651 737 5320
hbhovde@mmm.com



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Hi Hilary,

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Please provide your response as soon as possible.

Best regards,
Allan

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From: Guan, Allan
Sent: Tuesday, April 25, 2023 5:04 PM
To: 'Hilary Hovde' <hbhovde@mmm.com>
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,
Allan

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Allan.Guan@fda.hhs.gov



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Sent: Tuesday, April 25, 2023 4:04 PM
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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,
Hilary



Hilary S. Hovde | Regulatory Affairs Specialist - HCEG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hhhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, April 24, 2023 2:25 PM
To: Hilary Hovde <hhhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

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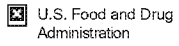
We kindly request your response by 4/27.

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Biomedical Engineer / Team Lead

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Hi Allan,

I have shared your request for additional information in regard to the (b)(4)

(b)(4)

I have copied Brad and Brendan (3M Regulatory Affairs Director and my direct manager) on this note as I would like to include them on the future call if you are able to accommodate this request.

Thank you for your guidance.

Best,

Hilary

[cid:image001.gif@01D98751.6DF69E80]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

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hbhovde@mmm.com<mailto:hbhovde@mmm.com>

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Thank you, Hilary.

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

(b)(4)

Please email me your response by COB tomorrow, 5/16.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

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

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Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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Sent: Monday, May 15, 2023 3:13 PM

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If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,

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[cid:image001.gif@01D98751.6DF69E80]

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Commercialization Strategy

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Allan

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Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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To: 'Hilary Hovde' <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

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

From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Tuesday, April 25, 2023 4:04 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: K222578/S001 interactive review

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open attachments unless you recognize the sender and know the content is safe.

Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a
quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,

Hilary

[cid:image001.gif@01D98751.6DF69E80]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com<mailto:hbhovde@mmm.com>

[cid:image007.png@01D98751.6DF69E80]<https://twitter.com/3m>[cid:image008.png@01D98751.6DF69E80]<https://www.linkedin.com/company/3m>[cid:image009.png@01D98751.6DF69E80]<https://www.facebook.com/3MCorporate>[cid:image010.png@01D98751.6DF69E80]<https://instagram.com/3m/>[cid:image011.png@01D98751.6DF69E80]<https://www.youtube.com/3m>[cid:image012.png@01D98751.6DF69E80]<http://www.3m.com/>

From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, April 24, 2023 2:25 PM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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Thursday, August 25, 2022

K222578

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation [510(K)]
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA/CDRH/DCC

AUG 25 2022

RECEIVED

**Re: Traditional 510(k) Premarket Notification for the 3M™ Ioban™ CHG
Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)**

Dear Sir or Madam:

In compliance with the Federal Food, Drug and Cosmetic Act (as amended) and as required in 21 CFR § 807, Subpart E, 3M Company, 3M Health Care submits this Premarket Notification for your review. This premarket submission is submitted online in eSTAR format via the FDA Customer Collaboration Portal (CCP).

The purpose of the submission is to notify the Agency of the intent of 3M to market the 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG) which will be shown to be substantially equivalent to the 3M™ Steri-Drape™ CHG Antimicrobial Incise Drape cleared per K140250.

We are identifying the 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG) as a combination device. The drug constituent part is Chlorhexidine gluconate (CHG). Paragraph I certification to NDA (b)(4) To the best of our knowledge no patent information has been submitted to the FDA.

Trade Name: 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape
(contains 2% w/w CHG)
Classification Name: Surgical drape and drape accessories
Device Classification: Class II, 21 CFR 878.4370
Product Code: KXX

The 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG) was reviewed by the Agency via the (b)(4)

3M considers the intent to market this device as confidential commercial information. Therefore, 3M considers the information provided under this submission to be a trade secret and confidential commercial information under 21 CFR §20.61 and requests that the Food and Drug Administration not disclose this information either in response to a Freedom of Information Request or by any other means.

3M Company

3M Health Care
Records processed under FOIA Request 2024-1745, Released by CDRH on 08-26-2024
2510 Conway Ave., Bldg. 275-5W-06
St. Paul, MN 55144 U.S.A.
651 733 1110

An electronic payment of \$ (b)(4) was made to FDA on January 13, 2022 in support of this submission, and 3M's Medical Device User Fee Payment Identification Number for this submission is (b)(4). Should you have any questions regarding this submission, please contact me at the email listed below. In the event that I cannot be reached, please contact Brendan Casey at bcasey@mmm.com.

Sincerely,

(b)(6)

Hilary B. Hovde
Regulatory Affairs Specialist
3M Health Care, 3M Center
2510 Conway Avenue, Bldg. 275-5W-06
St. Paul, MN 55144-1000 USA
hbhovdc@mmm.com



BIOCOMPATIBILITY REVIEW OF K222578_S001, 3M COMPANY

To: Allan Guan, CDRH/OPEQ/OHT4/OHT4B2

From: Sojan Abraham, CDRH/OPEQ/OHT4/OHT4B1

Through: Clarence Murray III, Assistant Director, CDRH/OPEQ/OHT4/OHT4B1

Consult Type: Biocompatibility

Consult : CON239518

Submission : K222578_S001

Device Name: 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape

Sponsor: 3M Company

Date: 05/17/2023

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

Digital Signature Concurrence Table (Doc ID: 04504.03.05)	
For each of the specific issues identified in the recommended requests to the applicant above, I contributing consulting reviewer, have provided a statement of basis for the request(s); and either cited as part of it an available, applicable, and relevant final rule, statute, final guidance, or FDA-recognized consensus standard, or confirmed to the best of my ability for requests.	
Reviewer Sign-Off	Sojan Abraham -S Digitally signed by Sojan Abraham -S Date: 2023.05.17 14:24:54 -04'00'



Confidential
Page 1 of 11

Test Method

(b)(4)
Determination of Chlorhexidine
Gluconate (CHG) and p-Chloroaniline
(PCA) in 3M CHG Incise Drape
Version: (b)(4)
Status: Release
Release Date: 08/03/2020 09:29:54 AM
CDT

Document Name: (b)(4)

Document Title: Determination of Chlorhexidine Gluconate (CHG) and p-Chloroaniline (PCA) in 3M CHG Incise Drape

Released Date: 08/03/2020 09:29:54 AM CDT

Superseded Date:

Owner: (b)(4)

Location Name	Description
3M MAPLEWOOD-3MUS-MN 3M HEADQUARTERS - 01J9C020	3M MAPLEWOOD-3MUS-MN 3M HEADQUARTERS - 01J9C020: 3M CENTER, MAPLEWOOD, MN, US

Operation Name	Description

Link to Current SOP: (b)(4)

APPROVERS:

(b)(4)

Determination of Chlorhexidine Gluconate (CHG) and p-Chloroaniline (PCA) in 3M CHG Incise Drape

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

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

From: DCCLetters@fda.hhs.gov [DCCLetters@fda.hhs.gov]
Sent: 8/25/2022 7:27:23 PM
To: hbhovde@mmm.com
CC: DCCLetters@fda.hhs.gov
Subject: K222578 Acknowledgement Letter
Attachments: K222578-Acknowledgement Letter.pdf

August 25, 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.

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ADMINISTRATION**

Acknowledgement Letter

08/25/2022

Hilary Hovde, Regulatory Affairs Specialist
3M Company
2510 Conway Ave. Building 275-5W-06
St. Paul, MN 55144
UNITED STATES

Dear Hilary Hovde:

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: K222578

Received: 08/25/2022

Applicant: 3M Company

Device: 3M Ioban CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)

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

3M Company

3M Health Care
Records processed under FOIA Request 2024-1745. Released by CDRH on 08-26-2024
2510 Conway Ave., Bldg. 275-5W-06
St. Paul, MN 55144 U.S.A.
651 733 1110



Thursday, August 25, 2022

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation [510(K)]
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

**Re: Patent Statement- 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape
(contains 2% w/w CHG)**

Dear Sir or Madam:

We are identifying the 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG) as a combination device. The drug constituent part is Chlorhexidine gluconate (CHG). Paragraph I certification to (b)(4) To the best of our knowledge no patent information has been submitted to the FDA.

Sincerely,

(b)(6)

Hilary B. Hovde
Regulatory Affairs Specialist
3M Health Care, 3M Center
2510 Conway Avenue, Bldg. 275-5W-06
St. Paul, MN 55144-1000 USA
hbhovde@mmm.com

(b)(4)

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TODAY'S DATE: 3/8/2023

TO:

(b)(4)

COMPANY: 3M Healthcare

E-MAIL ADDRESS:

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

October 20, 2022</br></br><p>We have reviewed your submission. Please see attached.</p>

<p>If you have any questions, please contact the lead reviewer assigned to your submission, Allan Guan. </p>

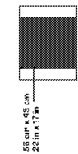
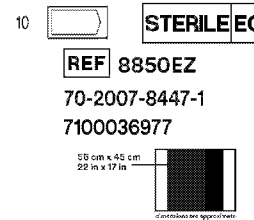
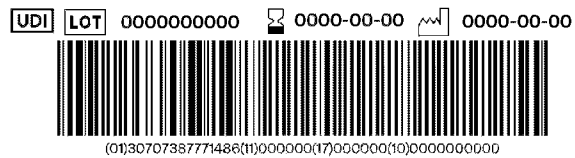
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Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)

Made in the USA with Globally Sourced Materials.

3M Company
2510 Conway Ave.
St. Paul, MN 55144 USA
1-800-228-3957 (USA only)
www.3M.com
HCBGRegulatory.3M.com
34-8728-7662-7



I can be reached either through a meeting...or if you want to call me, it is best to call my cell phone as I am not in the office.

(b)(6)

Thanks,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
bhovde@mmm.com



From: Hilary Hovde
Sent: Thursday, May 18, 2023 4:40 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: RE: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: RE: K222578/S001 interactive review

Yes, I am available.



Hilary B. Hovde | Regulatory Affairs Specialist – HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
bhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Thursday, May 18, 2023 4:39 PM
To: Hilary Hovde <bhovde@mmm.com>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: RE: RE: K222578/S001 interactive review

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Hi Hilary,

Are you available for a quick call at 5:45 or 6 pm ET?

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: Guan, Allan
Sent: Thursday, May 18, 2023 3:46 PM

To: 'Hilary Hovde' <hhhovde@mmm.com>
Cc: 'K222578@docs.fda.gov' <K222578@docs.fda.gov>; 'Brendan Casey' <bcasey@mmm.com>
Subject: RE: [EXTERNAL] RE: RE: RE: RE: RE: K222578/S001 interactive review

Thank you, Hilary.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: Hilary Hovde <hhhovde@mmm.com>
Sent: Thursday, May 18, 2023 3:34 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: RE: RE: RE: RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hhhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Thursday, May 18, 2023 1:36 PM
To: Hilary Hovde <hhhovde@mmm.com>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Thank you, Hilary. Yes, that's correct regarding the (b)(4)

(b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: Hilary Hovde <hbhovde@mmm.com>
Sent: Thursday, May 18, 2023 1:45 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hbhovde@mmm.com



-
-

From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Thursday, May 18, 2023 10:10 AM
To: Hilary Hovde <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



* * * * *

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From: Hilary Hovde <hhhovde@mmm.com>
Sent: Thursday, May 18, 2023 10:20 AM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hello Allan,

(b)(4)

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hhhovde@mmm.com



From: Hilary Hovde
Sent: Thursday, May 18, 2023 8:33 AM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>
Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Good Morning Allan,

(b)(4)

Thanks,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hhhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Thursday, May 18, 2023 8:18 AM
To: Hilary Hovde <hhhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Good morning Hilary,

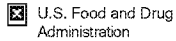
(b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Guan, Allan
Sent: Wednesday, May 17, 2023 3:36 PM
To: 'Hilary Hovde' <hbhovde@mmm.com>
Cc: K222578@docs.fda.gov; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Hi Hilary,

Thank you for providing your rationale and the prior Q-Sub feedback.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Hilary Hovde <hbhovde@mmm.com>
Sent: Wednesday, May 17, 2023 3:10 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>
Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hello Allan,

Thank you to you and the FDA team for the call today to discuss (b)(4)

(b)(4)

(b)(4)

Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
bhovde@mmm.com



From: Hilary Hovde
Sent: Monday, May 15, 2023 2:13 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,

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

Hilary



Hilary B. Hovde | Regulatory Affairs Specialist -- HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
bhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, May 15, 2023 8:56 AM
To: Hilary Hovde <bhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: Guan, Allan
Sent: Tuesday, April 25, 2023 5:04 PM
To: 'Hilary Hovde' <bhovde@mmm.com>
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

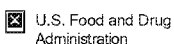
Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: Hilary Hovde <hhhovde@mmm.com>
Sent: Tuesday, April 25, 2023 4:04 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hhhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, April 24, 2023 2:25 PM
To: Hilary Hovde <hhhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
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Consult Memorandum



Date: October 11, 2022

From: Jon Weeks, PhD.
Microbiologist
CDRH/OSEL/DBCMS

To: Allan Guan, PhD
Team Lead
CDRH/OHT4/DHT4B/THT4B2

Subject: K222578
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(b)(5)

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Microbiology Consult

"

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Jon Weeks -S

Digitally signed by
Jon Weeks -S
Date: 2022.10.11
21:13:30 -04'00'

Jon W. Weeks, PhD.

Microbiologist

CDRH/OSEL/DBCMS

**R & D Supporting
Document**

(b)(4)

Version: 

Status: Release

Release Date: 06/22/2022 07:01:25 PM
CDT

Document Name:

(b)(4)

Document Title:

Results of Force at 25% Elongation for CHG Drape Stability

Released Date:

06/22/2022 07:01:25 PM CDT

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Results of Force at 25% Elongation for CHG Drape Stability

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Hi Hilary,

(b)(4)

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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From: Hilary Hovde <hbhovde@mmm.com>

Sent: Thursday, May 18, 2023 10:20 AM

To: Guan, Allan <Allan.Guan@fda.hhs.gov>

Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>

Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hello Allan,

(b)(4)

Best,

Hilary

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Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

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From: Hilary Hovde

Sent: Thursday, May 18, 2023 8:33 AM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Good Morning Allan,

(b)(4)

Thanks,

Hilary

[cid:image015.gif@01D98978.5AFE920]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Thursday, May 18, 2023 8:18 AM

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

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Good morning Hilary,

(b)(4)

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Office of Product Evaluation and Quality

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Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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From: Guan, Allan

Sent: Wednesday, May 17, 2023 3:36 PM

To: 'Hilary Hovde' <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Qian, Bifeng
<Bifeng.Qian@fda.hhs.gov<mailto:Bifeng.Qian@fda.hhs.gov>>; Murray III, Clarence
<Clarence.Murray@fda.hhs.gov<mailto:Clarence.Murray@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Hi Hilary,

Thank you for providing your rationale and the prior Q-Sub feedback.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Wednesday, May 17, 2023 3:10 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Qian, Bifeng
<Bifeng.Qian@fda.hhs.gov<mailto:Bifeng.Qian@fda.hhs.gov>>; Murray III, Clarence
<Clarence.Murray@fda.hhs.gov<mailto:Clarence.Murray@fda.hhs.gov>>

Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hello Allan,

Thank you to you and the FDA team for the call today to discuss

(b)(4)

(b)(4)

(b)(4)

Best Regards,

Hilary

[cid:image015.gif@01D98978.5AFE920]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

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From: Hilary Hovde

Sent: Monday, May 15, 2023 2:13 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,

Hilary

[cid:image015.gif@01D98978.5AFE920]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, May 15, 2023 8:56 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

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From: Guan, Allan

Sent: Tuesday, April 25, 2023 5:04 PM

To: 'Hilary Hovde' <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

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From: Hilary Hovde <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

Sent: Tuesday, April 25, 2023 4:04 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<<mailto:Allan.Guan@fda.hhs.gov>>>

Cc: K222578@docs.fda.gov<<mailto:K222578@docs.fda.gov>>

Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,

Hilary

[cid:image015.gif@01D98978.5AFE920]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, April 24, 2023 2:25 PM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

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

(b)(4)

We kindly request your response by 4/27.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

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I can be reached either through a meeting...or if you want to call me, it is best to call my cell phone as I am not in the office.

(b)(6)

Thanks,

Hilary

[cid:image001.gif@01D989A7.D8DFA720]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

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From: Hilary Hovde

Sent: Thursday, May 18, 2023 4:40 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov>

Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>

Subject: RE: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: RE: RE: K222578/S001 interactive review

Yes, I am available.

[cid:image001.gif@01D989A7.D8DFA720]

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Thursday, May 18, 2023 4:39 PM

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

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: RE: RE: K222578/S001 interactive
review

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Hi Hilary,

Are you available for a quick call at 5:45 or 6 pm ET?

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection 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, Bldg. 66 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

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From: Guan, Allan

Sent: Thursday, May 18, 2023 3:46 PM

To: 'Hilary Hovde' <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: 'K222578@docs.fda.gov' <K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>>;
'Brendan Casey' <bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: RE: [EXTERNAL] RE: RE: RE: RE: RE: K222578/S001 interactive review

Thank you, Hilary.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Thursday, May 18, 2023 3:34 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey <bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: RE: RE: RE: RE: RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Best,

Hilary

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Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs Commercialization Strategy

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hbhovde@mmm.com<mailto:hbhovde@mmm.com>

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Thursday, May 18, 2023 1:36 PM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey <bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Thank you, Hilary. Yes, that's correct regarding the

(b)(4)

(b)(4)

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Thursday, May 18, 2023 1:45 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: RE: RE: RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Best,

Hilary

[cid:image001.gif@01D989A7.D8DFA720]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Thursday, May 18, 2023 10:10 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hi Hilary,

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Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Thursday, May 18, 2023 10:20 AM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey <bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hello Allan,

(b)(4)

Best,

Hilary

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Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs

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

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From: Hilary Hovde

Sent: Thursday, May 18, 2023 8:33 AM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey <bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Good Morning Allan,

(b)(4)

Thanks,

Hilary

[cid:image001.gif@01D989A7.D8DFA720]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Thursday, May 18, 2023 8:18 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

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Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Good morning Hilary,

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Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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From: Guan, Allan

Sent: Wednesday, May 17, 2023 3:36 PM

To: 'Hilary Hovde' <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Qian, Bifeng
<Bifeng.Qian@fda.hhs.gov<mailto:Bifeng.Qian@fda.hhs.gov>>; Murray III, Clarence
<Clarence.Murray@fda.hhs.gov<mailto:Clarence.Murray@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Hi Hilary,

Thank you for providing your rationale and the prior Q-Sub feedback.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Wednesday, May 17, 2023 3:10 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Qian, Bifeng
<Bifeng.Qian@fda.hhs.gov<mailto:Bifeng.Qian@fda.hhs.gov>>; Murray III, Clarence
<Clarence.Murray@fda.hhs.gov<mailto:Clarence.Murray@fda.hhs.gov>>

Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hello Allan,

Thank you to you and the FDA team for the call today to discuss

(b)(4)

(b)(4)

(b)(4)

Best Regards,

Hilary

[cid:image001.gif@01D989A7.D8DFA720]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
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From: Hilary Hovde

Sent: Monday, May 15, 2023 2:13 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Allan,

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

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,

Hilary

[cid:image001.gif@01D989A7.D8DFA720]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, May 15, 2023 8:56 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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From: Guan, Allan

Sent: Tuesday, April 25, 2023 5:04 PM

To: 'Hilary Hovde' <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<<mailto:Allan.Guan@fda.hhs.gov>>

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From: Hilary Hovde <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

Sent: Tuesday, April 25, 2023 4:04 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<<mailto:Allan.Guan@fda.hhs.gov>>>

Cc: K222578@docs.fda.gov<<mailto:K222578@docs.fda.gov>>

Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,
Hilary

[cid:image001.gif@01D989A7.D8DFA720]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, April 24, 2023 2:25 PM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

(b)(4)

We kindly request your response by 4/27.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of
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Ph: (301) 796-2851

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Final Study Report	
Study Title	Skin Safety and Handling Performance of Full-Sized 3M™ Ioban™ CHG Antimicrobial Incise Drape DS-Verification Material under Dry Conditions
Study Number	(b)(4)
Release Date	03/05/2021 11:08:55 AM CST
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**3M™ Ioban™ CHG
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**Device Construction
Schematic**

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(b)(4)

May 18, 2023</br></br><p>We have completed our review. Please refer to the attached letter for details.</p>

<p>If you have any questions, please contact the lead reviewer assigned to your submission, Allan Guan.</p>

<p>*** This is a system-generated email notification ***</p>

Thank you, Hilary. Yes, that's correct regarding the

(b)(4)

(b)(4)

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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From: Hilary Hovde <hbhovde@mmm.com>

Sent: Thursday, May 18, 2023 1:45 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov>

Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>

Subject: [EXTERNAL] RE: RE: RE: RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Best,

Hilary

[cid:image015.gif@01D98991.01004B40]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Thursday, May 18, 2023 10:10 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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From: Hilary Hovde <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

Sent: Thursday, May 18, 2023 10:20 AM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<<mailto:Allan.Guan@fda.hhs.gov>>>

Cc: K222578@docs.fda.gov<<mailto:K222578@docs.fda.gov>>; Brendan Casey
<bcasey@mmm.com<<mailto:bcasey@mmm.com>>>

Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hello Allan,

(b)(4)

Best,

Hilary

[cid:image015.gif@01D98991.01004B40]

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Commercialization Strategy

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From: Hilary Hovde

Sent: Thursday, May 18, 2023 8:33 AM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<<mailto:Allan.Guan@fda.hhs.gov>>>

Cc: K222578@docs.fda.gov<<mailto:K222578@docs.fda.gov>>; Brendan Casey
<bcasey@mmm.com<<mailto:bcasey@mmm.com>>>

Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Good Morning Allan,

(b)(4)

Thanks,

Hilary

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Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Thursday, May 18, 2023 8:18 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Good morning Hilary,

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Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

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From: Guan, Allan

Sent: Wednesday, May 17, 2023 3:36 PM

To: 'Hilary Hovde' <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Qian, Bifeng
<Bifeng.Qian@fda.hhs.gov<mailto:Bifeng.Qian@fda.hhs.gov>>; Murray III, Clarence
<Clarence.Murray@fda.hhs.gov<mailto:Clarence.Murray@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Hi Hilary,

Thank you for providing your rationale and the prior Q-Sub feedback.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices

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From: Hilary Hovde <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

Sent: Wednesday, May 17, 2023 3:10 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<<mailto:Allan.Guan@fda.hhs.gov>>>

Cc: K222578@docs.fda.gov<<mailto:K222578@docs.fda.gov>>; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov<<mailto:Bifeng.Qian@fda.hhs.gov>>>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov<<mailto:Clarence.Murray@fda.hhs.gov>>>

Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hello Allan,

Thank you to you and the FDA team for the call today to discuss

(b)(4)

(b)(4)

(b)(4)

Best Regards,
Hilary

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Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
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From: Hilary Hovde

Sent: Monday, May 15, 2023 2:13 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

(b)(4)

Best Regards,

Hilary

[cid:image015.gif@01D98991.01004B40]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, May 15, 2023 8:56 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

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From: Guan, Allan

Sent: Tuesday, April 25, 2023 5:04 PM

To: 'Hilary Hovde' <hbhovde@mmm.com><<mailto:hbhovde@mmm.com>>>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Tuesday, April 25, 2023 4:04 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,

Hilary

[cid:image015.gif@01D98991.01004B40]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, April 24, 2023 2:25 PM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of
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Ph: (301) 796-2851

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Hi Hilary,

Thank you for providing your rationale and the prior Q-Sub feedback.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices

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From: Hilary Hovde <hbhovde@mmm.com>

Sent: Wednesday, May 17, 2023 3:10 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov>

Cc: K222578@docs.fda.gov; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>

Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hello Allan,

Thank you to you and the FDA team for the call today to discuss

(b)(4)

(b)(4)

(b)(4)

Best Regards,

Hilary

[cid:image015.gif@01D988D5.1535A8B0]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

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Office: 651 736 0364 | Fax: 651 737 5320

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From: Hilary Hovde

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

Sent: Monday, May 15, 2023 2:13 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,

Hilary

[cid:image015.gif@01D988D5.1535A8B0]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, May 15, 2023 8:56 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of
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From: Guan, Allan

Sent: Tuesday, April 25, 2023 5:04 PM

To: 'Hilary Hovde' <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Tuesday, April 25, 2023 4:04 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,

Hilary

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Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, April 24, 2023 2:25 PM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

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

(b)(4)

We kindly request your response by 4/27.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices

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Ph: (301) 796-2851

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Hi Allan,

(b)(4)

Best,

Hilary

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Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

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Office: 651 736 0364 | Fax: 651 737 5320

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From: Guan, Allan <Allan.Guan@fda.hhs.gov>

Sent: Thursday, May 18, 2023 1:36 PM

To: Hilary Hovde <hbhovde@mmm.com>

Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Thank you, Hilary. Yes, that's correct regarding the

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(b)(4)

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Thursday, May 18, 2023 1:45 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: RE: RE: RE: K222578/S001 interactive review

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Hi Allan,

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Best,

Hilary

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Thursday, May 18, 2023 10:10 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hi Hilary,

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Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Thursday, May 18, 2023 10:20 AM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hello Allan,

(b)(4)

Best,

Hilary

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Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

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Office: 651 736 0364 | Fax: 651 737 5320

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From: Hilary Hovde

Sent: Thursday, May 18, 2023 8:33 AM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Good Morning Allan,

(b)(4)

Thanks,

Hilary

[cid:image001.gif@01D98995.BCBB3C60]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Thursday, May 18, 2023 8:18 AM

To: Hilary Hovde <hbhove@mmm.com<mailto:hbhove@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Good morning Hilary,

(b)(4)

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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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Ph: (301) 796-2851

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From: Guan, Allan

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

Sent: Wednesday, May 17, 2023 3:36 PM

To: 'Hilary Hovde' <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Qian, Bifeng
<Bifeng.Qian@fda.hhs.gov<mailto:Bifeng.Qian@fda.hhs.gov>>; Murray III, Clarence
<Clarence.Murray@fda.hhs.gov<mailto:Clarence.Murray@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Hi Hilary,

Thank you for providing your rationale and the prior Q-Sub feedback.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

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

From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Wednesday, May 17, 2023 3:10 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Qian, Bifeng
<Bifeng.Qian@fda.hhs.gov<mailto:Bifeng.Qian@fda.hhs.gov>>; Murray III, Clarence
<Clarence.Murray@fda.hhs.gov<mailto:Clarence.Murray@fda.hhs.gov>>

Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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open attachments unless you recognize the sender and know the content is safe.

Hello Allan,

Thank you to you and the FDA team for the call today to discuss

(b)(4)

(b)(4)

Best Regards,

Hilary

[cid:image001.gif@01D98995.BCBB3C60]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

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From: Hilary Hovde

Sent: Monday, May 15, 2023 2:13 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,

Hilary

[cid:image001.gif@01D98995.BCBB3C60]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, May 15, 2023 8:56 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

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Please provide your response as soon as possible.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

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

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From: Guan, Allan

Sent: Tuesday, April 25, 2023 5:04 PM

To: 'Hilary Hovde' <hbhovde@mmm.com><mailto:hbhovde@mmm.com>>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

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From: Hilary Hovde <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

Sent: Tuesday, April 25, 2023 4:04 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<<mailto:Allan.Guan@fda.hhs.gov>>>

Cc: K222578@docs.fda.gov<<mailto:K222578@docs.fda.gov>>

Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,

Hilary

[cid:image001.gif@01D98995.BCBB3C60]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<<mailto:Allan.Guan@fda.hhs.gov>>>

Sent: Monday, April 24, 2023 2:25 PM

To: Hilary Hovde <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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Hi Hilary,

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(b)(4)

We kindly request your response by 4/27.

Best regards,

Allan

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Biomedical Engineer / Team Lead

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Hello Allan,

Thank you to you and the FDA team for the call today to discuss

(b)(4)

(b)(4)

Best Regards,

Hilary

[cid:image002.gif@01D988C8.66C12130]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

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From: Hilary Hovde

Sent: Monday, May 15, 2023 2:13 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov>

Cc: K222578@docs.fda.gov

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,

Hilary

[cid:image002.gif@01D988C8.66C12130]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, May 15, 2023 8:56 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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From: Guan, Allan

Sent: Tuesday, April 25, 2023 5:04 PM

To: 'Hilary Hovde' <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

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Sent: Tuesday, April 25, 2023 4:04 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<<mailto:Allan.Guan@fda.hhs.gov>>>

Cc: K222578@docs.fda.gov<<mailto:K222578@docs.fda.gov>>

Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

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Best,

Hilary

[cid:image002.gif@01D988C8.66C12130]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
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Office: 651 736 0364 | Fax: 651 737 5320

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<<mailto:Allan.Guan@fda.hhs.gov>>>

Sent: Monday, April 24, 2023 2:25 PM

To: Hilary Hovde <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

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Version: (b)(4)

Status: Release

Release Date: 06/10/2022 04:09:16 PM
CDT

Document Name:

(b)(4)

Document Title:

Results of CHG Drape Verification Testing for Synthetic Blood Penetration

Released Date:

06/10/2022 04:09:16 PM CDT

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Results of CHG Drape Verification Testing for Synthetic Blood Penetration
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TRADITIONAL PREMARKET NOTIFICATION [510(k)]
3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)

510(k) Summary for
3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape
(contains 2% w/w CHG)

K222578

(b)(4)

(b)(4)

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(b)(4)

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Version: (b)(4)

Status: Release

Release Date: 06/22/2022 03:15:30 PM
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Document Name:

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Document Title:

Results of Seal Strength Testing for CHG Drape Stability

Released Date:

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Results of Seal Strength Testing for CHG Drape Stability

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Thank you, Hilary.

Please see below for additional deficiency regarding the (b)(4)

(b)(4)

Please email me your response by COB tomorrow, 5/16.

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

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices

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From: Hilary Hovde <hbhovde@mmm.com>

Sent: Monday, May 15, 2023 3:13 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov>

Cc: K222578@docs.fda.gov

Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

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(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,

Hilary

[cid:image016.gif@01D98751.C2116180]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, May 15, 2023 8:56 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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From: Guan, Allan

Sent: Tuesday, April 25, 2023 5:04 PM

To: 'Hilary Hovde' <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Tuesday, April 25, 2023 4:04 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

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Please let me know if additional information is required. I am also happy to jump on a quick call **(b)(6)** at your convenience as needed.

Thanks so much.

Best,
Hilary

[cid:image016.gif@01D98751.C2116180]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, April 24, 2023 2:25 PM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,
Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

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Hi Hilary,

Sure, I'll try to find a time for a call tomorrow with our (b)(4)

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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Sent: Monday, May 15, 2023 6:34 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov; Brad Bagley <bdbagley@mmm.com>; Brendan Casey <bcasey@mmm.com>
Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review
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Hi Allan,

I have shared your request for additional information in regard to the (b)(4)

(b)(4)

I have copied Brad and Brendan (3M Regulatory Affairs Director and my direct manager) on this note as I would like to include them on the future call if you are able to accommodate this request.

Thank you for your guidance.

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-SW-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hhhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, May 15, 2023 4:29 PM
To: Hilary Hovde <hhhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Thank you, Hilary.

Please see below for additional deficiency regarding the (b)(4)

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Questions? Contact FDA/CDRH/OCE/DD at CDRH-FOIA@US@fda.hhs.gov or 301-796-8118

(b)(4)

Please email me your response by COB tomorrow, 5/16.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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From: Hilary Hovde <[hhbhovde@mmm.com](mailto:hbhovde@mmm.com)>
Sent: Monday, May 15, 2023 3:13 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

Questions? Contact FDA/CDRH/OCE/DTP at CDRH-FOI-STATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
bhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, May 15, 2023 8:56 AM
To: Hilary Hovde <bhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

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Please provide your response as soon as possible.

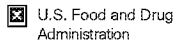
Best regards,
Allan

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Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection 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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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: Guan, Allan
Sent: Tuesday, April 25, 2023 5:04 PM
To: 'Hilary Hovde' <hbhovde@mmm.com>
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

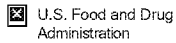
Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Sent: Tuesday, April 25, 2023 4:04 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

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Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,
Hilary



Hilary B. Hovde | Regulatory Affairs Specialist – HCSG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 735 8364 | Fax: 651 737 5320
hbhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, April 24, 2023 2:25 PM
To: Hilary Hovde <hbhovde@mmm.com>

Cc: K222578@docs.fda.gov

Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Allan.Guan@fda.hhs.gov

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Device Description

Device Description

The 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG) is used as a surgical incise drape with continuous antibacterial activity and is for external use only. It is a sterile adhesive film that is applied pre-operatively to skin. The film adheres and conforms to body contours, providing a sterile surface on top of the skin prior to surgery. The surgeon incises through the adhesive film and skin, ensuring a sterile film barrier all the way to the edge of the incision. The Chlorhexidine Gluconate (CHG) contained in the adhesive provides antibacterial activity to help reduce the risk of microbial contamination in the surgical wound.

The drape consists of a transparent, conformable, breathable, barrier film coated with an acrylic adhesive containing 2% w/w CHG. The adhesive drape is delivered on a release liner that is discarded after application.



Figure 1

Indications for Use

3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG) is indicated for use as an incise drape with continuous antibacterial activity based on in vitro time kill data out to 90 minutes. It is intended for external use only.

Principles of Operation

The 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG) is used as a surgical incise drape with continuous antibacterial activity.

The 3M™ Ioban™ CHG Incise Drapes are considered a non-invasive device containing an antimicrobial/antibacterial agent (chlorhexidine gluconate) in the adhesive. The primary mode of action of this device is to provide a sterile barrier during surgical procedures. The secondary mode of action, based on the CHG containing adhesive, is to provide continuous antibacterial activity and to reduce the risk of surgical site contamination due to skin flora. Surgical incisions can be made directly through the Ioban incise film which creates a sterile surface all the way to the wound edge.

Before applying the drape, the operative site is disinfected according to the healthcare facility policy, allowing the prepped skin to fully dry. The sterile drape should be removed from the pouch using aseptic technique, removing and discarding the overwrap.

This drape requires two sterile personnel for application. While positioned over the surgical site, the liner is removed by holding the drape with the printing on the handle facing up and separating the printed handle from the white handle. The printed handle is the CHG drape side and the white handle is the liner side.

One person holds the printed handle while the other person holds the white handle, pulling apart to deploy the drape. When the Stop symbol appears on the drape, discontinue peeling the liner. Using a sterile towel, press down firmly on the drape, first contacting the skin along the intended incision line to ensure good skin contact. Firmly smoothing the drape in place, working away from the intended incision line to achieve wrinkle free adhesion. The drape should be applied to the site without tension. If desired, the printed handle can be removed and discarded.

To remove, grasp the drape as close as possible to the junction of the drape to the skin. Place one hand on the skin for counter-traction. This prevents severe stretching. During the removal process, gently peel back drape at a 180-degree angle from the skin. This means folding the drape back on itself and maintaining that angle while pulling the drape away from the skin.

Device Construction:

(b)(4)

Device Components:

(b)(4)

Table 1

CHG Adhesive Components, Function, and Composition:

(b)(4)

Table 2

(b)(4)

Good morning Hilary,

(b)(4)

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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From: Guan, Allan

Sent: Wednesday, May 17, 2023 3:36 PM

To: 'Hilary Hovde' <hbhovde@mmm.com>

Cc: K222578@docs.fda.gov; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>

Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Hi Hilary,

Thank you for providing your rationale and the prior Q-Sub feedback.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Wednesday, May 17, 2023 3:10 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Qian, Bifeng
<Bifeng.Qian@fda.hhs.gov<mailto:Bifeng.Qian@fda.hhs.gov>>; Murray III, Clarence
<Clarence.Murray@fda.hhs.gov<mailto:Clarence.Murray@fda.hhs.gov>>

Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hello Allan,

Thank you to you and the FDA team for the call today to discuss

(b)(4)

(b)(4)

(b)(4)

Best Regards,

Hilary

[cid:image007.gif@01D98968.CE9A8EE0]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

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From: Hilary Hovde

Sent: Monday, May 15, 2023 2:13 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,

Hilary

[cid:image007.gif@01D98968.CE9A8EE0]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, May 15, 2023 8:56 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices

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From: Guan, Allan

Sent: Tuesday, April 25, 2023 5:04 PM

To: 'Hilary Hovde' <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices

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Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<<mailto:Allan.Guan@fda.hhs.gov>>

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From: Hilary Hovde <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

Sent: Tuesday, April 25, 2023 4:04 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<<mailto:Allan.Guan@fda.hhs.gov>>>

Cc: K222578@docs.fda.gov<<mailto:K222578@docs.fda.gov>>

Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,

Hilary

[cid:image007.gif@01D98968.CE9A8EE0]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, April 24, 2023 2:25 PM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices

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Hi Allan,

(b)(4)

Best,

Hilary

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Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

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From: Guan, Allan <Allan.Guan@fda.hhs.gov>

Sent: Thursday, May 18, 2023 10:10 AM

To: Hilary Hovde <hbhovde@mmm.com>

Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Thursday, May 18, 2023 10:20 AM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey
<bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hello Allan,

(b)(4)

Best,

Hilary

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Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

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From: Hilary Hovde

Sent: Thursday, May 18, 2023 8:33 AM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Brendan Casey <bcasey@mmm.com<mailto:bcasey@mmm.com>>

Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Good Morning Allan,

(b)(4)

Thanks,

Hilary

[cid:image001.gif@01D98986.577CCD00]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

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Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com<mailto:hbhovde@mmm.com>

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Thursday, May 18, 2023 8:18 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Good morning Hilary,

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(b)(4)

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices

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Ph: (301) 796-2851

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From: Guan, Allan

Sent: Wednesday, May 17, 2023 3:36 PM

To: 'Hilary Hovde' <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Qian, Bifeng
<Bifeng.Qian@fda.hhs.gov<mailto:Bifeng.Qian@fda.hhs.gov>>; Murray III, Clarence
<Clarence.Murray@fda.hhs.gov<mailto:Clarence.Murray@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Hi Hilary,

Thank you for providing your rationale and the prior Q-Sub feedback.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices

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Ph: (301) 796-2851

Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Wednesday, May 17, 2023 3:10 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Qian, Bifeng
<Bifeng.Qian@fda.hhs.gov<mailto:Bifeng.Qian@fda.hhs.gov>>; Murray III, Clarence
<Clarence.Murray@fda.hhs.gov<mailto:Clarence.Murray@fda.hhs.gov>>

Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hello Allan,

Thank you to you and the FDA team for the call today to discuss

(b)(4)

(b)(4)

(b)(4)

Best Regards,

Hilary

[cid:image001.gif@01D98986.577CCD00]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

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From: Hilary Hovde

Sent: Monday, May 15, 2023 2:13 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,

Hilary

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Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

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

From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, May 15, 2023 8:56 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices

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From: Guan, Allan

Sent: Tuesday, April 25, 2023 5:04 PM

To: 'Hilary Hovde' <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Ph: (301) 796-2851

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Tuesday, April 25, 2023 4:04 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,
Hilary

[cid:image001.gif@01D98986.577CCD00]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, April 24, 2023 2:25 PM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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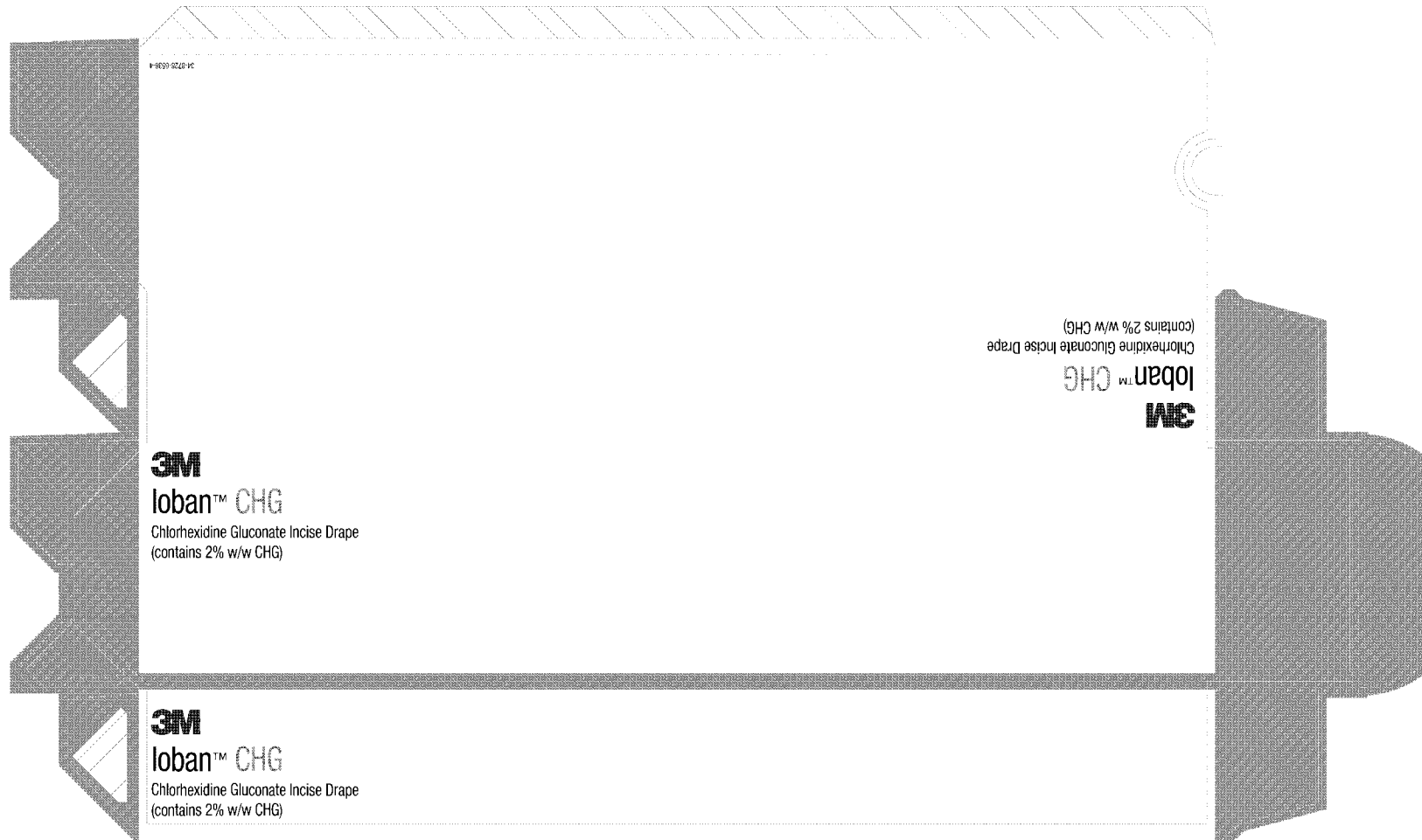
Ph: (301) 796-2851

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Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: Guan, Allan
Sent: Tuesday, April 25, 2023 5:04 PM
To: 'Hilary Hovde' <hbhovde@mmm.com>
Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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Ph: (301) 796-2851
Allan.Guan@fda.hhs.gov



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From: Hilary Hovde <hbhovde@mmm.com>
Sent: Tuesday, April 25, 2023 4:04 PM
To: Guan, Allan <Allan.Guan@fda.hhs.gov>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

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Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,
Hilary



Hilary S. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs Commercialization Strategy
3M Medical Solutions Division, Health Care Business Group
3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000
Office: 651 736 0364 | Fax: 651 737 5320
hhhovde@mmm.com



From: Guan, Allan <Allan.Guan@fda.hhs.gov>
Sent: Monday, April 24, 2023 2:25 PM
To: Hilary Hovde <hhhovde@mmm.com>
Cc: K222578@docs.fda.gov
Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,
Allan

Allan Guan, Ph.D.
Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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St. Paul, Minnesota 55144

STUDY TITLE

ISO Acute Systemic Toxicity Study in Mice

TEST ARTICLE NAME

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(b)(4)

3M STUDY NUMBER

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Thanks Allan. Working on it right now.

Hilary

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Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

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Office: 651 736 0364 | Fax: 651 737 5320

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From: Guan, Allan <Allan.Guan@fda.hhs.gov>

Sent: Thursday, May 18, 2023 10:10 AM

To: Hilary Hovde <hbhovde@mmm.com>

Cc: K222578@docs.fda.gov; Brendan Casey <bcasey@mmm.com>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hi Hilary,

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Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>

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From: Hilary Hovde <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

Sent: Thursday, May 18, 2023 10:20 AM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<<mailto:Allan.Guan@fda.hhs.gov>>>

Cc: K222578@docs.fda.gov<<mailto:K222578@docs.fda.gov>>; Brendan Casey
<bcasey@mmm.com<<mailto:bcasey@mmm.com>>>

Subject: [EXTERNAL] RE: RE: RE: K222578/S001 interactive review

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Hello Allan,

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Best,

Hilary

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Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

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From: Hilary Hovde

Sent: Thursday, May 18, 2023 8:33 AM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<<mailto:Allan.Guan@fda.hhs.gov>>>

Cc: K222578@docs.fda.gov<<mailto:K222578@docs.fda.gov>>; Brendan Casey
<bcasey@mmm.com<<mailto:bcasey@mmm.com>>>

Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Good Morning Allan,

(b)(4)

Thanks,

Hilary

[cid:image001.gif@01D98972.6A924C30]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

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Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com<mailto:hbhovde@mmm.com>

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Thursday, May 18, 2023 8:18 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Good morning Hilary,

(b)(4)

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of

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Ph: (301) 796-2851

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From: Guan, Allan

Sent: Wednesday, May 17, 2023 3:36 PM

To: 'Hilary Hovde' <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>; Qian, Bifeng
<Bifeng.Qian@fda.hhs.gov<mailto:Bifeng.Qian@fda.hhs.gov>>; Murray III, Clarence
<Clarence.Murray@fda.hhs.gov<mailto:Clarence.Murray@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: RE: K222578/S001 interactive review

Hi Hilary,

Thank you for providing your rationale and the prior Q-Sub feedback.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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From: Hilary Hovde <hbhovde@mmm.com<<mailto:hbhovde@mmm.com>>>

Sent: Wednesday, May 17, 2023 3:10 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<<mailto:Allan.Guan@fda.hhs.gov>>>

Cc: K222578@docs.fda.gov<<mailto:K222578@docs.fda.gov>>; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov<<mailto:Bifeng.Qian@fda.hhs.gov>>>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov<<mailto:Clarence.Murray@fda.hhs.gov>>>

Subject: [EXTERNAL] RE: RE: K222578/S001 interactive review

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Hello Allan,

Thank you to you and the FDA team for the call today to discuss

(b)(4)

(b)(4)

(b)(4)

Best Regards,

Hilary

[cid:image001.gif@01D98972.6A924C30]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

3M Center, Building 275-5W-06 | St. Paul, MN 55144-1000

Office: 651 736 0364 | Fax: 651 737 5320

hbhovde@mmm.com<mailto:hbhovde@mmm.com>

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From: Hilary Hovde

Sent: Monday, May 15, 2023 2:13 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Hi Allan,

Please find our responses to the interactive questions for K222578/S001 below:

(b)(4)

(b)(4)

If I can provide any further clarification please let me know. I am also happy to jump on a quick call if needed.

Best Regards,

Hilary

[cid:image001.gif@01D98972.6A924C30]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, May 15, 2023 8:56 AM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: [EXTERNAL] RE: K222578/S001 interactive review

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

Hi Hilary,

(b)(4)

Please provide your response as soon as possible.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices 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 Room 4535 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

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From: Guan, Allan

Sent: Tuesday, April 25, 2023 5:04 PM

To: 'Hilary Hovde' <hbhovde@mmm.com><<mailto:hbhovde@mmm.com>>>

Subject: RE: [EXTERNAL] RE: K222578/S001 interactive review

Thank you, Hilary. I will let you know if we have any additional questions.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

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From: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Sent: Tuesday, April 25, 2023 4:04 PM

To: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] RE: K222578/S001 interactive review

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Hi Allan,

(b)(4)

Please let me know if additional information is required. I am also happy to jump on a quick call (b)(6) at your convenience as needed.

Thanks so much.

Best,

Hilary

[cid:image001.gif@01D98972.6A924C30]

Hilary B. Hovde | Regulatory Affairs Specialist - HCBG Regulatory Affairs
Commercialization Strategy

3M Medical Solutions Division, Health Care Business Group

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From: Guan, Allan <Allan.Guan@fda.hhs.gov<mailto:Allan.Guan@fda.hhs.gov>>

Sent: Monday, April 24, 2023 2:25 PM

To: Hilary Hovde <hbhovde@mmm.com<mailto:hbhovde@mmm.com>>

Cc: K222578@docs.fda.gov<mailto:K222578@docs.fda.gov>

Subject: [EXTERNAL] K222578/S001 interactive review

Hi Hilary,

The team is reviewing your supplemental response (K222578/S001). At this time, please address the following:

(b)(4)

We kindly request your response by 4/27.

Best regards,

Allan

Allan Guan, Ph.D.

Biomedical Engineer / Team Lead

Personal Protective Equipment, Reprocessing & Disinfection Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of
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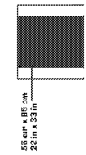
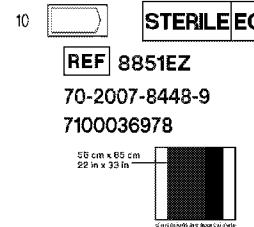
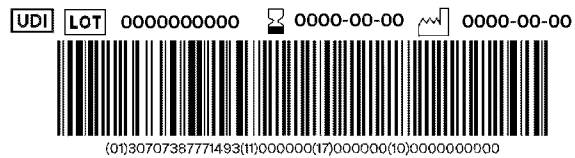
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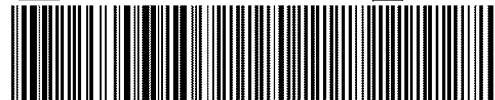
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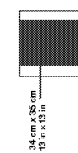
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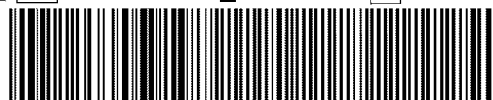
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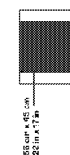
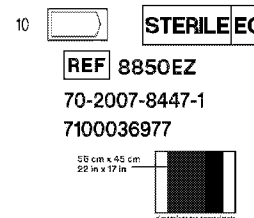
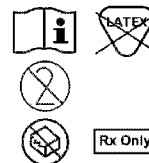
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