Records processed under FOIA Request 2023-0423; Released by CDRH on 05-21-2024

Document Type: Bench-top ☐ Verification ☒ Validation ☐
Protocol ☐ Report ☒

Report Name: (b)(4) – Compatibility evaluation of the MIS Wound Irrigation Solution through irrigation devices

Originator: (b)(4)

Type: Design Verification

Product: MIS Wound Irrigation Solution (b)(4)

Date: 05/05/2020

(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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Recommended RTA Advisory Comment E-Mail Format

Subject Line:

K203835 - Next Science, LLC., MIS Solution – FDA Advisory Comments

Body of E-mail:

Courtney Narain, Regulatory Affairs Specialist
Next Science, LLC
10550 Deerwood Park Blvd Ste 300, Jacksonville, FL 32256
cnarain@nextscience.com

Dear Ms. Narain:

I am reviewing your submission for the MIS Solution, which has been assigned file number K203835. I've completed the RTA review of your submission and the email notification of your RTA status was sent on today, January 13, 2021. While conducting the RTA review, I noted some issues unrelated to the RTA review that will need to be resolved prior to a final decision (Note: a complete review of the submission has not been conducted at this time). You do not need provide a response to these issues in your RTA response in order to be accepted; however, they are likely to be raised during the substantive review. I'm presenting them to you now to give you the opportunity to get an early start on addressing these issues:

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(b)(4)

If you choose, you may include your response to these issues along with your RTA response and I will assess your response to these issues during the substantive review of your submission. I suggest you distinguish your response to these issues from your RTA response in order to make it clear that these are not in response to the RTA notice (e.g., in a separate appendix or heading). If you have any questions about these issues or any issues raised in the RTA checklist, please contact me.

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

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Change Control Table

Version	Document Author	Revision	Date
(b)(4)	Nathan Ivey	SWIFT migration	11/29/2016

Document Clearance Table

Version	Name	Review Type	Date
(b)(4)	Nathan Ivey	author	11/29/2016
	Marjorie Shulman	510(k) staff concurrence	11/29/2016
	Barbara Zimmerman	approval	12/4/16

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

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Predicate Evaluation (510k Decision Making-Flowchart)

The following is an evaluation of the predicate choice, Next Science Irrigation Solution, for the MIS Solution 510(k). The evaluation below utilizes the FDA critical decision points outlined in the 510(k) Decision-Making Flowchart found FDA Guidance for Industry, "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]."

1. ***Is the predicate device legally marketed?***
   Yes. The predicate device is legally marketed. Next Science Irrigation Solution was cleared as K161165.

2. ***Do the devices have the same intended use?***
   Yes. MIS Solution and the predicate device are intended for use as a wound cleanser, to mechanically clean and remove debris from the wound. MIS Solution and the predicate device have the same indications for use.

3. ***Do the devices have the same technological characteristics?***
   Yes. MIS Solution and the predicate device have different formulations; however the two devices share the same technological characteristics. Both contain a surfactant, a buffering system, and a solvent. While not present in the predicate device, the ingredients in the MIS Solution are present in a legally marketed device (Next Science Wound Gel (K163188)), and also have the same technological characteristics of the predicate, as discussed in the tables below.

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The table below outlines the similarities:

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Therefore, the ingredients within the predicate device are functionally equivalent to the subject device as both the subject device and predicate device have the same basic core functional composition including a surfactant, buffer system, and solvent.

4. ***Do the devices raise different questions of safety and effectiveness?***

   No. Although the composition of the proposed device and the predicate device differs, the relevant questions of safety and effectiveness raised by both devices are whether the devices present any safety concerns and whether they are able to successfully remove debris from a wound. Furthermore, SLS was chosen as the surfactant because, at the same concentration, BZK demonstrates a higher irritant or cytotoxic potential than SLS both clinically and in vitro assay[7]. The test results of the biocompatibility testing and the porcine wound healing study and product performance testing demonstrate that MIS Solution is safe and effective for its intended use.

[7] http://elmygos.lsmuni.lt/springer/236/Part%20VII/3%20Item.pdf

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Toxicity and Safety Assessment Table

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As a result, the proposed device (MIS Solution) has an improved safety profile over the predicate Next Science Irrigation Solution when comparing toxicity of the individual components.

5. Are the methods acceptable?

Yes. MIS Solution has followed the FDA-recognized consensus standard ISO 10993 to perform biocompatibility testing of the solution

6. Do the data demonstrate equivalence and support the indications?

Yes. As demonstrated by biocompatibility, toxicological assessment, nonclinical testing and performance testing, MIS Solution is at least as safe and effective as the predicate device.

In addition to the above justification, Next Science's previous experience in submitting our cleared Irrigation Solution K161165, we relied on a similar predicate comparison whereby the ingredients of the predicate were significantly different from the subject device, but those ingredients were functionally equivalent as in our current submission.

Composition	**Next Science Irrigation Solution (Predicate - K161165)**	**Prontosan Wound Irrigation Solution (Reference - K072876)**
Surfactant	Benzalkonium chloride	Undecylenamidopropylbetaine
Antimicrobial	N/A	Polyaminopropyl biguanide
pH adjuster (buffer system)	Sodium acetate, Acetic acid	Sodium hydroxide
Vehicle (Solvent)	Purified water, Ethanol	Purified Water

(b)(4)

In regard to MIS Solution, we have also completed biocompatibility and porcine wound healing which both demonstrate that MIS Solution is safe for its intended use.

In sum, even though the ingredients are not identical, the data submitted in this 510(k) are sufficient to demonstrate substantial equivalence to the predicate device.

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

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From: Lively, Harmony * [Harmony.Lively@fda.hhs.gov]
Sent: 3/26/2021 3:54:34 PM
To: cnarain@nextscience.com
Subject: K203835/S002- Acknowledgment Notification
Attachments: K203835.S002- Letter.pdf

Harmony E. Lively
Records Management Specialist 1
CDRH Document Control Center
HeiTech Services, Inc.

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

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Acknowledgment Letter

3/26/2021

Courtney Narain, Regulatory Affairs Specialist
Next Science, LLC
10550 Deerwood Park Blvd Ste 300
Jacksonville, FL 32256
UNITED STATES

Dear Courtney Narain:

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 above letterhead address. 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: K203835/S002
Received: 3/25/2021
Applicant: Next Science, LLC
Device: MIS Solution

We will notify you when the review of this document has been completed or if any additional information is required. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

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

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From: Marquart, Laura
To: Liu, Lixin; Mazher, Mustafa; Ferlin, Kimberly
Subject: RE: K203835/S001 assigned: team (b)(5)
Date: Wednesday, March 17, 2021 8:50:04 AM
Attachments: image003.png

Hello,

(b)(5)

Thanks for checking with me!
Laura

From: Liu, Lixin <Lixin.Liu@fda.hhs.gov>
Sent: Tuesday, March 16, 2021 3:33 PM
To: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>; Marquart, Laura <Laura.Marquart@fda.hhs.gov>; Ferlin, Kimberly <Kimberly.Ferlin@fda.hhs.gov>
Subject: RE: K203835/S001 assigned: team (b)(5)

Hi, Mustafa:

(b)(5)

Thanks,

Lixin

From: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>
Sent: Tuesday, March 16, 2021 3:19 PM
To: Liu, Lixin <Lixin.Liu@fda.hhs.gov>; Marquart, Laura <Laura.Marquart@fda.hhs.gov>; Ferlin, Kimberly <Kimberly.Ferlin@fda.hhs.gov>
Subject: RE: K203835/S001 assigned: team (b)(5)

Hello,

(b)(5)

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(b)(5)

Thanks,

Mustafa

From: Liu, Lixin <Lixin.Liu@fda.hhs.gov>
Sent: Tuesday, March 16, 2021 10:35 AM
To: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>; Marquart, Laura <Laura.Marquart@fda.hhs.gov>; Ferlin, Kimberly <Kimberly.Ferlin@fda.hhs.gov>
Subject: RE: K203835/S001 assigned: team (b)(5)

Hi, Mustafa:

(b)(5)

Thanks,

Lixin

From: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>
Sent: Tuesday, March 16, 2021 9:54 AM
To: Liu, Lixin <Lixin.Liu@fda.hhs.gov>; Marquart, Laura <Laura.Marquart@fda.hhs.gov>; Ferlin, Kimberly <Kimberly.Ferlin@fda.hhs.gov>
Subject: RE: K203835/S001 assigned: team (b)(5)

(b)(5)

Best,

Mustafa

From: Liu, Lixin <Lixin.Liu@fda.hhs.gov>
Sent: Tuesday, March 16, 2021 9:37 AM
To: Marquart, Laura <Laura.Marquart@fda.hhs.gov>; Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>; Ferlin, Kimberly <Kimberly.Ferlin@fda.hhs.gov>
Subject: RE: K203835/S001 assigned: team (b)(5)

Hi, Laura:

(b)(5)

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(b)(5)

Thanks,

Lixin

From: Marquart, Laura <Laura.Marquart@fda.hhs.gov>
Sent: Tuesday, March 16, 2021 8:54 AM
To: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>; Liu, Lixin <Lixin.Liu@fda.hhs.gov>; Ferlin, Kimberly <Kimberly.Ferlin@fda.hhs.gov>
Subject: RE: K203835/S001 assigned: team (b)(5)

Hi Mustafa,

(b)(5)

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(b)(5)

Let me know what you think, Thanks,
Laura

From: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>
Sent: Thursday, March 11, 2021 3:57 PM
To: Marquart, Laura <Laura.Marquart@fda.hhs.gov>; Liu, Lixin <Lixin.Liu@fda.hhs.gov>; Ferlin, Kimberly <Kimberly.Ferlin@fda.hhs.gov>
Subject: RE: K203835/S001 assigned: team (b)(5)

Thanks, I will issue a consult to Laura.

From: Marquart, Laura <Laura.Marquart@fda.hhs.gov>
Sent: Thursday, March 11, 2021 3:35 PM
To: Liu, Lixin <Lixin.Liu@fda.hhs.gov>; Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>; Ferlin, Kimberly <Kimberly.Ferlin@fda.hhs.gov>
Subject: RE: K203835/S001 assigned: team (b)(5)

Sounds good!

From: Liu, Lixin <Lixin.Liu@fda.hhs.gov>
Sent: Thursday, March 11, 2021 3:08 PM
To: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>; Marquart, Laura <Laura.Marquart@fda.hhs.gov>; Ferlin, Kimberly <Kimberly.Ferlin@fda.hhs.gov>
Subject: RE: K203835/S001 assigned: team (b)(5)

Mustafa:

(b)(5)

Thanks,

Lixin

From: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>
Sent: Thursday, March 11, 2021 3:00 PM
To: Liu, Lixin <Lixin.Liu@fda.hhs.gov>; Marquart, Laura <Laura.Marquart@fda.hhs.gov>; Ferlin, Kimberly <Kimberly.Ferlin@fda.hhs.gov>
Subject: RE: K203835/S001 assigned: team (b)(5)

Hello Lixin,

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(b)(5)

Thanks,

Mustafa

From: Liu, Lixin <Lixin.Liu@fda.hhs.gov>
Sent: Thursday, March 11, 2021 2:37 PM
To: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>; Marquart, Laura <Laura.Marquart@fda.hhs.gov>; Ferlin, Kimberly <Kimberly.Ferlin@fda.hhs.gov>
Subject: RE: K203835/S001 assigned: team (b)(5)

Hi, Mustafa:

(b)(5)

Thanks,

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Lixin

From: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>
Sent: Thursday, March 11, 2021 2:20 PM
To: Marquart, Laura <Laura.Marquart@fda.hhs.gov>; Liu, Lixin <Lixin.Liu@fda.hhs.gov>; Ferlin, Kimberly <Kimberly.Ferlin@fda.hhs.gov>
Subject: RE: K203835/S001 assigned: team (b)(5)

Great, thank you!

From: Marquart, Laura <Laura.Marquart@fda.hhs.gov>
Sent: Thursday, March 11, 2021 1:01 PM
To: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>; Liu, Lixin <Lixin.Liu@fda.hhs.gov>; Ferlin, Kimberly <Kimberly.Ferlin@fda.hhs.gov>
Subject: RE: K203835/S001 assigned: team (b)(5)

Hi Mustafa,

(b)(5)

Please let me know if you have any other questions, Thanks,
Laura

From: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>
Sent: Thursday, March 11, 2021 12:52 PM
To: Marquart, Laura <Laura.Marquart@fda.hhs.gov>; Liu, Lixin <Lixin.Liu@fda.hhs.gov>; Ferlin, Kimberly <Kimberly.Ferlin@fda.hhs.gov>
Subject: RE: K203835/S001 assigned: team (b)(5)

Thanks again Laura!

(b)(5)

Please let me know if you have any questions for me.

Best,

Mustafa

From: Marquart, Laura <Laura.Marquart@fda.hhs.gov>
Sent: Thursday, March 11, 2021 6:59 AM
To: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>; Liu, Lixin <Lixin.Liu@fda.hhs.gov>; Ferlin, Kimberly <Kimberly.Ferlin@fda.hhs.gov>
Subject: RE: K203835/S001 assigned: team (b)(5)

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(b)(5)

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Please let me know if you have any questions, thanks,
Laura

From: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>
Sent: Thursday, February 18, 2021 11:36 AM
To: Marquart, Laura <Laura.Marquart@fda.hhs.gov>
Subject: FW: K203835/S001 assigned: team (b)(5)

Hey Laura,
Thank you for agreeing to take a consult for this submission. I will send a consult via CTS, shortly.

(b)(5)

Please let me know if you have any questions for me.

Best

Mustafa

From: Ferlin, Kimberly <Kimberly.Ferlin@fda.hhs.gov>
Sent: Friday, January 22, 2021 1:18 PM
To: Azeke, John <John.Azeke@fda.hhs.gov>; Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>
Cc: Liu, Lixin <Lixin.Liu@fda.hhs.gov>
Subject: RE: K203835/S001 assigned: team (b)(5)

Hi Mustafa and John,

(b)(5)

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

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Thanks,
Kim

Kimberly M. Ferlin, Ph.D.
Acting Assistant Director
Plastic Surgery Skin and Wound Devices Team
FDA|CDRH|OPEQ|OHT4|DHT4B
U.S. FOOD & DRUG ADMINISTRATION

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

From: Ferlin, Kimberly
Sent: Thursday, January 21, 2021 7:24 PM
To: Azeke, John <John.Azeke@fda.hhs.gov>
Cc: Liu, Lixin <Lixin.Liu@fda.hhs.gov>
Subject: K203835/S001 assigned: team **(b)(5)**

Hi John,

(b)(5)

The team due date for RTA is 1/28. Please let me know if you have any questions.

Thanks,
Kim

Kimberly M. Ferlin, Ph.D.
Acting Assistant Director
Plastic Surgery Skin and Wound Devices Team
FDA|CDRH|OPEQ|OHT4|DHT4B
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I am reviewing your submission for the MIS Solution, which has been assigned file number K203835. I've completed the RTA review of your submission and the email notification of your RTA status was sent on today, January 13, 2021. While conducting the RTA review, I noted some issues unrelated to the RTA review that will need to be resolved prior to a final decision (Note: a complete review of the submission has not been conducted at this time). You do not need provide a response to these issues in your RTA response in order to be accepted; however, they are likely to be raised during the substantive review. I'm presenting them to you now to give you the opportunity to get an early start on addressing these issues:

(b)(4)

If you choose, you may include your response to these issues along with your RTA response and I will assess your response to these issues during the substantive review of your submission. I suggest you distinguish your response to these issues from your RTA response in order to make it clear that these are not in response to the RTA notice (e.g., in a separate appendix or heading). If you have any questions about these issues or any issues raised in the RTA checklist, please contact me.

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

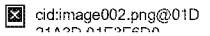
Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

Thank you!

Lixin Liu, Ph.D.
Biologist/Team Lead

Plastic Surgery Skin and Wound Devices 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
Tel: 301-796-3480
Lixin.Liu@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/r/cdrhcustomerservice?ID=2001&S=E

From: Lixin Liu <lixin.liu@fda.hhs.gov>
Sent: Wednesday, January 13, 2021 4:17 PM
To: cnarain@nextscience.com
Cc: Liu, Lixin <Lixin.Liu@fda.hhs.gov>
Subject: K203835 is on Hold Pending Your Response

January 13, 2021

Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your submission K203835. Our review indicates that your submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit one eCopy of your response, referencing your submission K203835, addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Your submission will remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist by 07/12/2021, we will consider this submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your submission. We will contact you if we require any additional information during the course of our administrative review. FDA aims to apply the least burdensome principles when requesting additional information.

The lead reviewer assigned to your submission is me, Lixin Liu. The file is being reviewed in Office of Health Technology 4, Division of Health Technology 4 B. The first line supervisor is the Assistant Director, Plastic Surgery Skin and Wound Devices. You may contact me at any point during the review if you have questions or concerns. You can provide valuable support for CDRH to continue to improve our programs by raising to the attention of management relevant issues that arise during the course of this review. If you feel there is an unresolved issue or a matter that requires additional attention, you should contact the Assistant Director. If your concern or issue is not addressed by the Assistant Director, you should contact the Division Director or OHT Director. The contact information for each management level can be found in the CDRH Management Directory.

For additional information about the Refuse to Accept Policy for for 510(k)s please refer to the guidance document available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf.

If you have general questions about the review process for your submission, you should contact OPEQSubmissionSupport@fda.hhs.gov.

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

Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

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Records processed under FOIA Request 2023-0423; Released by CDRH on 05-21-2024

NEXT SCIENCE

(b)(4)	MIS Wound Irrigation Solution	(b)(4)	
Issued by: (b)(4)		(b)(4)	Rev (b)(4) Pg. 1 of 3
(b)(4)			

(b)(4)

To: (b)(4)

Date: 16 November 2020

(b)(4)

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

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Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

U.S. FOOD & DRUG ADMINISTRATION

April 23, 2021

Next Science, LLC
Courtney Narain
Regulatory Affairs Specialist
10550 Deerwood Park Blvd Ste 300
Jacksonville, Florida 32256

Re: K203835
Trade/Device Name: MIS Solution
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 25, 2021
Received: March 26, 2021

Dear Courtney Narain:

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

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

Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

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,

Lixin Liu -S

Lixin Liu, Ph.D.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

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

Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

Hi, Courtney:

Thank you for reaching us on K203835 administrative review.

To help expediate our administrative review process for your future supplement, we will appreciate if you may provide response to each RTA item in your future cover letter. Please specify which section/attachment has been revised to align with your response to the RTA item. It is optional that you provide the entire 510k submission, or provide only the updated section/attachment in your future supplement.

(b)(4)

I hope this response may clarify your questions.

Thank you!

Lixin Liu, Ph.D.

Biologist/Team Lead

Plastic Surgery Skin and Wound Devices 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

Tel: 301-796-3480

Lixin.Liu@fda.hhs.gov<mailto:Lixin.Liu@fda.hhs.gov>

[cid:image002.png@01D21A3D.01E3F6D0]<http://www.fda.gov/>

[cid:image003.jpg@01D21A3D.01E3F6D0]<https://www.facebook.com/FDA>
[cid:image004.jpg@01D21A3D.01E3F6D0] <https://twitter.com/US_FDA>
[cid:image005.jpg@01D21A3D.01E3F6D0] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image006.jpg@01D21A3D.01E3F6D0] <http://www.flickr.com/photos/fdaphotos/>
[cid:image007.jpg@01D21A3D.01E3F6D0]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/r/cdrhcustomerservice?ID=2001&S=E

From: Courtney Narain <cnarain@nextscience.com>

Sent: Thursday, January 14, 2021 6:19 PM

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

Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

To: Liu, Lixin <Lixin.Liu@fda.hhs.gov>

Subject: RE: K203835 is on Hold Pending Your Response

Dear Lixin,

Thank you for the advisory comments. Next Science appreciates the collaborative gesture and looks forward to working with you on this submission.

(b)(4) Next Science wants to ensure the information and resolutions to issues are easily locatable. With that said, the following questions are being asked to ensure accurate RTA resolutions:

(b)(4)

Sincerely,

Courtney

[cid:image001.png@01D6EB33.0A0641D0]

From: Lixin Liu <lixin.liu@fda.hhs.gov<mailto:lixin.liu@fda.hhs.gov>>

Sent: Wednesday, January 13, 2021 4:17 PM

To: Courtney Narain <cnarain@nextscience.com<mailto:cnarain@nextscience.com>>

Cc: Lixin Liu <lixin.liu@fda.hhs.gov<mailto:lixin.liu@fda.hhs.gov>>

Subject: K203835 is on Hold Pending Your Response

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

January 13, 2021

Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your submission K203835. Our review indicates that your submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit one eCopy of your response, referencing your submission K203835, addressing the elements identified as missing or inconsistent in the attached checklist to:

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

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U.S. Food and Drug Administration

Center for Devices and Radiological Health

Document Control Center - WO66-G609

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

Your submission will remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist by 07/12/2021, we will consider this submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your submission. We will contact you if we require any additional information during the course of our administrative review. FDA aims to apply the least burdensome principles<https://www.fda.gov/media/73188/download> when requesting additional information.

The lead reviewer assigned to your submission is me, Lixin Liu. The file is being reviewed in Office of Health Technology 4, Division of Health Technology 4 B. The first line supervisor is the Assistant Director, Plastic Surgery Skin and Wound Devices. You may contact me at any point during the review if you have questions or concerns. You can provide valuable support for CDRH to continue to improve our programs by raising to the attention of management relevant issues that arise during the course of this review. If you feel there is an unresolved issue or a matter that requires additional attention, you should contact the Assistant Director. If your concern or issue is not addressed by the Assistant Director, you should contact the Division Director or OHT Director. The contact information for each management level can be found in the CDRH Management Directory<https://www.fda.gov/about-fda/cdrh-offices/cdrh-management-directory-organization>.

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If you have general questions about the review process for your submission, you should contact OPEQSubmissionSupport@fda.hhs.gov<mailto:OPEQSubmissionSupport@fda.hhs.gov>.

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

NEXT SCIENCE Records processed under FOIA Request 2023-0423, Released by CDRH on 05-21-2024
Next Science, LLC
Jacksonville, FL ~ www.nextscience.com

Document Type:	Bench-top ☐	Verification ☒	Validation ☐
	Protocol ☐	Report ☒	

Report Name: (b)(4) Combined Debris Removal Efficacy of MIS and Next Science Irrigation Solution

Originator: (b)(4)

Type: Verification

Product: Wound Irrigation Solutions

Date: 12/21/2020

(b)(4)

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

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Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

February 3, 2021</br></br>

Acceptance Review Notification - Accepted

An administrative acceptance review was conducted on your submission K203835/S001, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review.

The lead reviewer assigned to your submission is me, Mustafa Mazher. The file is being reviewed in Office of Health Technology 4, Division of Health Technology 4 B. The first line supervisor is the Assistant Director, Plastic Surgery Skin and Wound Devices. You may contact me at any point during the review if you have questions or concerns. You can provide valuable support for CDRH to continue to improve our programs by raising to the attention of management relevant issues that arise during the course of this review. If you feel there is an unresolved issue or a matter that requires additional attention, you should contact the Assistant Director. If your concern or issue is not addressed by the Assistant Director, you should contact the Division Director or OHT Director. The contact information for each management level can be found in the CDRH Management Directory.

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Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

Animal Study Consult Review Memo for: K203835/S001

Device Name: MIS Solution
Date: March 8, 2021
To: Mustafa Mazher, Ph.D. (CDRH\OHT4\DHT4B\THT4B4)
Reviewer: John Azeke, Ph.D. (CDRH\OHT4\DHT4B\THT4B4)

Company Name: Next Science, LLC
10550 Deerwood Park Blvd Ste 300
Jacksonville, FL 32256 USA
Contact: Courtney Narain, Regulatory Affairs Specialist
(855) 564-2762 Ext.6004 [voice]
cnarain@nextscience.com

(b)(5)

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(b)(5)

Digital Signature Concurrence Table	
Reviewer Sign-Off	John Azeke -S Digitally signed by John Azeke -S Date: 2021.03.08 18:34:44 -05'00'

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

Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

FINAL REPORT

IRRITATION EVALUATION OF TEST ITEMS IN THE INCISION WOUND HEALING MODEL IN PIGS

STUDY NUMBER

(b)(4)

Ethical Approval No. (b)(4)

Test Facility:

(b)(4)

Sponsor:
Next Science, Ltd.
10550 Deerwood Park Blvd., Suite 300
Jacksonville FL 32256,
USA

Study Director:
(b)(4)

Sponsor representative:
(b)(4)

Test Site:

(b)(4)

Principal Investigator:
(b)(4)

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

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תעודת בדיקה

(b)(4)

(b)(4)

התקבל באמבר דרום: (b)(4)

נבדק בתאריך:

יצור/משלוח:

תאריך הדפסה:

נקודת הדגימה: (b)(4)

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FINAL HISTOPATHOLOGY REPORT

IRRITATION EVALUATION OF TEST ITEMS IN THE INCISION WOUND HEALING MODEL IN PIGS

STUDY NUMBER

(b)(4)

Consulting Pathologist

(b)(4)

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Next Science
10550 Deerwood Park Blvd. #300
Jacksonville, FL, USA, 32256
Telephone: (855) 564 2762

XPERIENCE™ No Rinse Antimicrobial Solution
SDS Preparation Date (mm/dd/yyyy): (b)(4)

SAFETY DATA SHEET

(b)(4)

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Next Science
10550 Deerwood Park Blvd. #300
Jacksonville, FL, USA, 32256
Telephone: (855) 564 2762

Bactisure™ Wound Lavage
SDS Preparation Date (mm/dd/yyyy): (b)(4)

SAFETY DATA SHEET

(b)(4)

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(b)(4)	PiSA Lot (b)(4) Bactisure SL-0001	(b)(4)	
Issued by: (b)(4)		(b)(4) Rev (b)(4)	Pg. 1 of 8
(b)(4)			

NEXT SCIENCE

Certificate of Compliance

Date Issued: (b)(4)

Customer: (b)(4)

(b)(4)

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From: Marquart, Laura
To: Mazher, Mustafa; Liu, Lixin; Ferlin, Kimberly
Subject: RE: K203835/S001 assigned: team (b)(5)
Date: Thursday, March 11, 2021 6:59:16 AM
Attachments: image001.png

Hi Mustafa,

(b)(5)

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

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(b)(5)

Please let me know if you have any questions, thanks,
Laura

From: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>
Sent: Thursday, February 18, 2021 11:36 AM
To: Marquart, Laura <Laura.Marquart@fda.hhs.gov>
Subject: FW: K203835/S001 assigned: team (b)(5)

Hey Laura,
Thank you (b)(5)

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

Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

(b)(5)

Please let me know if you have any questions for me.

Best

Mustafa

From: Ferlin, Kimberly <Kimberly.Ferlin@fda.hhs.gov>
Sent: Friday, January 22, 2021 1:18 PM
To: Azeke, John <John.Azeke@fda.hhs.gov>; Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>
Cc: Liu, Lixin <Lixin.Liu@fda.hhs.gov>
Subject: RE: K203835/S001 assigned: team (b)(5)

Hi Mustafa and John,

(b)(5)

Thanks,
Kim

Kimberly M. Ferlin, Ph.D.
Acting Assistant Director
Plastic Surgery Skin and Wound Devices Team
FDA|CDRH|OPEQ|OHT4|DHT4B
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From: Ferlin, Kimberly
Sent: Thursday, January 21, 2021 7:24 PM
To: Azeke, John <John.Azeke@fda.hhs.gov>
Cc: Liu, Lixin <Lixin.Liu@fda.hhs.gov>
Subject: K203835/S001 assigned: team (b)(5)

Hi John,

(b)(5)

Thanks,
Kim

Kimberly M. Ferlin, Ph.D.
Acting Assistant Director
Plastic Surgery Skin and Wound Devices Team
FDA|CDRH|OPEQ|OHT4|DHT4B
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K203835
Next Science, LLC
Trade/Device Name: MIS Solution
Contact Name: Courtney Narain

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 K203835 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 K203835 to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Please refer to the eCopy guidance at https://www.fda.gov/media/83522/download for current information on eCopy requirements.

Your response is due within 180 days from the date of this request, which is the hold date plus 180 days. If a complete response is not received in CDRH's Document Control Center by this date, we will consider this submission to be withdrawn, and we will delete it from our review system.

You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without FDA clearance, you will be in violation of the Federal Food, Drug, and Cosmetic Act.

If you would like a meeting or teleconference with the review team and management to discuss your planned approach for responding to the attached deficiencies, please submit your request for feedback as a Submission Issue Q-Submission (Q-Sub). Please note that a Submission Issue Q-Sub does not take the place of a formal response to this email notification. As noted above, FDA will consider this submission to be withdrawn if FDA does not receive, in a submission to the Document Control Center, a complete response to all of the attached deficiencies within 180 calendar days of the date of this request.

This request for additional information has undergone supervisory review to ensure that the deficiencies cited are least burdensome and relevant to the marketing decision. Please see the revised guidance "Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions" issued on September 29, 2017 (https://www.fda.gov/media/71735/download) for clarification regarding major and minor deficiencies.

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

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MAJOR DEFICIENCY LIST

(b)(4)

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(b)(4)

FDA is offering a teleconference within 10 calendar days from the date on this letter to address any clarification questions you may have pertaining to the deficiencies. If you are interested in a teleconference, please provide (1) proposed dates and (2) a list of your clarification questions via email at least 48 hours before the teleconference to the lead reviewer assigned to your submission. We would like to emphasize that the purpose of the meeting is to address specific clarification questions. Please note that if the specific clarification questions are not received at least 48 hours before the teleconference, the review team might not be able to provide feedback. The teleconference is not intended for review of new information, test methods or data; these types of questions could be better addressed via a Submission Issue Q-Submission (Q-Sub). For additional information regarding Q-Subs, please refer to the Guidance for Industry and FDA Staff on Medical Devices: Requests for Feedback and Meetings for Medical Device Submissions at https://www.fda.gov/media/114034/download.

Least Burdensome (LB) Flag

The LB flag is an approach to allow submitters the opportunity for the informal review by or on behalf of Division management of an issue raised in an FDA request for additional information (i.e., a deficiency letter). The goal of the LB flag is to quickly address FDA requests that submitters do not believe are least burdensome or when submitters believe they are being held to a different standard than their legally marketed predicate device. The LB flag is not intended to clarify deficiencies, is not an appeal under 21 CFR 10.75, and is not intended to provide a review of a proposed response to deficiencies.

If you would like to throw the LB flag, FDA has several criteria that should be met before you submit your request:

- You should have tried to address your concern by discussing it with Division management before attempting to throw the LB flag. This discussion with Division management may take place as part of a teleconference (such as the voluntary teleconference held within 10 days following transmission of an Additional Information letter to clarify deficiencies), email, or a Q-Submission Submission Issue Request.
- Your flag should generally be limited to two topic areas. Topic areas are common premarket review deficiency categories that apply to many device types across multiple reviewing Divisions. Examples of topic areas include biocompatibility, sterility, reprocessing, software, electromagnetic compatibility, wireless, electrical safety, clinical, and non-clinical performance testing.
- If you would like to discuss issues pertaining to more than two topic areas, you should contact OPEQSubmissionSupport@fda.hhs.gov for more information.
- You should throw the LB flag within 60 calendar days of the date that FDA sent the deficiency letter.

Upon meeting the criteria, you should send a short email (e.g., 1-2 page) that includes: 1) a summary of the deficiencies under disagreement, 2) a summary of relevant communications with Division management, and 3) a proposed path forward. The LB flag should be sent to the lead reviewer and their Assistant Director. You should also copy OPEQSubmissionSupport@fda.hhs.gov on your LB flag email request. Within two

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business days of your email, your request will be acknowledged by the reviewing Division. If you do not meet the criteria for the LB flag, you will be notified in this acknowledgement email.

Your LB flag should contain sufficient information to determine whether the deficiency letter was not least burdensome, or you are being held to a different standard than your predicate device. FDA may request a phone call with you to discuss your concern further and intends to communicate feedback from Division management on LB flags through email no later than 21 calendar days of their receipt. Please note that the LB flag does not change the deadline for your response to the Document Control Center. If you have any questions, please contact OPEQSubmissionSupport@fda.hhs.gov.

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From: Rimmer, Ralph
To: Mazher, Mustafa
Subject: RE: K203835/S001 (b)(5)
Date: Wednesday, March 17, 2021 3:10:10 PM
Attachments: image001.png
image003.png

Hi Mustafa

Please consider this email as the closure of my consult for K203835.

(b)(5)

Sincerely
Dale Rimmer

R. Dale Rimmer, Ph.D.
Chemist, Lead Reviewer
Plastic Surgery Implant Devices Team
DHT4B: Division of Plastic Surgery Devices and Infection Control
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food & Drug Administration
White Oak, Bldg. 66 | 10903 New Hampshire Ave | Silver Spring, MD 20993

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

Tel: 240.402.4828
Ralph.Rimmer@fda.hhs.gov
U.S. FOOD & DRUG ADMINISTRATION

From: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>
Sent: Wednesday, March 17, 2021 2:02 PM
To: Rimmer, Ralph <Ralph.Rimmer@fda.hhs.gov>
Subject: RE: K203835/S001 (b)(5)

Hello Dale,

(b)(5)

Thanks,

Mustafa

From: Rimmer, Ralph <Ralph.Rimmer@fda.hhs.gov>
Sent: Monday, March 15, 2021 12:46 PM
To: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>
Cc: Hailemariam, Kiros <Kiros.Hailemariam@fda.hhs.gov>
Subject: RE: K203835/S001 (b)(5)

Thanks, Mustafa

(b)(5)

Dale

From: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>
Sent: Monday, March 15, 2021 12:23 PM

Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

To: Rimmer, Ralph <Ralph.Rimmer@fda.hhs.gov>
Cc: Hailemariam, Kiros <Kiros.Hailemariam@fda.hhs.gov>
Subject: RE: K203835/S001 **(b)(5)**

Hello Dale,

(b)(5)

Thanks for your help both, I understand that you all have heavy workloads.

Best,

Mustafa

From: Rimmer, Ralph <Ralph.Rimmer@fda.hhs.gov>
Sent: Monday, March 15, 2021 11:56 AM
To: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>
Cc: Hailemariam, Kiros <Kiros.Hailemariam@fda.hhs.gov>
Subject: RE: K203835/S001 **(b)(5)**

Hi Mustafa

(b)(5)

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

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(b)(5)

Sincerely
Dale

From: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>
Sent: Tuesday, February 9, 2021 3:51 PM
To: Rimmer, Ralph <Ralph.Rimmer@fda.hhs.gov>
Subject: FW: K203835/S001 assigned: team (b)(5)

Hello Dale,
I hope you are doing well. I had a request, if you have to capacity to accommodate it -

(b)(5)

Best,

Mustafa

From: Ferlin, Kimberly <Kimberly.Ferlin@fda.hhs.gov>
Sent: Friday, January 22, 2021 1:18 PM

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

To: Azeke, John <John.Azeke@fda.hhs.gov>; Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>
Cc: Liu, Lixin <Lixin.Liu@fda.hhs.gov>
Subject: RE: K203835/S001 assigned: team (b)(5)

Hi Mustafa and John,

(b)(5)

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Kim

Kimberly M. Ferlin, Ph.D.
Acting Assistant Director
Plastic Surgery Skin and Wound Devices Team
FDA|CDRH|OPEQ|OHT4|DHT4B
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From: Ferlin, Kimberly
Sent: Thursday, January 21, 2021 7:24 PM
To: Azeke, John <John.Azeke@fda.hhs.gov>
Cc: Liu, Lixin <Lixin.Liu@fda.hhs.gov>
Subject: K203835/S001 assigned: team (b)(5)

Hi John,

(b)(5)s

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(b)(5)

Thanks,
Kim

Kimberly M. Ferlin, Ph.D.
Acting Assistant Director
Plastic Surgery Skin and Wound Devices Team
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April 23, 2021</br></br> We have completed our review. Please refer to the attached letter for details.

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

 *** This is a system-generated email notification ***

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

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(b)(4)

Final Report

Test Description:	**ISO Guinea Pig Maximization Sensitization Test (GLP - Method for Liquid Test Article)**
Sponsor:	**Next Science, LLC** **10550 Deerwood Park Boulevard** **Suite 300** **Jacksonville, FL 32256** **US**
Sponsor Account Number:	(b)(4)
Performing Laboratory:	(b)(4)
Folder Number:	(b)(4)
Test Code:	(b)(4)
Report Number:	(b)(4)
Sample Number: **Test Article Name:** **Test Article Code, Batch, or Lot Number:**	(b)(4)

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

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U.S. FOOD & DRUG ADMINISTRATION

ood and Drug Administration
Office Location
Business Address
Phone Number

Premarket Notification 510(k) Review

Pre-Review Reminders

- ☐ ← Click this checkbox to delete these directions (**Click "Enable Content" above first, if present**). Blue text indicates the text is clickable. Clicking may display tips and/or directions specific to that sentence (e.g., "Appropriate Manual Labeling" below) or section (e.g., "Premarket Notification 510(k) Review" above); it may also link to a website, form or CARS report.
- ☐ Complete the RTA checklist
- ☐ Final guidance and recognized consensus standards are recommendations. They are not binding, and applicants may demonstrate substantial equivalence using an alternative approach.

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: March 19, 2021

Reviewer: Mustafa A. Mazher

Subject: Traditional 510(k)# K203835/S001

Applicant: Next Science, LLC

Device Trade Name: MIS Solution

Contact Name: Courtney Narain

Contact Title: Regulatory Affairs Specialist

Correspondent Firm: Next Science, LLC

Phone: (855) 564-2762 Ext.6004 **Email:** cnarain@nextscience.com

Received Date: January 19, 2021

Due Date: April 19, 2021

Pro Code(s): FRO **Class:** Unclassified **Reg #:**

Reg Name:

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K161165	FQH, FRO	Next Science Irrigation Solution	Next Science, LLC

(b)(5)

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Digital Signature Concurrence Table (Doc ID: 04500.14.04)		
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	Mustafa A. Mazher -S	Mustafa A. Mazher -S 2021.03.19 10:49:22 -04'00'

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Contains Nonbinding Recommendations

Print Form

510(k) Acceptance Checklist

Not for use with Third Party 510(k)s

Choose Submission Type: ☒ **Traditional** ☐ **Abbreviated** ☐ **Special**

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K203835 Date Received by DCC: Dec 30, 2020

Lead Reviewer: Lixin Liu

Center: CDRH Office: OHT 4 Division: DHT4B

Decision:

○ Accept. If Accept, notify submitter.

◉ Refuse to Accept. If Refuse to Accept, notify submitter electronically and include a copy of this checklist.

Is an Addendum attached?: ○ Yes ◉ No Click paperclip icon on the left panel if Addendum is attached.

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

Preliminary Questions Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDA's preliminary assessment of these questions at the time of administrative review.)	Yes	No	N/A
1 Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product (per 21 CFR 3.2(e)), or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action, and inform management. *Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If the product does not appear to be a device or such a combination product, mark "No."	☒	☐	
Comments:			
2 Is the submission with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If submission should not be reviewed by your Center mark "No."	☒	☐	
Comments:			

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3 If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: **a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?** **b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide a summary of Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."	☐	☐	☒
Comments:			
4 Is the submission for a combination product that contains as a constituent part a drug that has the same active moiety as an approved drug with exclusivity as described in 21 USC 503(g)(5)(C)(ii)-(v) (section 503(g)(5)(C)(ii)-(v) of the FD&C Act)? If "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide the summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.*	☐	☐	☒
Comments:			
5 Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), consult with the appropriate CDRH or CBER staff during the acceptance review, provide a summary of the discussion with them, and indicate their recommendation/action in the comment section below. If 510(k) is not the appropriate regulatory submission, mark "No."	☒	☐	
Comments:			
6 Is there a pending PMA for the same device with the same indications for use? If "Yes," consult your management and CDRH Office of Product Evaluation and Quality/Office of Regulatory Programs/Division of Regulatory Programs 1 (Submission Support) (OPEQ/ORP/DRP1) or appropriate CBER staff to determine the appropriate action.	☐	☒	
Comments:			
7 If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If "Yes," consult with the CDRH Office of Product Evaluation and Quality/ Office of Clinical Evidence and Analysis/Division of Clinical Science and Quality (OPEQ/OCEA/DCEA1) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action, provide a summary of the discussion with them, and indicate their recommendation/action. If no clinical studies have been submitted, mark "N/A." Check on the AIP list at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/application-integrity-policy/application-integrity-policy-list.	☐	☐	☒
Comments:			

- If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.
- If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.
- If the answer to 4 is "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer, provide a summary of the discussion with them, and indicate their recommendation/action.
- If the answer to 5 is "No," the lead reviewer should consult management and other Center resources to determine the appropriate action.
- If the answer to 6 is "Yes," then stop review of the 510(k), contact the CDRH/OPEQ/ORP/DRP1, or appropriate CBER staff.
- If the answer to 7 is "Yes," then contact CDRH/OPEQ/OCEA/DCEA1 or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DCEA1 or BMB Staff, and indicate their recommendation/action.

Records processed under FOIA Request 2023-3425. Released by CDRH on 05-21-2024

Organizational Elements

Failure to include these items should not result in an RTA designation.

*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	*Page #
1) Submission contains a Table of Contents	☒	☐	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	☒	☐	
3) All pages of the submission are numbered. *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2…).*	☒	☐	
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special). *If type of 510(k) is not designated, review as a Traditional 510(k).*	☒	☐	
Comments:			

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
A. Administrative					
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	☒	☐		☐	
2) Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form (Form 3514, available at https://www.fda.gov/media/72421/download)):				☐	
a) Device trade/proprietary name	☒	☐			
b) Device class and panel OR Classification regulation OR Statement that device has not been classified with rationale for that conclusion	☒	☐			
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/alternative-certain-prescription-device-labeling-requirements.) *See recommended* format (https://www.fda.gov/media/86323/download).	☒	☐		☐	
4) Submission contains a 510(k) Summary or 510(k) Statement.	☒	☐		☐	
5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(l) *See recommended format (https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-truthful-and-accurate-statement).*	☒	☐		☐	
6) Submission is a Class III 510(k) device.	☐		☒	☐	
7) Submission contains clinical data	☒		☐	☐	
a) Submission includes completed Financial Certification (FDA Form 3454, available at https://www.fda.gov/media/70465/download) or Disclosure (FDA Form 3455, available at https://www.fda.gov/media/69872/download) information for each covered clinical study included in the submission. *Select "N/A" if the submitted clinical data is not a "covered clinical study" as defined in the guidance entitled "Financial Disclosures by Clinical Investigators", available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/financial-disclosure-clinical-investigators.*	☒	☐	☐		
b) Submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (FDA Form 3674, available at https://www.fda.gov/media/69901/download) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission. *Select "N/A" if the submitted clinical data is not an "applicable device clinical trial" as defined in Title VIII of FDAAA, Sec. 801(j)*	☐	☐	☒		

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
c) Statements of Compliance for Clinical Investigations *Select "N/A" if the submission does not contain any clinical data from investigations (as defined in 21 CFR 812.3(h)) to demonstrate substantial equivalence.* *For multicenter clinical investigations involving both United States (US) and outside United States (OUS) sites, part (i) should be addressed for the US sites and part (ii) should be addressed for the OUS sites. 21 CFR 812.28 applies to all OUS clinical investigations that enroll the first subject on or after February 21, 2019.* *Please refer to the guidance document entitled "Acceptance of Clinical Data to Support Medical Device Applications and Submissions - Frequently Asked Questions," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-clinical-data-support-medical-device-applications-and-submissions-frequently-asked for more information.*	☒		☐		
i) For each clinical investigation conducted in the US, the submission includes a statement of compliance with 21 CFR parts 50, 56, and 812. **OR** The submission includes a brief statement of the reason for noncompliance with 21 CFR parts 50, 56, and 812.	☒	☐	☐		
ii) For each clinical investigation conducted OUS, the submission includes a statement that the clinical investigations were conducted in accordance with good clinical practice (GCP) as described in 21 CFR 812.28(a)(1). **OR** The submission includes a waiver request in accordance with 21 CFR 812.28(c). **OR** The submission includes a brief statement of the reason for not conducting the investigation in accordance with GCP and a description of steps taken to ensure that the data and results are credible and accurate and that the rights, safety, and well-being of subjects have been adequately protected.	☐	☐	☒		
8) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Q-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device.	☒	☐		☐	
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed.	☒	☐	☐		
9) The submission utilizes voluntary consensus standard(s) (See section 514(c) of the FD&C Act). *This includes both FDA-recognized and non-recognized consensus standards.*	☒		☐	☒	
a) The submission cites FDA-recognized voluntary consensus standard(s).	☒		☐		

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
i) The submission includes a Declaration of Conformity (DOC) as outlined in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices. **OR** If citing general use of a standard as noted in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," the basis of such use is included along with the underlying information or data that supports how the standard was used.	☒	☐			
b) The submission cites non-FDA-recognized voluntary consensus standard(s).	☒		☐		
i) The basis of use is included along with the underlying information or data that supports how the standard was used.	☐	☒			
Comments:	(b)(4)				
Combination Product Provisions - Per 503(g) of the FD&C Act. Select "N/A" if the product is not a combination product. 21 CFR 3.2(e). The remaining criteria in this section will be omitted from the checklist if "N/A" is selected. If you are unsure if the product is a combination product, consult with the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.			☒		
B. Device Description					
12) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding the device description that is applicable to the subject device.	☐		☒	☐	
13) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).	☒	☐		☐	
14) The submission includes descriptive information for the device, including the following:				☒	
a) A description of the principle of operation or mechanism of action for achieving the intended effect.	☒	☐			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	☐	☒	☐		
c) A list and description of each device for which clearance is requested.	☒	☐	☐		
d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).	☒	☐			
Comments:	(b)(4)				

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

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
(b)(4)					
15) Device is intended to be marketed with accessories and/or as part of a system.	☐		☒	☐	
C. Substantial Equivalence Discussion					
16) Submitter has identified a predicate device(s), including the following information:				☐	
a) Predicate device identifier provided (e.g., 510(k) number, De Novo number, reclassified PMA number, classification regulation reference, if exempt (e.g., 21 CFR 872.3710), or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online (https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/preamendment-status).*	☒	☐			
b) The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).	☒	☐			
17) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See the FDA guidance document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k for more information on comparing intended use and technological characteristics.*				☒	
a) Indications for Use	☒	☐			
b) Technology, including technical specifications, features, materials, and principles of operation	☐	☒			
Comments: (b)(4)					
D. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)					
18) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	☒	☐		☒	
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	☒	☐			

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
b) Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) **AND** - Includes adequate directions for use (see 21 CFR 801.5) **OR** - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D	☐	☒			
Comments:	(b)(4)				
19) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	☒	☐		☐	
20) Labeling includes the prescription statement [see 21 CFR 801.109(b)(1)] or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's guidance "Alternative to Certain Prescription Device Labeling Requirements," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/alternative-certain-prescription-device-labeling-requirements.	☒	☐	☐	☐	
21) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding labeling that is applicable to the subject device.	☐		☒		
22) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.	☐	☐	☒	☐	
E. Sterilization					
If an *in vitro* diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.			☐		
☒ Provided sterile, intended to be single-use					
☐ Requires processing during its use-life					
☐ Non-sterile when used (and no processing required)					
☐ Information regarding the sterility status of the device is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Sterility status not needed for this device (e.g., software-only device)					
☐ Sterility status needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *Please refer to the FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling, for additional information.*					
23) Assessment of the need for cleaning and subsequent disinfection or sterilization information				☐	

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
a) Identification of device and/or accessories, if applicable, that are provided sterile.	☒	☐	☐		
b) Identification of device and/or accessories, if applicable, that are end user sterilized or disinfected.	☐	☐	☒		
c) Identification of device, and/or accessories, if applicable, that are reusable.	☐	☐	☒		
24) If the device and/or accessories, if applicable, are provided sterile:			☐	☒	
a) Sterilization method is stated for each device (including dose for radiation sterilization).	☒	☐			
b) A description of method to validate the sterilization parameters is provided for each proposed sterilization method (e.g., half-cycle method and full citation of FDA-recognized standard, including date).	☐	☒			
c) For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.	☐	☐	☒		
d) Sterility Assurance Level (SAL) is stated.	☒	☐			
e) Submission includes description of packaging.	☒	☐			
f) For products labeled "non-pyrogenic," a description of the method used to make the determination stated (e.g., limulus amebocyte lysate [LAL]).	☐	☒	☐		
Comments:	(b)(4)				
25) If the device and/or accessory, if applicable, is reusable or end user sterilized or disinfected:			☒	☐	
a) Cleaning method is provided in labeling for each device and/or accessory, if applicable.	☐	☐	☒		
b) Disinfection method is provided in labeling for each device and/or accessory, if applicable.	☐	☐	☒		
c) Sterilization method is provided in labeling for each device and/or accessory, if applicable.	☐	☐	☒		
d) Device types in this submission are listed in the Federal Register (FR) Notice entitled "Validated Instructions for Use and Validation Data Requirements for Certain Reusable Medical Devices in Premarket Notifications" (Reprocessing FR Notice, available at https://www.federalregister.gov/documents/2017/06/09/2017-12007/medical-devices-validated-instructions-for-use-and-validation-data-requirements-for-certain-reusable).	☐		☒		
26) The device has a device-specific guidance document, special controls, and/or requirement in a device-specific regulation regarding sterility and/or reprocessing that is applicable to the subject device.	☐		☒	☐	

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
F. Shelf Life					
27) Proposed shelf life/expiration date stated **OR** Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation	☒	☐	☐	☐	
28) For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf life.	☐	☒	☐	☒	
Comments:	(b)(4)				
29) Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). **OR** Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	☒	☐		☐	
G. Biocompatibility					
If an vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.			☐		
Submission states that there: (one of the below must be checked)		☐		☐	
☒ Are direct or indirect tissue-contacting components.					
☐ Are no direct or indirect tissue-contacting components.					
☐ Information regarding tissue contact status of the device is not provided (if this box checked, please also check one of the two boxes below).					
☐ Tissue contact information not needed for this device (e.g., software-only device)					
☐ Tissue contact information needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
30) Submission includes a list identifying each of tissue-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.	☒	☐		☐	
31) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration) for each tissue-contacting device component (e.g., implant, delivery catheter)	☒	☐		☐	

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
32) For a biocompatibility assessment of tissue-contacting components, submission includes: – Each relevant endpoint for the device (as identified in device-specific guidance, or Attachment A of the FDA guidance document entitled "Use of International Standard ISO 10993-1, `Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and), has been addressed. - For any testing performed, test protocol (including identification and description of test article including whether the test article is the device in its final finished form using the recommended approach in Attachment F of "Use of International Standard ISO 10993-1, `Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" methods, and pass/fail criteria), and analysis of results (including tables with data points and statistical analyses, where appropriate), as described in Attachment E of the guidance document entitled "Use of International Standard ISO 10993-1, `Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" provided for each completed test. **OR** A statement that biocompatibility testing is not needed with a rationale that considers all relevant endpoints (e.g., materials and manufacturing/processing are identical to the predicate).	☒	☐		☐	
H. Software					
Submission states that the device: (one of the below must be checked)		☐		☐	
☐ Does contain software/firmware					
☒ Does not contain software/firmware					
☐ Information on whether device contains software/firmware is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Software/firmware information not needed for this device (e.g., surgical suture, condom)					
☐ Software/firmware information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
I. Cybersecurity					
Submission states that the device: *(one of the below must be checked)*		☐		☐	
☐ Does contain any external wired and/or wireless communication interfaces (Wired: USB, ethernet, SD, CD, RGA, etc. or Wireless: Wi-Fi, Bluetooth, RF, inductive, Cloud, etc.)					
☒ Does not contain external interfaces as described above					
☐ Information on whether device has external interfaces is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Cybersecurity information not needed for this device (e.g., surgical suture, condom)					
☐ Cybersecurity information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					

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

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J. Electrical Safety and EMC					
Electrical Safety Submission states that the device: *(one of the below must be checked)*		☐		☐	
☐ Does require electrical safety evaluation					
☒ Does not require electrical safety evaluation					
☐ Information on whether device requires electrical safety evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Electrical safety information not needed for this device (e.g., surgical suture, condom)					
☐ Electrical safety information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
EMC Submission states that the device: (one of the below must be checked)		☐		☐	
☐ Does require EMC evaluation					
☒ Does not require EMC evaluation					
☐ Information on whether device requires EMC evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ EMC information not needed for this device (e.g., surgical suture, condom)					
☐ EMC information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
K. Performance Data - General					
If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.			☐		
38) Summaries of the non-clinical laboratory studies and full test reports* are provided. *Summary and full test report content recommendations can be found in FDA's guidance "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket. If a submitter chooses to declare conformity to a voluntary consensus standard that FDA has recognized, submission of a full test report may not be necessary. Refer to 9a. See FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.	☐	☒	☐	☒	
a) Submission includes an explanation of how the data generated from each test supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.).	☐	☒			

Comments:	

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

(b)(4)

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(b)(4)					
39) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding performance data that is applicable to the subject device.	☐		☒	☐	
40) If literature is referenced in the submission, submission includes:			☒		
41) For each completed animal study, the submission provides the following:			☐	☒	
a) Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120.	☐	☒			
b) Submission includes final study report which includes all elements outlined in 21 CFR 58.185.	☒	☐			
c) Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.	☒	☐			
Comments: (b)(4)					

L. Performance Characteristics - In Vitro Diagnostic Devices Only
(Also see 21 CFR 809.10(b)(12))

Submission states that the device: (one of the below must be checked)	☐	
☐ is an in vitro diagnostic device.		
☒ is not an in vitro diagnostic device.		
If "is not" is selected, the performance data-related criteria below are omitted from the checklist.		

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Digital Signature Concurrence Table

Reviewer Sign-Off	Lixin Liu -S Digitally signed by Lixin Liu -S Date: 2021.01.07 09:40:50 -05'00'
Management Sign-Off (digital signature optional)*	Kimberly Ferlin -S 2021.01.13 16:13:35 -05'00'

* Management review of checklist and concurrence with with decision required.

Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

MIS Solution Instructions for Use

DESCRIPTION:

MIS Solution is a clear, colorless solution intended for cleansing and removal of debris, including microorganisms, from wounds.

Contains: Sodium Lauryl Sulfate, Citric Acid, Sodium Citrate, and Water.

INDICATIONS FOR USE:

MIS Solution is indicated for use in cleansing and removal of debris, including microorganisms, from wounds.

WARNINGS/PRECAUTIONS:

- NOT FOR IV USE - This product has been tested as a wound wash only. DO NOT inject.
- External Use Only
- The product is single-use and should be applied only once in a 24-hour period.
- Discard any unused solution.
- Do not use if there is a history of allergy to any of the ingredients.
- Avoid eye contact; product may cause ocular irritation.
- Do not use if container is damaged.
- Potential for temporary burning or discomfort may occur.
- Do not use with fibrin sealants due to the risk of material degradation. Application of fibrin sealants in the presence of MIS Solution may impact sealant setup.
- Do not use with hydroxyapatite (HA) implants due to the risk of accelerated material degradation.
- If product contacts unintended anatomy or materials, rinse away solution after irrigation.
- The Stryker StrykeFlow II laparoscopic irrigator does not provide adequate pressure to remove debris when used with MIS Solution.
- Do not use in the case of substantial tissue loss.

STORAGE AND HANDLING:

Store at 15°C to 25°C (59°F to 77°F).

HOW SUPPLIED:

MIS Solution is supplied in 500 mL single-dose semi-flexible container.

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

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INSTRUCTIONS FOR USE:

Preparation for Connection to Spike Port:

1. Check for leaks by squeezing container firmly. Discard unit if leaks are found, as sterility may be compromised.
2. Using aseptic technique, remove foil from the cap by pulling on the tabs at the bottom of the container.
3. With a twisting motion, insert piercing pin (spike) into either of the dimpled sections of the rubber seal until the pin is firmly seated.
4. Hang container, with the rubber seal facing down, to allow for the gravity-assisted release of the solution.

Preparation for Decanting:

1. Check for leaks by squeezing container firmly. Discard unit if leaks are found, as sterility may be compromised.
2. Using aseptic technique, remove foil from the cap by pulling on the tabs at the bottom of the container.
3. With a twisting motion, insert piercing pin (spike) into either of the dimpled sections of the rubber seal until the pin is firmly seated.
4. Squeeze the bottle to decant solution into a container.

Irrigation:

1. For powered or manual irrigation: Irrigate the wound bed with the contents of the supplied container following the manufacturer's instructions of the irrigation device and/or standard practice.
2. Suction solution and debris throughout the procedure.
3. Discard any unused solution.

	Not for IV Use	STERILE	Sterilized Using Steam or Dry Heat; Sterile Fluid Path
	Do Not Use if Package is Damaged	QTY	Quantity
		CONTAINS	List of Ingredients
	Do Not Re-Sterilize		Do Not Re-Use
LOT	Batch Code		Use-By-Date
Rx Only	CAUTION: Federal Law restricts this product to sale and use by or on the order of a physician		Manufacturer

NEXT SCIENCE®

MIS Solution IFU
NMS-40012 Rev. F

Manufactured for:
Next Science, LLC
10550 Deerwood Park Blvd
Suite 300
Jacksonville, FL 32256 USA
www.nextscience.com

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

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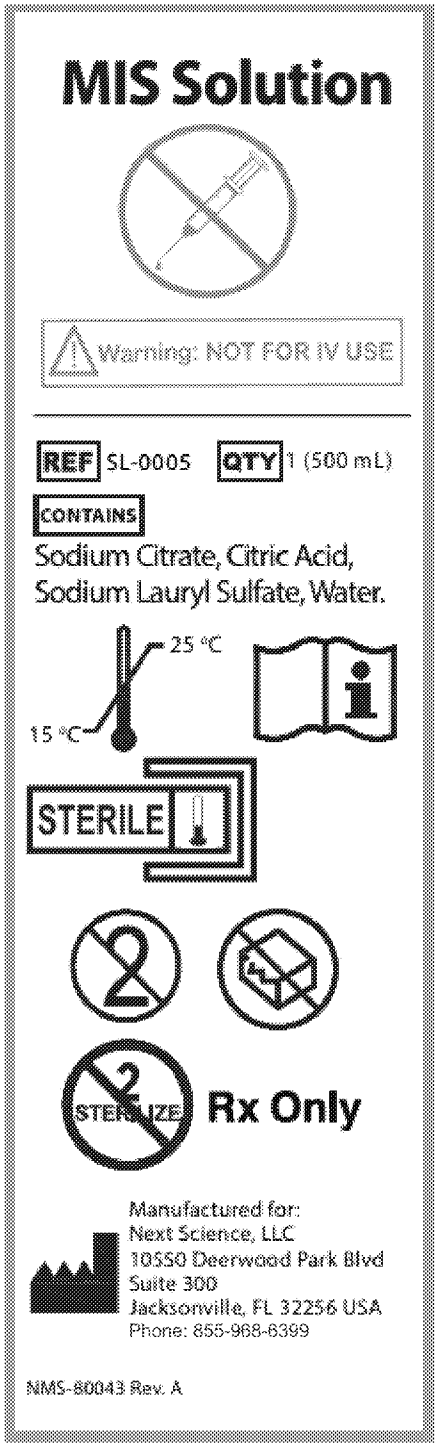
Front Bottle Labeling



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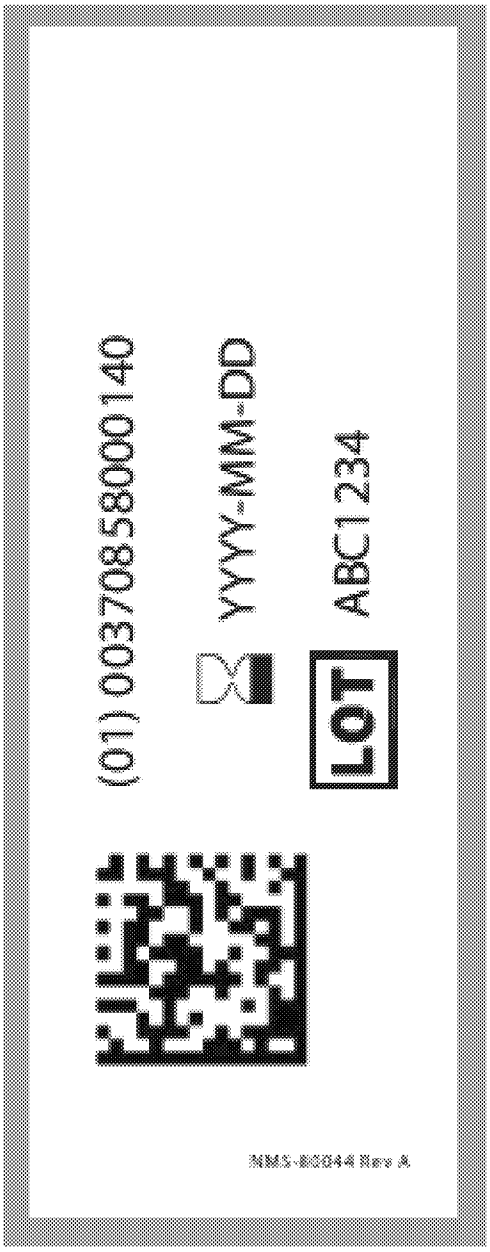
Back Bottle Label



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U.S. FOOD & DRUG ADMINISTRATION

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Office Location
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Premarket Notification 510(k) Review

Pre-Review Reminders

- ☐ ← Click this checkbox to delete these directions (**Click "Enable Content" above first, if present**). Blue text indicates the text is clickable. Clicking may display tips and/or directions specific to that sentence (e.g., "Appropriate Manual Labeling" below) or section (e.g., "Premarket Notification 510(k) Review" above); it may also link to a website, form or CARS report.
- ☐ Complete the RTA checklist
- ☐ Final guidance and recognized consensus standards are recommendations. They are not binding, and applicants may demonstrate substantial equivalence using an alternative approach.

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: April 22, 2021

Reviewer: Mustafa A. Mazher

Subject: Traditional 510(k)# K203835/S001

Applicant: Next Science, LLC

Device Trade Name: MIS Solution

Contact Name: Courtney Narain

Contact Title: Regulatory Affairs Specialist

Correspondent Firm: Next Science, LLC

Phone: (855) 564-2762 Ext.6004 **Email:** cnarain@nextscience.com

Received Date: January 19, 2021

Due Date: April 19, 2021

Pro Code(s): FRO **Class:** Unclassified **Reg #:**

Reg Name:

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K161165	FQH, FRO	Next Science Irrigation Solution	Next Science, LLC

(b)(5)

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Project ID: (b)(4) Date: July 17, 2019

(b)(4)

(b)(4) Laboratory Report MIS Solution Analysis

Report prepared for:

(b)(4)

Report Prepared by:

(b)(4)

For Further Assistance, Contact:

(b)(4)

(b)(4)

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

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Project ID: (b)(4) Date: July 19, 2019

(b)(4)

(b)(4) Laboratory Report MIS Solution Analysis

Report prepared for:

(b)(4)

Report Prepared by:

(b)(4)

For Further Assistance, Contact:

(b)(4)

(b)(4)

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Project ID: (b)(4) Date: October 24, 2019

(b)(4)

(b)(4) Laboratory Report Minimally MIS Solution Analysis

Report prepared for:

(b)(4)

Report Prepared by:

(b)(4)

For Further Assistance, Contact:

(b)(4)

(b)(4)

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Project ID: (b)(4) Date: April 16, 2021

(b)(4)

(b)(4) Laboratory Report Analysis

Report prepared for:

(b)(4)

Report Prepared by:

(b)(4)

For Further Assistance, Contact:

(b)(4)

(b)(4)

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Project ID: (b)(4) Date: May 08, 2020

(b)(4)

(b)(4) Laboratory Report Analysis

Report prepared for:

(b)(4)

Report Prepared by:

(b)(4)

For Further Assistance, Contact:

(b)(4)

(b)(4)

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From: Liu, Lixin
To: Lee, Michele; Mazher, Mustafa
Subject: FW: K203835/S001 (b)(5)
Date: Wednesday, April 21, 2021 10:34:42 AM
Attachments: image001.png
image002.png

Hi, Michele and Mustafa:

(b)(5)

Thanks,

Lixin

From: Rimmer, Ralph <Ralph.Rimmer@fda.hhs.gov>
Sent: Monday, March 22, 2021 4:44 PM
To: Liu, Lixin <Lixin.Liu@fda.hhs.gov>; Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>
Subject: RE: K203835/S001 **(b)(5)**

Ok, sounds good

Thanks,
Dale

From: Liu, Lixin <Lixin.Liu@fda.hhs.gov>
Sent: Monday, March 22, 2021 4:06 PM
To: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>; Rimmer, Ralph <Ralph.Rimmer@fda.hhs.gov>
Subject: RE: K203835/S001 **(b)(5)**

Hi, Dale:

(b)(5)

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

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(b)(5)

Thanks,

Lixin

From: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>
Sent: Monday, March 22, 2021 3:26 PM
To: Rimmer, Ralph <Ralph.Rimmer@fda.hhs.gov>
Cc: Liu, Lixin <Lixin.Liu@fda.hhs.gov>
Subject: RE: K203835/S001 (b)(5)

(b)(5)

Thanks,

Mustafa

From: Rimmer, Ralph <Ralph.Rimmer@fda.hhs.gov>
Sent: Monday, March 22, 2021 3:19 PM
To: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>
Cc: Liu, Lixin <Lixin.Liu@fda.hhs.gov>
Subject: RE: K203835/S001 (b)(5)

(b)(5)

Sincerely
Dale

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

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From: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>
Sent: Sunday, March 21, 2021 11:36 AM
To: Rimmer, Ralph <Ralph.Rimmer@fda.hhs.gov>
Cc: Liu, Lixin <Lixin.Liu@fda.hhs.gov>
Subject: RE: K203835/S001 **(b)(5)**

Hey Dale,

(b)(5)

Thanks,

Mustafa

From: Rimmer, Ralph <Ralph.Rimmer@fda.hhs.gov>
Sent: Saturday, March 20, 2021 10:21 AM
To: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>
Subject: RE: K203835/S001 **(b)(5)**

Hi Mustafa

(b)(5)

Sincerely
Dale

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

From: Rimmer, Ralph
Sent: Friday, March 19, 2021 8:34 AM
To: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>; Liu, Lixin <Lixin.Liu@fda.hhs.gov>; Hailemariam, Kiros <Kiros.Hailemariam@fda.hhs.gov>
Subject: RE: K203835/S001 **(b)(5)**

Hi Mustafa

(b)(5)

Ill check my email a few times today if you have other questions but I may be very slow to reply..

Dale

From: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>
Sent: Thursday, March 18, 2021 2:50 PM
To: Rimmer, Ralph <Ralph.Rimmer@fda.hhs.gov>; Liu, Lixin <Lixin.Liu@fda.hhs.gov>; Hailemariam, Kiros <Kiros.Hailemariam@fda.hhs.gov>
Subject: RE: K203835/S001 **(b)(5)**

Hello Dale,

(b)(5)

Thanks,

Mustafa

From: Rimmer, Ralph <Ralph.Rimmer@fda.hhs.gov>
Sent: Wednesday, March 17, 2021 3:10 PM
To: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>
Subject: RE: K203835/S001 **(b)(5)**

Hi Mustafa

(b)(5)

Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

(b)(5)

Sincerely

Dale Rimmer

R. Dale Rimmer, Ph.D.
Chemist, Lead Reviewer
Plastic Surgery Implant Devices Team
DHT4B: Division of Plastic Surgery Devices and Infection Control
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food & Drug Administration
White Oak, Bldg. 66 | 10903 New Hampshire Ave | Silver Spring, MD 20993
Tel: 240.402.4828
Ralph.Rimmer@fda.hhs.gov

From: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>
Sent: Wednesday, March 17, 2021 2:02 PM
To: Rimmer, Ralph <Ralph.Rimmer@fda.hhs.gov>
Subject: RE: K203835/S001 (b)(5)

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

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Hello Dale,

(b)(5)

Thanks,

Mustafa

From: Rimmer, Ralph <Ralph.Rimmer@fda.hhs.gov>
Sent: Monday, March 15, 2021 12:46 PM
To: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>
Cc: Hailemariam, Kiros <Kiros.Hailemariam@fda.hhs.gov>
Subject: RE: K203835/S001 (b)(5)

Thanks, Mustafa

(b)(5)

Dale

From: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>
Sent: Monday, March 15, 2021 12:23 PM
To: Rimmer, Ralph <Ralph.Rimmer@fda.hhs.gov>
Cc: Hailemariam, Kiros <Kiros.Hailemariam@fda.hhs.gov>
Subject: RE: K203835/S001 (b)(5)

Hello Dale,

(b)(5)

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

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(b)(5)

Thanks for your help both, I understand that you all have heavy workloads.

Best,

Mustafa

From: Rimmer, Ralph <Ralph.Rimmer@fda.hhs.gov>
Sent: Monday, March 15, 2021 11:56 AM
To: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>
Cc: Hailemariam, Kiros <Kiros.Hailemariam@fda.hhs.gov>
Subject: RE: K203835/S001 (b)(5)

Hi Mustafa

(b)(5)

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

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(b)(5)

Sincerely
Dale

From: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>
Sent: Tuesday, February 9, 2021 3:51 PM
To: Rimmer, Ralph <Ralph.Rimmer@fda.hhs.gov>
Subject: FW: K203835/S001 assigned: team (b)(5)

Hello Dale,

(b)(5)

Best,

Mustafa

From: Ferlin, Kimberly <Kimberly.Ferlin@fda.hhs.gov>
Sent: Friday, January 22, 2021 1:18 PM
To: Azeke, John <John.Azeke@fda.hhs.gov>; Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>
Cc: Liu, Lixin <Lixin.Liu@fda.hhs.gov>
Subject: RE: K203835/S001 assigned: team (b)(5)

Hi Mustafa and John,

(b)(5)

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

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(b)(5)

The team due date for RTA is 1/28.

(b)(5)

Thanks,
Kim

Kimberly M. Ferlin, Ph.D.
Acting Assistant Director
Plastic Surgery Skin and Wound Devices Team
FDA|CDRH|OPEQ|OHT4|DHT4B
U.S. FOOD & DRUG ADMINISTRATION

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

From: Ferlin, Kimberly
Sent: Thursday, January 21, 2021 7:24 PM
To: Azeke, John <John.Azeke@fda.hhs.gov>
Cc: Liu, Lixin <Lixin.Liu@fda.hhs.gov>
Subject: K203835/S001 assigned: team (b)(5)

Hi John,

(b)(5)

Thanks,
Kim

Kimberly M. Ferlin, Ph.D.
Acting Assistant Director
Plastic Surgery Skin and Wound Devices Team
FDA|CDRH|OPEQ|OHT4|DHT4B

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

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510(k) Summary

MIS Solution

Submitter: Next Science®, LLC
10550 Deerwood Park
Suite 300
Jacksonville, Florida 32256

Contact Person: Courtney Narain
Regulatory Affairs Specialist
855-564-2762 ext. 6004
855-564-2460 (fax)

Date Prepared: April 23, 2021

Device Trade Name: MIS Solution

Device Common Name: Wound Irrigation Solution

Classification Name: Dressing, Wound, Drug

Product Code: FRO

Classification: Unclassified

Predicate Device: Next Science® Irrigation Solution (K161165)

Indications For Use: MIS Solution is indicated for use in cleansing and removal of debris, including microorganisms, from wounds.

Device Description:

MIS Solution is a clear, colorless solution intended for cleansing and removal of debris, including microorganisms, from wounds.

The mechanical action of fluid moving across the wound provides the mechanism of action and aids in the removal of debris, including microorganism, from wounds. MIS Solution is provided in a soft polypropylene 500mL container with a spikeable port. MIS Solution is composed of water, citric acid, sodium citrate and sodium lauryl sulfate.

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Technological Characteristics:

MIS Solution (subject device) and Next Science® Irrigation Solution (predicate device) consist of different ingredients. However, while the device technology is different between the subject and predicate device, the function of each ingredient is analogous. Both devices incorporate a surfactant to assist in the solubilization of debris, a buffer system to maintain the pH of the formulation and a vehicle to carry away debris from the wound.

The table below compares MIS Solution to the predicate device.

Product	MIS Solution	Next Science® Irrigation Solution (Predicate)
Company	Next Science®, LLC	Next Science®, LLC
510(k) Number	K203835	K161165
Indications	MIS Solution is indicated for use in cleansing and removal of debris, including microorganisms, from wounds.	Next Science® Irrigation Solution is to be used with a jet lavage system and is indicated for use in cleansing and removal of debris, including micro-organisms, from wounds.
Composition	**pH Buffer** Sodium Citrate 31.33 g/L Citric Acid 32.50 g/L	**pH Buffer** Sodium Acetate 30.00 g/L Acetic Acid 50.00 g/L
	Surfactant Sodium Lauryl Sulfate 1.00g/L	**Surfactant** Benzalkonium Chloride 1.3 g/L
	Vehicle Water	**Vehicle** Ethanol 100 g/L Water
Sterility	Sterile	Sterile
Mechanism(s) of Action	Mechanical removal of debris via hydrodynamic shear. The mechanical action of moving across the wound aids in the removal of foreign material such as, microorganisms, dirt and debris. The mechanical action can be provided by either a manual syringe or powered irrigation device.	Mechanical removal of debris via hydrodynamic shear. The mechanical action of moving across the wound aids in the removal of foreign material such as dirt and debris. The mechanical action of the irrigation is provided by the Pulsavac Plus lavage systems.

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Biocompatibility

The biocompatibility of MIS Solution has been evaluated in accordance with ISO 10993-1:2018 and FDA guidance "Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing". The battery of studies includes the following:

- Material Mediated Pyrogenicity using USP <151>
- Guinea Pig Maximization Sensitization Test
- Porcine Wound Healing to address the cytotoxicity endpoint
- Toxicological Risk Assessment per ISO 10993-17
- Chemical Characterization of Extractables and Leachables for device packaging
- Irritation (Human)

Performance Bench Testing

The following bench tests were conducted to support the substantial equivalency of MIS Solution in removing debris from a surface and adequate irrigation:

- Compatibility and Irrigation Force Comparison – the test verified that use of the subject device in manual and powered irrigation devices were able to reach published pressures deemed adequate for wound irrigation.
- Combined Dissolution Efficacy – The test demonstrated that MIS Solution and the predicate device are substantially equivalent at removing debris under static conditions.

Animal Testing

A Porcine Wound Healing Study was conducted to evaluate the effect of the subject device components on the wound healing process.

In the animal study conducted, 16 domestic pigs were used, each receiving eight wounds, four on the left and right sides of the animal's back parallel to the spine line. Two or three of the animal's wounds were assigned to a treatment group of the subject device, the predicate device or a negative control.

Under the conditions of the study, MIS Solution did not inhibit normal wound healing over 25 days in this porcine wound healing study.

Clinical Study

MIS Solution was evaluated in a Human Repeat Patch Test to evaluate the irritation endpoint in humans. MIS Solution was determined to be a non-irritant. There were no adverse events or complications in this study.

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Conclusion:

The conclusions drawn from biocompatibility, performance tests and a clinical study demonstrate that MIS Solution is as safe and effective as the legally marketed device, Next Science® Irrigation Solution (K161165).

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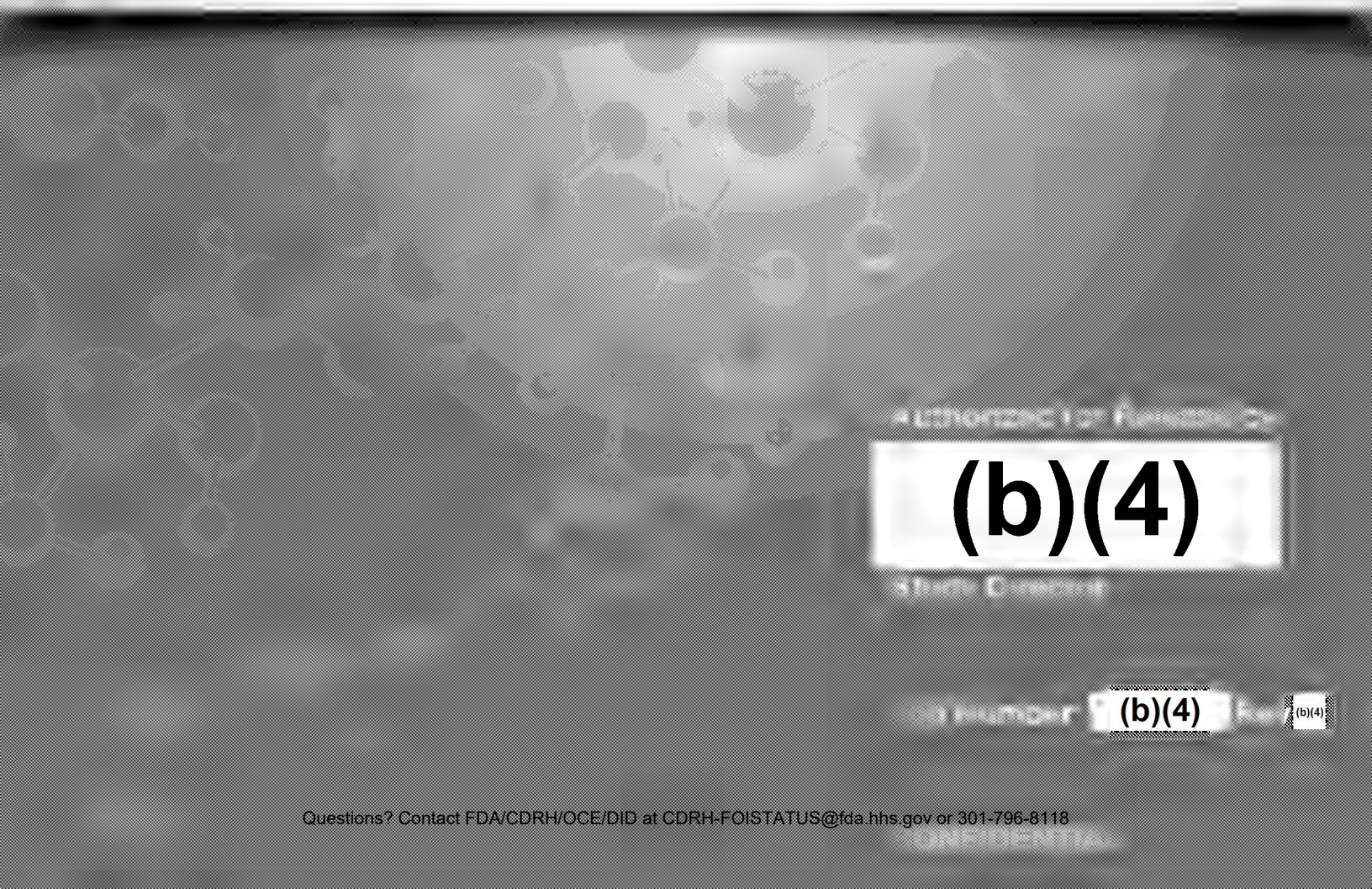
Chemical characterization of extractables and leachables for XPerience (MIS Wound Irrigation Solution) packaging

Sponsor: (b)(4)

Next Science



Authorized for Release by

(b)(4)

Study Director

Job Number (b)(4) Rev (b)(4)

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BIOCOMPATIBILITY ASSESSMENT FOR MIS SOLUTION

CONFIDENTIAL

(b)(4) **REPORT NO.:**

(b)(4)

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From: Liu, Lixin
To: Marquart, Laura; Mazher, Mustafa; Ferlin, Kimberly
Subject: RE: K203835/S001 assigned: team (b)(5)
Date: Tuesday, March 16, 2021 9:37:11 AM
Attachments: K20022[illegible] (b)(5)
image003.png

Hi, Laura:

(b)(5)

Thanks,

Lixin

From: Marquart, Laura <Laura.Marquart@fda.hhs.gov>
Sent: Tuesday, March 16, 2021 8:54 AM
To: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>; Liu, Lixin <Lixin.Liu@fda.hhs.gov>; Ferlin, Kimberly <Kimberly.Ferlin@fda.hhs.gov>
Subject: RE: K203835/S001 assigned: team (b)(5)

Hi Mustafa,

(b)(5)

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

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(b)(5)

Let me know what you think, Thanks,
Laura

From: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>
Sent: Thursday, March 11, 2021 3:57 PM
To: Marquart, Laura <Laura.Marquart@fda.hhs.gov>; Liu, Lixin <Lixin.Liu@fda.hhs.gov>; Ferlin, Kimberly <Kimberly.Ferlin@fda.hhs.gov>
Subject: RE: K203835/S001 assigned: team (b)(5)

Thanks, I will issue a consult to Laura.

From: Marquart, Laura <Laura.Marquart@fda.hhs.gov>
Sent: Thursday, March 11, 2021 3:35 PM
To: Liu, Lixin <Lixin.Liu@fda.hhs.gov>; Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>; Ferlin, Kimberly <Kimberly.Ferlin@fda.hhs.gov>
Subject: RE: K203835/S001 assigned: team (b)(5)

Sounds good!

From: Liu, Lixin <Lixin.Liu@fda.hhs.gov>
Sent: Thursday, March 11, 2021 3:08 PM
To: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>; Marquart, Laura <Laura.Marquart@fda.hhs.gov>; Ferlin, Kimberly <Kimberly.Ferlin@fda.hhs.gov>
Subject: RE: K203835/S001 assigned: team (b)(5)

Mustafa:

(b)(5)

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Thanks,

Lixin

From: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>
Sent: Thursday, March 11, 2021 3:00 PM
To: Liu, Lixin <Lixin.Liu@fda.hhs.gov>; Marquart, Laura <Laura.Marquart@fda.hhs.gov>; Ferlin, Kimberly <Kimberly.Ferlin@fda.hhs.gov>
Subject: RE: K203835/S001 assigned: team (b)(5)

Hello Lixin,

(b)(5)

Thanks,

Mustafa

From: Liu, Lixin <Lixin.Liu@fda.hhs.gov>

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Sent: Thursday, March 11, 2021 2:37 PM
To: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>; Marquart, Laura <Laura.Marquart@fda.hhs.gov>; Ferlin, Kimberly <Kimberly.Ferlin@fda.hhs.gov>
Subject: RE: K203835/S001 assigned: team (b)(5)

Hi, Mustafa:

(b)(5)

Thanks,

Lixin

From: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>
Sent: Thursday, March 11, 2021 2:20 PM
To: Marquart, Laura <Laura.Marquart@fda.hhs.gov>; Liu, Lixin <Lixin.Liu@fda.hhs.gov>; Ferlin, Kimberly <Kimberly.Ferlin@fda.hhs.gov>
Subject: RE: K203835/S001 assigned: team (b)(5)

Great, thank you!

From: Marquart, Laura <Laura.Marquart@fda.hhs.gov>
Sent: Thursday, March 11, 2021 1:01 PM
To: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>; Liu, Lixin <Lixin.Liu@fda.hhs.gov>; Ferlin, Kimberly <Kimberly.Ferlin@fda.hhs.gov>
Subject: RE: K203835/S001 assigned: team (b)(5)

Hi Mustafa,

(b)(5)

Please let me know if you have any other questions, Thanks,
Laura

From: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>
Sent: Thursday, March 11, 2021 12:52 PM
To: Marquart, Laura <Laura.Marquart@fda.hhs.gov>; Liu, Lixin <Lixin.Liu@fda.hhs.gov>; Ferlin, Kimberly <Kimberly.Ferlin@fda.hhs.gov>
Subject: RE: K203835/S001 assigned: team (b)(5)

Thanks again Laura!

(b)(5)

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(b)(5)

Please let me know if you have any questions for me.

Best,

Mustafa

From: Marquart, Laura <Laura.Marquart@fda.hhs.gov>
Sent: Thursday, March 11, 2021 6:59 AM
To: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>; Liu, Lixin <Lixin.Liu@fda.hhs.gov>; Ferlin, Kimberly <Kimberly.Ferlin@fda.hhs.gov>
Subject: RE: K203835/S001 assigned: team (b)(5)

Hi Mustafa,

(b)(5)

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(b)(5)

Please let me know if you have any questions, thanks,
Laura

From: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>
Sent: Thursday, February 18, 2021 11:36 AM
To: Marquart, Laura <Laura.Marquart@fda.hhs.gov>
Subject: FW: K203835/S001 assigned: team (b)(5)

Hey Laura,
Thank you for agreeing to take a consult for this submission. I will send a consult via CTS, shortly.

(b)(5)

Please let me know if you have any questions for me.

Best

Mustafa

From: Ferlin, Kimberly <Kimberly.Ferlin@fda.hhs.gov>
Sent: Friday, January 22, 2021 1:18 PM
To: Azeke, John <John.Azeke@fda.hhs.gov>; Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>
Cc: Liu, Lixin <Lixin.Liu@fda.hhs.gov>
Subject: RE: K203835/S001 assigned: team (b)(5)

Hi Mustafa and John,

Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

(b)(5)

Thanks,
Kim

Kimberly M. Ferlin, Ph.D.
Acting Assistant Director
Plastic Surgery Skin and Wound Devices Team
FDA|CDRH|OPEQ|OHT4|DHT4B
U.S. FOOD & DRUG ADMINISTRATION

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

From: Ferlin, Kimberly
Sent: Thursday, January 21, 2021 7:24 PM
To: Azeke, John <John.Azeke@fda.hhs.gov>
Cc: Liu, Lixin <Lixin.Liu@fda.hhs.gov>
Subject: K203835/S001 assigned: team (b)(5)

Hi John,

(b)(5)

Thanks,
Kim

Kimberly M. Ferlin, Ph.D.
Acting Assistant Director
Plastic Surgery Skin and Wound Devices Team
FDA|CDRH|OPEQ|OHT4|DHT4B
U.S. FOOD & DRUG ADMINISTRATION

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U.S. FOOD & DRUG ADMINISTRATION

ood and Drug Administration
Office Location
Business Address
Phone Number

Premarket Notification 510(k) Review

Pre-Review Reminders

- ☐ ← Click this checkbox to delete these directions (**Click "Enable Content" above first, if present**). Blue text indicates the text is clickable. Clicking may display tips and/or directions specific to that sentence (e.g., "Appropriate Manual Labeling" below) or section (e.g., "Premarket Notification 510(k) Review" above); it may also link to a website, form or CARS report.
- ☐ Complete the RTA checklist
- ☐ Final guidance and recognized consensus standards are recommendations. They are not binding, and applicants may demonstrate substantial equivalence using an alternative approach.

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: April 22, 2021

Reviewer: Mustafa A. Mazher

Subject: Traditional 510(k)# K203835/S001

Applicant: Next Science, LLC

Device Trade Name: MIS Solution

Contact Name: Courtney Narain

Contact Title: Regulatory Affairs Specialist

Correspondent Firm: Next Science, LLC

Phone: (855) 564-2762 Ext.6004 **Email:** cnarain@nextscience.com

Received Date: January 19, 2021

Due Date: April 19, 2021

Pro Code(s): FRO **Class:** Unclassified **Reg #:**

Reg Name:

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K161165	FQH, FRO	Next Science Irrigation Solution	Next Science, LLC

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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	Mustafa A. Mazher -S Mustafa A. Mazher -S 2021.04.22 18:04:25 -04'00'

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PROTOCOL

IRRITATION EVALUATION OF TEST ITEMS IN THE INCISION WOUND HEALING MODEL IN PIGS

Ethics Approval No.:
(b)(4)

STUDY NUMBER

(b)(4)

Testing Facility:
(b)(4)

Sponsor:
Next Science, Ltd.
10550 Deerwood Park Blvd., Suite 300
Jacksonville FL 32256,
USA

Study Director:
(b)(4)

Sponsor representative:
(b)(4)

Test Site:
(b)(4)

Principal Investigator:
(b)(4)

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FINAL REPORT

IRRITATION EVALUATION OF TEST ITEMS IN THE INCISION WOUND HEALING MODEL IN PIGS

STUDY NUMBER

(b)(4)

Ethical Approval No. (b)(4)

Test Facility:

(b)(4)

Sponsor:
Next Science, Ltd.
10550 Deerwood Park Blvd., Suite 300
Jacksonville FL 32256,
USA

Study Director:
(b)(4)

Sponsor representative:
(b)(4)

Test Site:

(b)(4)

Principal Investigator:
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FINAL HISTOPATHOLOGY REPORT

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Consulting Pathologist

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Date Issued: (b)(4)

Customer: (b)(4)

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Next Science, LLC
Jacksonville, FL ~ www.nextscience.com

Document Type:	Bench-top ☐	Verification ☒	Validation ☐
	Protocol ☐	Report ☒	

Report Number: (b)(4) - MIS Wound Irrigation Solution Initial Shelf Life

Type: Shelf Life

Product: Next Science MIS Wound Irrigation Solution (XPerience) (b)(4)

Date: 5/27/2020

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Issued by: (b)(4)		Effective Date: (b)(4)	Rev (b)(4) Pg. 1 of 1
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MEMORANDUM

DATE: May 8, 2020

TO: (b)(4)

FROM: (b)(4) Principal Biomaterials Engineer

(b)(4)

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U.S. FOOD & DRUG ADMINISTRATION

K203835
Next Science, LLC
Trade/Device Name: MIS Solution
Contact Name: Courtney Narain

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 K203835 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 K203835 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.

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FDA is offering a teleconference within 10 calendar days from the date on this letter to address any clarification questions you may have pertaining to the deficiencies. If you are interested in a teleconference, please provide (1) proposed dates and (2) a list of your clarification questions via email at least 48 hours before the teleconference to the lead reviewer assigned to your submission. We would like to emphasize that the purpose of the meeting is to address specific clarification questions. Please note that if the specific clarification questions are not received at least 48 hours before the teleconference, the review team might not be able to provide feedback. The teleconference is not intended for review of new information, test methods or data; these types of questions could be better addressed via a Submission Issue Q-Submission (Q-Sub). For additional information regarding Q-Subs, please refer to the Guidance for Industry and FDA Staff on Medical Devices: Requests for Feedback and Meetings for Medical Device Submissions at https://www.fda.gov/media/114034/download.

Least Burdensome (LB) Flag

The LB flag is an approach to allow submitters the opportunity for the informal review by or on behalf of Division management of an issue raised in an FDA request for additional information (i.e., a deficiency letter). The goal of the LB flag is to quickly address FDA requests that submitters do not believe are least burdensome or when submitters believe they are being held to a different standard than their legally marketed predicate device. The LB flag is not intended to clarify deficiencies, is not an appeal under 21 CFR 10.75, and is not intended to provide a review of a proposed response to deficiencies.

If you would like to throw the LB flag, FDA has several criteria that should be met before you submit your request:

- You should have tried to address your concern by discussing it with Division management before attempting to throw the LB flag. This discussion with Division management may take place as part of a teleconference (such as the voluntary teleconference held within 10 days following transmission of an Additional Information letter to clarify deficiencies), email, or a Q-Submission Submission Issue Request.
- Your flag should generally be limited to two topic areas. Topic areas are common premarket review deficiency categories that apply to many device types across multiple reviewing Divisions. Examples of topic areas include biocompatibility, sterility, reprocessing, software, electromagnetic compatibility, wireless, electrical safety, clinical, and non-clinical performance testing.
- If you would like to discuss issues pertaining to more than two topic areas, you should contact OPEQSubmissionSupport@fda.hhs.gov for more information.
- You should throw the LB flag within 60 calendar days of the date that FDA sent the deficiency letter.

Upon meeting the criteria, you should send a short email (e.g., 1-2 page) that includes: 1) a summary of the deficiencies under disagreement, 2) a summary of relevant communications with Division management, and 3) a proposed path forward. The LB flag should be sent to the lead reviewer and their Assistant Director. You should also copy OPEQSubmissionSupport@fda.hhs.gov on your LB flag email request. Within two

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business days of your email, your request will be acknowledged by the reviewing Division. If you do not meet the criteria for the LB flag, you will be notified in this acknowledgement email.

Your LB flag should contain sufficient information to determine whether the deficiency letter was not least burdensome, or you are being held to a different standard than your predicate device. FDA may request a phone call with you to discuss your concern further and intends to communicate feedback from Division management on LB flags through email no later than 21 calendar days of their receipt. Please note that the LB flag does not change the deadline for your response to the Document Control Center. If you have any questions, please contact OPEQSubmissionSupport@fda.hhs.gov.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K203835

Device Name
MIS Solution

Indications for Use *(Describe)*

MIS Solution is indicated for use in cleansing and removal of debris, including microorganisms from wounds.

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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Food and Drug Administration
Office of Chief Information Officer
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PRAStaff@fda.hhs.gov

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From: Liu, Lixin
To: Ferlin, Kimberly
Subject: RE: K203835 assigned (b)(5)
Date: Thursday, January 07, 2021 10:32:00 AM
Attachments: image001.png
image003.png

Hi, Kim:

(b)(5)

Thanks,

Lixin Liu, Ph.D.
Biologist/Team Lead

Plastic Surgery Skin and Wound Devices 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
Tel: 301-796-3480
Lixin.Liu@fda.hhs.gov

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

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From: Ferlin, Kimberly <Kimberly.Ferlin@fda.hhs.gov>
Sent: Monday, January 04, 2021 1:02 PM
To: Liu, Lixin <Lixin.Liu@fda.hhs.gov>
Subject: K203835 assigned: **(b)(5)**

Hi Lixin,

(b)(5)

Thanks,
Kim

Kimberly M. Ferlin, Ph.D.
Acting Assistant Director
Plastic Surgery Skin and Wound Devices Team
FDA|CDRH|OPEQ|OHT4|DHT4B
U.S. FOOD & DRUG ADMINISTRATION

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FDA Queries:

(b)(4)

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Next Science Irrigation Solution

Instructions for Use

Description:
Next Science Irrigation Solution is an aqueous solution for irrigation and debridement of wounds. The solution is a clear, colorless, low-odor aqueous solution that is used to remove debris, including microorganisms, from wounds through the use of the Zimmer Pulsavac Plus or Pulsavac Plus AC lavage systems.

Next Science Irrigation Solution contains: Ethanol, 100g/L, Acetic acid, 60g/L, Sodium acetate, 20g/L, Benzalkonium chloride, 1.3g/L, Purified water.

Next Science Irrigation Solution has been tested for compliance with ISO 10993 for a surface device with limited contact (≤24 hours) with breached or compromised surfaces.

Indications for Use:
Next Science Irrigation Solution is to be used with a jet lavage system and is indicated for use in cleansing and removal of debris, including microorganisms, from wounds. This product is NOT intended for repeated use, nor is it indicated for use during dressing changes or for use by soaking the product into dressings.

Contraindications:
Next Science Irrigation Solution should not be used if there is a history of allergy to any of the ingredients.

Warnings:
- NOT FOR IV USE ⚠
- Do not use flexible container in series connections.

Precautions:
- Avoid eye contact
- Avoid contact with mucosal membranes
- Do not ingest
- Do not aspirate
- The safety of leaving the device on the skin for greater than one minute is unknown

Adverse Reactions:
There are no known adverse reactions associated with the use of Next Science Irrigation Solution.

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Instructions for Use:
Circulating staff:

1. Remove the overwrap.
2. Check for leaks by squeezing container firmly. If leaks are found, discard unit as sterility may be impaired.
3. Use aseptic technique. See appropriate irrigation set Instructions for Use.

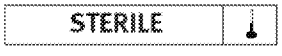
Preparation for Administration with the Pulsavac Plus or Pulsavac Plus AC jet lavage system:

1. Remove cap from sterile administration set port at bottom of container.
2. Insert piercing pin of irrigation set into port with a twisting motion until the pin is firmly seated.
3. Suspend container.
4. Assemble pulse lavage system per manufacturer's instructions.

Surgeon:

1. Rinse the wound bed with the entire liter of solution following the system manufacturer's instructions and/or standard practice.
2. Right after cleansing the wound, the wound MUST BE rinsed with an equal volume of normal saline.
3. Use universal precautions in accordance with hospital protocol for the handling and disposal of contaminated waste.
4. Discard any unused solution.

How Supplied:
Next Science Irrigation Solution is supplied in 1000mL single-dose flexible plastic containers.

Sterile by autoclave sterilization, non-pyrogenic 

Protect from freezing. Store at 20 to 25°C (68 to 77°F).

Caution: Federal law restricts this device to sale by or on the order of a physician or licensed healthcare practitione

Manufactured for Next Science, LLC, Jacksonville, FL 32256
1-800-xxx-xxxx

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

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From: Marquart, Laura
To: Liu, Lixin; Mazher, Mustafa
Cc: Guan, Allan
Subject: RE: Consult request - K203835/S002 (b)(5)
Date: Monday, April 12, 2021 7:19:58 AM
Attachments: image001.png

Hi Mustafa,

(b)(5)

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

Please let me know if you have any further questions, Thanks,
Laura

From: Liu, Lixin <Lixin.Liu@fda.hhs.gov>
Sent: Friday, March 26, 2021 1:01 PM
To: Marquart, Laura <Laura.Marquart@fda.hhs.gov>
Cc: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>; Ferlin, Kimberly <Kimberly.Ferlin@fda.hhs.gov>
Subject: Consult request - K203835/S002 - (b)(5)

Hi, Laura:

(b)(5)

Thanks,

Lixin Liu, Ph.D.
Biologist/Team Lead

Plastic Surgery Skin and Wound Devices 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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April 23, 2021

Next Science, LLC
Courtney Narain
Regulatory Affairs Specialist
10550 Deerwood Park Blvd Ste 300
Jacksonville, Florida 32256

Re: K203835
Trade/Device Name: MIS Solution
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 25, 2021
Received: March 26, 2021

Dear Courtney Narain:

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

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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,

Lixin Liu -S

Lixin Liu, Ph.D.
Acting 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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K203835

Device Name
MIS Solution

Indications for Use *(Describe)*

MIS Solution is indicated for use in cleansing and removal of debris, including microorganisms from wounds.

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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510(k) Summary

MIS Solution

Submitter: Next Science®, LLC
10550 Deerwood Park
Suite 300
Jacksonville, Florida 32256

Contact Person: Courtney Narain
Regulatory Affairs Specialist
855-564-2762 ext. 6004
855-564-2460 (fax)

Date Prepared: April 23, 2021

Device Trade Name: MIS Solution

Device Common Name: Wound Irrigation Solution

Classification Name: Dressing, Wound, Drug

Product Code: FRO

Classification: Unclassified

Predicate Device: Next Science® Irrigation Solution (K161165)

Indications For Use: MIS Solution is indicated for use in cleansing and removal of debris, including microorganisms, from wounds.

Device Description:

MIS Solution is a clear, colorless solution intended for cleansing and removal of debris, including microorganisms, from wounds.

The mechanical action of fluid moving across the wound provides the mechanism of action and aids in the removal of debris, including microorganism, from wounds. MIS Solution is provided in a soft polypropylene 500mL container with a spikeable port. MIS Solution is composed of water, citric acid, sodium citrate and sodium lauryl sulfate.

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Technological Characteristics:

MIS Solution (subject device) and Next Science® Irrigation Solution (predicate device) consist of different ingredients. However, while the device technology is different between the subject and predicate device, the function of each ingredient is analogous. Both devices incorporate a surfactant to assist in the solubilization of debris, a buffer system to maintain the pH of the formulation and a vehicle to carry away debris from the wound.

The table below compares MIS Solution to the predicate device.

Product	MIS Solution	Next Science® Irrigation Solution (Predicate)
Company	Next Science®, LLC	Next Science®, LLC
510(k) Number	K203835	K161165
Indications	MIS Solution is indicated for use in cleansing and removal of debris, including microorganisms, from wounds.	Next Science® Irrigation Solution is to be used with a jet lavage system and is indicated for use in cleansing and removal of debris, including micro-organisms, from wounds.
Composition	**pH Buffer** Sodium Citrate 31.33 g/L Citric Acid 32.50 g/L	**pH Buffer** Sodium Acetate 30.00 g/L Acetic Acid 50.00 g/L
	Surfactant Sodium Lauryl Sulfate 1.00g/L	**Surfactant** Benzalkonium Chloride 1.3 g/L
	Vehicle Water	**Vehicle** Ethanol 100 g/L Water
Sterility	Sterile	Sterile
Mechanism(s) of Action	Mechanical removal of debris via hydrodynamic shear. The mechanical action of moving across the wound aids in the removal of foreign material such as, microorganisms, dirt and debris. The mechanical action can be provided by either a manual syringe or powered irrigation device.	Mechanical removal of debris via hydrodynamic shear. The mechanical action of moving across the wound aids in the removal of foreign material such as dirt and debris. The mechanical action of the irrigation is provided by the Pulsavac Plus lavage systems.

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Biocompatibility

The biocompatibility of MIS Solution has been evaluated in accordance with ISO 10993-1:2018 and FDA guidance "Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing". The battery of studies includes the following:

- Material Mediated Pyrogenicity using USP <151>
- Guinea Pig Maximization Sensitization Test
- Porcine Wound Healing to address the cytotoxicity endpoint
- Toxicological Risk Assessment per ISO 10993-17
- Chemical Characterization of Extractables and Leachables for device packaging
- Irritation (Human)

Performance Bench Testing

The following bench tests were conducted to support the substantial equivalency of MIS Solution in removing debris from a surface and adequate irrigation:

- Compatibility and Irrigation Force Comparison – the test verified that use of the subject device in manual and powered irrigation devices were able to reach published pressures deemed adequate for wound irrigation.
- Combined Dissolution Efficacy – The test demonstrated that MIS Solution and the predicate device are substantially equivalent at removing debris under static conditions.

Animal Testing

A Porcine Wound Healing Study was conducted to evaluate the effect of the subject device components on the wound healing process.

In the animal study conducted, 16 domestic pigs were used, each receiving eight wounds, four on the left and right sides of the animal's back parallel to the spine line. Two or three of the animal's wounds were assigned to a treatment group of the subject device, the predicate device or a negative control.

Under the conditions of the study, MIS Solution did not inhibit normal wound healing over 25 days in this porcine wound healing study.

Clinical Study

MIS Solution was evaluated in a Human Repeat Patch Test to evaluate the irritation endpoint in humans. MIS Solution was determined to be a non-irritant. There were no adverse events or complications in this study.

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

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Conclusion:

The conclusions drawn from biocompatibility, performance tests and a clinical study demonstrate that MIS Solution is as safe and effective as the legally marketed device, Next Science® Irrigation Solution (K161165).

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

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March 25, 2021

K203835/S002

BY FEDEX DELIVERY
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: K203835/S001 – Additional Information Request

MIS Solution Traditional 510(k) Premarket Notification

Dear Mustafa Mazher:

Next Science submits this letter in response to the Additional Information (AI) request, provided on March 19, 2021.

The enclosed submission is being provided via eCopy in accordance with the proposed rule 83 FR 46444. If there are any additional questions regarding our responses, we would appreciate an interactive review and the opportunity to discuss and clarify issues as they arise.

Please feel free to contact me by email at cnarain@nextscience.com if you have any additional questions.

Thank you,

(b)(6)

Courtney Narain

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

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March 19, 2021</br></br> We have reviewed your submission. Please see attached.

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

 *** This is a system-generated email notification ***

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

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(b)(4)

Safety data sheet

(b)(4)

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CERTIFICATE OF ANALYSIS

(b)(4)

PRODUKT: Water for Injections (Ph.Eur./ USP)

Date of Compounding: (b)(4)

(b)(4)

D-Untergröningen,

(b)(6)

Quality Control Management

(b)(4)

Questions? Contact FDA/CDRH/OC/DD at CDRHFOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Certificate of Analysis

(b)(4) tri-Sodium citrate dihydrate powder EMPROVE® ESSENTIAL Ph Eur,BP, JP,USP,E 331

Batch (b)(4)

(b)(4)

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

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(b)(4)

SAFETY DATA SHEET

according to Regulation (EC) No. (b)(4)

Revision Date 24.08.2018 Version (b)(4)

(b)(4)

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

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(b)(4)

Certificate of Analysis

(b)(4) Citric acid anhydrous fine-granular EMPROVE® ESSENTIAL Ph Eur,BP,JP, USP,E 330,FCC

Batch (b)(4)

(b)(4)

(b)(6)

Responsible laboratory manager quality control

This document has been produced electronically and is valid without a signature.

(b)(4)

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(b)(4)

SAFETY DATA SHEET

according to Regulation (EC) No. (b)(4)

Revision Date 03.11.2017 Version (b)(4)

(b)(4)

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

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From: Seearam, Tulsidai * [Tulsidai.Seearam@fda.hhs.gov]
Sent: 12/30/2020 5:03:32 PM
To: cnarain@nextscience.com
Subject: K203835 Acknowledgement Notification
Attachments: K203835 Letter.pdf

Respectfully,

Tulsidai Seearam

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

Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

U.S. FOOD & DRUG ADMINISTRATION

Acknowledgment Letter

12/30/2020

Courtney Narain, Regulatory Affairs Specialist
Next Science, LLC
10550 Deerwood Park Blvd Ste 300
Jacksonville, FL 32256
UNITED STATES

Dear Courtney Narain:

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 above letterhead address. 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: K203835
Received: 12/30/2020
Applicant: Next Science, LLC
Device: MIS Solution

We will notify you when the review of this document has been completed or if any additional information is required. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

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

Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

January 13, 2021</br></br>

Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your submission K203835. Our review indicates that your submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit one eCopy of your response, referencing your submission K203835, addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration

Center for Devices and Radiological Health

Document Control Center - WO66-G609

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

Your submission will remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist by 07/12/2021, we will consider this submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your submission. We will contact you if we require any additional information during the course of our administrative review. FDA aims to apply the least burdensome principles when requesting additional information.

The lead reviewer assigned to your submission is me, Lixin Liu. The file is being reviewed in Office of Health Technology 4, Division of Health Technology 4 B. The first line supervisor is the Assistant Director, Plastic Surgery Skin and Wound Devices. You may contact me at any point during the review if you have questions or concerns. You can provide valuable support for CDRH to continue to improve our programs by raising to the attention of management relevant issues that arise during the course of this review. If you feel there is an unresolved issue or a matter that requires additional attention, you should contact the Assistant Director. If your concern or issue is not addressed by the Assistant Director, you should contact the Division Director or OHT Director. The contact information for each management level can be found in the CDRH Management Directory.

For additional information about the Refuse to Accept Policy for for 510(k)s please refer to the guidance document available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf.

If you have general questions about the review process for your submission, you should contact OPEQSubmissionSupport@fda.hhs.gov.

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

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From: Hailemariam, Kiros
To: Mazher, Mustafa
Subject: FW: (b)(5) on K203835/S001
Date: Wednesday, March 17, 2021 10:23:20 AM

Hi Mustafa,

(b)(5)

Thank you,

Kiros

From: Hailemariam, Kiros
Sent: Wednesday, March 17, 2021 10:17 AM
To: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>
Subject: RE: (b)(5) on K203835/S001

Hi Mustafa,

(b)(5)

From: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>
Sent: Wednesday, March 17, 2021 9:22 AM
To: Hailemariam, Kiros <Kiros.Hailemariam@fda.hhs.gov>
Subject: RE: (b)(5) on K203835/S001

Hello Kiros,

(b)(5)

Thanks,

Mustafa

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

From: Hailemariam, Kiros <Kiros.Hailemariam@fda.hhs.gov>
Sent: Wednesday, March 17, 2021 7:30 AM
To: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>
Subject: RE: (b)(5) on K203835/S001

You are most welcome, Mustafa!

Kiros

From: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>
Sent: Tuesday, March 16, 2021 6:35 PM
To: Hailemariam, Kiros <Kiros.Hailemariam@fda.hhs.gov>
Subject: RE (b)(5) on K203835/S001

Thank you very much Kiros!

From: Hailemariam, Kiros <Kiros.Hailemariam@fda.hhs.gov>
Sent: Tuesday, March 16, 2021 6:02 PM
To: Mazher, Mustafa <Mustafa.Mazher@fda.hhs.gov>; Rimmer, Ralph <Ralph.Rimmer@fda.hhs.gov>
Cc: Murray III, Clarence <Clarence.Murray@fda.hhs.gov>; Dugard, Christopher <Christopher.Dugard@fda.hhs.gov>
Subject: (b)(5) on K203835/S001

Hi Mustafa,

(b)(5)

Thank you,
Kiros

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Hello Lixin,

Thank you for the prompt response!

(b)(4)

Thank you,

Courtney

From: Liu, Lixin <Lixin.Liu@fda.hhs.gov>

Sent: Friday, January 15, 2021 11:56 AM

To: Courtney Narain <cnarain@nextscience.com>

Cc: K203835@docs.fda.gov

Subject: RE: K203835 is on Hold Pending Your Response

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

Hi, Courtney:

Thank you for reaching us on K203835 administrative review.

To help expediate our administrative review process for your future supplement, we will appreciate if you may provide response to each RTA item in your future cover letter. Please specify which section/attachment has been revised to align with your response to the RTA item. It is optional that you provide the entire 510k submission, or provide only the updated section/attachment in your future supplement.

(b)(4)

I hope this response may clarify your questions.

Thank you!

Lixin Liu, Ph.D.

Biologist/Team Lead

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

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Plastic Surgery Skin and Wound Devices Team

DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

Tel: 301-796-3480

Lixin.Liu@fda.hhs.gov<mailto:Lixin.Liu@fda.hhs.gov>

[cid:image002.png@01D6EB41.EB0281E0]<http://www.fda.gov/>

[cid:image004.jpg@01D6EB41.EB0281E0]<https://www.facebook.com/FDA>
[cid:image006.jpg@01D6EB41.EB0281E0] <https://twitter.com/US_FDA>
[cid:image008.jpg@01D6EB41.EB0281E0] <http://www.youtube.com/user/USFoodandDrugAdmin>
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<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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https://www.research.net/r/cdrhcustomerservice?ID=2001&S=E

From: Courtney Narain <cnarain@nextscience.com<mailto:cnarain@nextscience.com>>

Sent: Thursday, January 14, 2021 6:19 PM

To: Liu, Lixin <Lixin.Liu@fda.hhs.gov<mailto:Lixin.Liu@fda.hhs.gov>>

Subject: RE: K203835 is on Hold Pending Your Response

Dear Lixin,

Thank you for the advisory comments. Next Science appreciates the collaborative gesture and looks forward to working with you on this submission.

(b)(4) Next Science wants to ensure the information and resolutions to issues are easily locatable. With that said, the following questions are being asked to ensure accurate RTA resolutions:

(b)(4)

Sincerely,

Courtney

[cid:image014.png@01D6EB3D.86F03570]

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

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From: Lixin Liu <lixin.liu@fda.hhs.gov<mailto:lixin.liu@fda.hhs.gov>>

Sent: Wednesday, January 13, 2021 4:17 PM

To: Courtney Narain <cnarain@nextscience.com<mailto:cnarain@nextscience.com>>

Cc: Lixin Liu <lixin.liu@fda.hhs.gov<mailto:lixin.liu@fda.hhs.gov>>

Subject: K203835 is on Hold Pending Your Response

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January 13, 2021

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Document Control Center - WO66-G609

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

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The lead reviewer assigned to your submission is me, Lixin Liu. The file is being reviewed in Office of Health Technology 4, Division of Health Technology 4 B. The first line supervisor is the Assistant Director, Plastic Surgery Skin and Wound Devices. You may contact me at any point during the review if you have questions or concerns. You can provide valuable support for CDRH to continue to improve our programs by raising to the attention of management relevant issues that arise during the course of this review. If you feel there is an unresolved issue or a matter that requires additional attention, you should contact the Assistant Director. If your concern or issue is not addressed by the Assistant Director, you should contact the Division Director or OHT Director. The contact information for each management level can be found in the CDRH Management Directory<https://www.fda.gov/about-fda/cdrh-offices/cdrh-management-directory-organization>.

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http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocumen

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ts/UCM315014.pdf.

If you have general questions about the review process for your submission, you should contact OPEQSubmissionSupport@fda.hhs.gov<mailto:OPEQSubmissionSupport@fda.hhs.gov>.

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Contains Nonbinding Recommendations

Print Form

510(k) Acceptance Checklist

Not for use with Third Party 510(k)s

Choose Submission Type: ☒ **Traditional** ☐ **Abbreviated** ☐ **Special**

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K203835 Date Received by DCC: Jan 19, 2021

Lead Reviewer: Mustafa A. Mazher

Center: CDRH Office: OHT 4 Division: DHT4B

Decision:

◉ Accept. If Accept, notify submitter.

○ Refuse to Accept. If Refuse to Accept, notify submitter electronically and include a copy of this checklist.

Is an Addendum attached?: ○ Yes ◉ No Click paperclip icon on the left panel if Addendum is attached.

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

Preliminary Questions

Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDA's preliminary assessment of these questions at the time of administrative review.)	Yes	No	N/A
1 Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product (per 21 CFR 3.2(e)), or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action, and inform management. *Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If the product does not appear to be a device or such a combination product, mark "No."	☒	☐	
Comments:			
2 Is the submission with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If submission should not be reviewed by your Center mark "No."	☒	☐	
Comments:			

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3 If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: **a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?** **b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide a summary of Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."	☐	☐	☒
Comments:			
4 Is the submission for a combination product that contains as a constituent part a drug that has the same active moiety as an approved drug with exclusivity as described in 21 USC 503(g)(5)(C)(ii)-(v) (section 503(g)(5)(C)(ii)-(v) of the FD&C Act)? If "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide the summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below*.	☐	☐	☒
Comments:			
5 Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), consult with the appropriate CDRH or CBER staff during the acceptance review, provide a summary of the discussion with them, and indicate their recommendation/action in the comment section below. If 510(k) is not the appropriate regulatory submission, mark "No."	☒	☐	
Comments:			
6 Is there a pending PMA for the same device with the same indications for use? If "Yes," consult your management and CDRH Office of Product Evaluation and Quality/Office of Regulatory Programs/Division of Regulatory Programs 1 (Submission Support) (OPEQ/ORP/DRP1) or appropriate CBER staff to determine the appropriate action.	☐	☒	
Comments:			
7 If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If "Yes," consult with the CDRH Office of Product Evaluation and Quality/ Office of Clinical Evidence and Analysis/Division of Clinical Science and Quality (OPEQ/OCEA/DCEA1) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action, provide a summary of the discussion with them, and indicate their recommendation/action. If no clinical studies have been submitted, mark "N/A." Check on the AIP list at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/application-integrity-policy/application-integrity-policy-list.	☐	☐	☒
Comments:			

- If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.
- If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.
- If the answer to 4 is "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer, provide a summary of the discussion with them, and indicate their recommendation/action.
- If the answer to 5 is "No," the lead reviewer should consult management and other Center resources to determine the appropriate action.
- If the answer to 6 is "Yes," then stop review of the 510(k), contact the CDRH/OPEQ/ORP/DRP1, or appropriate CBER staff.
- If the answer to 7 is "Yes," then contact CDRH/OPEQ/OCEA/DCEA1 or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DCEA1 or BMB Staff, and indicate their recommendation/action.

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Organizational Elements

Failure to include these items should not result in an RTA designation.

*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	*Page #
1) Submission contains a Table of Contents	☒	☐	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	☒	☐	
3) All pages of the submission are numbered. *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2…).*	☒	☐	
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special). *If type of 510(k) is not designated, review as a Traditional 510(k).*	☒	☐	
Comments:			

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
A. Administrative					
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	☒	☐		☐	
2) Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form (Form 3514, available at https://www.fda.gov/media/72421/download)):				☐	
a) Device trade/proprietary name	☒	☐			
b) Device class and panel OR Classification regulation OR Statement that device has not been classified with rationale for that conclusion	☒	☐			
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/alternative-certain-prescription-device-labeling-requirements.) *See recommended* format (https://www.fda.gov/media/86323/download).	☒	☐		☐	
4) Submission contains a 510(k) Summary or 510(k) Statement.	☒	☐		☐	
5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(l) *See recommended format (https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-truthful-and-accurate-statement).*	☒	☐		☐	
6) Submission is a Class III 510(k) device.	☐		☒	☐	
7) Submission contains clinical data	☒		☐	☐	
a) Submission includes completed Financial Certification (FDA Form 3454, available at https://www.fda.gov/media/70465/download) or Disclosure (FDA Form 3455, available at https://www.fda.gov/media/69872/download) information for each covered clinical study included in the submission. *Select "N/A" if the submitted clinical data is not a "covered clinical study" as defined in the guidance entitled "Financial Disclosures by Clinical Investigators", available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/financial-disclosure-clinical-investigators.*	☒	☐	☐		
b) Submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (FDA Form 3674, available at https://www.fda.gov/media/69901/download) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission. *Select "N/A" if the submitted clinical data is not an "applicable device clinical trial" as defined in Title VIII of FDAAA, Sec. 801(j)*	☐	☐	☒		

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
c) Statements of Compliance for Clinical Investigations *Select "N/A" if the submission does not contain any clinical data from investigations (as defined in 21 CFR 812.3(h)) to demonstrate substantial equivalence.* *For multicenter clinical investigations involving both United States (US) and outside United States (OUS) sites, part (i) should be addressed for the US sites and part (ii) should be addressed for the OUS sites. 21 CFR 812.28 applies to all OUS clinical investigations that enroll the first subject on or after February 21, 2019.* *Please refer to the guidance document entitled "Acceptance of Clinical Data to Support Medical Device Applications and Submissions - Frequently Asked Questions," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-clinical-data-support-medical-device-applications-and-submissions-frequently-asked for more information.*	☒		☐		
i) For each clinical investigation conducted in the US, the submission includes a statement of compliance with 21 CFR parts 50, 56, and 812. **OR** The submission includes a brief statement of the reason for noncompliance with 21 CFR parts 50, 56, and 812.	☐	☐	☒		
ii) For each clinical investigation conducted OUS, the submission includes a statement that the clinical investigations were conducted in accordance with good clinical practice (GCP) as described in 21 CFR 812.28(a)(1). **OR** The submission includes a waiver request in accordance with 21 CFR 812.28(c). **OR** The submission includes a brief statement of the reason for not conducting the investigation in accordance with GCP and a description of steps taken to ensure that the data and results are credible and accurate and that the rights, safety, and well-being of subjects have been adequately protected.	☐	☐	☒		
8) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Q-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device.	☒	☐		☐	
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed.	☒	☐	☐		
9) The submission utilizes voluntary consensus standard(s) (See section 514(c) of the FD&C Act). *This includes both FDA-recognized and non-recognized consensus standards.*	☒		☐	☐	
a) The submission cites FDA-recognized voluntary consensus standard(s).	☒		☐		

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
i) The submission includes a Declaration of Conformity (DOC) as outlined in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices. **OR** If citing general use of a standard as noted in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," the basis of such use is included along with the underlying information or data that supports how the standard was used.	☒	☐			
b) The submission cites non-FDA-recognized voluntary consensus standard(s).	☐		☒		
Combination Product Provisions - Per 503(g) of the FD&C Act. Select "N/A" if the product is not a combination product. 21 CFR 3.2(e). The remaining criteria in this section will be omitted from the checklist if "N/A" is selected. If you are unsure if the product is a combination product, consult with the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.			☒		
B. Device Description					
12) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding the device description that is applicable to the subject device.	☐		☒	☐	
13) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).	☒	☐		☐	
14) The submission includes descriptive information for the device, including the following:				☐	
a) A description of the principle of operation or mechanism of action for achieving the intended effect.	☒	☐			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	☒	☐	☐		
c) A list and description of each device for which clearance is requested.	☐	☐	☒		
d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).	☒	☐			
15) Device is intended to be marketed with accessories and/or as part of a system.	☐		☒	☐	
C. Substantial Equivalence Discussion					
16) Submitter has identified a predicate device(s), including the following information:				☐	

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
a) Predicate device identifier provided (e.g., 510(k) number, De Novo number, reclassified PMA number, classification regulation reference, if exempt (e.g., 21 CFR 872.3710), or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online (https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/preamendment-status).*	☒	☐			
b) The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).	☒	☐			
17) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See the FDA guidance document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k for more information on comparing intended use and technological characteristics.*				☐	
a) Indications for Use	☒	☐			
b) Technology, including technical specifications, features, materials, and principles of operation	☒	☐			
D. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)					
18) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	☒	☐		☐	
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	☒	☐			
b) Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) **AND** - Includes adequate directions for use (see 21 CFR 801.5) **OR** - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D	☒	☐			
19) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	☒	☐		☐	
20) Labeling includes the prescription statement [see 21 CFR 801.109(b)(1)] or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's guidance "Alternative to Certain Prescription Device Labeling Requirements," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/alternative-certain-prescription-device-labeling-requirements.	☒	☐	☐	☐	
21) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding labeling that is applicable to the subject device.	☐		☒		

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

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
22) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.	☐	☐	☒	☐	
E. Sterilization					
If an *in vitro* diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.			☐		
☒ Provided sterile, intended to be single-use					
☐ Requires processing during its use-life					
☐ Non-sterile when used (and no processing required)					
☐ Information regarding the sterility status of the device is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Sterility status not needed for this device (e.g., software-only device)					
☐ Sterility status needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *Please refer to the FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling, for additional information.*					
23) Assessment of the need for cleaning and subsequent disinfection or sterilization information				☐	
a) Identification of device and/or accessories, if applicable, that are provided sterile.	☒	☐	☐		
b) Identification of device and/or accessories, if applicable, that are end user sterilized or disinfected.	☐	☐	☒		
c) Identification of device, and/or accessories, if applicable, that are reusable.	☐	☐	☒		
24) If the device and/or accessories, if applicable, are provided sterile:			☐	☐	
a) Sterilization method is stated for each device (including dose for radiation sterilization).	☒	☐			
b) A description of method to validate the sterilization parameters is provided for each proposed sterilization method (e.g., half-cycle method and full citation of FDA-recognized standard, including date).	☒	☐			
c) For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.	☐	☐	☒		
d) Sterility Assurance Level (SAL) is stated.	☒	☐			
e) Submission includes description of packaging.	☒	☐			
f) For products labeled "non-pyrogenic," a description of the method used to make the determination stated (e.g., limulus amebocyte lysate [LAL]).	☒	☐	☐		
25) If the device and/or accessory, if applicable, is reusable or end user sterilized or disinfected:			☒	☐	

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
a) Cleaning method is provided in labeling for each device and/or accessory, if applicable.	☐	☐	☒		
b) Disinfection method is provided in labeling for each device and/or accessory, if applicable.	☐	☐	☒		
c) Sterilization method is provided in labeling for each device and/or accessory, if applicable.	☒	☐	☐		
d) Device types in this submission are listed in the Federal Register (FR) Notice entitled "Validated Instructions for Use and Validation Data Requirements for Certain Reusable Medical Devices in Premarket Notifications" (Reprocessing FR Notice, available at https://www.federalregister.gov / documents/2017/06/09/2017-12007/medical-devices-validated-instructions-for-use-and-validation-data-requirements-for-certain-reusable).	☐		☒		
26) The device has a device-specific guidance document, special controls, and/or requirement in a device-specific regulation regarding sterility and/or reprocessing that is applicable to the subject device.	☐		☒	☐	
F. Shelf Life					
27) Proposed shelf life/expiration date stated **OR** Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation	☒	☐	☐	☐	
28) For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf life.	☒	☐	☐	☐	
29) Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). **OR** Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	☒	☐		☐	
G. Biocompatibility					
If an vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.			☐		
Submission states that there: (one of the below must be checked)		☐		☐	
☒ Are direct or indirect tissue-contacting components.					
☐ Are no direct or indirect tissue-contacting components.					
☐ Information regarding tissue contact status of the device is not provided (if this box checked, please also check one of the two boxes below).					
☐ Tissue contact information not needed for this device (e.g., software-only device)					
☐ Tissue contact information needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
30) Submission includes a list identifying each of tissue-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.	☒	☐		☐	

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

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
31) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration) for each tissue-contacting device component (e.g., implant, delivery catheter)	☒	☐		☐	
32) For a biocompatibility assessment of tissue-contacting components, submission includes: – Each relevant endpoint for the device (as identified in device-specific guidance, or Attachment A of the FDA guidance document entitled "Use of International Standard ISO 10993-1, `Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and), has been addressed. - For any testing performed, test protocol (including identification and description of test article including whether the test article is the device in its final finished form using the recommended approach in Attachment F of "Use of International Standard ISO 10993-1, `Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" methods, and pass/fail criteria), and analysis of results (including tables with data points and statistical analyses, where appropriate), as described in Attachment E of the guidance document entitled "Use of International Standard ISO 10993-1, `Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" provided for each completed test. **OR** A statement that biocompatibility testing is not needed with a rationale that considers all relevant endpoints (e.g., materials and manufacturing/processing are identical to the predicate).	☒	☐		☐	
H. Software					
Submission states that the device: (one of the below must be checked)		☐		☐	
☐ Does contain software/firmware					
☒ Does not contain software/firmware					
☐ Information on whether device contains software/firmware is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Software/firmware information not needed for this device (e.g., surgical suture, condom)					
☐ Software/firmware information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
I. Cybersecurity					
Submission states that the device: *(one of the below must be checked)*		☐		☐	
☐ Does contain any external wired and/or wireless communication interfaces (Wired: USB, ethernet, SD, CD, RGA, etc. or Wireless: Wi-Fi, Bluetooth, RF, inductive, Cloud, etc.)					
☒ Does not contain external interfaces as described above					
☐ Information on whether device has external interfaces is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Cybersecurity information not needed for this device (e.g., surgical suture, condom)					
☐ Cybersecurity information is needed or need unclear					

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

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
J. Electrical Safety and EMC					
Electrical Safety Submission states that the device: *(one of the below must be checked)*		☐		☐	
☐ Does require electrical safety evaluation					
☒ Does not require electrical safety evaluation					
☐ Information on whether device requires electrical safety evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Electrical safety information not needed for this device (e.g., surgical suture, condom)					
☐ Electrical safety information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
EMC Submission states that the device: (one of the below must be checked)		☐		☐	
☐ Does require EMC evaluation					
☒ Does not require EMC evaluation					
☐ Information on whether device requires EMC evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ EMC information not needed for this device (e.g., surgical suture, condom)					
☐ EMC information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
K. Performance Data - General					
If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.			☐		
38) Summaries of the non-clinical laboratory studies and full test reports* are provided. *Summary and full test report content recommendations can be found in FDA's guidance "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket. If a submitter chooses to declare conformity to a voluntary consensus standard that FDA has recognized, submission of a full test report may not be necessary. Refer to 9a. See FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.	☒	☐	☐	☐	

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
a) Submission includes an explanation of how the data generated from each test supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.).	☒	☐			
39) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding performance data that is applicable to the subject device.	☐		☒	☐	
40) If literature is referenced in the submission, submission includes:			☒		
41) For each completed animal study, the submission provides the following:			☐	☐	
a) Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120.	☒	☐			
b) Submission includes final study report which includes all elements outlined in 21 CFR 58.185.	☒	☐			
c) Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.	☒	☐			
L. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**					
Submission states that the device: (one of the below must be checked)				☐	
☐ is an in vitro diagnostic device.					
☒ is not an in vitro diagnostic device.					
If "is not" is selected, the performance data-related criteria below are omitted from the checklist.					

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Digital Signature Concurrence Table

Reviewer Sign-Off	Mustafa A. Mazher -S Mustafa A. Mazher -S 2021.02.03 17:18:35 -05'00'
Management Sign-Off (digital signature optional)*	Lixin Liu -S Digitally signed by Lixin Liu -S Date: 2021.02.03 17:34:13 -05'00'

* Management review of checklist and concurrence with with decision required.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K203835

Device Name
MIS Solution

Indications for Use *(Describe)*

MIS Solution is indicated for use in cleansing and removal of debris, including microorganisms from wounds.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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(b)(4)

(b)(4) PRIMARY IRRITATION PATCH TEST

(b)(4) STUDY NO. (b)(4)

NEXT SCIENCE STUDY NO. (b)(4)

SUBMITTED TO:

Next Science, LLC
10550 Deerwood Park Blvd., Suite 300
Jacksonville, FL 32256

Attention: (b)(4)

SUBMITTED BY:

(b)(4)

DATE OF FINAL REPORT :

August 4, 2020

Version (b)(4)

(b)(4)

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APPENDIX I

TABLES AND DATA LISTINGS

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APPENDIX II

INFORMED CONSENT DOCUMENT

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APPENDIX III

PROTOCOL

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(b)(4)

PROTOCOL

(b)(4) PRIMARY IRRITATION PATCH TEST

(b)(4) STUDY NO. (b)(4)

PROTOCOL NO. (b)(4)

(b)(4)

30 SUBJECTS

SUBMITTED TO:

Next Science, LLC
10550 Deerwood Park Blvd., Suite 300
Jacksonville, FL 32256

Attention: Dianne Porral

SUBMITTED BY:

(b)(4)

DATE:
(b)(4)

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APPENDIX IV

STATISTICAL ANALYSIS PLAN

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7-DAY PRIMARY IRRITATION PATCH TEST

(b)(4) Study (b)(4)

Statistical Analysis Plan

17 July 2020

Matthew Myntti, PhD
Chief Technology Officer
Next Science, LLC

(b)(4)
Signature

07/17/2020
Date

(b)(4)
Vice President, Data Management, Biostatistics, and Medical Communications
(b)(4)

(b)(4)
Signature

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DEPARTMENT OF HEALTH AND HUMAN SERVICES **M E M O R A N D U M**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

CON213637 for K203835/S001
Toxicology Consult Review

Date: March 16, 2021

To: Mustafa Mazher, Ph.D.

From: Kiros Hailemariam, Ph.D.

Through: CAPTAIN Elizabeth Claverie, MS, Branch Chief, Infection Control Devices Branch, DHT4B/OHT4

(b)(5)

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Kiros Hailemariam, Ph.D.
Reviewer

Kiros F. Hailemariam -S
Digitally signed by Kiros F. Hailemariam -S
Date: 2021.03.16 17:58:07 -04'00'

March 16, 2021
Date

Clarence W. Murray, III, Ph.D.
Asst. Director, DHT4B/OHT4

March 16, 2021
Date

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NEXT SCIENCE®

10550 Deerwood Park Blvd
Suite 300
Jacksonville, FL 32256
P: 855-564-2762

FDA/CDRH/DCC
JAN 19 2021
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K203835/S001

BY FEDEX DELIVERY
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: **Traditional Premarket Notification 510(k):** K203835
Device Common Name: Dressing, Wound, Drug
Classification: Unclassified
Combination Product: Yes
Product Code: FRO

Dear Dr. Liu:

In accordance with your request, this cover letter provides a response to all of the RTA items presented to Next Science on January 13, 2020:

(b)(4)

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(b)(4)

The Traditional 510(k) submission enclosed herein is being provided via eCopy only in accordance with the final rule 84 FR 68334.

Please contact me by email at cnarain@nextscience.com, if you need additional information or have any questions.

Sincerely,

(b)(6)

Courtney Narain
Regulatory Affairs Specialist
Next Science®, LLC

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

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GLP REPORT

TEST FACILITY

(b)(4)

SPONSOR

Courtney Narain
Next Science
10550 Deerwood Park Boulevard, Suite 300
Jacksonville, Florida 32256

CONFIDENTIAL

STUDY TITLE

USP Rabbit Pyrogen Study

TEST ARTICLE NAME

MIS Lavage

TEST ARTICLE IDENTIFICATION

(b)(4)

(b)(4)

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GLP PROTOCOL

TEST FACILITY

(b)(4)

SPONSOR

Courtney Narain
Next Science
10550 Deerwood Park Boulevard, Suite 300
Jacksonville, Florida 32256

STUDY TITLE

USP Rabbit Pyrogen Study

(b)(4)

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Project ID: (b)(4) Date: July 19, 2019

(b)(4)

(b)(4) Laboratory Report MIS Solution Analysis

Report prepared for:

(b)(4)

Report Prepared by:

(b)(4)

MIS Solution (b)(4)

(b)(4)

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

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Project ID: (b)(4) Date: July 22, 2019

(b)(4)

(b)(4) Laboratory Report MIS Solution Analysis

Report prepared for:

(b)(4)

Report Prepared by:

(b)(4)

MIS Solution (b)(4)

(b)(4)

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

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Project ID: (b)(4) Date: October 28, 2019

(b)(4)

(b)(4) Laboratory Report MIS Solution Analysis

Report prepared for:

(b)(4)

Report Prepared by:

(b)(4)

MIS Solution (b)(4)

(b)(4)

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Project ID: (b)(4) Date: February 3rd, 2020

(b)(4)

(b)(4) Laboratory Report MIS Solution Analysis

Report prepared for:

(b)(4)

Report Prepared by:

(b)(4)

MIS Solution (b)(4)

(b)(4)

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Project ID: (b)(4) Date: May 04, 2020

(b)(4)

(b)(4) Laboratory Report MIS Solution Analysis

Report prepared for:

(b)(4)

Report Prepared by:

(b)(4)

MIS Solution (b)(4)

(b)(4)

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NEXT SCIENCE®

March 25, 2021

BY FEDEX DELIVERY
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: K203835/S001 – Additional Information Request

MIS Solution Traditional 510(k) Premarket Notification

Dear Mustafa Mazher:

Next Science submits this letter in response to the Additional Information (AI) request, provided on March 19, 2021.

The enclosed submission is being provided via eCopy in accordance with the proposed rule 83 FR 46444. If there are any additional questions regarding our responses, we would appreciate an interactive review and the opportunity to discuss and clarify issues as they arise.

Please feel free to contact me by email at cnarain@nextscience.com if you have any additional questions.

Thank you,

(b)(6)

Courtney Narain

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Major Deficiency

(b)(4)

Minor Deficiency

(b)(4)

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10. Device Description

A. General Information

The following information is provided as required by 21 C.F.R. § 807.87 for MIS Solution 510(k) premarket notification:

1. **Name of Device**

Trade Name:	MIS Solution
Common Name:	Wound Irrigation Solution
Classification:	Unclassified
Product Code:	FRO

2. **Establishment Registration Information**

Specification Developer:	Next Science®, LLC
Specification Dev Registration Number:	3012271775
Contract Manufacturer:	(b)(4)
Manufacturer Registration Number:	(b)(4)

3. **Device Classification**

MIS Solution is classified as a Dressing, Wound, Drug under the product code, FRO. This product code is presently unclassified.

B. Device Description

Indications for Use of the Device

MIS Solution is intended for use in cleansing and removal of debris, including microorganisms, from wounds.

Principles of Operation

MIS Solution is a clear, colorless, aqueous solution containing water, citric acid, sodium citrate and sodium lauryl sulfate. The sodium lauryl sulfate acts as a surfactant to assist in the solubilization of debris. The mechanism of action is the mechanical removal of debris via hydrodynamic shear across the wound which aids in the removal of foreign material such as,

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microorganisms, dirt and debris. Performance testing demonstrates that the device provides sufficient force to irrigate the wound. The MIS Solution was designed, such that, it does not require a saline rinse post irrigation; in contrast to the predicate device which requires a saline rinse after 1 minute of contact. This allows the irrigation to take place as a single step without the need to manage contact times. Suction is then used to remove the irrigation solution and resulting debris from the wound.

Physical Characteristics

The table below provides the concentration for all the components for MIS Solution.

MIS Solution Composition		
Component	**Concentration (g/L)**	**Purpose**
Sodium Lauryl Sulfate	1.00	Surfactant
Sodium Citrate*	31.33	Buffer system / pH adjusters
Citric Acid	32.50	
Water	(b)(4)	Vehicle / Irrigation Solution

*Sodium Citrate Dihydrate is used in the manufacturing process and the molecular weight with the additional water molecules provide a concentration of 35.70 g/L. Since the product is provided as an aqueous solution, Next Science is presenting the Sodium Citrate concentration without the water molecule weight.

There are no processing aids used during the manufacturing process. Certificates of analysis and safety data can be found in Attachment 13.

Physical Description/Packaging

MIS Solution is provided in a single-use 500mL soft Purell PP RP270G polypropylene container with a cap made of the same material. The cap has a peelable aluminum foil cover. The product will be provided steam sterilized with a sterile fluid path.

A chemical characterization of extractables and leachables were conducted on the final, finished device polypropylene packaging, Purell PP RP270G. The purpose of the study was to identify and quantitate the compounds that can be extracted from the packaging under exaggerated conditions. The results of the study can be found in Attachment 14.

Images 1, 2, and 3 below are representative examples of the proposed packaging.

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Image 1: Front view of MIS Solution

Image 2: Back view of MIS Solution

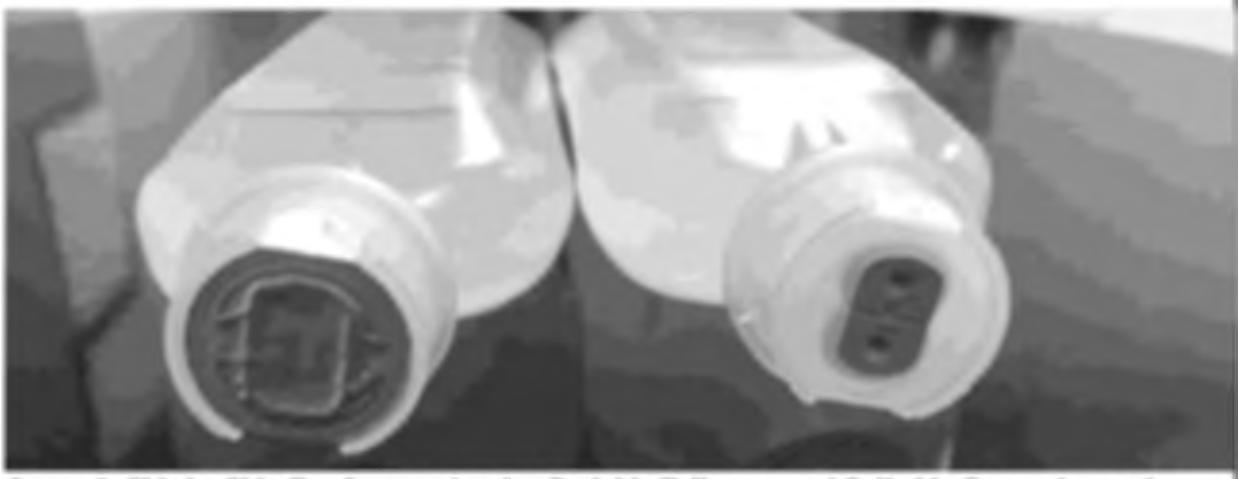

Image 3: Side by Side Cap Images showing Peelable Foil cover and Spikable Cap underneath

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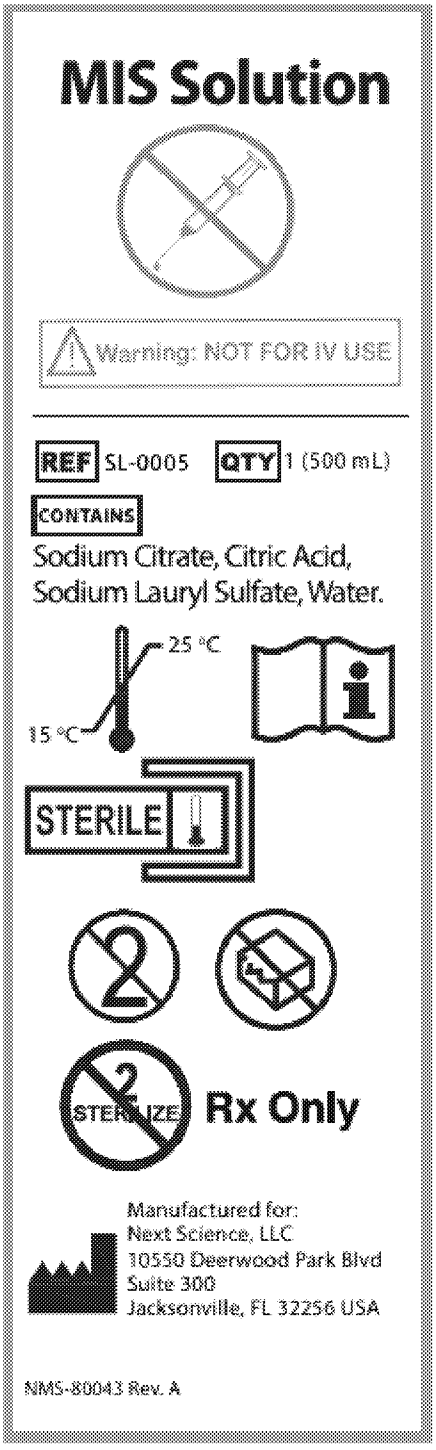
Front Bottle Labeling



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Irrigation:

1. For powered or manual irrigation: Irrigate the wound bed with the contents of the supplied container following the manufacturer's instructions of the irrigation device and/or standard practice.
2. Suction solution and debris throughout the procedure.
3. Use universal precautions in accordance with hospital protocol for the handling and disposal of contaminated waste.
4. Discard any unused solution.

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From: Arepalli, Sambasiva
To: Liu, Lixin
Cc: Ferlin, Kimberly
Subject: RE: K203835 - combo consult needed?
Date: Tuesday, January 05, 2021 1:38:08 PM
Attachments: image001.png
image008.png
image015.png
image022.png

(b)(5)

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

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

From: Liu, Lixin <Lixin.Liu@fda.hhs.gov>
Sent: Tuesday, January 5, 2021 1:37 PM
To: Arepalli, Sambasiva <Sambasiva.Arepalli@fda.hhs.gov>
Cc: Ferlin, Kimberly <Kimberly.Ferlin@fda.hhs.gov>
Subject: RE: K203835 - combo consult needed?

Hi, Sam:

(b)(5)

Thanks,

Lixin Liu, Ph.D.
Biologist/Team Lead

Plastic Surgery Skin and Wound Devices 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
Tel: 301-796-3480
Lixin.Liu@fda.hhs.gov

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From: Arepalli, Sambasiva <Sambasiva.Arepalli@fda.hhs.gov>
Sent: Tuesday, January 05, 2021 11:59 AM
To: Liu, Lixin <Lixin.Liu@fda.hhs.gov>
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Sent: Tuesday, January 5, 2021 10:24 AM
To: Arepalli, Sambasiva <Sambasiva.Arepalli@fda.hhs.gov>
Cc: Ferlin, Kimberly <Kimberly.Ferlin@fda.hhs.gov>
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EXTRACTABLES EVALUATION TO SUPPORT MIS SOLUTION

CONFIDENTIAL

(b)(4) **REPORT NUMBER:**

(b)(4)

PREPARED FOR:

Next Science, LLC
10550 Deerwood Park Blvd., Suite 300
Jacksonville, FL
32256 USA

PREPARED BY:

(b)(4)

DATE:

(b)(4)

(b)(4)

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Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

Project ID: (b)(4) Date: July 19, 2019

(b)(4)

(b)(4) Laboratory Report MIS Solution Analysis

Report prepared for:

(b)(4)

Report Prepared by:

(b)(4)

MIS Solution (b)(4)

(b)(4)

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Project ID: (b)(4) Date: July 19, 2019

(b)(4)

(b)(4) Laboratory Report MIS Solution Analysis

Report prepared for:

(b)(4)

Report Prepared by:

(b)(4)

MIS Solution (b)(4)

(b)(4)

Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

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Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

Project ID: (b)(4) Date: August 27, 2019

(b)(4)

(b)(4) Laboratory Report MIS Solution Analysis

Report prepared for:

(b)(4)

Report Prepared by:

(b)(4)

MIS Solution (b)(4)

(b)(4)

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Project ID: (b)(4) Date: October 15th, 2019

(b)(4)

(b)(4) Laboratory Report MIS Solution Analysis

Report prepared for:

(b)(4)

Report Prepared by:

(b)(4)

(b)(4)

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Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

Project ID: (b)(4) Date: December 16th, 2019

(b)(4)

(b)(4) Laboratory Report MIS Solution Analysis

Report prepared for:

(b)(4)

Report Prepared by:

(b)(4)

MIS Solution (b)(4)

(b)(4)

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

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Records processed under FOIA Request 2023-0423; Released by CDRH on 05-21-2024

(b)(4)

To: Alicia Tetlak, Director, Biological Sciences
Date: 16 November 2020

Subject: Endotoxin Limit for XPERIENCE™

(b)(4)

Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

(b)(4)

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

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(b)(4)

ENDOTOXIN TESTING REPORT

Next Science
Attn.: Alicia Tetlak
10550 Deerwood Park Blvd.
Suite 300
Jacksonville, FL 32256

Date of Report: 13 Jan 2021

Dear Alicia,

(b)(4)

Results for all testing are listed in the following tables on the following pages.

Should you have any questions concerning the results please call the Testing Service at (b)(4)

(b)(4) Thank you.

(b)(4)
Testing Laboratory Representative
Date: 13 Jan 2021

(b)(4)
Testing Laboratory Reviewer
Date: 13 Jan 2021

(b)(4)
Quality Assurance Representative
Date: 15 JAN 2021

(b)(4)

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

Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

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Records processed under FOIA Request 2023-9423; Released by CDRH on 16-Jan-2024

(b)(4)

ENDOTOXIN TESTING REPORT

Next Science
Attn.: Alicia Tetlak
10550 Deerwood Park Blvd.
Suite 300
Jacksonville, FL 32256

Date of Report: 14 Jan 2021

Dear Alicia,

(b)(4)

Results for all testing are listed in the following tables on the following pages.

Should you have any questions concerning the results please call the Testing Service at (b)(4) Thank you.

(b)(4)
Testing Laboratory Representative
Date: 14 Jan 2021

(b)(4)
Testing Laboratory Reviewer
Date: 14 Jan 2021

(b)(4)
Quality Assurance Representative
Date: 15 JAN 2021

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

Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

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Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

510(k) Summary

MIS Solution

Submitter: Next Science®, LLC
10550 Deerwood Park
Suite 300
Jacksonville, Florida 32256

Contact Person: Courtney Narain
Regulatory Affairs Specialist
855-564-2762 ext. 6004
855-564-2460 (fax)

Date Prepared: April 23, 2021

Device Trade Name: MIS Solution

Device Common Name: Wound Irrigation Solution

Classification Name: Dressing, Wound, Drug

Product Code: FRO

Classification: Unclassified

Predicate Device: Next Science® Irrigation Solution (K161165)

Indications For Use: MIS Solution is indicated for use in cleansing and removal of debris, including microorganisms, from wounds.

Device Description:

MIS Solution is a clear, colorless solution intended for cleansing and removal of debris, including microorganisms, from wounds.

The mechanical action of fluid moving across the wound provides the mechanism of action and aids in the removal of debris, including microorganism, from wounds. MIS Solution is provided in a soft polypropylene 500mL container with a spikeable port. MIS Solution is composed of water, citric acid, sodium citrate and sodium lauryl sulfate.

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

Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

Technological Characteristics:

MIS Solution (subject device) and Next Science® Irrigation Solution (predicate device) consist of different ingredients. However, while the device technology is different between the subject and predicate device, the function of each ingredient is analogous. Both devices incorporate a surfactant to assist in the solubilization of debris, a buffer system to maintain the pH of the formulation and a vehicle to carry away debris from the wound.

The table below compares MIS Solution to the predicate device.

Product	MIS Solution	Next Science® Irrigation Solution (Predicate)
Company	Next Science®, LLC	Next Science®, LLC
510(k) Number	K203835	K161165
Indications	MIS Solution is indicated for use in cleansing and removal of debris, including microorganisms, from wounds.	Next Science® Irrigation Solution is to be used with a jet lavage system and is indicated for use in cleansing and removal of debris, including micro-organisms, from wounds.
Composition	**pH Buffer** Sodium Citrate 31.33 g/L Citric Acid 32.50 g/L	**pH Buffer** Sodium Acetate 30.00 g/L Acetic Acid 50.00 g/L
	Surfactant Sodium Lauryl Sulfate 1.00g/L	**Surfactant** Benzalkonium Chloride 1.3 g/L
	Vehicle Water	**Vehicle** Ethanol 100 g/L Water
Sterility	Sterile	Sterile
Mechanism(s) of Action	Mechanical removal of debris via hydrodynamic shear. The mechanical action of moving across the wound aids in the removal of foreign material such as, microorganisms, dirt and debris. The mechanical action can be provided by either a manual syringe or powered irrigation device.	Mechanical removal of debris via hydrodynamic shear. The mechanical action of moving across the wound aids in the removal of foreign material such as dirt and debris. The mechanical action of the irrigation is provided by the Pulsavac Plus lavage systems.

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

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Biocompatibility

The biocompatibility of MIS Solution has been evaluated in accordance with ISO 10993-1:2018 and FDA guidance "Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing". The battery of studies includes the following:

- Material Mediated Pyrogenicity using USP <151>
- Guinea Pig Maximization Sensitization Test
- Porcine Wound Healing to address the cytotoxicity endpoint
- Toxicological Risk Assessment per ISO 10993-17
- Chemical Characterization of Extractables and Leachables for device packaging
- Irritation (Human)

Performance Bench Testing

The following bench tests were conducted to support the substantial equivalency of MIS Solution in removing debris from a surface and adequate irrigation:

- Compatibility and Irrigation Force Comparison – the test verified that use of the subject device in manual and powered irrigation devices were able to reach published pressures deemed adequate for wound irrigation.
- Combined Dissolution Efficacy – The test demonstrated that MIS Solution and the predicate device are substantially equivalent at removing debris under static conditions.

Animal Testing

A Porcine Wound Healing Study was conducted to evaluate the effect of the subject device components on the wound healing process.

In the animal study conducted, 16 domestic pigs were used, each receiving eight wounds, four on the left and right sides of the animal's back parallel to the spine line. Two or three of the animal's wounds were assigned to a treatment group of the subject device, the predicate device or a negative control.

Under the conditions of the study, MIS Solution did not inhibit normal wound healing over 25 days in this porcine wound healing study.

Clinical Study

MIS Solution was evaluated in a Human Repeat Patch Test to evaluate the irritation endpoint in humans. MIS Solution was determined to be a non-irritant. There were no adverse events or complications in this study.

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

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Conclusion:

The conclusions drawn from biocompatibility, performance tests and a clinical study demonstrate that MIS Solution is as safe and effective as the legally marketed device, Next Science® Irrigation Solution (K161165).

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

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Hi, Courtney:

Thank you for reaching us on K203835 administrative review.

To help expediate our administrative review process for your future supplement, we will appreciate if you may provide response to each RTA item in your future cover letter. Please specify which section/attachment has been revised to align with your response to the RTA item. It is optional that you provide the entire 510k submission, or provide only the updated section/attachment in your future supplement.

(b)(4)

I hope this response may clarify your questions.

Thank you!

Lixin Liu, Ph.D.
Biologist/Team Lead

Plastic Surgery Skin and Wound Devices 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
Tel: 301-796-3480
Lixin.Liu@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/r/cdrhcustomerservice?ID=2001&S=E

From: Courtney Narain <cnarain@nextscience.com>
Sent: Thursday, January 14, 2021 6:19 PM
To: Liu, Lixin <Lixin.Liu@fda.hhs.gov>
Subject: RE: K203835 is on Hold Pending Your Response

Dear Lixin,

Thank you for the advisory comments. Next Science appreciates the collaborative gesture and looks forward to working with you on this submission.

(b)(4) Next Science wants to ensure the information and resolutions to issues are easily locatable. With that said, the following questions are being asked to ensure accurate RTA resolutions:

(b)(4)

Sincerely,

Courtney

From: Lixin Liu <lixin.liu@fda.hhs.gov>

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

Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

Sent: Wednesday, January 13, 2021 4:17 PM
To: Courtney Narain <cnarain@nextscience.com>
Cc: Lixin Liu <lixin.liu@fda.hhs.gov>
Subject: K203835 is on Hold Pending Your Response

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

January 13, 2021

Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your submission K203835. Our review indicates that your submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit one eCopy of your response, referencing your submission K203835, addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Your submission will remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist by 07/12/2021, we will consider this submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your submission. We will contact you if we require any additional information during the course of our administrative review. FDA aims to apply the least burdensome principles when requesting additional information.

The lead reviewer assigned to your submission is me, Lixin Liu. The file is being reviewed in Office of Health Technology 4, Division of Health Technology 4 B. The first line supervisor is the Assistant Director, Plastic Surgery Skin and Wound Devices. You may contact me at any point during the review if you have questions or concerns. You can provide valuable support for CDRH to continue to improve our programs by raising to the attention of management relevant issues that arise during the course of this review. If you feel there is an unresolved issue or a matter that requires additional attention, you should contact the Assistant Director. If your concern or issue is not addressed by the Assistant Director, you should contact the Division Director or OHT Director. The contact information for each management level can be found in the CDRH Management Directory.

For additional information about the Refuse to Accept Policy for for 510(k)s please refer to the guidance document available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf.

If you have general questions about the review process for your submission, you should contact OPEQSubmissionSupport@fda.hhs.gov.

****This is a system generated email notification****

*** This is a system-generated email notification ***

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

Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

From: Lively, Harmony * [Harmony.Lively@fda.hhs.gov]
Sent: 1/19/2021 7:10:09 PM
To: cnarain@nextscience.com
Subject: K203835/S001- Acknowledgment Notification
Attachments: K203835.S001- Letter.pdf

Harmony E. Lively
Records Management Specialist 1
CDRH Document Control Center

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

Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

U.S. FOOD & DRUG ADMINISTRATION

Acknowledgment Letter

1/19/2021

Courtney Narain, Regulatory Affairs Specialist
Next Science, LLC
10550 Deerwood Park Blvd Ste 300
Jacksonville, FL 32256
UNITED STATES

Dear Courtney Narain:

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 above letterhead address. 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: K203835/S001
Received: 1/19/2021
Applicant: Next Science, LLC
Device: MIS Solution

We will notify you when the review of this document has been completed or if any additional information is required. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

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

Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

Prontosan® Wound Irrigation Solution

For cleansing wounds.
Also may be used for moistening and lubricating wound dressings.

STERILE A
Aseptic filtration <1 CFU/mL, until the product is first opened.
NONPYROGENIC fluid and fluid path prior to removal of cap.

Expiration Date

LOT Lot Number

REF Reorder Number

See Instructions for Use.

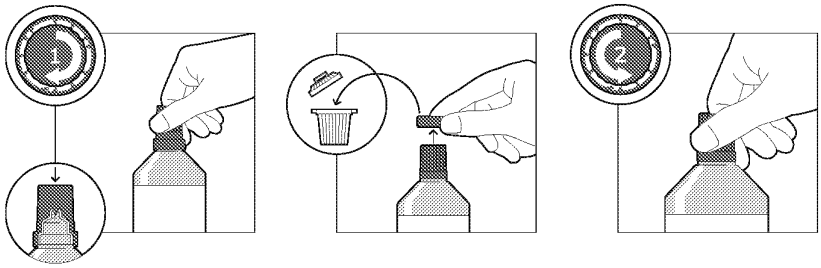
Pictorials are for reference only.

For single patient use only. Do not resterilize.

Not made with natural rubber latex or DEHP.

Rx only

880287 P-7579-8 REV. 2/20



Description:
Prontosan Wound Irrigation Solution cleanses the tissue surface, even when surfaces are difficult to access such as ***deep wound cavities, fissures, and wound pockets***. Prontosan Wound Irrigation Solution is a clear, colorless, and virtually odorless aqueous wound cleanser with surfactants.

Ingredients:
Prontosan Wound Irrigation Solution contains:
Purified Water, 0.1% Undecylenamidopropyl Betaine, 0.1% Polyaminopropyl Biguanide (Polyhexanide [PHMB]).
pH may be adjusted with Sodium Hydroxide

Indications:
Prontosan Wound Irrigation Solution is intended for cleansing wounds and for moistening and lubricating absorbent wound dressings for the management of ulcers, burns, post-surgical wounds and abrasions.

Prontosan Wound Irrigation Solution may be used:

- For cleansing infected and non-infected wounds.
- For cleansing and moistening chronic skin wounds
- For moistening of bandages and wound dressings, such as compresses, gauze, pads, sponges, gels, hydrofibres, alginates, hydrocolloids, etc.
- During dressing changes to loosen encrusted bandaging or other encrusted wound dressings.

Adverse Reactions:
In very rare cases there may be a mild burning sensation after application which subsides after a few minutes.
Prontosan can cause allergic reactions such as itching and rashes. In rare cases (less than 1 out of 10,000), anaphylactic shock has been reported.

Contraindications:

- Prontosan Wound Irrigation Solution should not be used if there is a history of allergy to any of the ingredients.
- Do not use in the presence of hyaline cartilage.
- Do not use in combination with anionic tensides as these may impair preservation.
- Mixing Prontosan Wound Irrigation Solution with other wound cleansing soaps, lotions, ointments, oils, or enzymes may lower efficacy. When such substances need to be removed from a wound, ensure the entire wound area is thoroughly rinsed with Prontosan Wound Irrigation Solution.

Warning:
Do not infuse, inject, or ingest. For external use only.

Storage Conditions:
Store at room temperature. Avoid excessive heat. Do not refrigerate or freeze.

Shelf-life:
Use prior to expiration date noted on the package label.
Although no longer sterile once the bottle has been opened, because of preservative, there is a shelf-life of 28 days after opening the bottle as long as it is closed immediately after use and the top of the bottle is protected from contamination or direct contact.
Bottles that become contaminated or have come into direct contact with the wound must be discarded.

Instructions For Use

For General Use:
Cleanse the wounds with Prontosan Wound Irrigation Solution before further treatment is carried out.
When required, wash and decontaminate the whole section of the body or the whole body of the person affected according to institutional protocol.
Bandages or dressings soaked in Prontosan Wound Irrigation Solution can be used for cleaning as required.

Cleansing the Wound Site:
Cleansing of a large area around the whole wound site with Prontosan Wound Irrigation Solution is recommended.
For acute wounds rinsing may be sufficient. For wounds covering a large area and wounds difficult to access, bathe the whole section of the body with Prontosan Wound Irrigation Solution, for at least 15 minutes. The solution should be used in an undiluted form.

For Use In the Case of Encrusted Bandages or when Changing Dressings Is Problematic:
In cases where bandages are difficult to release, wetting the wound dressing with Prontosan Wound Irrigation Solution is advisable until the bandages can be gently released without traumatizing the surface of the wound. If stubborn, large encrustations are present, the whole section of the body with the dressing can be saturated or bathed in Prontosan Wound Irrigation Solution until the dressing can be easily released.

Directions: Use Aseptic Technique.

1. Screw cap down fully to pierce container.
2. Remove ring.
3. Remove cap and proceed with use as required in accordance with institutional protocol.
4. Replace cap after use in accordance with institutional protocol.
5. Record date opened on bottle.
6. Solution may be used for up to 28 days.
7. Discard any unused solution and bottle.

Antimicrobial Effectiveness Testing

Successfully meets USP<51> Category 2 Criteria

Preservative Testing

No microbial growth was observed at 7, 14 and 28 days for the following organisms:

Acinetobacter baumannii
Enterobacter cloacae
Enterococcus faecalis
Vancomycin Resistant *Enterococcus faecalis* (VRE)
Escherichia coli
Proteus mirabilis
Pseudomonas aeruginosa
Serratia marcescans
Staphylococcus aureus
Methicillin Resistant *Staphylococcus aureus* (MRSA)
Staphylococcus epidermidis
Candida albicans

Preservative testing demonstrated using USP<51>, with an expanded list of organisms and additional 7 day time-point, to support the role of PHMB as a preservative to inhibit microbial growth within the product during shelf storage.

Manufactured for:
B. Braun Medical Inc.
Bethlehem, PA 18018-3524 USA
1-800-227-2862

B|BRAUN

Questions? Contact FDA/CDRH/CDER at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8112

Hello Lixin,

Thank you for the prompt response!

(b)(4)

(b)(4)

Thank you,
Courtney

From: Liu, Lixin <Lixin.Liu@fda.hhs.gov>
Sent: Friday, January 15, 2021 11:56 AM
To: Courtney Narain <cnarain@nextscience.com>
Cc: K203835@docs.fda.gov
Subject: RE: K203835 is on Hold Pending Your Response

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

Hi, Courtney:

Thank you for reaching us on K203835 administrative review.

To help expediate our administrative review process for your future supplement, we will appreciate if you may provide response to each RTA item in your future cover letter. Please specify which section/attachment has been revised to align with your response to the RTA item. It is optional that you provide the entire 510k submission, or provide only the updated section/attachment in your future supplement.

(b)(4)

I hope this response may clarify your questions.

Thank you!

Lixin Liu, Ph.D.
Biologist/Team Lead

Plastic Surgery Skin and Wound Devices 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
Tel: 301-796-3480
Lixin.Liu@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/r/cdrhcustomerservice?ID=2001&S=E

From: Courtney Narain <cnarain@nextscience.com>
Sent: Thursday, January 14, 2021 6:19 PM
To: Liu, Lixin <Lixin.Liu@fda.hhs.gov>

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Subject: RE: K203835 is on Hold Pending Your Response

Dear Lixin,

Thank you for the advisory comments. Next Science appreciates the collaborative gesture and looks forward to working with you on this submission.

(b)(4) Next Science wants to ensure the information and resolutions to issues are easily locatable. With that said, the following questions are being asked to ensure accurate RTA resolutions:

(b)(4)

Sincerely,

Courtney

From: Lixin Liu <lixin.liu@fda.hhs.gov>
Sent: Wednesday, January 13, 2021 4:17 PM
To: Courtney Narain <cnarain@nextscience.com>
Cc: Lixin Liu <lixin.liu@fda.hhs.gov>
Subject: K203835 is on Hold Pending Your Response

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January 13, 2021

Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your submission K203835. Our review indicates that your submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit one eCopy of your response, referencing your submission K203835, addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Your submission will remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist by 07/12/2021, we will consider this submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your submission. We will contact you if we require any additional information during the course of our administrative review. FDA aims to apply the least burdensome principles when requesting additional information.

The lead reviewer assigned to your submission is me, Lixin Liu. The file is being reviewed in Office of Health Technology 4, Division of Health Technology 4 B. The first line supervisor is the Assistant Director, Plastic Surgery Skin and Wound Devices. You may contact me at any point during the review if you have questions or concerns. You can provide valuable support for CDRH to continue to improve our programs by raising to the attention of management relevant issues that arise during the course of this review. If you feel there is an unresolved issue or a matter that requires additional attention, you should contact the Assistant Director. If your concern or issue is not addressed by the Assistant Director, you should contact the Division Director or OHT Director. The contact information for each management level can be found in the CDRH Management Directory.

For additional information about the Refuse to Accept Policy for for 510(k)s please refer to the guidance document available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf.

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

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If you have general questions about the review process for your submission, you should contact OPEQSubmissionSupport@fda.hhs.gov.

****This is a system generated email notification****

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NEXT SCIENCE Records processed under FOIA Request 2023-0423, Released by CDRH on 05-21-2024
Next Science, LLC
Jacksonville, FL ~ www.nextscience.com

(b)(4)	MIS Wound Irrigation Solution Shelf Life			
Issued by: (b)(4)		Effective Date: (b)(4)	Rev. (b)(4)	Pg. 1 of 11
(b)(4)				

Document Type:	Bench-top ☐	Verification ☒	Validation ☐
	Protocol ☐	Report ☒	

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Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

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1. Medical Device User Fee Cover Sheet (Form FDA 3601)

Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

Form Approved: OMB No. 0910-0511 Expiration Date: August 31, 2022. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/ucm370879.htm

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
NEXT SCIENCE, LLC 10550 Deerwood Park Blvd 300 Jacksonville FL 32256 US	Jackie Skrzydlewski 2.1 E-MAIL ADDRESS jskrzydlewski@nextscience.com 2.2 TELEPHONE NUMBER (include Area code) 855-564-2762 2.3 FACSIMILE (FAX) NUMBER (Include Area code)
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****3282	

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] Real-Time (PMA, PMR, PDP)
[ ] De Novo Request	[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[X] 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: SBD218286

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of your establishments have registered and paid the fee, or this is your first device and you will register and pay the fee within 30 days after entering into an operation that requires you to register and submit device listing information.)

[ ] NO (If you currently market a medical device and your establishment is required to register and submit device listing information, FDA will not accept your submission until you have paid all fees due to FDA. See http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] 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 [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information,

Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

including suggestions for reducing this burden, to the address below:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paper Reduction Act (PRA) Staff
PRAStaff@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) 18-Dec-2020

Form FDA 3601 (08/19)

"Close Window" Print Cover sheet

Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

2. CDRH Premarket Review Submission Cover Sheet

Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approved: OMB No. 0910-0120
Expiration Date: June 30, 2023
See PRA Statement on last page.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(If known)*
12/23/2020	(b)(4)	

SECTION A TYPE OF SUBMISSION

PMA & PDP
- ☐ Original
- ☐ Modular Submission
- ☐ Amendment
- ☐ Report (annual or PAS)
- ☐ Report Amendment
- ☐ Other:
  - ☐ Premarket Report (reprocessed SUD)
  - ☐ Licensing Agreement

PMA/PDP Supplement
- ☐ 180 day - PAS protocol or labeling change, location change, trade name change
- ☐ 180 day - Design or labeling change
- ☐ Special CBE
- ☐ Panel Track
- ☐ 30-day Notice
- ☐ Real-time Review
- ☐ Amendment to PMA/PDP Supplement

510(k)
- ☒ Original Submission:
  - ☒ Traditional
  - ☐ Special
  - ☐ Abbreviated
  - ☐ 3rd Party Traditional
  - ☐ 3rd Party Special
  - ☐ 3rd Party Abbreviated
  - ☐ Dual Track (Dual 510 (k) and CLIA Waiver by Application)
- ☐ Amendment
- ☐ Supplement

CLIA

CLIA Categorization Record (CR)
- ☐ Original
- ☐ Amendment

CLIA Waiver by Application (CW)
- ☐ Original
- ☐ Amendment
- ☐ Supplement

Q-Submission
- ☐ Pre-Submission
- ☐ Informational Meeting
- ☐ Submission Issue Meeting
- ☐ Day 100 Meeting
- ☐ Agreement Meeting
- ☐ Determination Meeting
- ☐ Study Risk Determination
- ☐ Other *(Specify below)*

IDE
- ☐ Original IDE:
  - ☐ Amendment to Original IDE
- ☐ Supplement:
  - ☐ Amendment to Supplement
- ☐ Report:
  - ☐ Amendment to Report

HDE
- ☐ Original Submission
- ☐ Amendment to Original
- ☐ Report
- ☐ Report Amendment
- ☐ HDE Supplement:
  - ☐ 75-day Supplement
  - ☐ 30-day Notice
  - ☐ Special CBE
  - ☐ Amendment to Supplement

Class II Exemption Petition
- ☐ Original Submission
- ☐ Additional Information

Emergency Use Authorization
- ☐ Original
- ☐ Supplement
- ☐ Amendment
- ☐ Report

De Novo
- ☐ Original:
  - ☐ Direct
  - ☐ Post-NSE
- ☐ Amendment
- ☐ Supplement

Pre-Emergency Use Authorization
- ☐ Original
- ☐ Supplement
- ☐ Amendment

Other Submission
- ☐ 513(g)
- ☐ Appeal
- ☐ Other *(Briefly describe submission below)*

Expanded Access to Devices
- ☐ Compassionate Use Request **NOT associated with an IDE**
- ☐ Follow-up Report for Compassionate Use **NOT associated with an IDE**
- ☐ Emergency Use Follow-up Report **NOT associated with an IDE**

SECTION B APPLICANT / SPONSOR

Company/Institution Name		Establishment Registration Number/FEI *(if known)*
Next Science, LLC		3012271775
Street Address		**City**
10550 Deerwood Park Blvd Ste 300		Jacksonville
State/Province	**ZIP/Postal Code**	**Country**
Florida	32256	USA

Contact Name	Contact Title
Courtney Narain	Regulatory Affairs Specialist
Division Name *(if applicable)*	**Phone Number *(including area code)***
	855-564-2762 ext 6004
Fax Number *(including area code)*	**Contact Email Address**
	cnarain@nextscience.com

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SECTION C OFFICIAL CORRESPONDENT (e.g., may be a consultant and/or 510(k) Third Party) (if different from Section B)

Company/Institution Name		Establishment Registration Number/FEI *(if known)*
Street Address		City
State/Province	ZIP/Postal Code	Country

Contact 1 Name	Contact 1 Title
Contact 1 Division Name *(if applicable)*	Contact 1 Phone Number *(including area code)*
Contact 1 Fax Number *(including area code)*	Contact 1 Email Address
Contact 2 Name	Contact 2 Title
Contact 2 Division Name *(if applicable)*	Contact 2 Phone Number *(including area code)*
Contact 2 Fax Number *(including area code)*	Contact 2 Email Address
Contact 3 Name	Contact 3 Title
Contact 3 Division Name *(if applicable)*	Contact 3 Phone Number *(including area code)*
Contact 3 Fax Number *(including area code)*	Contact 3 Email Address

To add another set of Section C items, please click on the button to the right. May be repeated as needed. Add Section C

SECTION D INTENDED USE POPULATION

Check all that apply.

- ☐ Adults Only (greater than 21 years of age)
- ☒ Adults and Pediatrics
- ☐ Neonate/Newborn (birth through 28 days)
- ☐ Infant (from 29 days to 2 years of age)
- ☐ Child (from 2 years to 12 years of age)
- ☐ Adolescent (from 12 years to 18 years of age)
- ☐ Transitional Adolescent A (18 through 21 years of age)
- ☐ Transitional Adolescent B (18 through 21 years of age)
- ☐ Other *(Specify below)*

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SECTION E PRODUCT INFORMATION – APPLICABLE TO ALL SUBMISSIONS

	Trade Name
1	MIS Solution
2	
3	
4	
5	
	Common/Generic Name *(Include if no Trade Name)*

SECTION F PRIOR RELATED SUBMISSIONS FOR THIS DEVICE OR STUDY

FDA document numbers of all prior related submissions *(regardless of outcome)* or state no prior submission in box 1.

1 (b)(4)	2	3
4	5	6
7	8	9
10	11	12

SECTION G PRODUCT CLASSIFICATION – APPLICABLE TO ALL SUBMISSIONS

Product Code(s) *(when applicable) (If more than one, please separate with commas.)*

FRO

C.F.R. Section *(If applicable)*	Classification Panel/Medical Specialty
	General & Plastic Surgery

Device Class

☐ Class I ☐ Class II ☐ Class III ☒ Unclassified

SECTION H1 REASON FOR APPLICATION – PMA, PDP, OR HDE

Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

- ☐ New Device
- ☐ STED

- ☐ Post-approval Study Protocol

- ☐ HDE Request for Annual Distribution Number (ADN)

- ☐ Change in Design, Component, or Specification:
  - ☐ Software/Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(Specify below)*

- ☐ Location Change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study

- ☐ Process Change:
  - ☐ Manufacturing
  - ☐ Packaging
  - ☐ Sterilization
  - ☐ Vendor/Supplier Change
  - ☐ Other *(Specify below)*

- ☐ Labeling Change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ PAS update
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(Specify below)*

- ☐ Amendment:
  - ☐ Withdrawal
  - ☐ Change in Ownership
  - ☐ Change in Correspondent
  - ☐ Change of Address
  - ☐ Request for Extension
  - ☐ Response to FDA Correspondence
  - ☐ Other *(Specify below)*

☐ Bundle Submission – *If this is selected, list in the spaces below any PMAs in the Bundle.*

1	2	3
4	5	6
7	8	9

SECTION H2 REASON FOR APPLICATION – IDE

- ☐ Original IDE

- ☐ Supplement:
  - ☐ New Study/New Protocol
  - ☐ Change in Correspondent
  - ☐ Change in Manufacturer
  - ☐ Change in Sponsor
  - ☐ Change in Design
  - ☐ Change in Informed Consent
  - ☐ Change in Manufacturing
  - ☐ Change in Protocol
  - ☐ 5-Day Notice – Device or Manufacturing
  - ☐ 5-Day Notice – Protocol
  - ☐ Compassionate Use Request (under an IDE)
  - ☐ Live Case Request
  - ☐ Request Deviation from Protocol
  - ☐ Expansion of Study (Study/Sites)
  - ☐ Extension of Time to Submit Annual Report or Respond to FDA Letter

Supplement *(Continued)*
- ☐ Request for Waiver
- ☐ IRB Certification
- ☐ Request for CMS Recategorization
- ☐ Study Resumed
- ☐ Study Suspension
- ☐ Other *(Specify below)*

- ☐ Report:
  - ☐ Adverse Effect
  - ☐ Final, Study Completed
  - ☐ Annual Progress
  - ☐ Interim Progress
  - ☐ Semiannual Investigator List
  - ☐ Failure to Obtain Informed Consent
  - ☐ Compassionate Use Follow-up
  - ☐ Emergency Use
  - ☐ Live Case Follow-up
  - ☐ Completion of Patient Enrollment
  - ☐ Completion of Patient Follow-up
  - ☐ Other *(Specify below)*

Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

- ☐ Amendment to Original IDE:
  - ☐ Amendment Before Final Decision
  - ☐ Response to Refuse to Accept
  - ☐ Response to Disapproval
  - ☐ Response to Approval with Conditions
  - ☐ Withdrawal
  - ☐ Other *(Specify below)*
- ☐ Amendment to Supplement:
  - ☐ Response to Disapproval
  - ☐ Response to Approval with Conditions
  - ☐ Withdrawal
  - ☐ Amendment Before Final Decision (additional Information)
  - ☐ Other *(Specify below)*
- ☐ Amendment to Report:
  - ☐ Response to Deficiency Letter
  - ☐ Withdrawal
  - ☐ Amendment Before Final Decision (additional Information)
  - ☐ Other *(Specify below)*

SECTION H3 REASON FOR SUBMISSION – Q-SUBMISSION

- ☐ Pre-Submission:
  - ☐ Request Face-to-Face Meeting
  - ☐ Request Teleconference
  - ☐ Request Email Response
  - ☐ Submit Meeting Minutes
  - ☐ Request Meeting Minutes Disagreement T-con
- ☐ Submission Issue Meeting:
  - ☐ Request Face-to-Face Meeting
  - ☐ Request Teleconference
  - ☐ Request Email Response
  - ☐ Submit Meeting Minutes
  - ☐ Request Meeting Minutes Disagreement T-con
- ☐ Additional Information
- ☐ Change in Legal Entity:
  - ☐ Change in Correspondent
  - ☐ Change in Sponsors
  - ☐ Change in Manufacturer
  - ☐ Other *(Specify below)*
- ☐ Agreement Meeting:
  - ☐ Request Face-to-Face Meeting
  - ☐ Request Teleconference
- ☐ Determination Meeting:
  - ☐ Request Face-to-Face Meeting
  - ☐ Request Teleconference
- ☐ Informational Meeting:
  - ☐ Request Face-to-Face Meeting
  - ☐ Request Teleconference
  - ☐ Submit Meeting Minutes
  - ☐ Request Meeting Minutes Disagreement T-Con
- ☐ Other *(Specify):*

SECTION H4 REASON FOR SUBMISSION – 510(k)

- ☒ Original
- ☐ Withdrawal of Original
- ☐ Amendment Before Final Decision:
  - ☐ Change in Ownership
  - ☐ Change in Correspondent
  - ☐ Withdrawal
- ☐ Amendment After Final Decision
- ☐ Supplement:
  - ☐ Response to Refuse to Accept (RTA)
  - ☐ Response to Additional Information Request
  - ☐ Withdrawal
- ☐ Reprocessed SUD
- ☐ Corrective Action
- ☐ STED
- ☐ Third Party *(Complete Section C)*
- ☐ Other Reason *(Specify):*

Information on devices to which substantial equivalence is claimed *(If known)*

	510(k) Number	***Trade Name***	***Submitter***	***Product Code***
Primary Predicate (A)	K161165	Next Science® Irrigation Solution	Next Science, LLC	FQH, FRO

Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

Predicate or Reference Device (B)	K072876	Prontosan Wound Irrigation Solution	B. Braun	FRO
Predicate or Reference Device (B)	K163188	Next Science® Wound Gel	Next Science, LLC	FRO

To add another Predicate or Reference Device (B) entry row, please click on the button to the right. May be repeated as needed. Add Device Information

SECTION H5 DE NOVO SUBMISSIONS

☐ Post NSE De Novo: Number of the 510(k) that was NSE'd in the past 30 days:

☐ Withdrawal

SECTION H6 REASON FOR APPLICATION – CLIA

Includes CLIA Parent Document number, CR number, or CW number.

☐ **CLIA Categorization Record (CR):**

- ☐ CLIA Categorization of marketed device (include marketing submission number)
- ☐ CLIA Categorization of device exempt from premarket review
- ☐ Additional information regarding an open CR (include CR number)

☐ **CLIA Waiver by Application (CW):**

- ☐ Request for CLIA Waiver by Application for marketed device (include marketing submission number)
- ☐ Request for Dual 510(k) Clearance and CLIA Waiver by Application (include Pre-submission number)
- ☐ Response to FDA correspondence
- ☐ Additional information regarding an open CW (include CW number)

☐ **Other Reason** *(Specify)*

SECTION I MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

Applicable only to IDEs

Note: Submission of this information does not affect Registration and Listing.	FDA Document Number *(if known)*

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager/Relabeler

Company/Institution Name		Establishment Registration Number/FEI *(if known)*
Street Address		City
State/Province	ZIP/Postal Code	Country

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Contact 1 Name	Contact 1 Title
Contact 1 Division Name *(if applicable)*	Contact 1 Phone Number *(including area code)*
Contact 1 Fax Number *(including area code)*	Contact 1 Email Address
Contact 2 Name	Contact 2 Title
Contact 2 Division Name *(if applicable)*	Contact 2 Phone Number *(including area code)*
Contact 2 Fax Number *(including area code)*	Contact 2 Email Address
Contact 3 Name	Contact 3 Title
Contact 3 Division Name *(if applicable)*	Contact 3 Phone Number *(including area code)*
Contact 3 Fax Number *(including area code)*	Contact 3 Email Address

To add another set of Section I items, please click on the button to the right. May be repeated as needed. Add Section I

SECTION J UTILIZATION OF STANDARDS

Note: Please see guidance document titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices" for details on the Declaration of Conformity.

How to fill out this section:

Recognition Number: State the FDA recognition number. If the standard is not recognized, write **NR**.

Declaration of Conformity or General Use: Select 'Declaration of Conformity' if including a "Declaration of Conformity to a Recognized Standard" statement. For all other uses, select 'General Use' and indicate if you have made deviations from the Recognized/Non-recognized standard.

Standard: State the Standards Development Organization (SDO), the Designation Number (including year), and the Title.

Location: State the section and/or the page number(s) in the submission where the standard is applied.

Examples

	Recognition Number	Declaration of Conformity or General Use		Standards Development Organization (SDO), Designation Number-Year, and Title	Location
1 X	8-185	Declaration of Conformity	*If General Use, Deviation?*	ASTM F451-08, standard specification for acrylic bone cement.	Section 3, p. 15
2 X	3-44	General Use	*If General Use, Deviation?* Yes	AAMI ANSI BP22:1994 (R) 2011 Blood Pressure Transducers	Section 4, p. 32

Entries for Utilization of Standards

	Recognition Number	Declaration of Conformity or General Use		Standards Development Organization (SDO), Designation Number-Year, and Title	Location
1 X	2-258	General Use	*If General Use, Deviation?* No	ISO 10993-1:2018, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process"	Sections 11 & 15
1 X	2-247	General Use	*If General Use, Deviation?* No	ISO 10093-6:2016, "Biological Evaluation of Medical Devices – Part 6: Tests for Local Effects after Implantation"	Sections 11 & 15
1 X	2-174	General Use	*If General Use, Deviation?* No	ISO 10993-10:2010, "Biological Evaluation of Medical Devices – Part 10, Tests for Irritation and Skin Sensitization."	Sections 11 & 15
1 X	2-237	General Use	*If General Use, Deviation?* No	ISO 10993-17:2002, "Biological Evaluation of Medical Devices – Part 17: Toxicological Risk Assessment of Medical Device Constituents."	Section 15

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1 X	2-276	General Use	*If General Use, Deviation?* No	ISO 10993-18:2020, "Biological Evaluation of Medical Devices – Part 18: Chemical Characterization of Medical Device Materials within a Risk Management Process."	Section 15
1 X	14-333	General Use	*If General Use, Deviation?* No	ISO 17665-1:2006 Sterilization of Health Care Products – Moist Heat – Part 1: Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices	Section 14

To add another row for Section J, please click on the button to the right. May be repeated as needed.
(To remove a particular row, please click on the "X" button at the beginning of the row.)

Add Row/Standard

SECTION K UTILIZATION OF CDRH GUIDANCE DOCUMENTS

How to fill out this section:

Title: Enter the title of the guidance documents used in the preparation of your premarket submission. CDRH guidance documents can be found at ***http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm***.

Entries for Utilization of CDRH Guidance Documents

	Title of Guidance Document
1 X	"Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"

To add another row for Section K, please click on the button to the right. May be repeated as needed.
(To remove a particular row, please click on the "X" button at the beginning of the row.)

Add Row/Document

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NEXT SCIENCE®

10550 Deerwood Park Blvd
Suite 300
Jacksonville, FL 32256
P: 855-564-2762

BY FEDEX DELIVERY
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: **Traditional Premarket Notification 510(k):** K203835
Device Common Name: Dressing, Wound, Drug
Classification: Unclassified
Combination Product: Yes
Product Code: FRO

Dear Dr. Liu:

In accordance with your request, this cover letter provides a response to all of the RTA items presented to Next Science on January 13, 2020:

(b)(4)

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(b)(4)

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

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(b)(4)

Pursuant to 21 C.F.R. § 807.95(b), Next Science requests that FDA not disclose the existence of this application until such time as a substantial equivalence determination on the submission is rendered. In addition, this 510(k) submission may contain trade secret or confidential commercial information that is exempt from disclosure pursuant to 21 C.F.R. § 20.61, 21 U.S.C. § 331(j), and the Freedom of Information Act, 5 U.S.C. § 552(b)(4). We ask that you consult with Next Science as provided in 21 C.F.R. §20.47 before making any part of this submission publicly available.

We believe that the information provided in the 510(k) submission is sufficient for FDA to find that the **MIS Solution** is substantially equivalent to the predicate device for the proposed indications.

The Traditional 510(k) submission enclosed herein is being provided via eCopy only in accordance with the final rule 84 FR 68334.

Please contact me by email at cnarain@nextscience.com, if you need additional information or have any questions.

Sincerely,

(b)(6)

Courtney Narain
Regulatory Affairs Specialist
Next Science®, LLC

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4. Indications for Use Statement (FDA Form 3881)

Records processed under FOIA Request 2023-8428; Released by CDRH on 05-21-2024

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name
MIS Solution

Indications for Use *(Describe)*
MIS Solution is indicated for use in cleansing and removal of debris, including microorganisms from wounds.

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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5. 510(k) Summary

(b)(4)

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

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(b)(4)

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

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6. Truthful and Accurate Statement

I certify that, in my capacity as Regulatory Affairs Specialist of Next Science®, LLC, 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)

(Signature)

Courtney Narain

(Typed Name)

December 22, 2020

(Date)

TBD

*(Premarket Notification [510(k)] Number)

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7. Class III Summary and Certification

The subject device, **MIS Solution**, is not a Class III device. Therefore, this section is not applicable.

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8. Financial Certification or Disclosure Statement

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0396
Expiration Date: April 30, 2022

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable check box.

☒ (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

Clinical Investigators	
(b)(6)	

☐ (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

☐ (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME	TITLE
Courtney Narain	Regulatory Affairs Specialist
FIRM/ORGANIZATION Next Science, LLC	
SIGNATURE (b)(6)	DATE *(mm/dd/yyyy)* 12/23/2020

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Do NOT send your completed form to the PRA Staff email address below.

Department of Health and Human Services
Food and Drug Administration
Office of Operations
PRAStaff@fda.hhs.gov

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9. Declarations of Conformity

A Declaration of Conformity (DOC) is not included. As provided by FDA guidance, "Format for Traditional and Abbreviated 510(k)s," if the general use of consensus standard is claimed, a DOC is not required.

The recognized consensus standards were used in whole. The basis for use of these standards was to demonstrate the biocompatibility and sterility of the subject product.

a. A list of standards that were used in the evaluation of the subject device **MIS Solution** is as follows:

1. ISO 10993-1:2018, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process" and FDA's Draft Guidance for Industry and Food and Drug Administration Staff "Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" (September, 2020)
2. ISO 10093-6:2016, "Biological Evaluation of Medical Devices -- Part 6: Tests for Local Effects after Implantation"
3. ISO 10993-10:2010, "Biological Evaluation of Medical Devices – Part 10, Tests for Irritation and Skin Sensitization."
4. ISO 10993-17:2002, "Biological Evaluation of Medical Devices – Part 17: Toxicological Risk Assessment of Medical Device Constituents."
5. ISO 10993-18:2020, "Biological Evaluation of Medical Devices – Part 18: Chemical Characterization of Medical Device Materials within a Risk Management Process."
6. ISO 17665-1:2006 Sterilization of Health Care Products – Moist Heat – Part 1: Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices
7. USP <85> Bacterial Endotoxin Test
8. USP <151> Pyrogen Test (USP Rabbit Test)

b. The FDA recognition number for each standard.

Standard	Recognized Consensus Standard
ISO 10993-1:2018	2-258
ISO 10993-6:2016	2-247
ISO 10993-10:2010	2-174
ISO 10993-11:2006	2-176
ISO 10993-17:2002	2-237
ISO 10993-18:2020	2-276
ISO 17665-1:2006	14-333
USP <85>	14-561
USP <151>	2-287

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10. Device Description

(b)(4)

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

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

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11. Executive Summary

A. General Information

1. Name of Device

Trade Name:	MIS Solution
Common Name:	Wound Irrigation Solution
Classification:	Unclassified
Product Code:	FRO

2. Indications for Use

MIS Solution is intended for use in cleansing and removal of debris, including microorganisms, from wounds.

3. Device Description

MIS Solution is a clear, colorless, odorless aqueous solution containing water, citric acid, sodium citrate, and sodium lauryl sulfate. The sodium lauryl sulfate acts as a surfactant to assist in the solubilization of debris. The solution is provided in a single-use 500mL soft Purell PP RP270G polypropylene container that is terminally sterilized to provide a sterile fluid path. The primary mode of action is the mechanical removal of debris via hydrodynamic shear. The mechanical action can be provided by either a manual syringe or powered irrigation device.

4. Prior Submission

(b)(4)

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(b)(4)

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

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5. Device Comparison Table

(b)(4)

(b)(4)

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(b)(4)

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6. Performance Testing – Bench

A. Summary Table

Test Performed	Device/Sample Description	Test Methods / Applicable Standards	Acceptance Criteria	Unexpected Results/Deviations	Results
Combined Dissolution Efficacy (Attachment 1)	(b)(4)				
Compatibility and Irrigation Force Comparison (Attachment 2)					

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Test Performed	Device/Sample Description	Test Methods / Applicable Standards	Acceptance Criteria	Unexpected Results/Deviations	Results
	(b)(4)				

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B. Bench Testing Discussion/Conclusions

(b)(4)

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

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(b)(4)

8. **Performance Testing – Clinical**

(b)(4)

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12. Substantial Equivalence Discussion

A. Predicate Device Information

Predicate Device:	Next Science® Irrigation Solution
510(k) Holder:	Next Science, LLC
510(k) Number:	K161165

B. MIS Solution vs Next Science® Irrigation Solution Discussion

(b)(4)

(b)(4)

Product	(b)(4)
Company	
510(k) Number	
Classification	
Composition	

(b)(4)

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(b)(4)

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

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(b)(4)

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

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13. Proposed Labeling

Labeling for MIS Solution will meet 510(k) requirements of 21 CFR Part 801, Subpart A, General Labeling Provisions.

Included is the representative labeling for the MIS Solution are the following:

- Instructions for Use
- Front Bottle Labeling
- Back Bottle Labeling

The product is to be used for the cleansing and removal of debris, including microorganisms, from wounds via hydrodynamic shear. This product is not intended for repeated use.

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Instructions for Use

(b)(4)

Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

MIS Solution Instructions for Use

(b)(4)

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

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(b)(4)

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

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

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

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14. Sterilization and Shelf Life

A. Sterilization

(b)(4)

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B. Shelf-Life Testing

(b)(4)

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(b)(4)

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

Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

15. Biocompatibility

(b)(4)

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

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(b)(4)

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

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16. Software

The subject device, MIS Solution, does not contain software nor does it contain external wired and/or wireless communication interfaces. Therefore, this section is not applicable.

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17. Electromagnetic Compatibility and Electrical Safety

The subject device, MIS Solution, is not an electrical device, and thus, does not require electromagnetic (EMC) or Electrical Safety evaluation. Therefore, this section is not applicable.

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18. Performance Testing – Bench

(b)(4)

Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

19. Performance Testing – Animal

(b)(4)

Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

20. Performance Testing – Clinical

(b)(4)

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21. Acceptance Checklist for Traditional 510(k)s

Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

Appendix A. Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the application.

510(k)#: **Date Received by DCC:**

510(k) Lead Reviewer:

Center: **Office:** **Division:**

Decision: **Accept_____ Refuse to Accept_____**

If Accept, notify the submitter.

If Refuse to Accept, notify submitter electronically and include a copy of this checklist.

Is an Addendum attached?: Yes No

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

Preliminary Questions			
Answers in the shaded blocks indicate consultation with an identified Center advisor is needed. (Boxes checked in this section represent FDA's preliminary assessment of these questions at the time of administrative review.)	**Yes**	**No**	**N/A**
1. Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product (per 21 CFR 3.2(e)), or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action, and inform management. *Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If the product does not appear to be a device or such a combination product, mark	☑	☐	

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

"No."			
Comments:			
2. Is the submission with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If submission should not be reviewed by your Center mark "No."	☑	☐	
Comments:			
3. If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: **(a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?** **(b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide a summary of Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."	☐	☐	☑
Comments:			
4. Is the submission for a combination product that contains as a constituent part a drug that has the same active moiety as an approved drug with exclusivity as described in 21 USC 503(g)(5)(C)(ii)-(v) (section 503(g)(5)(C)(ii)-(v) of the FD&C Act)? If "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide the summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.*	☐	☑	☐
Comments:			

5. Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), consult with the appropriate CDRH or CBER staff during the acceptance review, provide a summary of the discussion with them, and indicate their recommendation/action in the comment section below. If 510(k) is not the appropriate regulatory submission, mark "No."	☑	☐	
Comments:			
6. Is there a pending PMA for the same device with the same indications for use? If "Yes," consult your management and CDRH Office of Product Evaluation and Quality/Office of Regulatory Programs/Division of Regulatory Programs 1 (Submission Support) (OPEQ/ORP/DRP1) or appropriate CBER staff to determine the appropriate action.	☐	☑	
Comments:			
7. If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If "Yes," consult with the CDRH Office of Product Evaluation and Quality/Office of Clinical Evidence and Analysis/Division of Clinical Science and Quality (OPEQ/OCEA/DCEA1) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action, provide a summary of the discussion with them, and indicate their recommendation/action. If no clinical studies have been submitted, mark "N/A." Check on the AIP list at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/application-integrity-policy/application-integrity-policy-list.	☐	☐	☑
Comments:			

- **If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.**
- **If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.**
- **If the answer to 4 is "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer, provide a summary of the discussion with them, and indicate their recommendation/action.**
- **If the answer to 5 is "No", the lead reviewer should consult division management and other Center resources to determine the appropriate action.**
- **If the answer to 6 is "Yes," then stop review of the 510(k), contact CDRH/OPEQ/ORP/DRP1,**

or appropriate CBER staff.

- **If the answer to 7 is "Yes," then contact CDRH/OPEQ/OCEA/DCEA1 or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DCEA1 or BMB Staff, and indicate their recommendation/action.**

Organizational Elements Failure to include these items should not result in an RTA designation.				
***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**		**Yes**	**No**	***Page #**
1.	Submission contains a Table of Contents.	☑	☐	001-13
2.	Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.).	☑	☐	ALL
3.	All pages of the submission are numbered. *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2…).*	☑	☐	ALL
4.	Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special) *If type of 510(k) is not designated, review as a Traditional 510(k).*	☑	☐	001-14
Comments:				

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed.
• Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during the RTA review. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
A.	**Administrative**						
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.).		☑	☐		ALL
		Comments:					
	2.	Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form (Form 3514, available at https://www.fda.gov/media/72421/download)):					
		a.	Device trade/proprietary name	☑	☐		001-7
		b.	Device class and panel OR Classification regulation OR Statement that device has not been classified with rationale for that conclusion	☑	☐		001-7
		Comments:					
	3.	Submission contains an Indications for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/alternative-certain-prescription-device-labeling-requirements.) *See recommended format (https://www.fda.gov/media/86323/download).*		☑	☐		001-18
		Comments:					
	4.	Submission contains a 510(k) Summary or 510(k) Statement. *Refer to 21 CFR 807.92 and 21 CFR 807.93 for contents of 510(k) Summary and Statement, respectively. Adequacy of the content will be assessed during substantive review.*		☑	☐		001-19
		Comments:					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
	5.	Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(*l*). *See recommended format (https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-truthful-and-accurate-statement).*		☑	☐		001-22
		Comments:					
	6.	Submission is a Class III 510(k) Device. *Select "N/A" only if submission is not a Class III 510(k).*		☐		☑	
		a.	Contains Class III Summary and Certification per 21 CFR 807.87(k). *See recommended content (https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-class-iii-certification-and-summary). Select "N/A" only if submission is not a Class III 510(k).*	☐	☐	☐	
		Comments:					
	7.	Submission contains clinical data. *Select "N/A" if the submission does not contain clinical data. If "N/A" is selected, parts a, b, and c below are omitted from the checklist.*		☑		☐	
		a.	Submission includes completed Financial Certification (FDA Form 3454, available at https://www.fda.gov/media/70465/download) or Disclosure (FDA Form 3455, available at https://www.fda.gov/media/69872/download) information for each covered clinical study included in the submission. *Select "N/A" if the submitted clinical data is not a "covered clinical study" as defined in the guidance entitled "Financial Disclosures by Clinical Investigators," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/financial-disclosure-clinical-investigators.*	☑	☐	☐	001-25

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**					**Yes**	**No**	**N/A**	***Page #**
		b.		Submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (FDA Form 3674, available at https://www.fda.gov/media/69901/download) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission. *Select "N/A" if the submitted clinical data is not an "applicable device clinical trial" as defined in Title VIII of FDAAA, Sec. 801(j).*	☐	☐	☑	
		c.		Statements of Compliance for Clinical Investigations *Select "N/A" if the submission does not contain any clinical data from investigations (as defined in 21 CFR 812.3(h)) to demonstrate substantial equivalence.* *For multicenter clinical investigations involving both United States (US) and outside United States (OUS) sites, part (i) should be addressed for the US sites and part (ii) should be addressed for the OUS sites. 21 CFR 812.28 applies to all OUS clinical investigations that enroll the first subject on or after February 21, 2019.* *Please refer to the guidance document entitled "Acceptance of Clinical Data to Support Medical Device Applications and Submissions - Frequently Asked Questions," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-clinical-data-support-medical-device-applications-and-submissions-frequently-asked for more information.*	☑		☐	002-attachment 8
			i.	For each clinical investigation conducted in the US, the submission includes a statement of compliance with 21 CFR parts 50, 56, and 812. **OR** The submission includes a brief statement of the reason for noncompliance with 21 CFR parts 50, 56, and 812. *Select "N/A" if the clinical investigations were conducted solely OUS.*	☑	☐	☐	002-Attachment 8, pp 7, 22, 155, 170

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**					**Yes**	**No**	**N/A**	***Page #**
			ii.	For each clinical investigation conducted OUS, the submission includes a statement that the clinical investigations were conducted in accordance with good clinical practice (GCP) as described in 21 CFR 812.28(a)(1). **OR** The submission includes a waiver request in accordance with 21 CFR 812.28(c). **OR** The submission includes a brief statement of the reason for not conducting the investigation in accordance with GCP and a description of steps taken to ensure that the data and results are credible and accurate and that the rights, safety, and well-being of subjects have been adequately protected. *Select "N/A" if the clinical investigations were conducted solely inside the US.*	☐	☐	☑	
			Comments:					
	8.	The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Q-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device. *Prior submissions (or no prior submissions) for this device should be included in Section F (prior related submissions) of the CDRH Premarket Review Submission Cover Sheet form (Form 3514, available at https://www.fda.gov/media/72421/download). This information may also be included in the Cover Letter (i.e., as a statement that there were no prior submissions for the device or a listing of the number(s) of the prior submissions).*					☑	☐		001-9,10

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		a.	If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed. *To address this criterion, it is recommended that the submission include a separate section with the prior submission number(s), a copy of the FDA feedback (e.g., letter, meeting minutes), and a statement of how or where in the submission this prior feedback was addressed. Note that adequacy of how the feedback was addressed will be assessed during the substantive review.* *Select "N/A" if the submitter states there were no prior submissions.*	☑	☐	☐	002_ attachments 10, 12
			Comments:				
	9.	The submission utilizes voluntary consensus standard(s) (See section 514(c) of the FD&C Act). *This includes both FDA-recognized and non-recognized consensus standards. Select "N/A" if the submission does not utilize voluntary consensus standards.*		☑		☐	001-11, 26
		a.	The submission cites FDA-recognized voluntary consensus standard(s).	☑		☐	001-11, 26

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**					**Yes**	**No**	**N/A**	***Page #**
			i.	The submission includes a Declaration of Conformity (DOC) as outlined in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices. **OR** If citing general use of a standard as noted in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," the basis of such use is included along with the underlying information or data that supports how the standard was used.	☑	☐		001-26
		b.	The submission cites non-FDA-recognized voluntary consensus standard(s).		☐		☑	
			i.	The basis of use is included along with the underlying information or data that supports how the standard was used.	☐	☐		
		Comments:						
	Combination Product Provisions – Per 503(g) of the FD&C Act. Select "N/A" if the product is not a combination product. 21 CFR 3.2(e). The remaining criteria in this section will be omitted from the checklist if "N/A" is selected. If you are unsure if the product is a combination product, consult with the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.						☐	
	10.	Submission identifies the product as a combination product.			☑	☐		001-14
	11.	The combination product contains as a constituent part an approved drug as defined in section 503(g)(5)(B) of the FD&C Act. Select "N/A" if the combination product does not contain as a constituent part an approved drug. Please also select "N/A" if a right of reference or use for the drug constituent part(s) is included with the submission. If "N/A" is selected, part a below is omitted from the checklist.			☐		☑	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		a.	The submission includes appropriate patent statement or certification and a statement that the submitter will give notice, as applicable. See 503(g)(5)(A)&(C).	☐	☐		
			Comments:				
B.	**Device Description**						
	12.		The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding the device description that is applicable to the subject device. *If "N/A" is selected, parts a and b below are omitted from the checklist.*	☐		☑	
		a.	The submission addresses device description recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		b.	The submission includes device description information that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there are no applicable special controls or device-specific classification regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*	☐	☐	☐	
			Comments:				
	13.	Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).		☑	☐		ALL
		Comments:					
	14.	The submission includes descriptive information for the device, including the following:					
		a.	A description of the principle of operation or mechanism of action for achieving the intended effect.	☑	☐		001-20
		b.	A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	☑	☐		001-20
		c.	A list and description of each device for which clearance is requested. *Select "N/A" if there is only one device or model. "Device" may refer to models, part numbers, various sizes, etc.*	☐	☐	☑	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		d.	Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device). *In lieu of engineering drawings, schematics, etc. of each device to be marketed, "representative" drawings, etc. may be provided, where "representative" is intended to mean that the drawings, etc. provided capture the differences in design, size, and other important characteristics of the various models, sizes, or versions of the device(s) to be marketed.*	☑	☐		001-29
			Comments:				
	15.	Device is intended to be marketed with accessories and/or as part of a system. *Select "N/A" if the device is not intended to be marketed with accessories and/or as part of a system. If "N/A" is selected, parts a-c below are omitted from the checklist.*		☐		☑	
		a.	Submission includes a list of all accessories to be marketed with the subject device.	☐	☐		
		b.	Submission includes a description (as detailed in item 14a., 14b., and 14d. above) of each accessory. *Select "N/A" if the accessory(ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.*	☐	☐	☐	
		c.	A 510(k) number is provided for each accessory that received a prior 510(k) clearance. **AND** A statement is provided that identifies accessories that have not received prior 510(k) clearance.	☐	☐		
			Comments:				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
C.	**Substantial Equivalence Discussion**						
	16.	Submitter has identified a predicate device(s), including the following information:					
		a.	Predicate device identifier provided (e.g., 510(k) number, De Novo number, reclassified PMA number, classification regulation reference, if exempt (e.g., 21 CFR 872.3710), or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online (https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/preamendment-status).*	☑	☐		001-39
		b.	The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	☑	☐		ALL
			Comments:				
	17.	Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)]. *See the FDA guidance document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k for more information on comparing intended use and technological characteristics.*				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		a.	Indications for use *If there are no differences between the subject device and the predicate(s) with respect to indications and intended use, this should be explicitly stated.*	☑	☐		001-41
		b.	Technology, including technical specifications, features, materials, and principles of operation *Examples of technological characteristics include, but are not limited to design, features, materials, energy source, and principle of operation.* *FDA recommends a tabular format for comparing technological characteristics. Any characteristic that is the same as the predicate(s) should be explicitly stated. Differences in technological characteristics should be identified and a rationale provided why they do not raise different questions of safety and effectiveness.*	☑	☐		001-40-42
			Comments:				
D.	**Proposed Labeling (see also 21 CFR parts 801 and 809 as applicable)**						
	18.	Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).		☑	☐		001-45-48
		a.	Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	☑	☐		
		b.	Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) **AND** - Includes adequate directions for use (see 21 CFR 801.5) **OR** - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D	☑	☐		001-45

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
			Comments:				
	19.		Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	☑	☐		001-46, 47
			Comments:				
	20.		Labeling includes the prescription statement (see 21 CFR 801.109(b)(1)) or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's guidance "Alternative to Certain Prescription Device Labeling Requirements," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/alternative-certain-prescription-device-labeling-requirements. *Select "N/A" if not indicated for prescription use.*	☑	☐	☐	001-46, 47
			Comments:				
	21.		The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding labeling that is applicable to the subject device. *If "N/A" is selected, parts a and b below are omitted from the checklist.*	☐		☑	
		a.	The submission addresses labeling recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		b.	The submission includes labeling information that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there are no applicable special controls or device-specific classification regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*	☐	☐	☐	
			Comments:				
	22.	If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10. *Select "N/A" if not an in vitro diagnostic device.*		☐	☐	☑	
		Comment:					
E.	**Sterilization** *If an in vitro diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.*					☐	

			Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	*Page #
	Submission states that the device and/or accessories, if applicable, are: (*one of the below must be checked*) ☑ Provided sterile, intended to be single-use ☐ Requires processing during its use-life ☐ Non-sterile when used (and no processing required) ☐ Information regarding the sterility status of the device is not provided (if this box is checked, please also check one of the two boxes below) ☐ Sterility status not needed for this device (e.g., software-only device) ☐ Sterility status needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "non-sterile when used" or "not provided and not needed" is selected, the sterility-related criteria below are omitted from the checklist.* *If information on sterility status is not provided, and it is needed or the need for this information is unclear, select "No."* *The "Requires processing during its use-life" option refers to devices falling into one of the four categories below:* • *Supplied sterile and requires reprocessing prior to subsequent patient use* • *Supplied non-sterile and requires user to process the device for initial use, as well as to reprocess the device after each use* • *Reusable medical device (single-user) reprocessed between each use* • *Single-use medical devices initially supplied as non-sterile to the user, and requiring the user to process the device prior to its use* *Please refer to the FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling, for additional information.*			☐		001-46, 47
	Comments:						
	23.	Assessment of the need for cleaning and subsequent disinfection or sterilization information.					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		a.	Identification of device and/or accessories, if applicable, that are provided sterile. *Select "N/A" if no part of the device or accessories are provided sterile.*	☑	☐	☐	001-46, 47
		b.	Identification of device and/or accessories, if applicable, that are end user sterilized or disinfected. *Select "N/A" if no part of the device are accessories are end user sterilized or disinfected.*	☐	☐	☑	
		c.	Identification of device and/or accessories, if applicable, that are reusable. *Select "N/A" if no part of the device or accessories, are reusable.*	☐	☐	☑	
			Comments:				
	24.	If the device and/or accessories, if applicable, are provided sterile: *Select "N/A" if no part of the device or accessories are provided sterile, otherwise complete a-f below.*				☐	
		a.	Sterilization method is stated for each device (including dose for radiation sterilization)	☑	☐		001-49
		b.	A description of method to validate the sterilization parameters is provided for each proposed sterilization method (e.g., half-cycle method and full citation of FDA-recognized standard, including date). *Note: the sterilization validation report is not required.*	☑	☐		001-49
		c.	For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits. *Select "N/A" if not sterilized using chemical sterilants.*	☐	☐	☑	
		d.	Sterility Assurance Level (SAL) stated	☑	☐		001-49
		e.	Submission includes description of packaging	☑	☐		001-28,29

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		f.	For products labeled "non-pyrogenic," a description of the method used to make the determination stated (e.g., limulus amebocyte lysate [LAL]). *Select "N/A" if not labeled "non-pyrogenic."*	☑	☐	☐	001-49
			Comments:				
	25.	If the device and/or accessory, if applicable, is reusable or end user sterilized or disinfected: *Select "N/A" if no part of the device or accessories are reusable or end user sterilized or disinfected, otherwise complete a-d below.*				☑	
		a.	Cleaning method is provided in labeling for each device and/or accessory, if applicable. *Select "N/A" if not reusable and does not need cleaning prior to disinfection or sterilization.*	☐	☐	☐	
		b.	Disinfection method is provided in labeling for each device and/or accessory, if applicable. *Select "N/A" if not disinfected (i.e., undergoes terminal sterilization) prior to use.*	☐	☐	☐	
		c.	Sterilization method is provided in labeling for each device and/or accessory, if applicable. *Select "N/A" if not sterilized (i.e., undergoes disinfection) prior to use.*	☐	☐	☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**					**Yes**	**No**	**N/A**	***Page #**
		d.	Device types in this submission are listed in the Federal Register (FR) Notice entitled "Validated Instructions for Use and Validation Data Requirements for Certain Reusable Medical Devices in Premarket Notifications" (Reprocessing FR Notice, available at https://www.federalregister.gov /documents/2017/06/09/2017-12007/medical-devices-validated-instructions-for-use-and-validation-data-requirements-for-certain-reusable). *Device types identified in the Reprocessing FR Notice represent devices posing a greater likelihood of microbial transmission and represent a high risk of infection. Select "N/A" if the device type in the submission is not included in the Reprocessing FR Notice.*		☐		☑	
			i.	If device types in this submission are included in the Reprocessing FR Notice, the submission includes protocols and test reports for validating the reprocessing instructions. *Select "N/A" if the device type in the submission is not included in the Reprocessing FR Notice.*	☐	☐	☑	
			Comments:					
	26.	The device has a device-specific guidance document, special controls, and/or requirement in a device-specific classification regulation regarding sterility and/or reprocessing that is applicable to the subject device. *If "N/A" is selected, parts a and b below are omitted from the checklist.*			☐		☑	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		a.	The submission addresses sterility and/or reprocessing recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		b.	The submission includes sterility and/or reprocessing information that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there are no applicable special controls or device-specific classification regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*	☐	☐	☐	
			Comments:				
F.	**Shelf-Life**						
	27.		Proposed shelf life/ expiration date stated **OR** Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation.	☑	☐		001-50

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**			**Yes**	**No**	**N/A**	***Page #**
		Comments:				
	28.	For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf-life. *Select "N/A" if the device is not provided sterile.*	☑	☐	☐	001-50 Attachments 3 & 4
		Comments:				
	29.	Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). **OR** Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	☑	☐	☐	001-50 Attachment 3
		Comments:				
G.	**Biocompatibility** *If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.*				☐	

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

		Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**	**Yes**	**No**	**N/A**	***Page #**
	Submission states that there: (*one of the below must be checked*) ☑ Are direct or indirect tissue-contacting components ☐ Are no direct or indirect tissue-contacting components ☐ Information regarding tissue contact status of the device is not provided (if this box checked, please also check one of the two boxes below) ☐ Tissue contact information not needed for this device (e.g., software-only device) ☐ Tissue contact information is needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "are no" or "not provided and not needed" is selected, the biocompatibility-related criteria below are omitted from the checklist. If information on the tissue-contact status is not provided, and contact information is needed or its contact status is unclear, select "No."* *An example of a direct tissue-contacting device would be an implant that has direct contact with tissues during use. An example of an indirect tissue-contacting device would be fluid entering the body following passing through device/device components not in direct contact with the tissue.*			☐		001-51
	Comments:					
	30.	Submission includes a list identifying each tissue-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.	☑	☐		001-51
		Comments:				
	31.	Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration) for each tissue-contacting device component (e.g., implant, delivery catheter).	☑	☐		001-51
		Comments:				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**			**Yes**	**No**	**N/A**	***Page #**
	32.	For a biocompatibility assessment of tissue-contacting components, submission includes: • Each relevant endpoint for the device (as identified in device-specific guidance, or Attachment A of the FDA guidance document entitled "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and), has been addressed. • For any testing performed, test protocol (including identification and description of test article including whether the test article is the device in its final finished form using the recommended approach in Attachment F of "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" methods, and pass/fail criteria), and analysis of results (including tables with data points and statistical analyses, where appropriate), as described in Attachment E of the guidance document entitled "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" provided for each completed test. **OR** A statement that biocompatibility testing is not needed with a rationale that considers all relevant endpoints (e.g., materials and manufacturing/processing are identical to the predicate).	☑	☐		001-51
		Comments:				
H.	**Software**					

		Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**	**Yes**	**No**	**N/A**	***Page #**
	Submission states that the device: (*one of the below must be checked*) ☐ Does contain software/firmware ☑ Does not contain software/firmware ☐ Information on whether device contains software/firmware is not provided (if this box checked, please also check one of the two boxes below) ☐ Software/firmware information not needed for this device (e.g., surgical suture, condom) ☐ Software/firmware information is needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not contain" or "not provided and not needed" is selected, the software-related criteria below are omitted from the checklist. If information on software is not provided, and this information is needed or the need is unclear, select "No."*			☐		
	Comments:					
	33.	Submission includes a statement of software level of concern and rationale for the software level of concern	☐	☐		
		Comments:				
	34.	All applicable software documentation provided based on level of concern identified by the submitter, as described in "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices, or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale). *Note: This element is also applicable to non-internally generated or off-the-shelf (OTS) software used in the device.*	☐	☐		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**			**Yes**	**No**	**N/A**	***Page #**
		Comments:				
I.	**Cybersecurity**					
	Submission states that the device: (*one of the below must be checked*) ☐ Does contain any external wired and/or wireless communication interfaces (Wired: USB, ethernet, SD, CD, RGA, etc. or Wireless: Wi-Fi, Bluetooth, RF, inductive, Cloud, etc.) ☑ Does not contain external interfaces as described above ☐ Information on whether device has external interfaces is not provided (if this box is checked, please also check one of the two boxes below) ☐ Cybersecurity information not needed for this device (e.g., surgical suture, condom) ☐ Cybersecurity information is needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not contain" or "not provided and not needed" is selected, the cybersecurity criteria below are omitted from the checklist. If information on cybersecurity is not provided, and this information is needed or the need is unclear, select "No."*			☐		
	35.	All applicable documentation identified by the submitter, as described in "Guidance for the Content of Premarket Submissions for Management of Cybersecurity in Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices-0. **OR** Submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale).	☐	☐		
		Comments:				
J.	**Electrical Safety and EMC**					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**			**Yes**	**No**	**N/A**	***Page #**
	Electrical Safety: Submission states that the device: (*one of the below must be checked*) ☐ Does require electrical safety evaluation ☑ Does not require electrical safety evaluation ☐ Information on whether device requires electrical safety evaluation is not provided (if this box checked, please also check one of the two boxes below) ☐ Electrical safety information not needed for this device (e.g., surgical suture, condom) ☐ Electrical safety information needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not require" or "not provided and not needed" is selected, the electrical safety criteria below are omitted from the checklist. If information on electrical safety is not provided, and it is needed or the need for this information is unclear, select "No."*			☐		
	36.	Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, a device-specific standard). **OR** Submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☐	☐		
		Comments:				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**			**Yes**	**No**	**N/A**	***Page #**
	EMC: Submission states that the device: (*one of the below must be checked*) ☐ Does require EMC evaluation ☑ Does not require EMC evaluation ☐ Information on whether device requires EMC evaluation not provided (if this box checked, please also check one of the two boxes below) ☐ EMC information not needed for this device (e.g., surgical suture, condom) ☐ EMC information needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not require" or "not provided and not needed" is selected, the EMC criteria below are omitted from the checklist. If information on EMC is not provided, and it is needed or the need for this information is unclear, select "No."*			☐		
	Comments:					
	37.	Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, a device-specific standard). **OR** Submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☐	☐		
		Comments:				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
K.	**Performance Data General** *If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section L.*					☐	
	Comments:						
	38.	Summaries of the non-clinical laboratory studies and full test reports* are provided. *Summary and full test report content recommendations can be found in FDA's guidance "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket. If a submitter chooses to declare conformity to a voluntary consensus standard that FDA has recognized, submission of a full test report may not be necessary. Refer to 9a. See FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices. *Select "N/A" if the submission appropriately does not include performance data or there are no completed tests without a Declaration of Conformity.*		☑	☐	☐	001_55-57
		a.	Submission includes an explanation of how the data generated from each test supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.). *Select "N/A" if the submission does not include performance data.*	☑	☐	☐	001_55-57
			Comments:				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
	39.	The device has a device-specific guidance document, special controls, and/or requirement in a device-specific classification regulation regarding performance data that is applicable to the subject device. *If "N/A" is selected, parts a and b below are omitted from the checklist.*		☐		☑	
		a.	The submission addresses performance data recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		b.	The submission includes performance data that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there are no applicable special controls or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*	☐	☐	☐	
			Comments:				

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
	40.	If literature is referenced in the submission, submission includes: *Select "N/A" if the submission does not reference literature. If "N/A" is selected, parts a and b below are omitted from the checklist.* *Note that the applicability of the referenced article to support a substantial equivalence finding should be assessed during the substantive review; only the presence of a discussion is required to support acceptance.*				☑	
		a.	Legible reprints or a summary of each article.	☐	☐		
		b.	Discussion of how each article is applicable to support the substantial equivalence of the subject device to the predicate.	☐	☐		
			Comments:				
	41.	For each completed animal study, the submission provides the following: *Select "N/A" if no animal study was conducted. If "N/A" is selected, parts a-c below are omitted from the checklist. Note that this section does not address biocompatibility evaluations, which are assessed in Section G of the checklist.*				☐	002_Attachments 6, 7, 9
		a.	Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120	☑	☐		
		b.	Submission includes final study report which includes all elements outlined in 21 CFR 58.185	☑	☐		
		c.	Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), OR, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.	☑	☐		
			Comments:				

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

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
L.	**Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))**						
	Submission indicates that device: (*one of the below must be checked*) ☐ Is an in vitro diagnostic device ☑ Is not an in vitro diagnostic device *If "is not" is selected, the performance data-related criteria below are omitted from the checklist.*						
	42.	Submission includes the following studies, as appropriate for the device type, including associated protocol descriptions, study results and line data:					
		a.	Precision/reproducibility	☐	☐	☐	
		b.	Accuracy (includes as appropriate linearity; calibrator or assay traceability; calibrator and/or assay stability protocol and acceptance criteria; assay cut-off; method comparison or comparison to clinical outcome; matrix comparison; and clinical reference range or cutoff).	☐	☐	☐	
		c.	Sensitivity (detection limits, LoB, LoD, LoQ where relevant for the device type).	☐	☐	☐	
		d.	Analytical specificity	☐	☐	☐	
			Comments:				
	43.	The device has a device-specific guidance document, special controls, and/or requirement in a device-specific classification regulation regarding performance data that is applicable to the subject device. *If "N/A" is selected, parts a and b below are omitted from the checklist.*		☐	☐	☑	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		a.	The submission addresses performance data recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		b.	The submission includes performance data that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there are no applicable special controls or device-specific classification regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*	☐	☐	☐	
			Comments:				

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Digital Signature Concurrence Table	
Reviewer Sign-Off	
Management Sign-Off (digital signature optional)*	

*Management review of checklist and concurrence with decision required.

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

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22. Attachments

Attachment #	Title of Attachment
1	Dissolution Efficacy
2	Compatibility and Irrigation Force Comparison
3	Product Shelf Life Testing Report
4	Packaging Shelf Life Testing Report
5	Biocompatibility Evaluation
6	Guinea Pig Maximization Sensitization
7	Rabbit Mediated Pyrogen Test
8	Human Irritation Testing Report
9	Porcine Dermal Full-Thickness Wound Healing Study
10	510(k) Decision-Making - Substantial Equivalency
11	Endotoxin Memo
12	(b)(4) Substantive Review and (b)(4)
13	Certificates of Analysis & Safety Data Sheets
14	Extractables & Leachables Report
15	Extractables Evaluation
16	Predicate Device Instructions for Use
17	Reference Device Instructions for Use

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Business Address
Phone Number

Premarket Notification 510(k) Review

Pre-Review Reminders

- ☐ ← Click this checkbox to delete these directions (**Click "Enable Content" above first, if present**). Blue text indicates the text is clickable. Clicking may display tips and/or directions specific to that sentence (e.g., "Appropriate Manual Labeling" below) or section (e.g., "Premarket Notification 510(k) Review" above); it may also link to a website, form or CARS report.
- ☐ Complete the RTA checklist
- ☐ Final guidance and recognized consensus standards are recommendations. They are not binding, and applicants may demonstrate substantial equivalence using an alternative approach.

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: March 19, 2021

Reviewer: Mustafa A. Mazher

Subject: Traditional 510(k)# K203835/S001

Applicant: Next Science, LLC

Device Trade Name: MIS Solution

Contact Name: Courtney Narain

Contact Title: Regulatory Affairs Specialist

Correspondent Firm: Next Science, LLC

Phone: (855) 564-2762 Ext.6004 **Email:** cnarain@nextscience.com

Received Date: January 19, 2021

Due Date: April 19, 2021

Pro Code(s): FRO **Class:** Unclassified **Reg #:**

Reg Name:

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K161165	FQH, FRO	Next Science Irrigation Solution	Next Science, LLC

(b)(5)

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

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FDA/CDRH/DCC
DEC 30 2020
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K203835

3. Cover letter

10550 Deerwood Park Blvd
Suite 300
Jacksonville, FL 32256
P: 855-564-2762

December 22, 2020

BY FEDEX DELIVERY
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Traditional Premarket Notification 510(k)
Device Common Name: Dressing, Wound, Drug
Classification: Unclassified
Combination Product: Yes
Product Code: FRO

Dear Sir or Madam:

Next Science®, LLC (Next Science) is submitting this Traditional Premarket Notification 510(k) for **MIS Solution**.

MIS Solution is indicated for cleansing and removal of debris, including microorganisms, from wounds. The product utilizes the same technology as the predicate device where a surfactant is incorporated within a buffered solution to irrigate wounds. Both devices are formulated to assist in the solubilization of contaminants that are subsequently removed by the hydrodynamic shear of the irrigation solution, that is, by the physical act of washing the contaminant away from the wound. The advantages of the MIS Solution over the predicate device are:

1) **No need for an additional rinse**

   Biocompatibility testing supports that proposed device does not require a rinse with an equal amount of normal saline after irrigation. While irrigating, the solution will be suctioned and therefore can be used in a single step. This decreases surgical times and also reduces supplies, resulting in lower health care costs.

2) **No need for a specific jet lavage**

   Performance testing supports that the hydrodynamic shear can be provided with either a powered irrigator or a standard irrigation syringe. This provides the user additional options and can reduce the need for costly powered irrigation devices if they are not deemed necessary for the wound.

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The primary predicate device is **Next Science® Irrigation Solution, K161165**. Next Science is including the Prontosan Wound Irrigation Solution (K072876) as a reference device that, like the subject device, does not require a powered irrigator or a saline rinse. Additionally, Next Science® Wound Gel is included as a reference device as it shares 3 of the same components as the proposed device.

(b)(4)

The principal factors concerning the design and use of the **MIS Solution** are as follows:

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 801 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		X
Does the device contain a drug?	X	
Does the device contain a biologic?		X
Does the device use software?		X

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Question	YES	NO
Does the submission include clinical information?	X	
Is the device implanted?		X

Pursuant to 21 C.F.R. § 807.95(b), Next Science requests that FDA not disclose the existence of this application until such time as a substantial equivalence determination on the submission is rendered. In addition, this 510(k) submission may contain trade secret or confidential commercial information that is exempt from disclosure pursuant to 21 C.F.R. § 20.61, 21 U.S.C. § 331(j), and the Freedom of Information Act, 5 U.S.C. § 552(b)(4). We ask that you consult with Next Science as provided in 21 C.F.R. §20.47 before making any part of this submission publicly available.

We believe that the information provided in the 510(k) submission is sufficient for FDA to find that the **MIS Solution** is substantially equivalent to the predicate device for the proposed indications.

The Traditional 510(k) submission enclosed herein is being provided via eCopy only in accordance with the final rule 84 FR 68334.

Please contact me by email at cnarain@nextscience.com, if you need additional information or have any questions.

Sincerely,

(b)(6)

Courtney Narain
Regulatory Affairs Specialist
Next Science®, LLC

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

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Dear Ms. Narain:

I am reviewing your submission for the MIS Solution, which has been assigned file number K203835. Iâ€™ve completed the RTA review of your submission and the email notification of your RTA status was sent on today, January 13, 2021. While conducting the RTA review, I noted some issues unrelated to the RTA review that will need to be resolved prior to a final decision (Note: a complete review of the submission has not been conducted at this time). You do not need provide a response to these issues in your RTA response in order to be accepted; however, they are likely to be raised during the substantive review. Iâ€™m presenting them to you now to give you the opportunity to get an early start on addressing these issues:

(b)(4)

Thank you!

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

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Lixin Liu, Ph.D.

Biologist/Team Lead

Plastic Surgery Skin and Wound Devices 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

Tel: 301-796-3480

Lixin.Liu@fda.hhs.gov<mailto:Lixin.Liu@fda.hhs.gov>

[cid:image002.png@01D21A3D.01E3F6D0]<http://www.fda.gov/>

[cid:image003.jpg@01D21A3D.01E3F6D0]<https://www.facebook.com/FDA>
[cid:image004.jpg@01D21A3D.01E3F6D0] <https://twitter.com/US_FDA>
[cid:image005.jpg@01D21A3D.01E3F6D0] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image006.jpg@01D21A3D.01E3F6D0] <http://www.flickr.com/photos/fdaphotos/>
[cid:image007.jpg@01D21A3D.01E3F6D0]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/r/cdrhcustomerservice?ID=2001&S=E

From: Lixin Liu <lixin.liu@fda.hhs.gov>

Sent: Wednesday, January 13, 2021 4:17 PM

To: cnarain@nextscience.com

Cc: Liu, Lixin <Lixin.Liu@fda.hhs.gov>

Subject: K203835 is on Hold Pending Your Response

January 13, 2021

Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your submission K203835. Our review indicates that your submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit one eCopy of your response, referencing your submission K203835, addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration

Center for Devices and Radiological Health

Document Control Center - WO66-G609

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

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

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Your submission will remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist by 07/12/2021, we will consider this submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your submission. We will contact you if we require any additional information during the course of our administrative review. FDA aims to apply the least burdensome principles<https://www.fda.gov/media/73188/download> when requesting additional information.

The lead reviewer assigned to your submission is me, Lixin Liu. The file is being reviewed in Office of Health Technology 4, Division of Health Technology 4 B. The first line supervisor is the Assistant Director, Plastic Surgery Skin and Wound Devices. You may contact me at any point during the review if you have questions or concerns. You can provide valuable support for CDRH to continue to improve our programs by raising to the attention of management relevant issues that arise during the course of this review. If you feel there is an unresolved issue or a matter that requires additional attention, you should contact the Assistant Director. If your concern or issue is not addressed by the Assistant Director, you should contact the Division Director or OHT Director. The contact information for each management level can be found in the CDRH Management Directory<https://www.fda.gov/about-fda/cdrh-offices/cdrh-management-directory-organization>.

For additional information about the Refuse to Accept Policy for for 510(k)s please refer to the guidance document available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf.

If you have general questions about the review process for your submission, you should contact OPEQSubmissionSupport@fda.hhs.gov<mailto:OPEQSubmissionSupport@fda.hhs.gov>.

****This is a system generated email notification****

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Project ID: (b)(4) Date: July 16, 2019

(b)(4)

(b)(4) Laboratory Report MIS Solution Analysis

Report prepared for:

(b)(4)

Report Prepared by:

(b)(4)

(b)(4)

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Project ID: (b)(4) Date: July 16, 2019

(b)(4)

(b)(4) Laboratory Report MIS Solution Analysis

Report prepared for:

(b)(4)

Report Prepared by:

(b)(4)

(b)(4)

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

Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

Project ID: (b)(4) Date: August 23, 2019

(b)(4)

(b)(4) Laboratory Report MIS Solution Analysis

Report prepared for:

(b)(4)

Report Prepared by:

(b)(4)

(b)(4)

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

Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

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Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

Project ID: (b)(4) Date: October 15, 2019

(b)(4)

(b)(4) Laboratory Report MIS Solution Analysis

Report prepared for:

(b)(4)

Report Prepared by:

(b)(4)

(b)(4)

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

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Records processed under FOIA Request 2023-9423; Released by CDRH on 05-21-2024

Project ID: (b)(4) Date: December 30, 2019

(b)(4)

(b)(4) Laboratory Report Analysis

Report prepared for:

(b)(4)

Report Prepared by:

(b)(4)

(b)(4)

Rev 1

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

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