May 18, 2023

3M Company
Hilary Hovde
Regulatory Affairs Specialist
2510 Conway Ave.
Building 275-5W-06
St. Paul, Minnesota 55144

Re: K222578
Trade/Device Name: 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape And Drape Accessories
Regulatory Class: Class II
Product Code: KKX
Dated: April 14, 2023
Received: April 14, 2023

Dear Hilary Hovde:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bifeng Qian -S

Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
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and Infection Control Devices
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Enclosure

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)*
K222578

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

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

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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

K222578

3M Company
3M Health Care
2510 Conway Ave.
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144-1000

Contact: Hilary B. Hovde
Regulatory Affairs Specialist
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Submission Date: May 18, 2023

TRADITIONAL PREMARKET NOTIFICATION [510(k)]
3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)

Device Name and Classification

Trade Name:	3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)
Common/Usual Name:	Surgical drape
Device Classification:	Class II
Classification Name:	Surgical drape and drape accessories [21 CFR § 878.4370, KKX]

Predicate Device

3M™ Steri-Drape™ CHG Antimicrobial Incise Drape, K140250

Indications for Use

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

Description of Device

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

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

TRADITIONAL PREMARKET NOTIFICATION [510(k)]
3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)

Comparison of Technological Characteristics with the Predicate Device

Feature	Submission Device: 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)	Predicate Device (K140250): 3M™ Steri-Drape™ CHG Antimicrobial Incise Drape	Comparison
Classification Name	Surgical drape and drape accessories	Surgical drape and drape accessories	Identical
Regulation	21 CFR 878.4370	21 CFR 878.4370	Identical
Product Code	KKX	KKX	Identical
Classification	Class II	Class II	Identical
Committee	General Hospital	General Hospital	Identical
Indications for use	3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG) is indicated for use as an incise drape with continuous antibacterial activity based on in vitro time kill data out to 90 minutes. It is intended for external use only.	3M™ Steri-Drape™ CHG Antimicrobial Incise Drape is indicated for use as an incise drape with continuous antimicrobial activity based on in vitro time kill data out to 90 minutes. It is intended for external use only.	Similar Both the submission and predicate devices are intended to be used as an incise drape. The testing of the submission device supports that the drape is antibacterial rather than antimicrobial.
Design/Materials	Antibacterial impregnated adhesive coated on breathable film with silicone-coated release liner.	Antimicrobial impregnated adhesive coated on breathable film with silicone-coated release liner.	Similar Some minor modifications were made to the adhesive formulation, adhesive coat weight, and film of the submission device as compared to the predicate device.
Active Ingredient	Chlorhexidine Gluconate (2% w/w CHG)	Chlorhexidine Gluconate (2% w/w CHG)	Identical
Sterilization	Modality: Ethylene Oxide SAL: 10^{-6}	Modality: Ethylene Oxide	Identical

TRADITIONAL PREMARKET NOTIFICATION [510(k)]
3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)

Feature	Submission Device: 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)	Predicate Device (K140250): 3M™ Steri-Drape™ CHG Antimicrobial Incise Drape	Comparison
	Residuals meet ISO 10993-7: 2008; Amd 1: 2019 requirements	SAL: 10^{-6} Residuals meet ISO 10993-7 (R) 2012 requirements	
Packaging	Film/Tyvek pouch	Film/Tyvek pouch	Identical
Principles of Operation	The 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG) is considered a non-invasive device containing an antimicrobial/antibacterial agent (chlorhexidine gluconate) in the adhesive. The primary mode of action of this device is to provide a sterile barrier during surgical procedures. The secondary mode of action, based on the CHG containing adhesive, is to provide continuous antibacterial activity and to reduce the risk of surgical site contamination due to skin flora. Surgical incisions can be made directly through the Ioban incise film which creates a sterile surface all the way to the wound edge.	The 3M™ Steri-Drape™ CHG Antimicrobial Drape is a sterile adhesive film that is applied pre-operatively to skin. The film adheres and conforms to the body contours, providing a sterile surface on top of the skin prior to surgery. The surgeon incises through the adhesive film and skin, ensuring a sterile film barrier all the way to the edge of the incision. The CHG contained in the adhesive provides additional antimicrobial activity to reduce the risk of microbial contamination of the surgical wound.	Identical
Performance Characteristics	• Barrier performance per AAMI PB70:2012 using ASTM 1670 *Resistance to Synthetic Blood Penetration* • Force at 25% Elongation • Assessment of Tear Resistance	• Barrier performance per AAMI PB70:2012 using ASTM 1670 *Resistance to Synthetic Blood Penetration*	The same testing was completed to assess the barrier, mechanical and antimicrobial properties of the subject device in

TRADITIONAL PREMARKET NOTIFICATION [510(k)]
3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)

Feature	Submission Device: 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG)	Predicate Device (K140250): 3M™ Steri-Drape™ CHG Antimicrobial Incise Drape	Comparison
	• Flammability testing per 16 CFR 1610 • Moisture Vapor Transmission Rate • *In vitro* Direct Time Kill • Minimum Effective Concentration • CHG Release Kinetics	• Tensile and Elongation • Flammability testing per 16 CFR 1610 • Moisture Vapor Transmission Rate • *In vitro* Direct Time Kill • Minimum Effective Concentration • CHG Release Kinetics	addition to an assessment of tear resistance.
Biocompatibility	Not cytotoxic, slight irritant, not a potential skin sensitizer, not pyrogenic, not acutely systemically toxic, non-hemolytic	Non cytotoxic, slight irritant, not a potential skin sensitizer	Duration and type of contact are identical. Additional endpoints tested are in alignment with updates to ISO 10993.
Clinical Testing	None provided	Adhesion to skin study	No clinical testing was provided to support substantial equivalence since this was a minor change. Adhesion was assessed through bench testing.

Summary of Non-Clinical Testing

Bench Testing and biocompatibility testing were completed to demonstrate substantial equivalence of the submission device, the 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG), to the predicate device.

The device performance was verified through the following tests:

Test	Test Method Description	Acceptance Criteria	Results
Barrier Performance	AAMI PB70:2012 using ASTM F1670 *Resistance to Synthetic Blood Penetration*	Level 4	PASS
Force at 25% Elongation	Based on PSTC-131, ASTM D882, ASTM D3759	< 425 g/in	PASS
Assessment of Tear Resistance	N/A	Rationalization Provided	PASS
Flammability	16 CFR 1610	Class I (Normal)	PASS
Moisture Vapor Transmission Rate	Based on ASTM E96	> 400 g/m^2/24 hours	PASS
in vitro Direct Time Kill and Minimum Effective Concentration	Based on ASTM E2315	> 4 log reduction at 90 minutes	PASS
CHG Release Kinetics	3M CHG Kinetic Release Test Method	> 0.0% after 90 minute extraction	PASS
Ethylene Oxide Residuals	ISO 10993-7: 2008; Amd 1: 2019	Per ISO 10993-7: 2008; Amd 1: 2019	PASS

Device samples passed the following biocompatibility tests performed in accordance with ISO 10993-1, *Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process* as recognized by FDA. The 3M™ Ioban™ CHG Chlorhexidine Gluconate Incise Drape (contains 2% w/w CHG) is categorized as a surface contacting device, with breached or compromised skin contact of limited duration in accordance with ISO 10993-1 and FDA Guidance, *Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process."* The battery of tests included the following:

- Chemical Characterization and Toxicology Risk Assessment of Extractables
- Hemolysis
- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Material-Mediated Pyrogenicity

Summary of Clinical Testing

Clinical testing was not provided to support substantial equivalence.

Conclusion

The conclusions drawn from the non-clinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K140250.