3M Health Care

3M Infection Prevention

3M Center
2510 Conway, Bldg 275-05-W-06
St. Paul, MN 55144
651 733 1110

k140250

JUL 2 5 2014

3M

510(k) SUMMARY
Sponsor Information:

Applicant Name	3M Company 3M Health Care Infection Prevention Division 3M Center 2510 Conway Ave., Bldg 275-5W-06 St. Paul, MN 55144
Contact Person:	Kristin Totushek Regulatory Affairs
Phone Number: Fax Number: e-mail:	651-736-6117 651-737-5320 ktotushek@mmm.com
Date Prepared:	July 23, 2014

Device Name and Classification:

Trade Name:	3M™ Steri-Drape™ CHG Antimicrobial Incise Drape
Common or Usual Name:	Antimicrobial Incise Drape
Classification Name:	Surgical Drape and Drape Accessories
Product Code:	KKX per 21CFR 878.4370
Predicate Device:	3M™ Ioban™ 2 Antimicrobial Incise Drape (K801550)

Description of Device:

The 3M™ Steri-Drape™ CHG Antimicrobial Incise Drape is a sterile adhesive film that is applied pre-operatively to skin. The film adheres and conforms to body contours, providing a sterile surface on top of the skin prior to surgery. The surgeon incises through the adhesive film and skin, ensuring a sterile film barrier all the way to the edge of the incision. The CHG contained in the adhesive provides antimicrobial activity to reduce the risk of microbial contamination in the surgical wound.

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The 3M™ Steri-Drape™ CHG Antimicrobial Incise Drape consists of a transparent, conformable, breathable fluid barrier film laminated to a lightly-tinted, acrylic pressure-sensitive adhesive that contains 2% w/w Chlorhexidine Gluconate (CHG). The adhesive drape is delivered on a silicone-coated release liner that is discarded after application.

In vitro testing demonstrates that 3M™ Steri-Drape™ CHG Antimicrobial Incise Drape has broad spectrum antimicrobial activity.

Indications for Use:

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.

Catalog #	Color	Size	
8840EZ	Light pink	13 in x 13 in	34 cm x 35 cm
8848EZ	Light pink	22 in x 23 in	56 cm x 60 cm
8850EZ	Light pink	22 in x 17 in	56 cm x 45 cm
8851EZ	Light pink	22 in x 33 in	56 cm x 85 cm

Substantial Equivalence:

3M™ Steri-Drape™ CHG Antimicrobial Incise Drape is substantially equivalent to the predicate device, 3M™ Ioban™ 2 Antimicrobial Incise Drape cleared under K801550.

3M™ Steri-Drape™ CHG Antimicrobial Incise Drape is composed of the same or similar components and has the same or similar performance, intended use and indications for use as the predicate device.

Based on the similarities to the predicate device, the minor differences do not present any new safety or effectiveness issues and the device is substantially equivalent to the predicate.

Comparative Data for Determining Substantial Equivalence of New Device to Predicate Device:

Characteristic	3M™ Steri-Drape™ CHG Antimicrobial Incise Drape	3M™ Ioban™ 2 Antimicrobial Incise Drape	Comparison
Intended Use	3M™ Steri-Drape™ CHG Antimicrobial	3M™ Ioban™ 2 Antimicrobial Incise	Same

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Characteristic	3M™ Steri-Drape™ CHG Antimicrobial Incise Drape	3M™ Ioban™ 2 Antimicrobial Incise Drape	Comparison
	Incise Drape is indicated for use as an incise drape with continuous antimicrobial activity. It is intended for external use only.	Drape is indicated for use as an incise drape with continuous antimicrobial activity. It is intended for external use only.	
Design/Materials	Antimicrobial impregnated adhesive coated on breathable film with silicone-coated release liner.	Antimicrobial impregnated adhesive coated on breathable film with silicone-coated release liner.	Same
Antimicrobial	Chlorhexidine Gluconate (CHG)	Iodine	Both are well characterized, broad spectrum, antimicrobials. Safety and efficacy testing demonstrates substantial equivalence.
Sold Sterile	Yes	Yes	Same
Sterilization Method	Ethylene Oxide sterilized, 10^{-6} SAL per ISO 11135	Gamma Sterilized, 10^{-6} SAL per ISO 11137	Different sterilization method but same sterility assurance level (SAL). Iodine is not compatible with Ethylene Oxide. CHG is not compatible with gamma irradiation. Both devices are sterilized to 10^{-6} SAL per respective ISO standards.
Packaging	Film/Tyvek Pouch	Foil Pouch	Foil laminate is used to protect Ioban from EO exposure if sterilized in a kit. Film/Tyvek is used to enable sterilization of CHG drape with EO.
Sterility Assurance Level	SAL 10^{-6}	SAL 10^{-6}	Same

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Characteristic	3M™ Steri-Drape™ CHG Antimicrobial Incise Drape	3M™ Ioban™ 2 Antimicrobial Incise Drape	Comparison
Prinicipals of Operation	The 3M™ Steri-Drape™ CHG Antimicrobial Incise Drape is a sterile adhesive film that is applied pre-operatively to skin. The film adheres and conforms to body contours, providing a sterile surface on top of the skin prior to surgery. The surgeon incises through the adhesive film and skin, ensuring a sterile film barrier all the way to the edge of the incision. The CHG contained in the adhesive provides additional antimicrobial activity to reduce the risk of microbial contamination of the surgical wound.	The 3M™ Ioban™ 2 Antimicrobial Incise Drape is a sterile adhesive film that is applied pre-operatively to skin. The film adheres and conforms to body contours, providing a sterile surface on top of the skin prior to surgery. The surgeon incises through the adhesive film and skin, ensuring a sterile film barrier all the way to the edge of the incision. The iodine contained in the adhesive provides additional antimicrobial activity to reduce the risk of microbial contamination of the surgical wound.	Same
Biocompatibility	Not cytotoxic, slight irritant, not a potential skin sensitizer	Not cytotoxic, slight irritant, not a potential skin sensitizer	Same

Bench Testing Performance Data:

Bench testing was performed to demonstrate substantial equivalence for this submission, as recommended by the FDA Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes and the additional recommendations from FDA Draft Guidance on Premarket Notification [510(k)]

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Submissions for Medical Devices that Include Antimicrobial Agents. Data submitted includes:

- Barrier performance per AAMI PB70:2012 using ASTM F1670 "Resistance to Synthetic Blood Penetration"
- Tensile and Elongation
- Flammability testing was performed per 16 CFR 1610
- Moisture Vapor Transmission Rate (MVTR)
- *in vitro* Antimicrobial Activity Spectrum and Minimum Effective Concentration (MEC) per ASTM E2315
- CHG Release Kinetics

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Characteristic	Test Method Description	Device Component Tested	Data Summary		Comparison
			Test Article: 3M™ Steri-Drape™ CHG Anti-microbial Incise Drape	**Predicate: 3M™ Ioban™ 2 Anti-microbial Incise Drape**	
Tensile and Elongation	Based on PSTC-131, ASTM D882, ASTM D3759	Finished Drape Incise Area, sample cut to size	Tensile > 1365 g/25mm and Elongation >500%	Tensile > 1365 g/25mm and Elongation >500%	Same
MVTR	Based on ASTM E96 and Payne Cup Method	Finished Drape sample, cut to size	> 400 g/m^2/24 hrs	> 400 g/m^2/24 hrs	Same
Flammability	16 CFR 1610	Finished Drape Sample	Class I (Normal)	Class I (Normal)	Same
Barrier Performance	AAMI PB70:2012	Finished Drape Sample, cut to size	Level 4	Level 4	Same
Antimicrobial performance	ASTM E2315	Finished Drape Sample, cut to size	Broad Spectrum, > 4 log reduction at 90 min	Broad Spectrum, > 4 log reduction at 90 min	Same

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In vivo Animal Efficacy Data

In vivo animal testing was performed to demonstrate antimicrobial efficacy compared with a placebo incise drape.

Characteristic	Description of Test Method	Device Component Tested		Data Summary	Conclusion
		Test Article	Placebo		
Antimicrobial efficacy study- in vivo porcine model	Wound contamination rates of test versus placebo drape in an in vivo porcine surgical model	Finished Drape sample, cut to size.	Placebo drape sample, cut to size.	T_0 Log_{10} CFU/sample CHG drape lower than placebo (observed difference 0.35 log_{10}, P= 0.026)	Test article reduces microbial contamination of surgical wound compared to the placebo
				T_4 Log_{10} CFU/sample CHG drape lower than placebo (observed difference 0.68 log_{10}, P=0.001)	
				Difference in change in log_{10} counts/sample T_0 to T_4, observed difference 0.34 log_{10}, P=0.14	
				Log_{10} CFU/cm^2 under drape lower than placebo (observed difference 0.70 log_{10}, P= 0.0002)	

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Clinical Performance Data:

In house clinical panels were performed to demonstrate good adhesion to skin. Outside clinical adhesion studies were conducted to demonstrate safety and adhesion to various skin types.

Safety data were collected in these studies to demonstrate substantial equivalence for this submission to the predicate, 3M™ Ioban™ 2 Antimicrobial Incise Drape.

Test	Device Component Tested	Testing Summary	Summary	Comparison
Adhesion to Skin – in house clinical panels	Finished Drape Samples, cut to size	Adhesion comparison of 3M™ Steri-Drape™ CHG Antimicrobial Incise Drape and 3M™ Ioban™ 2 Antimicrobial Incise Drape on skin prepped with DuraPrep Solution or a leading PVP-I prep solution during a wet challenge wear study	No statistical difference in skin adhesion over either DuraPrep Solution or PVP-I prep solutions	Same performance as predicate
Adhesion to skin – in house clinical panels	Finished Drape Samples, cut to size	Adhesion comparison of 3M™ Steri-Drape™ CHG Antimicrobial Incise Drape and 3M Ioban 2 Antimicrobial Incise Drape on skin during a dry challenge wear study	Removal force of test article is higher than predicate, no difference in skin reactions	Similar performance to predicate
Adhesion to skin – external clinical study	Finished Drape Samples, cut to size	Evaluation of skin condition and removal force post- wear on subjects with very dry and potentially fragile skin types	No adverse events associated with test article post-wear; removal force slightly higher for test article	Similar performance to predicate

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Performance, Safety and Efficacy Conclusion:

Based on bench, animal and clinical studies, 3M™ Steri-Drape™ CHG Antimicrobial Incise Drape is as safe, as effective and is demonstrated to be substantially equivalent to the predicate device, 3M™ Ioban™ 2 Antimicrobial Incise Drape.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 25, 2014

3M Health Care
Infection Prevention Division
Ms. Kristin Totushek
Regulatory Affairs Specialist
3M Center, 2510 Conway Ave. Bldg 275-5W-06
St. Paul, MN 55144

Re: K140250
Trade/Device Name: 3M™ Steri-Drape ™ CHG Antimicrobial Incise Drape
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape Accessories
Regulatory Class: Class II
Product Code: KKX
Dated: June 23, 2014
Received: June 24, 2014

Dear Ms. Totushek,

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. 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and Part 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140250

Device Name
3M™ Steri-Drape™ CHG Antimicrobial Incise Drape

Indications for Use *(Describe)*

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.

Catalog #	Color	Size	
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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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Sreekanth Gutala -S

Digitally signed by Sreekanth Gutala -S
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Date: 2014.07.24 11:04:33 -04'00'

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