DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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July 11, 2017

3M Company
Melissa Forth
Regulatory Affairs Specialist
3M Center, 2510 Conway Ave, Bldg 275-5W-06
St. Paul, Minnesota 55144

Re: K171908
Trade/Device Name: 3M Tegaderm CHG Chlorhexidine Gluconate I.V. Securement Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 22, 2017
Received: June 26, 2017

Dear Melissa Forth:

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); 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), please contact the Division of Industry and Consumer Education 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 Industry and Consumer Education 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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 below.

510(k) Number *(if known)*
K171908

Device Name
3M™ Tegaderm™ CHG Chlorhexidine Gluconate I.V. Securement Dressing

Indications for Use *(Describe)*

3M™ Tegaderm™ CHG Chlorhexidine Gluconate I.V. Securement Dressing can be used to cover and protect catheter sites and to secure devices to skin. Common applications include securing and covering IV catheters, other intravascular catheters and percutaneous devices.

Tegaderm™ CHG I.V. Securement Dressing is intended to reduce vascular catheter colonization and catheter-related bloodstream infections (CRBSI) in patients with central venous or arterial catheters.

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

510(k) Summary

This 510(k) summary is submitted in accordance with the requirements of 21 CFR Part 807.92.

I. SUBMITTER

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

Contact Person: Melissa J. Forth
Regulatory Affairs Specialist

Phone: (651) 737-5016
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Email: mjforth@mmm.com

Date Prepared: June 22, 2017

II. DEVICE

Trade Name: 3M™ Tegaderm™ CHG Chlorhexidine Gluconate I.V. Securement Dressing

Common or Usual Name: Antimicrobial I.V. Securement Dressing

Classification: Unclassified

Product Code: FRO

Classification Name: Dressing, wound, drug

III. PREDICATE DEVICE

3M™ Tegaderm™ CHG Chlorhexidine Gluconate I.V. Securement Dressing
(K063458, K080620, K153410)

No reference devices are used in this submission.

IV. DEVICE DESCRIPTION

3M™ Tegaderm™ CHG Chlorhexidine Gluconate I.V. Securement Dressing is used to cover and protect catheter sites and to secure devices to skin. It is available in a variety of shapes and sizes.
Tegaderm™ CHG I.V. Securement Dressing consists of a transparent adhesive dressing and an integrated gel pad containing 2% w/w Chlorhexidine Gluconate (CHG), a well-known antiseptic agent with broad spectrum antimicrobial and antifungal activity. The transparent film provides an effective barrier against external contamination including fluids (waterproof), bacteria, viruses* and yeast, and protects the IV site.

In vitro testing (log reduction and barrier testing) demonstrates that the Tegaderm™ CHG gel pad in the Tegaderm™ CHG I.V. Securement Dressing has an antimicrobial effect against, and is a barrier to, a variety of gram-positive and gram-negative bacteria, and yeast in the dressing. The gel pad absorbs fluid.

**In vitro* testing shows that the transparent film of the Tegaderm™ CHG dressing provides a viral barrier from viruses 27 nm in diameter or larger while the dressing remains intact without leakage.

Tegaderm™ CHG dressing is transparent, allowing continual site observation, and is breathable, allowing good moisture vapor exchange.

The device is single-use, provided sterile and the sterilization method is ethylene oxide. There are no associated accessories.

Catalog Number	**Device Name**	**Dressing Size**	**Average Amount of CHG per Dressing** (mg based on gel pad size)
1657	3M™ Tegaderm™ CHG Chlorhexidine Gluconate I.V. Securement Dressing	8.5 cm x 11.5 cm (3-1/2 X 4-1/2 in)	45 mg
1658	3M™ Tegaderm™ CHG Chlorhexidine Gluconate I.V. Securement Dressing	10 cm X 12 cm (4 X 4-3/4 in)	45 mg
1659	3M™ Tegaderm™ CHG Chlorhexidine Gluconate I.V. Securement Dressing	10 cm x 15.5 cm (4 X 6-1/8 in)	78 mg

Catalog Number	Device Name	Dressing Size	Average Amount of CHG per Dressing (mg based on gel pad size)
1660	3M™ Tegaderm™ CHG Chlorhexidine Gluconate I.V. Securement Dressing	7 cm x 8.5 cm (2 3/4 in. x 3 3/8 in.)	15 mg
1877*	3M™ PICC / CVC Securement Device + Tegaderm™ CHG Chlorhexidine Gluconate I.V. Securement Dressing	8.5 cm x 11.5 cm (3 1/2 x 4 1/2 in)	45 mg
1879*	3M™ PICC / CVC Securement Device + Tegaderm™ CHG Chlorhexidine Gluconate I.V. Securement Dressing	10 cm x 15.5 cm (4 x 6 1/8 in)	78 mg

* Note: Catalog numbers 1877 and 1879 are convenience kits. The 3M™ PICC / CVC Securement Device portion of the kit is a US Class I device.

V. INDICATIONS FOR USE

3M™ Tegaderm™ CHG Chlorhexidine Gluconate I.V. Securement Dressing can be used to cover and protect catheter sites and to secure devices to skin. Common applications include securing and covering I.V. catheters, other intravascular catheters and percutaneous devices.

Tegaderm™ CHG I.V. Securement Dressing is intended to reduce vascular catheter colonization and catheter-related bloodstream infections (CRBSI) in patients with central venous or arterial catheters.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Characteristic	3M™ Tegaderm™ CHG I.V. Securement Dressing (Submission Subject)	3M™ Tegaderm™ CHG I.V. Securement Dressing (K063458, K080620, K153410)
Intended Use	No changes. Same intended use as predicate device.	3M™ Tegaderm™ CHG Chlorhexidine Gluconate I.V. Securement Dressing can be used to cover and protect catheter sites and to secure devices to skin.
Indications for Use	No changes. Same Indications for Use as predicate device.	3M™ Tegaderm™ CHG Chlorhexidine Gluconate I.V. Securement Dressing can be used to cover and protect catheter sites and to secure devices to skin. Common applications include securing and covering I.V. catheters, other intravascular catheters and percutaneous devices.

Characteristic	3M™ Tegaderm™ CHG I.V. Securement Dressing (Submission Subject)	3M™ Tegaderm™ CHG I.V. Securement Dressing (K063458, K080620, K153410)
		Tegaderm™ CHG I.V. Securement Dressing is intended to reduce vascular catheter colonization and catheter-related bloodstream infections (CRBSI) in patients with central venous or arterial catheters.
Operating Principle	No change. Same operating principle as predicate.	Catheter securement device.
Antimicrobial agent	No change. Same as predicate device.	CHG Chlorhexidine Gluconate (CHG) Gel pad contains 2% w/w chlorhexidine gluconate (CHG) or 15-78 mg CHG per pad (depending on dressing size).
Technology description	No change. Same as predicate device.	The Chlorhexidine Gluconate I.V. Securement Dressing consists of a transparent adhesive dressing and an integrated hydrophilic gel pad containing 2% w/w Chlorhexidine Gluconate (CHG). The gel pad absorbs fluid.
Absorbent	No change. Same as predicate device.	Yes
Transparent	No change. Same as predicate device.	Yes
Breathable	No change. Same as predicate device.	Yes
Secures	No change. Same as predicate device.	Yes
Broad spectrum, continuous, antimicrobial / Broad spectrum antifungal	No change. Same as predicate device.	*In vitro* testing (log reduction and barrier testing) demonstrates that the Tegaderm™ CHG gel pad in the Tegaderm™ CHG I.V. Securement Dressing has an antimicrobial effect against, and is a barrier to, a variety of gram-positive and gram-negative bacteria, and yeast in the dressing.
Suppresses re-growth of microorganisms	No change. Same as predicate device.	Yes
Reduces vascular catheter colonization	No change. Same as predicate device.	Yes
Reduces catheter-related bloodstream infection (CRBSI)	No change. Same as predicate device.	Yes

VII. SUMMARY OF PERFORMANCE (NON-CLINICAL TESTING) DATA

Non-clinical testing of the subject device for viral barrier performance at the end of shelf-life was performed. The device's performance is substantially equivalent to the predicate device. No biocompatibility, animal studies or clinical studies were needed to support this change.