DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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May 15, 2017

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

Re: K153410
Trade/Device Name: 3M Tegaderm CHG Chlorhexidine Gluconate I.V. Securement Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: February 23, 2017
Received: February 24, 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 yours,

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)*
K153410

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 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.

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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3M Company

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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: Fax: Email:	(651) 737-5016 (651) 737-5320 mjforth@mmm.com
Date Prepared:	May 10, 2017

II. DEVICE

Trade Names:	**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(S)

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

BIOPATCH Antimicrobial Dressing (K003229)

No reference devices are used in this submission.

IV. DEVICE DESCRIPTION

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

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, and yeast, and protects the I.V. 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.

Tegaderm™ CHG I.V. Securement 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

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

Intended Use and Indications for Use

The Intended Use of the subject and predicate devices is that they are antimicrobial dressings with CHG, used at catheter insertion sites. Indications for Use of the subject and the predicate devices are set forth in detail in the table directly below.

3M™ Tegaderm™ CHG Chlorhexidine Gluconate I.V. Securement Dressing (Submission Subject, K153410)	**BIOPATCH Antimicrobial Dressing (K003229)**	**3M™ Tegaderm™ CHG Chlorhexidine Gluconate I.V. Securement Dressing (K063458, K080620)**
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 I.V. catheters, other intravascular catheters and percutaneous devices. Tegaderm™ CHG Chlorhexidine Gluconate 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.	BIOPATCH containing Chlorhexidine Gluconate is intended for use as a hydrophilic wound dressing that is used to absorb exudate and to cover a wound caused by the use of vascular and non-vascular percutaneous medical devices such as: IV catheters, central venous lines, arterial catheters, dialysis catheters peripherally inserted coronary catheters, mid-line catheters, drains, chest tubes, externally placed orthopedic pins, and epidural catheters. It is also intended to reduce local infections, catheter-related blood stream infections (CRBSI), and skin colonization of microorganisms commonly related to CRBSI, in patients with central venous or arterial catheters.	3M™ Tegaderm™ CHG Dressings (Chlorhexidine Gluconate I.V. Securement Dressing) can be used to cover and protect catheter sites and to secure devices to skin. Common applications include IV catheters, other intravascular catheters and percutaneous devices.

The indications for use statement is different between the subject device and the predicate device. Specifically, the subject device indications for use includes an indication expansion “to reduce vascular catheter colonization and catheter-related bloodstream infections (CRBSI) in patients with central venous or arterial catheters.” This statement is not included in the predicate: 3M™ Tegaderm™ CHG Chlorhexidine Gluconate I.V. Securement Dressing. However, it pertains to a performance characteristic associated with the same intended use of being an antimicrobial dressing with CHG. To support this portion of the indications, 3M has provided performance data to show that the Tegaderm™ CHG I.V. Securement Dressings perform as claimed.

In addition, the indications for use statement is different between the Tegaderm™ CHG I.V. Securement Dressing and the BIOPATCH Antimicrobial Dressing predicate. The Tegaderm™ CHG I.V. Securement Dressing indication expansion "to reduce vascular catheter colonization and catheter-related bloodstream infections (CRBSI) in patients with central venous or arterial catheters" is similar to BIOPATCH's indication "to reduce local infections, catheter-related blood stream infections (CRBSI), and skin colonization of microorganisms commonly related to CRBSI, in patients with central venous or arterial catheters," The differences in the Indications do not affect the safety and effectiveness of the device, and again, as stated above, do not alter the intended therapeutic, diagnostic, prosthetic, or surgical use of the subject device.

Technology Comparison

The Tegaderm™ CHG I.V. Securement Dressing and the BIOPATCH Antimicrobial Dressing have similar technological characteristics. Both devices contain the same antimicrobial, chlorhexidine gluconate (CHG). The minor differences in technological characteristics do not raise different questions of safety or effectiveness, as confirmed by the testing activities described in this submission.

Characteristic	**3M™ Tegaderm™ CHG I.V Securement Dressing** **(Submission Subject, K153410)**	**BIOPATCH Antimicrobial Dressing** **(K003229)**	**3M™ Tegaderm™ CHG Chlorhexidine Gluconate I.V. Securement Dressing** **(K063458, K080620)**
Antimicrobial agent	CHG Chlorhexidine Gluconate (CHG) Gel pad contains 2% w/w chlorhexidine gluconate	CHG Chlorhexidine Gluconate (CHG) contains chlorhexidine gluconate (no subsequent 510k filings)	CHG Chlorhexidine Gluconate (CHG) Gel pad contains 2% w/w chlorhexidine gluconate (unchanged from original 510k clearance)
Dressing configuration	The Chlorhexidine Gluconate I.V. Securement Dressing consists of a transparent, semi-permeable adhesive dressing and an integrated hydrophilic gel pad containing 2% w/w Chlorhexidine Gluconate (CHG).	A hydrophilic polyurethane absorptive foam with Chlorhexidine Gluconate (CHG). A separate unspecified dressing cover is needed.	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).
Absorbent	Yes	Yes	Yes
Transparent	Yes	N/A (opaque)	Yes
Breathable	Yes	Yes	Yes

3M Company

3M™ Tegaderm™ CHG
Chlorhexidine Gluconate Dressings
510(k) Premarket Notification - Traditional

Characteristic	**3M™ Tegaderm™ CHG I.V Securement Dressing** **(Submission Subject, K153410)**	**BIOPATCH Antimicrobial Dressing** **(K003229)**	**3M™ Tegaderm™ CHG Chlorhexidine Gluconate I.V. Securement Dressing** **(K063458, K080620)**
Broad spectrum, continuous, antimicrobial / Broad spectrum antifungal	Yes	Yes	Yes

VII. PERFORMANCE DATA

The following performance data are provided in support of the substantial equivalence determination for this indication expansion submission.

Performance Tests

The following performance testing was provided in this submission to support a determination of substantial equivalence to the predicate device.

- Suppression of regrowth over time
- *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.

Clinical Studies -- Randomized Controlled Clinical Trial

The proposed broadened indication for use for 3M Tegaderm CHG Chlorhexidine Gluconate I.V. Securement Dressing is supported by a randomized, multi-arm, controlled clinical trial consisting of 1,879 subjects with 4,163 central venous and arterial catheters conducted at 11 hospitals in France (12 ICUs). This trial found that the addition of 3M Tegaderm CHG Chlorhexidine Gluconate I.V. Securement Dressing in institutions already following routine infection control techniques led to a reduction in catheter colonization and catheter-related infections. The full study details are available in Timsit JF et al. *Randomized controlled trial of chlorhexidine dressing and highly adhesive dressing for preventing catheter-related infections in critically ill adults.* Am J Crit Care Med. 2012;186(12): 1272-1278.

The Timsit study defined a catheter-related bloodstream infection (CRBSI) as:

"CRBSI was a combination of (a) one or more positive peripheral blood cultures sampled immediately before or within 48 hours after catheter removal; (b) a positive quantitative catheter-tip culture positive (using the 1,000 CFU/ml threshold when vortexing technique was used or 100 CFU/ml threshold when sonication technique was used) for the same microorganisms (same species and same susceptibility pattern) or a blood-culture differential time-to-positivity of 2 hours or more; and (c) no other infectious focus explaining the positive blood cultures. In patients with blood cultures positive for coagulase-negative staphylococci, the same pulse-field gel electrophoresis patterns in the catheter tip and blood cultures was required for a diagnosis of CRBSI."

Utilizing the definition of CRBSI described in the Timsit et al. (2012) publication, the study authors found that a dressing containing CHG (i.e. Tegaderm CHG Securement Dressing), reduced the risk of CRBSI by 57% compared to dressings without CHG (control). The following results were obtained:

Control Group (non CHG dressing)		Test Group (Tegaderm™ CHG I.V. Securement Dressing)		Comparison		P-value
Patients with Infection	Infections per 1000 Catheter Days	Patients with Infection	Infections per 1000 Catheter Days	Percent Reduction in Patients with Infections	Percent Reduction per 1000 Catheter Days	
2.2% (21/941)	1.29	0.96% (9/938)	0.52	57%	60%	0.020

It should be noted that the Timsit definition differs from the CRBSI definition published by the Infectious Diseases Society of America (IDSA). See below for the IDSA definition. As a sensitivity analysis for the Timsit study results, the data was re-analyzed applying the Infectious Diseases Society of America (IDSA) 2009 guidelines, *Clinical Practice Guidelines for the Diagnosis and Management of Intravascular Catheter-Related Infection: 2009 Update by the Infectious Diseases Society of America*. In a re-analysis of all 31 CRBSI cases, each subject was reviewed to determine whether they fully satisfied criteria for CRBSI per the IDSA Guidelines.

The IDSA 2009 guidelines use the following definition for CRBSI:

"Catheter related Bacteremia or fungemia in a patient who has an intravascular device and >1 positive blood culture result obtained from the peripheral vein, clinical manifestations of infection (e.g., fever, chills, and/ or hypotension), and no apparent source for bloodstream infection (with the exception of the catheter). One of the following should be present: a positive result of semiquantitative (>15 cfu per catheter segment) or quantitative ($>10^2$ cfu per catheter segment) catheter culture, whereby the same organism (species) is isolated from a catheter segment and a peripheral blood culture; simultaneous quantitative cultures of blood with a ratio of >3:1 cfu/mL of blood (catheter vs. peripheral blood); differential time to positivity (growth in a culture of blood obtained through a catheter hub is detected by an automated blood culture system at least 2 h earlier than a culture of simultaneously drawn peripheral blood of equal volume)."

The following results were obtained from the re-analysis with the IDSA guidelines:

Control Group (non CHG dressing)		Test Group (Tegaderm™ CHG I.V. Securement Dressing)		Comparison		P-value
Patients with Infection	Infections per 1000 Catheter Days	Patients with Infection	Infections per 1000 Catheter Days	Percent Reduction in Patients with Infections	Percent Reduction per 1000 Catheter Days	
1.7% (16/941)	0.94	0.85% (8/938)	0.46	50%	51%	0.095

VIII. CONCLUSIONS

3M™ Tegaderm™ CHG Chlorhexidine Gluconate I.V. Securement Dressing has been shown to reduce the incidence of catheter-related bloodstream infection (CRBSI) and catheter colonization in a large, randomized, controlled clinical trial. The Timsit 2012 study supports the expanded indication statement requested by 3M.

The 3M™ Tegaderm™ CHG Chlorhexidine Gluconate I.V. Securement Dressing remains substantially equivalent to 3M Company's currently cleared and marketed 3M™ Tegaderm™ CHG I.V. Securement Dressing, and is substantially equivalent to the BIOPATCH predicate. The differences proposed do not affect the safety and effectiveness of the device when used as labeled.