November 20, 2017

3M Company, 3M Health Care
Maria Ruiz
Regulatory Affairs Specialist
3M Center, 2510 Conway Ave., Bldg. 275-5W-06
St. Paul, Minnesota 55144

Re: K170754
Trade/Device Name: 3M Tegaderm Antimicrobial Transparent Dressing, 3M Tegaderm Antimicrobial I.V. Advanced Securement Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: October 25, 2017
Received: October 26, 2017

Dear Maria Ruiz:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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)*
K170754

Device Name
3M™ Tegaderm™ Antimicrobial Transparent Dressing, 3M™ Tegaderm™ Antimicrobial I.V. Advanced Securement Dressing

Indications for Use *(Describe)*
3M™ Tegaderm™ Antimicrobial Transparent Dressing and 3M™ Tegaderm™ Antimicrobial I.V. Advanced Securement Dressing are intended to be used to cover and protect catheter sites and to secure devices to the skin. Common applications include covering and securing IV catheters, other intravascular catheters and percutaneous devices.

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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510K SUMMARY

I. SUBMITTER

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Date Prepared: March 10, 2017

II. DEVICE

Name of Device:	3M™ Tegaderm™ Antimicrobial Transparent Dressing and 3M™ Tegaderm™ Antimicrobial I.V. Advanced Securement Dressing
Common or Usual Name:	Dressing, Wound, Drug
Regulatory Class:	Unclassified
Product Code:	FRO

III. PREDICATE DEVICE

BD ChloraShield™ I.V. Dressing with CHG Antimicrobial (K113836, originally cleared September 24, 2012 under the device name Benehold CHG Transparent Film Dressing)

IV. DEVICE DESCRIPTION

3M™ Tegaderm™ Antimicrobial Transparent Dressing and 3M™ Tegaderm™ Antimicrobial I.V. Advanced Securement Dressing are similar dressings with one provided as a film dressing and the latter provided as a film dressing with a soft cloth border. Performance data supports both product configurations.

3M™ Tegaderm™ Antimicrobial Transparent Dressing and 3M™ Tegaderm™ Antimicrobial I.V. Advanced Securement Dressing consists of a polyurethane film coated with a transparent chlorhexidine gluconate (CHG) acrylic adhesive. CHG, a broad

spectrum antimicrobial/antifungal agent known to inhibit microbial growth has been formulated into the acrylic adhesive.

The transparent film is breathable, allowing oxygen and moisture vapor exchange, yet is impermeable to external contaminants, including fluids (waterproof), bacteria, viruses* and yeast. The dressing must remain intact to protect the IV site from external contaminants.

3M™ Tegaderm™ Antimicrobial I.V. Advanced Securement Dressing is bordered, notched and reinforced with soft cloth tape and is designed to provide securement around catheters and other devices.

In vitro testing (time kill) demonstrates that the 3M™ Tegaderm™ Antimicrobial Transparent Dressing and 3M™ Tegaderm™ Antimicrobial I.V. Advanced Securement Dressing has an antimicrobial effect against a variety of gram-positive bacteria, gram-negative bacteria, yeast and mold in the dressing.

**In vitro* testing shows that the film of the dressing provides a barrier to viruses 27 nm in diameter or larger while the dressing remains intact without leakage. These results have not been studied with regard to prevention of viral infection. No clinical study has been conducted regarding the ability of the dressing to prevent viral infections.

V. INDICATIONS FOR USE

3M™ Tegaderm™ Antimicrobial Transparent Dressing and 3M™ Tegaderm™ Antimicrobial I.V. Advanced Securement Dressing is intended to be used to cover and protect catheter sites and to secure devices to the skin. Common applications include covering and securing IV catheters, other intravascular catheters and percutaneous devices.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The technological principle for the subject device and the predicate device, BD ChloraShield™ I.V. Dressing with CHG Antimicrobial, are that they are both transparent dressings containing chlorhexidine gluconate (CHG) in the adhesive. They are both intended to cover and protect catheter sites and secure devices to the skin.

The subject device and predicate device have similar technological elements which include:

- Operational principle
- Device is transparent
- Device is provided with an adhesive containing Chlorhexidine Gluconate (CHG)
- Device is breathable
- Device is conformable
- Device is waterproof
- Device is a barrier to viruses

The minor differences do not raise different questions of safety and effectiveness. The following technological differences exist between the subject device and the predicate device:

- Sterilization method
- Concentration of CHG
- Absorption

VII. PERFORMANCE DATA

The following performance data is provided in support of the substantial equivalence determination.

Biocompatibility Testing

The biocompatibility evaluation for 3M™ Tegaderm™ Antimicrobial Transparent Dressing and 3M™ Tegaderm™ Antimicrobial I.V. Advanced Securement Dressing was conducted in accordance with International Organization for Standardization ISO-10993, Biological Evaluation of Medical Devices and FDA's guidance, *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*, issued June 16, 2016. 3M™ Tegaderm™ Antimicrobial Transparent Dressing and 3M™ Tegaderm™ Antimicrobial I.V. Advanced Securement Dressing are characterized as a surface contacting device for use on breached or compromised skin for prolonged duration (less than 30 days). The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Pyrogenicity

- Acute System Toxicity and Subacute/Subchronic Toxicity
- Implantation

Bench Testing

Bench testing for 3M™ Tegaderm™ Antimicrobial Transparent Dressing was conducted in support of substantial equivalence to the predicate devices. The bench testing included the following tests:

- Tensile and Elongation*
- Moisture Vapor Transmission Rate*
- Waterproof*
- Amount of CHG within the device throughout the use life through Release Kinetics*
- Barrier Performance
- Antimicrobial activity spectrum (Time kill)*

*Studies conducted in comparison with the predicate device.

Clinical Study

A randomized, controlled, open-label study on 24 healthy subjects was conducted to assess wear performance at three (3) and seven (7) days with the subject device and the predicate device, BD ChloraShield™ I.V. Dressing with CHG Antimicrobial. A Mixed Model ANOVA was used to analyze wear/lift of the dressing. At 72 hours (3 days), all dressings remained on the arms for both the subject and predicate device. At 168 hours (7 days), the subject device remained on the arms and three of the predicate devices had been removed due to excess lift <168 hours. The lift of the subject device was substantially equivalent to the predicate device at both the 72 and 168 hour time points. The study demonstrated that the subject device secured catheters for seven days.

VIII. CONCLUSIONS

The Indications for Use statement for the subject device, 3M™ Tegaderm™ Antimicrobial Transparent Dressing and 3M™ Tegaderm™ Antimicrobial I.V. Advanced Securement Dressing, is the identical to the predicate device, BD ChloraShield™ I.V. Dressing with CHG Antimicrobial (K113836). Both the subject device and predicate device have the same intended use to cover and protect catheter sites and to secure devices to the skin.

3M™ Tegaderm™ Antimicrobial Transparent Dressing and 3M™ Tegaderm™ Antimicrobial I.V. Advanced Securement Dressing is composed of similar components and the differences in technology do not raise new questions of safety and effectiveness.

Performance data provided demonstrates performance and safety of the subject device is substantially equivalent to the predicate device, BD ChloraShield™ I.V. Dressing with CHG Antimicrobial (K113836).