September 4, 2020

3M Company
Hilary Hovde
Regulatory Affairs Specialist
Bldg. 275-5W-06
St. Paul, Minnesota 55144

Re: K200835
Trade/Device Name: 3M Tegaderm CHG Chlorhexidine Gluconate Gel Pad
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 1, 2020
Received: April 29, 2020

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,

Anjana Jain, Ph.D.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200835

Device Name
3M™ Tegaderm™ CHG Chlorhexidine Gluconate Gel Pad

Indications for Use *(Describe)*
The 3M™ Tegaderm™ CHG Chlorhexidine Gluconate Gel Pad can be used to cover and protect catheter sites. Common applications include covering 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.

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510(k) Summary for
3M™ Tegaderm™ CHG Chlorhexidine Gluconate Gel Pad

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3M Health Care
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Contact: Hilary B. Hovde
Regulatory Affairs Specialist
Phone Number: (651) 736-0364
FAX Number: (651) 737-5320

Preparation Date: September 1, 2020

TRADITIONAL PREMARKET NOTIFICATION [510(k)]
3M™ Tegaderm™ CHG Chlorhexidine Gluconate Gel Pad

Device Name and Classification

Trade Name:	3M™ Tegaderm™ CHG Chlorhexidine Gluconate Gel Pad
Common/Usual Name:	Dressing, Wound, Drug
Device Classification:	Unclassified
Product Code:	FRO

Predicate Device

3M™ Tegaderm™ CHG Chlorhexidine Gluconate I.V. Port Dressing, K123679

Reference Device

BIOPATCH® Antimicrobial Dressing, K003229

Indications for Use

The 3M™ Tegaderm™ CHG Chlorhexidine Gluconate Gel Pad can be used to cover and protect catheter sites. Common applications include covering intravascular catheters and percutaneous devices.

Description of Device

The 3M™ Tegaderm™ CHG Chlorhexidine Gluconate (CHG Gel Pad) is used to cover and protect vascular and non-vascular percutaneous medical devices. The CHG Gel Pad is breathable and transparent, allowing continuous site observation.

The CHG Gel Pad contains 2% w/w Chlorhexidine Gluconate (CHG), an antiseptic agent with broad spectrum antimicrobial and antifungal activity. The CHG Gel Pad absorbs fluid.
In vitro testing (log reduction) demonstrates that the CHG Gel Pad has an antimicrobial effect against a variety of gram-positive and gram-negative bacteria, mold, and yeast.

Comparison of Technological Characteristics with the Predicate and Reference Devices

The predicate device, 3M™ Tegaderm™ CHG Chlorhexidine Gluconate I.V. Port Dressing, K123679, contains the identical CHG Gel Pad and a cover dressing whereas the subject device contains only the CHG Gel Pad which may be used with or without a cover dressing.
The CHG Gel Pad is identical to the predicate device gel pad, therefore both devices are transparent, breathable, absorbent, and contain Chlorhexidine gluconate (CHG). Both devices are intended to cover and protect catheter sites and other percutaneous devices. Although the

subject standalone CHG Gel Pad does adhere, it is not intended to provide securement and may be used with or without a cover dressing.

Substantial Equivalence and Summary of Studies

The difference between the subject and predicate device has been evaluated through performance and biocompatibility tests to provide evidence of substantial equivalence for the 3M™ Tegaderm™ CHG Chlorhexidine Gluconate Gel Pad.

The device substantial equivalence was verified through the following tests:

- *in vitro* Direct Time Kill
- Absorption
- Moisture Vapor Transmission Rate

The 3M™ Tegaderm™ CHG Chlorhexidine Gluconate Gel Pad is categorized as a surface contacting device, with breached or compromised skin contact of prolonged 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 biocompatibility data from predicate device, K123679, were provided in the current submission to address biocompatibility.

Conclusion

Based on the intended use, technological characteristics, performance data, and non-clinical tests performed, the subject device is substantially equivalent to the 3M™ Tegaderm™ CHG Chlorhexidine Gluconate I.V. Port Dressing (cleared under K123679), Unclassified, product code FRO and does not raise new questions of safety or effectiveness.