K123679
p 1/2

FEB 28 2013

008_510k SUMMARY

Sponsor Information:

Applicant Name:	3M Company 3M Health Care Skin and Wound Care Division 3M Center 2510 Conway Ave., Bldg. 275-5W-06 St. Paul, Minnesota 55144
Contact Person:	Joann Huehn Regulatory Affairs
Phone Number:	651-733-9209
Fax Number:	651-737-5320
Email:	jlhuehn1@mmm.com

Date Prepared: November 29, 2012

Device Name and Classification:

Trade Name:	3M™ Tegaderm™ CHG Chlorhexidine Gluconate I.V. Port Dressing
Common or Usual Name:	I.V. Dressing with CHG
Classification Name:	Unclassified
Product Code:	FRO
Performance Standards:	Not Applicable
Predicate Device:	3M™ Tegaderm™ CHG Dressing (Chlorhexidine Gluconate Securement Dressing)

Description of Device:

3M™ Tegaderm™ CHG Chlorhexidine Gluconate I.V. Port Dressing is used to cover and protect vascular access sites and to secure devices to the skin. The Chlorhexidine Gluconate I.V. Port Dressing is a two part system consisting of a bordered, transparent film cover dressing with an adhesive free window and an antimicrobial CHG Gel Device. The Chlorhexidine Gluconate I.V. Port Dressing is breathable and transparent, allowing continuous site observation.

K123679
p2/2

The cover dressing provides an effective barrier against external contamination including fluids (waterproof), bacteria, and yeast.

The CHG gel pad device consists of an integrated gel pad containing 2% w/w Chlorhexidine Gluconate (CHG), an antiseptic agent with broad spectrum antimicrobial and antifungal activity. The gel absorbs fluid.

In vitro testing (time kill and zone of inhibition) demonstrates that the gel pad in the device has an antimicrobial effect against a variety gram-positive and gram-negative bacteria and yeast.

Indications for Use:

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

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

Tegaderm™ CHG Chlorhexidine Gluconate I.V. Port Dressing is substantially equivalent to the predicate device, Tegaderm™ CHG Dressing (Chlorhexidine Gluconate Securement Dressing), cleared under K063458.

The Tegaderm™ CHG Chlorhexidine Gluconate I.V. Port Dressing is composed of the same or similar components, has same or similar performance, intended use and indications for use as the predicate device.

Non-Clinical Performance Data:
Bench testing was collected to demonstrate substantial equivalence for this submission.

Clinical Performance Data:
Clinical information previously provided supports the subject device, therefore, no additional clinical information was determined to be needed.

Non-Clinical and Clinical Conclusion:
Tegaderm™ CHG Chlorhexidine Gluconate I.V. Port Dressing is safe for human use and acceptable for its intended use.

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

3M Company
% Ms. Joann Huehn
Regulatory Affairs
3M Center, 2510 Conway Avenue, Building 275-5W-06
St. Paul, Minnesota 55144

Letter dated: February 28, 2013

Re: K123679
Trade/Device Name: 3M™ Tegaderm™ CHG Chlorhexidine Gluconate I.V. Port Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 29, 2012
Received: November 30, 2012

Dear Ms. Huehn:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

007_INDICATION FOR USE STATEMENT

510(k) Number (if known): To be Assigned

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

Indications for Use:

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

Prescription Use____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N. Melkerson -S
2013.02.28 13:26:08 -05'00'

(Division Sign-Off)
Division of Surgical Devices
510(k) Number ___K123679_____