K110457

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DEC - 7 2011

510(K) SUMMARY

Sponsor Information:

Applicant Name:	3M Health Care 3M Center, Bldg 275-5W-06 St. Paul, MN 55144-1000
Contact Person:	Maria Ruiz Regulatory Affairs
Phone Number:	651-736-2733
Fax Number:	651-737-5320
Date Prepared:	February 16, 2011

Device Name and Classification:

Common or Usual Name:	Impregnated Wound Dressing
Trade Name:	Tegaderm™ Matrix Dressing
Classification Name:	Unclassified
Product Code:	FRO
Performance Standards:	Not applicable.
Predicate Device:	Epi-Max® Wound Dressing, K041059

Description of Device:
3M™ Tegaderm™ Matrix Dressing is a sterile cellulose acetate wound dressing impregnated with a low pH ointment containing 1.93% w/w potassium citrate, 0.008% w/w rubidium chloride, 0.0005% w/w calcium chloride, and 0.0002% w/w zinc chloride to constitute a saline solution that provides a moist environment. A moist environment is known to be conducive to wound healing. This dressing is permeable to both air and wound exudates.

Dressings are gamma irradiated for sterility.

Indications for Use:
Tegaderm™ Matrix dressing is intended for use on chronic, partial thickness wounds including: pressure ulcers, venous stasis ulcers and diabetic ulcers. It can also be used on skin irritations, cuts and abrasions.

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

Tegaderm™ Matrix dressing is substantially equivalent to the predicate device, Epi-Max® Wound Dressing, cleared under K041059, May 17, 2005.

Tegaderm™ Matrix dressing is similar in intended use, indications for use, composition, physical properties and technological characteristics as the predicate device, Epi-Max® Wound Dressing.

Non-Clinical Performance Data
Tegaderm™ Matrix dressing has been tested per ISO 10993-1 and determined to be safe for the intended use.

Clinical Performance Data
N/A

Non-Clinical and Clinical Conclusion
Tegaderm™ Matrix 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 Room - WO66-G609
Silver Spring, MD 20993-0002

3M Company
% Ms. Maria Ruiz
Regulatory Affairs Specialist
3M Center, Building 275-5W-06
Saint Paul, Minnesota 54144-1000

JAN - 4 2012

Re: K110457
Trade/Device Name: 3M™ Tegaderm™ Matrix Dressing
Regulation Name: Unclassified
Product Code: FRO
Dated: December 7, 2011
Received: December 7, 2011

Dear Ms. Ruiz:

This letter corrects our substantially equivalent letter of December 7, 2011.

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 (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.

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,

For

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

Enclosure

Attachment 3.

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K110457

Device Name: 3M ™ Tegaderm™ Matrix Dressing

Indications for Use:

3M™ Tegaderm™ Matrix dressing is intended for use on chronic, partial thickness wounds and full thickness wounds including: pressure ulcers, venous stasis ulcers and diabetic ulcers. It can also be used on skin irritations, cuts and abrasions.

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)

David Krueger for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K110457