K061554
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510(k) SUMMARY

Applicant:

Mölnlycke Health Care
5550 Peachtree Parkway
Suite 500
Norcross, GA 30092

Contact Person:

Steven Dowdley
Director of Regulatory Affairs
Tel.: 678-250-7930
Fax: 678-250-7992

JAN 25 2007

Device Name:

Proprietary Name:	Mepilex Ag Absorbent Silicone-Coated Dressing
Common/Usual Name:	Silver Dressing
Device Classification:	Unclassified

Substantial Equivalence:
The Mepilex Ag is substantially equivalent in composition, function and "indications for use" to the Contreet Foam Dressings and the 3M Tegaderm Silver Nonwoven Dressing. In addition, Mepilex Ag is substantially equivalent in design to the currently marketed Mepilex Absorbent Silicone-Coated Dressing.

Intended Use:
Mepelix Ag Dressing is indicated for the management of low to moderately exuding wounds such as leg and foot ulcers, pressure ulcers and partial thickness burns. Silver sulphate present in the dressing helps reduce microbial colonization on the dressing.

Description:
Mepilex Ag is an anti-microbial, absorbent soft silicone dressing consisting of a flexible, absorbent polyurethane foam pad with added silver and activated charcoal, which is coated with a silicone wound contact layer and a wrinkled water vapor permeable polyurethane film backing. The silicone layer is covered with a polyethylene release film.

Summary of Biocompatibility Testing:
Using the FDA-modified matrix, Mepilex Ag is a surface device which is used on breached or compromised surfaces and may be used for up to several days depending on the condition of the wound. Therefore, the Mepilex Ag was tested for cytotoxicity, sensitization and irritation and was found to be non-cytotoxic, non-irritating and non-sensitizing.

Summary of Testing for Anti-microbial Properties

- The Mepilex Ag has been shown to provide a barrier against microbial contamination and inactivates a wide range of bacteria and fungi during a 24 hour period as shown in-vitro in the Corrected Zone of Inhibition (CZOI) test method.
- Mepilex Ag has also been shown to inactivate representative bacteria up to 7 days, as shown *in vitro* in CZOI.
- Mepilex Ag has also been shown to inactivate bacteria within 30 hours, as shown *in vitro* in Shake flask method ASTM E2141-01.

Based on the test results, Mepilex Ag has demonstrated effective anti-microbial properties by providing an anti-microbial barrier and an anti-microbial effect within and under the dressing. The Mepilex Ag has demonstrated a sustained release of silver Ions for up to 7 days.

Conclusion:
The date provided in this 510(k) summary concludes that Mepilex Ag Absorbent Silicone-Coated Dressing is substantially equivalent to Mepilex Absorbent Silicone-Coated Dressing, Contreet Foam Dressing and the 3M Tegaderm Silver Non-woven Dressing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mölnlycke Health Care
% Mr. Steven Dowdleyt
5550 Peachtree Parkway, Suite 500
Norcross, Georgia 30092

JAN 25 2007

Re: K061554
Trade/Device Name: Mepilex® Ag Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: December 20, 2006
Received: December 21, 2006

Dear Mr. Dowdlevt:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

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

Enclosure

Section 3: Indications for Use Statement

PREMARKET NOTIFICATION

Indications for Use

510(k) Number (if known): K061554

Device Name: Mepilex® Ag Dressing

Indications for Use:

Mepelix Ag Dressing is indicated for the management of low to moderately exuding wounds such as leg and foot ulcers, pressure ulcers and partial thickness burns. Silver sulphate present in the dressing helps reduce microbial colonization on the dressing.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061554