

K983184

OCT 28 1998

510(k) SUMMARY

**Applicant:** Mölnlycke Health Care, Inc.  
500 Baldwin Tower  
Eddystone, PA 19022

**Proprietary Name:** Mepilex™

**Contact Person:** Miguel A. Negron, Manager, Regulatory Affairs & Quality  
Tel. 610-499-3383

**Substantially  
Equivalent Device:** Cutinova® Foam Dressing (Beiersdorf AG)

The Mepilex is a sterile, absorbent silicone-coated dressing designed for a wide range of shallow wounds, which have low to moderate levels of exudate, e.g., leg ulcers, pressure ulcers and skin lesions.

Mepilex is substantially equivalent in composition, function and intended use to the Beiersdorf AG Cutinova® Foam Dressing.

Mepilex have been found to be non-toxic and non-irritating when tested by the above biological tests in accordance with the ISO 10993 Part I, "Biological Evaluation of Medical Devices" with FDA modified matrix (Guidance effective July 1, 1995).



OCT 28 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Miguel A. Negrón  
Manager, Regulatory Affairs & Quality  
Molnlycke Health Care, Inc.  
500 Baldwin Tower  
Eddystone, Pennsylvania 19022

Re: K983184  
Trade Name: Mepilex™  
Regulatory Class: Unclassified  
Product Code: MGP  
Dated: September 10, 1998  
Received: September 11, 1998

Dear Mr. Negrón:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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 (the Act). You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. This device may not be labeled for use on third degree burns.
2. This device may not be labeled as having any accelerating effect on the rate of wound healing or epithelization.
3. This device may not be labeled as a long-term, permanent, or no-change dressing, or as an artificial (synthetic) skin.
4. This device may not be labeled as a treatment or a cure for any type of wound.

The labeling claims listed above would be considered a major modification in the intended use of the device and would require a premarket notification submission (21 CFR 807.81).

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against

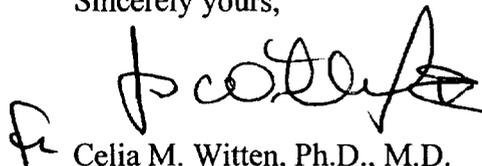
misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) for Medical Devices: General GMP regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or 301-443-6597 or at its internet address <http://www.fda.gov/cdrh/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'C. Witten', is written over a faint circular stamp. The signature is fluid and cursive.

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Section 8: Indications for Use Statement**

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**PREMARKET NOTIFICATION**

**INDICATIONS FOR USE STATEMENT**

**510(k) Number:** Unassigned K983184

Mölnlycke Health Care

**Device Name:** Mepilex™

**Indications for Use:**

Mepilex is designed for a wide range of shallow wounds, which have low to moderate levels of exudate, e.g., leg ulcers, pressure ulcers and skin lesions.

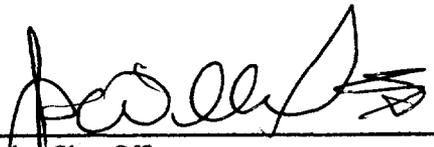
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

Or Over-The-Counter Use

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K983184

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**Premarket Notification: Mepilex™**

**Mölnlycke Health Care**