

3/3/99

K984371

510(k) SUMMARY

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

Proprietary Name: Mepitel® Non Adherent Silicone Dressing

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

**Substantially
Equivalent Device:** Mepitel® Non Adherent Silicone Dressing

Mepitel® Non Adherent Silicone Dressing is intended for the management of wounds in the granulation phase, especially painful wounds and wounds with newly formed delicate tissue such as pressure ulcers, venous and arterial leg ulcers, diabetic ulcers, surgical incisions, second degree burns, skin abrasions, lacerations, partial and full thickness grafts, and skin tears.

Mepitel is a sterile wound dressing which consists of three components: a medical grade silicone gel, a polyamide tricot net, and a low density polyethylene protective release liner. Mepitel® Non Adherent Silicone Dressing is substantially equivalent in composition, function and intended use to the Mölnlycke Health Care's own Mepitel® Non Adherent Silicone Dressing placed in commercial distribution pursuant to 510(k) notification number K914604.

The dressing is delivered sterile in single packs and is available in the following sizes: 2" x 3" (5 cm x 7.5 cm); 3" x 4" (7.5 cm x 10 cm); 4" x 8" (10 cm x 18 cm); and 9" x 12" (20 cm x 30 cm).

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



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 3 1999

Mr. Miguel A. Negron
Molnlycke Health Care
500 Baldwin Tower
Eddystone, Pennsylvania 19022

Re: K984371
Trade Name: Mepitel Non-Adherent Silicone Dressing
Regulatory Class: Unclassified
Product Code: MGP
Dated: December 4, 1998
Received: December 7, 1998

Dear Mr. Negron:

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 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). You may, therefore, market the device, subject to the general controls provisions of the 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.

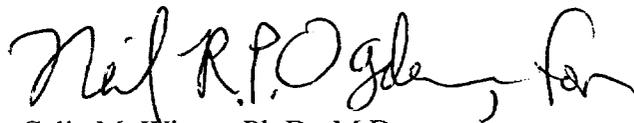
The labeling claims listed above would be considered a major modification in the intended use of the device and would require a premarket notification submission (21 CFR 807.81). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, 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, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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/dsma/dsmamain.html>".

Sincerely yours,



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

K984371

Section 9: Indications for Use Statement

**PREMARKET NOTIFICATION
INDICATIONS FOR USE STATEMENT**

510(k) Number: K984371

Mölnlycke Health Care

Device Name: Mepitel® Non Adherent Silicone Dressing

Indications for Use:

Mepitel is intended for the management of wounds in the granulation phase, especially painful wounds and wounds with newly formed delicate tissue such as pressure ulcers, venous and arterial leg ulcers, diabetic ulcers, surgical incisions, second degree burns, skin abrasions, lacerations, partial and full thickness grafts, and skin tears.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

MRO

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984371

Prescription Use X
(Per 21 CFR 801.109)

Or

Over-The-Counter Use _____