

K 974354

MAR - 5 1998

510(k) SUMMARY

Proprietary Name: Mepiform

Common Name: Adherent Silicone Dressing for Scar Care

Classification: Unclassified

Submitter: SCA Mölnlycke
500 Baldwin Tower
Eddystone, PA 19022

Contact Person: Miguel A. Negrón
Tel. 610-499-3383
Fax. 610-499-3396

Predicate Device: Smith & Nephew Cica-Care™ Adhesive Gel Sheet

Description:

The Mepiform Adherent Silicone Dressing for Scar Care consists of a silicone coated nonwoven bonded to an adhesive thermoplastic polyurethane film. The silicone dressing is protected by a low density polyethylene release film.

The Mepiform dressing is individually sealed in a medical grade paper pouches and packaged in cartons of five (5) pouches each. The Mepiform dressings are available in two sizes: 5 cm x 7.5 cm (2" x 3") and 10 cm x 18 cm (4" x 7").

Mepiform Adherent Silicone Dressing for Scar Care is intended for the management of both old and new hypertrophic and keloid scars. It can also be used as a prophylactic therapy on close wounds which may prevent hypertrophic or keloid scarring.

Mepiform Adherent Silicone Dressing for Scar Care have been shown in laboratory tests to be nontoxic, nonirritant, and nonsensitizing.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Miguel A. Negrón
Manager,
Regulatory Affairs & Quality Assurance
North America
SCA Molnlycke
500 Baldwin Tower
Eddystone, Pennsylvania 19022

MAR - 5 1998

Re: K974354
Trade Name: Mepiform Adherent Silicone Dressing for
Scar Care
Regulatory Class: Unclassified
Product Code: MDA
Dated: February 18, 1998
Received: February 19, 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 (Act). 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.

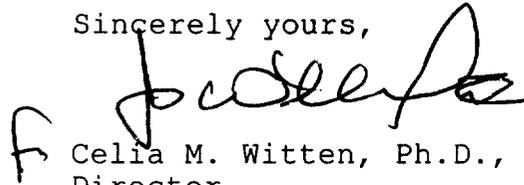
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, 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 pre-market 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.

Page 2 - Mr. Negron

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,



f 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

K974354

PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

510(k) Number: K974354
SCA Mölnlycke

Device Name: Mepiform Adherent Silicone Dressing for Scar Care

Indications for Use:

Mepiform Adherent Silicone Dressing is intended for the management of both old and new hypertrophic and keloid scars. It can also be used as a prophylactic therapy on closed wounds which may prevent hypertrophic or keloid scarring.

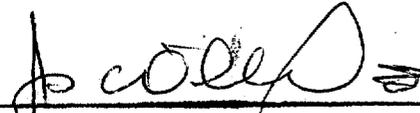
(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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 _____

K974354