

MAY 27 1999

K990875

510(k) Dermaphylyx Film Wound Dressing
Dermaphylyx, Inc.

510(k) Summary

Proprietary Name: Dermaphylyx Film Wound Dressing
Common Name: Dressing
Classification: Unclassified
Submitter's Details: Dermaphylyx, Inc.
78-E, Olympia Avenue,
Woburn, MA 01801-2057
Tel: (781) 933-4772
Fax: (781) 933-3933

Description:

Dermaphylyx Film Wound Dressings are self-adhesive and semi-occlusive.

The wound contact surface is composed of a porous adhesive. A second layer consists of a polyurethane film. The product provides a barrier to exogenous water and dirt while maintaining breathability.

Dermaphylyx Film Wound Dressings are intended for use in the management of partial and full-thickness wounds in both a professional and OTC environment. They may be used on the following wounds:

Dermal Ulcers
Donor Sites
Incisions

Superficial Burns
Abrasions and lacerations
IV Catheter Sites

Over the Counter applications include abrasions, minor cuts, minor lacerations, as well as minor burns and blisters.

Dermaphylyx Film Wound Dressings are substantially equivalent to SpyroFilm® (a.k.a. SpyroDerm®) and Mitrasheer™ Wound Dressings (Innovative Technologies US, Inc.). These devices are self-adhesive polyurethane film wound dressings, which provide a degree breathability. They are intended for use in the management of a wide variety of wounds.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 1999

Andrew M. Reed, Ph.D.
Principal
Dermaphylyx, Inc.
12106 West 75th Lane
Arvada, Colorado 80005

Re: K990875
Trade Name: Film Wound Dressing
Regulatory Class: Unclassified
Product Code: MGP
Dated: March 12, 1999
Received: March 16, 1999

Dear Dr. Reed:

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).

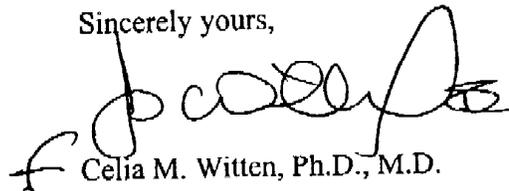
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

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,



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

PREMARKET NOTIFICATION
INDICATIONS FOR USE STATEMENT

510(k) Number: K 990875
Dermaphylyx, Inc.

Device Name: Dermaphylyx Film Wound Dressings

Indications for Use:

Dermaphylyx Film Wound Dressings are self-adhesive and semi-occlusive. They are intended for use in the management of a variety of partial and full-thickness wounds.

The following Indications are for Prescription Use or under the direction of a health care professional:

Dermal Ulcers
Donor Sites
Incisions

Superficial Burns
Abrasions and lacerations
IV Catheter Sites

The following Indications are for Over-the-Counter Use:

Abrasions
Minor Burns
Minor Cuts
Minor Lacerations
Blisters
As a Cover for gauze and gel bandages.

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

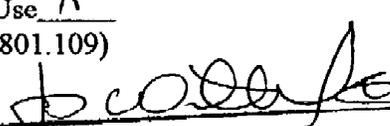
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

(Optional Format 1-2-96)


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

K990875