AUG 12

K991920

510(k), K991920, Dermaphylyx Hydrophilic Foam Wound Dressing
Dermaphylyx, Inc.

510(k) Summary

Proprietary Name: Dermaphylyx Hydrophilic Foam 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 Hydrophilic Foam Wound Dressings are sterile, and absorptive.

Dermaphylyx Hydrophilic Foam Wound Dressing is composed of a hydrophilic polyurethane foam. The product provides absorptive qualities to assist in the management of wound drainage.

Dermaphylyx Hydrophilic Foam 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:

- Venous stasis ulcers
- Diabetic ulcers
- Pressure sores
- Donor sites
- Burns, (superficial).
- Abrasions and laccrations
- Incisions

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

Dermaphylyx Hydrophilic Foam Wound Dressings are substantially equivalent to Spyrofoam®Wound Dressings (Innovative Technologies US, Inc.), and Hydrasorb® Sterile Dressings (ConvaTec/Calgon Vestal Laboratories).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 12 1999

Andrew M. Reed, Ph.D.
Principal
Dermaphylyx, Inc.
12106 West 75th Lane
Arvada, Colorado 80005-5306

Re: K991920
Trade Name: Hydrophilic Foam Wound Dressing
Regulatory Class: Unclassified
Product Code: KMF
Dated: June 4, 1999
Received: June 7, 1999

Dear Dr. Reed:

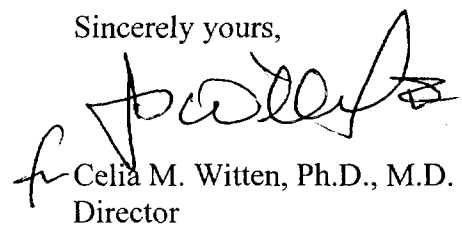
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (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 (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 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 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

K991920

510(k), K991920, Dermaphylyx Hydrophilic Foam Wound Dressing
Dermaphylyx, Inc.

PRE-MARKET NOTIFICATION
INDICATIONS FOR USE STATEMENT

510(k) Number: K991920
Dermaphylyx, Inc.

Device Name: Dermaphylyx Hydrophilic Foam Wound Dressing

Indications for Use:

Dermaphylyx Hydrophilic Foam Dressing Foam Wound Dressings provide a degree of exudate absorption. They are intended for use in the management of partial and full-thickness wounds.

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

- Venous stasis ulcers
- Diabetic ulcers
- Pressure sores
- Donor sites
- Burns, (superficial)
- Abrasions and lacerations
- Incisions

Additionally Fenestrated dressings are intended for use in the management of surgically induced drainage sites such as:

G-tubes, J-tubes, Penrose drains, chest tubes, nephrotomy tubes, and sump drains.

The following indications for use are for Over-the-Counter Use:

- Minor Burns
- Minor cuts
- Minor abrasions
- Minor lacerations

(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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991920