JUL 20 1999

K991609

510(k) Dermaphylyx Absorbent Fiber Wound Dressing
K991609, Dermaphylyx, Inc.

510(k) Summary

Proprietary Name: Dermaphylyx Absorbent Fiber 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 Absorbent Fiber Wound Dressings are soft, non-woven, and absorptive. The Dressings consist of Absorbent fibers fabricated into a felt or rope configuration.

Dermaphylyx Absorbent Fiber Wound Dressings are engineered to absorb substantial quantities of wound exudate. During the absorption of exudate the dressing forms a fiber mat which provides an environment conducive to moist wound healing. The formation of the fiber mat facilitates trauma free removal from the wound.

Dermaphylyx Absorbent Fiber 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:

Venous ulcers	Superficial burns
Diabetic ulcers	Abrasions and lacerations
Pressure ulcers	Donor sites
Arterial ulcers	Incisions

Dermaphylyx Absorbent Fiber Wound Dressings may also be used to control minor bleeding.

Over the Counter applications include abrasions, minor cuts, minor lacerations, as well as minor burns and the control of minor bleeding by application of pressure to the wound.

Dermaphylyx Absorbent Fiber Wound Dressings are substantially equivalent to Aquacel™ Hydrofiber™ Wound Dressings (Convatec), and Kaltostat® Wound Dressings (Calgon Vestal Laboratories). These devices are absorptive Wound Dressings, manufactured from Absorbent fibers. They are intended for use in the management of a wide variety of wounds.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 20 1999

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

Re: K991609
Trade Name: Absorbent Fiber Wound Dressing
Regulatory Class: Unclassified
Product Code: KMF
Dated: May 6, 1999
Received: May 10, 1999

Dear Dr. Reed:

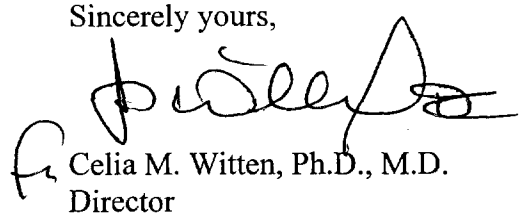
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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

K991609

PREMARKET NOTIFICATION
INDICATIONS FOR USE STATEMENT

510(k) Number: K991609
Dermaphylyx, Inc.

Device Name: Dermaphylyx Absorbent Fiber Wound Dressing

Indications for Use:

Dermaphylyx Absorbent Fiber Wound Dressings are soft, non-woven, and absorptive. They are intended for use in the management of a variety of partial and full-thickness wounds. The dressings are additionally intended to help control minor bleeding by application of pressure to the wound.

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

- Venous ulcers
- Diabetic ulcers
- Pressure ulcers
- Arterial ulcers
- Superficial burns
- Abrasions and lacerations
- Donor sites
- Incisions

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

- Abrasions
- Minor Burns
- Minor Cuts
- 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 X

(Optional Format 1-2-96)

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(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991609