

MAY 18 1999

K990955

5:3

**BIODERM, INC.****510(k) SUMMARY PER 807.92**

CONFIDENTIAL

**(a) (1)**

**Submitters Name:** George Worthley  
**Submitters Address:** PO Box 4882  
Wheaton, Illinois 60189  
**Submitters Phone:** (630) 590-8339  
**Contact Person:** George Worthley  
**Date Prepared:** May 7, 1999

**(a) (2)**

**Device Trade Name:** Bioderm Foam Wound Dressing  
**Device Common Name:** Wound Dressing  
**Classification Name:** 79 FRO Dressing

**(a) (3)**

**Predicate Device:** Hydrasorb (K976230)

**(a) (4)**

**Device Description:** The device has not changed from those approved under Bioderm, Inc. K982778 and consist of square, hydrophilic foam pads for wound care and square foam pads with a slit to fit around tracheostomy or gastrostomy tubes. The device provides a means to absorb exudate from draining wounds.

**(a) (5)**

**Revised Indications for Use Statement**

**520(k): K990955**

**Device Name:** Bioderm Foam Wound Dressing

**Indications for Use:**

The Bioderm, Inc. foam dressing is an external wound dressing designed to help maintain a moist healing environment, manage exudate, and protect the wound from contamination. The dressing is indicated for the management of the following types of wounds:

Partial and full-thickness wounds, moderate to heavily exudating wounds such as; lower extremity ulcers including; venous stasis ulcers, arterial ulcers, or mixed etiology (venous & arterial) and post surgical incisions, pressure sores, and diabetic foot ulcers.

Partial thickness wounds such as; donor sites, abrasions, lacerations, and superficial burns.

Other indications include; a drainage dressing for tracheostomy, G-tube, J-tube, Penrose drain, chest tube, or sump drain, as well as a secondary or cover dressing for packed wounds.

(1.)

3.3

**SUMMARY (CONTINUED)**

(a) (6)

**Technological Characteristics:** This device has the same design, material, and chemical composition as the predicate device indicated in paragraph (a) (3) above.

(b) (1):

**Nonclinical Testing:**

**Test Article: Hydrophilic Polyurethane Foam HPF-L0562 & L0562-6  
(Formerly Coded HPF/L62)**

**Sponsor: Rynel Ltd. Inc., Boothbay, Maine**

**Test Facility: Toxicon Laboratories**

**Primary Skin Irritation**

The test article, HPF-L0562, was tested for its potential to produce primary dermal irritation after a single topical 24 hour application to the skin of albino rabbits. The test article is considered a non-irritant.

**Kligman Maximization Study (Sodium Chloride Extract)**

Based on the standards set by the study protocol, HPF-L0562, exhibited no reaction to the challenge (0% sensitization). Therefore, as defined by the scoring system of Kligman, this is a Grade I reaction and the test article is classified as having a weak allergic potential. A Grade I sensitization rate is not considered significant according to Magnusson and Kligman (1969, 1970).

**Systemic Injection Test**

This test is considered negative based on standards set by the study protocol. The extract of the test article, HPF/L62, did not show a significantly greater biological reaction than the control extract, when tested in albino Swiss mice.

**14 Day Repeated Intravenous Toxicity Study-Subchronic**

The results indicate that the test article, HPF-L0562, is not toxic according to the procedure described in the study protocol when administered by the intravenous injection each weekday (5 days/week) for 14 days. The lack of toxicity was based upon clinical observations and histopathological assessment of selected tissue.

**Cytotoxicity-Agar Diffusion Test**

No biological reactivity (Grade 0) was observed in the L929 mammalian cells by 48 hours post exposure to the test article. The observed cellular response obtained from the positive control article (Grade 4) and the negative (Grade 0) confirmed the suitability of the test system. The test article is considered non-cytotoxic and meets the requirements of the Agar Diffusion Test, USP XXIII.

**Hemolysis-Rabbit Blood**

The test article, HPF/L62, is considered non-hemolytic at 0.12% Hemolysis, under the experimental conditions employed.



MAY 18 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. George Worthley  
President  
Bioderm, Inc.  
P.O. Box 4882  
Wheaton, Illinois 60189

Re: K990955  
Trade Name: Foam Wound Dressing  
Regulatory Class: Unclassified  
Product Code: KMF  
Dated: March 16, 1999  
Received: March 22, 1999

Dear Mr. Worthley:

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).

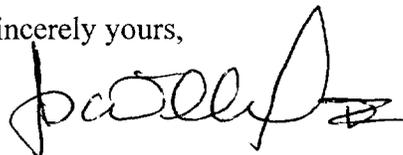
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

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,

  
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

Bioderm, Inc.

Attachment # 1.

5/11/99

**Revised Indications for Use Statement**

510(k) Number (if known): K990955

Device Name: Bioderm Foam Wound Dressing

**Indications for Use:**

The Bioderm, Inc. foam dressing is an external wound dressing designed to help maintain a moist healing environment, manage exudate, and protect the wound from contamination. The dressing is indicated for the local management of the following types of wounds:

Partial and full-thickness wounds, moderate to heavily exudating wounds such as; lower extremity ulcers including; venous stasis ulcers, arterial ulcers, or mixed etiology (venous & arterial) and post surgical incisions, pressure sores and diabetic foot ulcers.

Partial thickness wounds such as; donor sites, abrasions, lacerations, superficial burns,

Other indications include; a drainage dressing for tracheostomy, G-tube, J-tub, Penrose drain, chest tube, or sump drain, as well as a secondary or cover dressing for packed wounds.

(DO NOT WRITE BELOW THIS LINE-USE ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  (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 K990955