

AUG 19 1999

K992032**Summary of Safety and Effectiveness**

**Contact Person:** Dr. Bruce L. Gibbins, Chairman & Chief Technical Officer  
**Date of preparation:** June 11, 1999  
**Device Name (proprietary):** AcryDerm® Island Border Dressing  
**Common Name:** Moist wound island border dressing  
**Classification Name:** Hydrophilic wound dressing  
**Classification:** Unclassified; as recommended by the General and Plastic Surgery Devices Panel 79

**Legally marketed device(s) for substantial equivalence comparison:**

AcryDerm® Advanced Wound Dressing, (AcryMed, Inc.)  
 Clearsite™ Bordered Dressing, (New Dimension Medicine (NDM), Inc.)  
 Uni-Site™ Breathable Transparent Dressing (TTL Medical)

**Description of Device:** AcryDerm Island Border Dressing is a composite thin film adhesive backed moist hydrophilic wound dressing. The composite dressing has an island of polyacrylate AcryDerm Advanced Wound Dressing matrix centrally placed on the adhesive side of a medical grade polyurethane transparent thin film. The composite product is a moist wound dressing for external use. AcryDerm Island Border Dressing will be supplied sterile (E-beam radiation), in single use individual primary heat sealed pouches, packed in dispenser boxes along with an appropriate insert of instructions for use.

**Biocompatibility:** An assessment of the biocompatibility issues has been established according to Part-1 of the ISO standard (*Biological Evaluation of Medical Devices*).

**Intended Use of the Device:** AcryDerm Island Border Dressing is intended for use as an external wound dressing for the management of wound exudate moisture from acute and chronic wounds. Typical acute wounds would included incision wounds, lacerations, donor site, minor burns, skin tears and abrasions. Typical chronic wounds would include pressure sores, diabetic ulcers, and venous and arterial stasis ulcers. AcryDerm Island Border Dressing is contra-indicated for the treatment of third degree burns.

**Technological Characteristics:** The AcryDerm Island Border Dressing is a multi-layered construction. Sequentially the components are a semi-rigid disposable PET casting sheet, an adhesive polyurethane transparent thin film identical to that used in Uni-Site Breathable Transparent Dressing (predicate product), AcryDerm Advanced Wound Dressing (predicate product) matrix island, and disposable PE release liners. The wound contact matrix, when placed against the wound, absorbs exudate and transpires excess moisture, as vapor, through the matrix and polyurethane film. This construction is substantially similar to that used in Clearsite Bordered Dressing (predicate product). The classification, intended uses, composition, and methods of manufacturing of AcryDerm Island Border Dressing are substantially equivalent to the predicate devices.

**Performance Characteristics:** The island component of the dressing is an absorbent hydrogel matrix that absorbs in excess of 7 times its weight in moisture. The polyurethane thin film is a high moisture vapor transmission rate transparent cover dressing. Their combination as a composite construct is done to make a single use wound management product. Laboratory tests have shown that this construct absorbs in the presence of excess moisture and donates moisture when in contact with a dry substrate. This product has utility in the management of exudate.

**Manufacturing:** AcryDerm Island Border Dressing will be manufactured according to the product specifications and under good manufacturing practices that ensure the device is safe and effective for its intended use.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 19 1999

Bruce Gibbins, Ph.D.  
Chairman & Chief Technical Officer  
AcryMed, Inc.  
12232 SW Garden Place  
Portland, Oregon 97223

Re: K992032  
Trade Name: AcryDerm Island Border Dressing  
Regulatory Class: Unclassified  
Product Code: KMF  
Dated: June 11, 1999  
Received: June 16, 1999

Dear Dr. Gibbins:

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.

Page 2 – Bruce Gibbins, Ph.D.

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,

A handwritten signature in black ink, appearing to read "Neil R. P. Ogden" followed by a stylized flourish.

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

K992032

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510(k) Number (if known): K992032

Device Name: AcryDerm Island Border Dressing

**Indications For Use:**

Cover dressing for the following wounds:

Over the Counter uses include:

- Lacerations
- Minor burns
- Skin tears
- Abrasions

Use prescribed by a healthcare professional include:

- Pressure sores
- Diabetic ulcers
- Incision wounds
- Donor site wounds
- Venous stasis ulcers
- Arterial stasis ulcers

Contra-Indications:

- Not indicated for the treatment of third degree burns

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*NRW*

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

K992032

Prescription Use X  
(Per 21 CFR 801.109)

~~OR~~

Over-The-Counter Use X

(Optional Format I-2-96)