

APR 17 2000

K991818

510(k) Summary

**Contact Person:** Dr. Bruce L. Gibbins, Chairman & CTO

**Date of preparation:** May 20, 1999

**Device Name (proprietary):** AcryDerm Silver Antimicrobial Barrier Wound Dressing

**Common Name:** Moist wound dressing

**Classification Name:** Hydrophilic wound dressing

**Classification:** Unclassified

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

AcryDerm Advanced Wound Dressing, (AcryMed, Inc.)

Arglaes Controlled Release Film Dressing (Maersk Medical Limited, UK)

Acticoat Silver Coated Dressing, (Westaim Biomedical Inc., NH)

**Description of Device:** AcryDerm Silver Antimicrobial Barrier Wound Dressing is a moist sheet wound dressing that contains silver halide that may help to reduce growth of microbial contaminants of the dressing. The base matrix is composed of a hydrophilic polyacrylate absorbent sheet containing silver halide and stabilizers. AcryDerm Silver Antimicrobial Barrier Wound Dressing will be supplied as sterile sheets of 2x2"; 2x4"; 4x4"; 4x8"; of 8x8" sizes, packaged in single use heat sealed medical grade foil pouches. The single use primaries will be packed, with a product insert, as 10 primaries per intermediate dispenser chipboard carton, and 5 intermediate cartons per case. Biocompatibility has been assessed according to Part-1 of the ISO standard (*Biological Evaluation of Medical Devices*).

**Intended Use of the Device:** AcryDerm Silver Antimicrobial Barrier Wound Dressing is intended for use on partial and full thickness external wounds such as pressure sores, arterial ulcers, diabetic ulcers, and venous stasis ulcers and on acute wounds such as draining surgical wounds, lacerations, donor site, and exudating first and second degree burns, and abrasions. It is not intended for the treatment of third degree burns.

**Technological Characteristics:** AcryDerm Silver Antimicrobial Barrier Wound Dressing is a sterile, single use unsupported synthetic absorbent polyacrylate hydrogel containing silver halide and stabilizers. The product carries the general classification name, "Hydrophilic wound dressing", as would apply to AcryDerm Advanced Wound Dressing (AcryMed, Inc.). The composition of AcryDerm Silver Antimicrobial Barrier Wound Dressing is substantially similar to the predicate device, AcryDerm Advanced Wound Dressing. The method of manufacturing of the product is similar, with the exception for the addition of the silver halide, to that used for the production of the predicate device, AcryDerm Advanced Wound Dressing. AcryDerm Silver Antimicrobial Barrier Wound Dressing contains silver that may control microbial contamination of the dressing similar to the silver in Arglaes Controlled Release Film Dressing (Maersk Ltd.) and Acticoat Silver Coated Dressing (Westaim Biomedical).

**Manufacturing:** AcryDerm Silver Antimicrobial Barrier Wound 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

MAR 19 2007

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

Re: K991818

Trade/Device Name: AcryDerm Silver Antimicrobial Barrier Wound Dressing  
Regulatory Class: Unclassified  
Product Code: FRO  
Dated: March 20, 2000  
Received: March 21, 2000

Dear Dr. Gibbins:

This letter corrects our substantially equivalent letter of April 17, 2000.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Bruce Gibbins, Ph.D.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a horizontal line extending to the right.

Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K991818

510(k) Number (if known): K991818

Device Name: AcryDerm Silver Antimicrobial Dressing

Indications For Use:

Wound cover dressing for the following wounds:

Acute Wounds such as:

- Surgical wounds
- Lacerations
- Donor site wounds
- First and second degree burns
- Skin tears
- Abrasions

Chronic Wounds such as:

- Pressure sores
- Diabetic ulcers
- 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)

James R. Lochner  
 (Division Signatory)  
 Division of General Restorative Devices  
 510(k) Number: K991818

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)