

OCT 13 2000

K002909

Special 510(k) Summary

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

Contact Information: AcryMed Incorporated
12232 SW Garden Place
Portland, OR 97223
Phone: (503) 624-9830
Fax: (503) 639-0846

Date of preparation: September 13, 2000

Device Name (proprietary): AcryDerm Silver Anti-microbial Strands

Common Name: Moist wound 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 Silver Antimicrobial Dressing, (AcryMed, Inc.)
AcryNoodles Absorbent Wound Dressing (AcryDerm, Inc.)

Description of Device: AcryDerm Silver Antimicrobial Strands is an absorbent hydrophilic polyacrylate based wound dressing that contains antimicrobial silver. The new product is made from the same base matrix material that is used in the production of its predicate, AcryDerm Silver Antimicrobial Dressing (K991818). The new product is a stranded version of the silver containing sheet format. This format is identical to our previously cleared AcryNoodles Absorbent Dressing (K962851) excepting that it is composed of substrate identical to that used in AcryDerm Silver Antimicrobial Dressing that is currently manufactured for market.

Indications and Intended Use of the Device: AcryDerm Silver Antimicrobial Strands is an effective barrier to bacterial penetration. The barrier function of the dressing may help reduce infection in partial and full thickness wounds including decubitus ulcers, venous stasis ulcers, diabetic ulcers, first and second degree burns, abrasions and lacerations, donor sites and surgical wounds. AcryDerm Silver may be used over debrided and grafted partial thickness wounds.

Technological Characteristics: AcryDerm Silver Antimicrobial Strands is composed of the same material used in the production of the predicate, AcryDerm Silver Antimicrobial Dressing. The device contains a form of silver that is converted to ionic silver upon contact with aqueous moisture such as that found in exudate.

Performance Standards. There are performance standards that apply to AcryDerm Silver Antimicrobial Strands.

Manufacturing: AcryDerm Silver Antimicrobial Strands 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 L. Gibbins, Ph.D.
Chairman and Chief Technical Officer
AcryMed, Inc.
12232 SW Garden Place
Portland, Oregon 97223

Re: K002909
Trade/Device Name: AcryDerm Silver Antimicrobial Strands
Regulatory Class: Unclassified
Product Code: FRO
Dated: September 12, 2000
Received: September 18, 2000

Dear Dr. Gibbins:

This letter corrects our substantially equivalent letter of October 13, 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 – Dr. Bruce L. Gibbins

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 that reads "Mark N. Melkerson". The signature is written in a cursive style with a large, stylized "M" and "N".

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

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510(k) NUMBER (IF KNOWN): K002909

DEVICE NAME: AcryDerm Silver Antimicrobial Strands

INDICATIONS FOR USE:

AcryDerm Silver Antimicrobial Strands is an effective barrier to bacterial penetration. The barrier function of the dressing may help reduce infection in partial and full thickness wounds including decubitus ulcers, venous stasis ulcers, diabetic ulcers, first and second degree burns, abrasions and lacerations, donor sites and surgical wounds. AcryDerm Silver may be used over debrided and grafted partial thickness wounds.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON 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)

Mark N. Miller
(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K002909

David Johnson 9-28-00