K061232

510(k) Summary

OCT - 6 2006

Sponsor:	AcryMed, Inc. 9560 SW Nimbus Avenue Beaverton, OR 97008
Contact Person:	Dr. Bruce L. Gibbins; (503)-624-9830
Device Name	AcryDerm Silver Antimicrobial Thin Film
Common Name:	Tape and Bandage, Adhesive
Classification Product Code:	MGP
Classification Advisory Panel:	General and Plastic Surgery

Legally marketed device(s) for substantial equivalence comparison:

SilvaSorb Silver Antimicrobial Wound Dressing (AcryMed, Inc., OR)
Opsite Dressing (Smith & Nephew, FL)
Arglaes Antimicrobial Wound Dressing (Maersk Medical, MO)

Description of Device: The new product is sterile single use silver antimicrobial adherent transparent film. Sterility assurance will conform to AAMI/ANSI/ISO 11137-1994.

Intended Use of the Device: AcryDerm Silver Antimicrobial Thin Film is indicated for use on intact and breached skin. This device is intended for use in for securing devices to the skin and as a primary and secondary wound dressing. This product aids in securing devices such as indwelling catheters, drains, monitoring leads and airway management apparatus to patients skin. It is also intended as a cover dressing or in direct contact of wounds such as pressure ulcers, stasis ulcers, diabetic ulcers, first and second degree burns, lacerations, abrasions, skin tears, surgical incision sites, device insertion site wounds, graft sites, and donor sites.

Technological Characteristics: The AcryDerm Silver Antimicrobial Thin Film is a polyurethane adhesive film that contains ionic silver. The combination functions as an antimicrobial barrier when used as intended.

Pre-Clinical Testing: The AcryDerm Silver Antimicrobial Thin Film has been tested and shown to be effective by zone of inhibition studies against clinical isolates of coagulase negative *Staphylococcus sp., E. coli, Pseudomonas aeruginosa, Staphylococcus aureus (*MRSA), *Candida albicans,* and *Enterococcus sp.* The product has also been shown to be antimicrobial against *Klebsiella pneumoniae* (3 strains), *Candida parapsilosis, Candida galbrata , Bacillus subtilis, Enterobacter cloacae* (2 strains), *Enterococcus faecalis* (2 strains), *Aspergillus niger, Serratia marcescens, Citrobacter diversus, Citrobacter kasseri, and Staphylococcus saprophyticus.* Silver antimicrobial wound gauze has been shown by in vitro serial transfer testing to be active for in excess of 7 days. Safety and biocompatibility assurance has been established in accordance with Part-1 of the ISO standard (*Biological Evaluation of Medical Devices*).

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Manufacturing: AcryDerm Silver Antimicrobial Wound Gauze 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.

Performance Standards: No performance standards are prescribed for the new product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AcryMed
% Bruce Gibbins, Ph.D
Chief Technical Officer
9560 SW Nimbus Avenue
Beaverton, Oregon 97008

OCT - 6 2006

Re: K061232
Trade/Device Name: AcryDerm Silver Antimicrobial Adhesive Thin Film
Regulatory Class: Unclassified
Product Code: FRO
Dated: August 24, 2006
Received: September 1, 2006

Dear Dr. Gibbins:

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.

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,

Barbara Paeme

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

Enclosure

Indications for Use

510(k) Number (if known): K061232

Device Name: AcryDerm Silver Antimicrobial Adhesive Thin Film

Indications For Use: To secure devices such as indwelling catheters, drains, monitoring leads and airway management apparatus to patients skin.

For use as a cover dressing or in direct contact of wounds such as pressure ulcers, stasis ulcers, diabetic ulcers, first and second degree burns, lacerations, abrasions, skin tears, surgical incision sites, device insertion site wounds, graft sites, and donor sites.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Mudrow

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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