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510(k) Summary

Sponsor:	AcryMed, Inc. 9560 SW Nimbus Avenue Beaverton, OR 97008
Contact Person:	Dr. Bruce L. Gibbins; (503)-624-9830 ext 301
Device Name	AcryDerm Absorbent Oxygen Dressing
Common Name:	Hydrophilic wound dressing
Classification Product Code:	FRO
Classification Advisory Panel:	General and Plastic Surgery

Legally marketed device(s) for substantial equivalence comparison:

AcryDerm Advanced Wound Dressing-Noodles (AcryMed, Inc., OR)
OxyBand Wound Dressing (Oxyband Technologies, MA)
Oxybox System (Oxyfast Corporation, OH)

Description of Device: AcryDerm Absorbent Oxygen Dressing is a single use, sterile, hydrophilic absorbent closed cell foam enriched with gaseous and dissolved oxygen intended for use in the management of wounds. The oxygen enriched product is intended to be used as a topical moisture management wound dressing.

Intended use of the Device: The new oxygen enriched topical hydrophilic closed cell foam wound dressings are indicated for use in the management of acute and chronic wounds. The products are intended as a primary topical wound contact dressings for use in the management of wound exudates for wounds such as pressure ulcers, stasis ulcers, diabetic ulcers, first and second degree burns, lacerations, puncture wounds, abrasions, skin tears, surgical incision sites, device insertion site wounds, graft sites, and donor sites.

Technological Characteristics: The AcryDerm Absorbent Oxygen Dressings are topical enriched oxygen containing hydrophilic moisture absorbent dressings capable of absorbing between 5 to 10 times their weight in moisture as defined by in vitro absorbency studies.

Testing: the new products meets or exceeds safety and biocompatibility assurance guidelines as provided in the guidance of Part-1 of the ISO standard (*Biological Evaluation of Medical Devices*) and the NIH Publication 99-4494. The product sterility assurance conforms to AAMI/ANSI/ISO 11137-1994.

Manufacturing: AcryDerm Absorbent Oxygen Dressings will be manufactured according to the product specifications and in accordance with good manufacturing practices to ensure the device is safe and effective for their intended uses.

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

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Introductory Information

A.	APPLICANT'S NAME:	AcryMed, Incorporated
B.	APPLICANT'S ADDRESS	9650 SW Nimbus Avenue Beaverton, OR 97008
C.	CONTACT PERSON	Dr. Bruce Gibbins (503) 624-9830 (ext. 301) phone (503) 639-0846 fax
D.	DATE OF PREPARATION:	July 2008
E.	DEVICE NAME:	The AcryDerm Absorbent Oxygen Dressing
F.	PROPRIETARY NAME:	NA
G.	COMMON NAME:	Hydrophilic wound dressing
H.	ESTABLISHMENT NUMBER:	9010208
I.	CLASSIFICATION:	FRO
J.	CLASSIFICATION PANEL:	General and Plastic Surgery
I.	REASON FOR NOTIFICATION:	Clearance to enter a new product into the market
J.	PREDICATE DEVICE(s):	AcryDerm Advanced Wound Dressing-Noodles-Noodles OxyBand Wound Dressing OxyBox System
K.	SPECIAL CONTROLS OR PERFORMANCE STANDARDS:	No special controls (section 513) or performance standards (section 514) applicable to this device have been established by the Food and Drug Administration.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 19 2008

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

Re: K082459
Trade/Device Name: AcryDerm Absorbent Oxygen Dressing
AcryDerm Absorbent Oxygen Dressing OTC
Regulatory Class: Unclassified
Product Code: FRO
Dated: August 22, 2008
Received: August 26, 2008

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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,

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): K082459

Device Name: AcryDerm Absorbent Oxygen Dressing

Indications For Use: The new oxygen enriched topical hydrophilic closed cell foam wound dressings are indicated for use in the management of acute and chronic wounds. The products are intended as a primary topical wound contact dressings for use in the management of wound exudates for wounds such as pressure ulcers, stasis ulcers, diabetic ulcers, first and second degree burns, lacerations, puncture wounds, abrasions, skin tears, surgical incision sites, device insertion site wounds, graft sites, and donor sites.

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

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

510(k) Number K082459

Indications for Use

510(k) Number (if known): K082459

Device Name: AcryDerm Absorbent Oxygen Dressing OTC

Over the Counter Use: AcryDerm Absorbent Oxygen Dressings are intended to be used on minor wounds including lacerations scrapes, skin tears, abrasions, blister wounds, and minor burns.

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

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

Division Sign-Off

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of General, Restorative, and Neurological Devices