K093188

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Traditional 510(k) Summary
for
AFM Ultra Ag Dressings

FEB 17 2010

1. SPONSOR

Milliken Chemical
920 Milliken Rd.
Spartanburg, SC 29303
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Telephone: 864-503-2844
Date Prepared: February 16, 2010

2. DEVICE NAME

Proprietary Name:	AFM Ultra Ag Dressings
Common/Usual Name:	Wound Dressing
Classification Name:	Dressing, Wound, Drug

3. PREDICATE DEVICES

- Milliken Silver Wound Dressing (K051445)
- Contreet Foam Adhesive/Nonadhesive (K022416)

4. DEVICE DESCRIPTION

The AFM Ultra Ag Dressings are sterile, single-use wound care dressings for use in moist wound management. The dressings are comprised of 4 layers, each performing a specific function; an occlusive synthetic top layer, a polyurethane foam layer, a hotmelt adhesive and a layer of a silver-containing knitted composite fabric.

5. INTENDED USE

The AFM Ultra Ag Dressings are indicated for management of partial thickness burns, incisions, skin grafts, donor sites, lacerations, abrasions, and Stage I-IV dermal ulcers (vascular, venous, pressure and diabetic).

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The technological characteristics of AFM Ultra Ag Dressings and the predicate products are substantially equivalent in that they are all dressings suitable for use on pressure sores, leg ulcers, post-operative wounds, superficial wounds and abrasions.

AFM Ultra Ag Dressings and the predicate devices are also similar in that they all contain silver which provides an effective barrier to microbial activity in the dressing itself. AFM Ultra Ag Dressings are manufactured from a silver coated nylon, lycra and polyester fabric laminated onto a polyurethane foam whereas the predicate Contreet Foam Adhesive/Nonadhesive (K022416) dressing is made from silver-impregnated polyurethane foam, and the Milliken Silver Wound Dressings (K051445) is made from the same silver coated nylon, lycra and polyester fabric. The differences between AFM Ultra Ag Dressings and the predicate devices include construction details and slightly different silver concentrations, which are minor and do not affect safety and effectiveness of the device, as demonstrated by the biocompatibility and efficacy testing.

7. PERFORMANCE TESTING

Biocompatibility testing was performed in accordance with the International Organization for Standardization recommendations. Results of the biocompatibility tests demonstrate that the device is suitable for its intended use. Antimicrobial testing was performed which showed that AFM Ultra Ag Dressings provide an effective microbial barrier to the dressing itself. Milliken believes that the data included in this submission including the technical characteristics, physical properties, silver extraction, zone-of-inhibition and antimicrobial testing demonstrates that AFM Ultra Ag Dressings are substantially equivalent in design, function and intended use to Milliken Silver Wound Dressings (K051445) and Contreet Foam Adhesive/ Nonadhesive (K022416).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Milliken & Company
% Medical Device Consultants, Inc.
Ms. Mary McNamara-Cullinane, RAC
49 Plain Street
North Attleboro, Massachusetts 02760

FEB 17 2010

Re: K093188
Trade/Device Name: AFM Ultra Ag Dressings
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 21, 2010
Received: January 25, 2010

Dear Ms. McNamara-Cullinane:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

K093188

Indications for Use

510(k) Number (if known): K093188

Device Name: AFM Ultra Ag Dressings

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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)

David Krause for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093188