K103441

510(k) Summary
(per 21 CFR 807.92)
Low Adherent AFM Ag Dressings

JAN 21 2011

1. Sponsor

Milliken Healthcare Products, LLC
920 Milliken Road
Spartanburg, SC 29303
Contact Person: Brian J. Lindsay
Telephone: (864) 503-1323

Date Prepared: October 22, 2010

2. Consultant/Contact

Medical Device Consultants, Inc.
11440 West Bernardo Drive, Suite 300
San Diego, CA 92127
Telephone: 858-753-1961
Facsimile: 858-753-1962

Primary Contact: Ron Warren

3. Device Name

Proprietary Name: Low Adherent AFM Ag Dressings
Common/Usual Name: Wound Dressing
Classification Name: Dressing, Wound, Drug (Product Code, FRO)

4. Device Classification

FDA has not finally classified silver-containing wound dressings. The Office of Device Evaluation has published the document, Draft Guidance for the Preparation of a Premarket Notification for a Non-Interactive Wound and Burn Dressing, revision March 31, 1995, which includes Hydrophilic (procode KMF), Occlusive (procode MGP), Hydrogel (procode MGQ), and Porcine dressings (procode KGN). Other types of wound dressings are also non-interactive, and the guidance document is applicable to them as well, including Dressing (procode FRO) and Dressing, Wound, Hydrophilic (procode NAC). Most silver-containing wound dressing devices have been given the product code FRO but not classified, including the applicable predicate devices.

5. Predicate Devices

- Milliken Silver Wound Dressing (Milliken Healthcare Products, LLC) Cleared August 22, 2005 under *K051445.*

6. Device Description

The Low Adherent AFM Ag Dressings are sterile, single-use wound care dressings for use in moist wound management. The dressings are designed to contact the wound as a primary dressing and permit the passage of fluids. The dressings provide a protective environment for the wound and an effective protection against microbial contamination in the dressing. The devices are effective antimicrobial barrier dressings against both Gram-positive and Gram-negative bacteria, including the following organisms: methicillin-resistant *Staphylococcus aureus* (MRSA), methicillin- resistant *Staphylococcus epidermidis* (MRSE), vancomycin-resistant *Enterococcus faecalis* (VRE), *Pseudomonas aeruginosa*, and *Acinetobacter baumannii.*

7. Intended Use

Low Adherent AFM 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). The Low Adherent AFM Ag Dressings provide an antimicrobial barrier to microbial colonization in the dressing and reduce microbial penetration through the dressing.

8. Technological Characteristics and Substantial Equivalence

The subject of this Special 510(k) is a modification of the Milliken Silver Wound Dressing that was previously cleared on August 22, 2005 under Premarket Notification Number K051445. The subject of this Special 510(k) is the addition of a low adherent wound contact layer.

No modification is being made to any other components. The Low Adherent AFM Ag Dressings is identical to the original Milliken Silver Wound Dressings (K051445) except that it has been modified by the addition of a low adherent wound contact layer. The modification is minor and does not affect safety and effectiveness of the device.

9. Performance Testing

Validation activities to support the use of the Low Adherent AFM Ag Dressings consisted of three main elements:

- Biocompatibility Testing
- Validation of Antimicrobial Effectiveness
- Sterility Validation

Testing of the Low Adherent AFM Ag Dressings has demonstrated that the wound dressing fulfills prospectively defined performance criteria and that the modified system meets user needs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Milliken Healthcare Products, LLC
% Medical Device Consultants, Inc.
Mr. Ronald S. Warren
11440 West Bernardo Court, Suite 300
San Diego, California 92127

JAN 21 2011

Re: K103141
Trade/Device Name: Low Adherent AFM Ag Dressings
Regulatory Class: Unclassified
Product Code: FRO
Dated: December 10, 2010
Received: December 13, 2010

Dear Ms. Warren:

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

Indications for Use

510(k) Number (if known): K103141

Device Name: Low Adherent AFM Ag Dressings

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Prescription Use ___X___ (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)

David Krome

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

510(k) Number K103141