AUG 2 2 2005

510(k) Summary
for
Milliken Silver Wound Dressings

1. SPONSOR

Milliken Chemical
920 Milliken Rd.
PO Box 1927, M-209
Spartanburg, SC 29304
Contact Person: John D. Bruhnke, Ph.D.

Telephone: 864-503-2844
Date Prepared: August 10, 2005

2. DEVICE NAME

Proprietary Name: Milliken Silver Wound Dressings
Common/Usual Name: Wound Dressing
Classification Name: Dressing

3. PREDICATE DEVICES

- Argentum Medical LLC Silverlon® Wound Contact Dressing (K023612)
- Westaim Biomedical Acticoat™ 7 Dressing (K001519)

4. DEVICE DESCRIPTION

Milliken's Silver Wound Dressings are sterile, single-use wound care dressings for use in moist wound management. The dressing consists of a nylon, lycra, and polyester continuous filament Jersey knit textile substrate which is pad coated with an aqueous suspension of silver sodium hydrogen zirconium phosphate (AlphaSan® RC-2000) and a polyurethane binder to provide an antimicrobial coating to the fabric. The textile substrate has a nylon face and polyester back providing a moisture affinity gradient across the thickness of the dressing.

Milliken Silver Wound Dressings are offered in several configurations including the following: 2" x 2", 4.25" x 4.25", 6" x 6", 1" x 24" and 4" x 48" (wrap).

5. INTENDED USE

Milliken Silver Wound Dressings provide an antimicrobial barrier to microbial colonization in the dressing and reduce microbial penetration through the dressing.

Milliken Silver Wound 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

Technological characteristics of the Milliken Silver Wound 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. The Milliken Silver Wound Dressings are substantially equivalent in design, function and intended use to the Argentum Medical LLC Silverlon® Wound Contact Dressing (K023612) and the Westaim Biomedical Acticoat™ 7 Dressing (K001519). The Milliken Silver Wound Dressings and the predicate devices contain silver, which provides an effective barrier to microbial activity in the dressing itself. The Milliken dressings are manufactured from a silver coated nylon, lycra and polyester fabric whereas the predicate Silverlon® dressing is made from nylon fabric with a metallic silver coating, and the Acticoat™ 7 is made from multi-layer fabrics comprised of rayon/polyester nonwoven layers and silver coated high density polyethylene mesh. Differences between the Milliken Silver Wound Dressings and the predicate devices include slightly different silver concentrations. These differences are minor and do not affect safety and effectiveness of the device, as demonstrated by the animal and biocompatibility testing performed on the Milliken Silver Wound Dressings and the specific construction of the fabric base.

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. A full thickness wound healing study was conducted using swine in order to characterize the healing process following treatment with the Milliken Silver Wound Dressings. All wounds appeared to heal without complication. Microscopically, the test articles were considered nonirritant as compared to the negative and comparative controls. Antimicrobial testing was performed which showed that the Milliken Wound 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 antimicrobial and animal testing demonstrates that the Milliken Silver Wound Dressings are substantially equivalent in design, function and intended use to the Argentum Medical LLC Silverlon® Wound Contact Dressing (K023612) and the Westaim Biomedical Acticoat™ 7 Dressing (K001519).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 2 2005

Milliken Chemical
c/o Ms. Mary McNamara-Cullinane, RAC
Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K051445
Trade/Device Name: Milliken Silver Wound Dressings
Regulatory Class: Unclassified
Product Code: FRO
Dated: August 12, 2005
Received: August 15, 2005

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.

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for

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

Enclosure

K051445

Indications for Use

510(k) Number (if known): K051445

Device Name: Milliken Silver Wound Dressings

Indications for Use:

The Milliken Silver Wound Dressings provide an antimicrobial barrier to microbial colonization in the dressing and reduce microbial penetration through the dressing. Milliken Silver Wound 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).

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)

Barbara Buehler for MXM

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

510(k) Number K051445