K023612

10. 510(k) Summary

10.1 Summary Information

JAN 2 4 2003

10.1.1 Submitter's Name and Address

Argentum Medical LLC
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Lakemont, Georgia 30552

Contact person and telephone number:
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Date summary was prepared: 15 November 2002

10.1.2 Device Name

Professional Trade Name: Antimicrobial Barrier Wound Contact Dressing
Antimicrobial Barrier Burn Wrap Dressing
Antimicrobial Barrier Burn Contact Dressing
Silverlon® Acute Burn Glove

10.1.3 Identification of predicate device substantial equivalence is being claimed

Silverlon® Antimicrobial Barrier Wound Contact Dressing and the Silverlon® Acute Burn Glove are substantially equivalent in function and intended use to the Silverlon Wound Contact Dressing (K#981299)

10.1.4 Device Description

Explanation of how the device functions: Silverlon® Contact Wound Dressings are designed to intimately contact the wound as a primary dressing and permit the passage of fluids. The silver provides effective protection of the dressing against microbial contamination.

Basic scientific concepts that form the basis for the device: The nylon fabric permits the passage of oxygen and fluids to and from the wound. The surface of the nylon fibers in Silverlon® Wound Contact Dressings consists of a thin layer of metallic silver containing approximately one percent silver oxide that provides effective protection of the dressing against microbial contamination.

Significant physical and performance characteristics of the device such as device design, materials used, and physical properties: Silverlon® Contact Wound Dressings are made of flexible, elastomeric, sterile, silver plated fabric consisting of a knitted continuous nylon fiber substrate with a metallic silver surface containing approximately one percent silver oxide. The coating of silver is circumferential between 0.8 and 1.0 μm thick

10.1.5 Statement of the intended use of the device, including general description of the conditions the device will mitigate and the patient population for which the device is intended.

Silverlon® Contact Wound Dressings are external wound dressings that are designed as an interface between the wound and a conventional occlusive dressing. For the over-the-counter market, the Silverlon® Antimicrobial Wound Contact Dressings are sterile wound contact dressings are intended for local management of superficial wounds, minor burns, and abrasions and lacerations. For the professional wound care market, the family of Silverlon® Antimicrobial Wound Contact Dressings are indicated for local management of partial thickness burns, incisions, skin grafts, donor sites, lacerations, abrasions, and Stage I–IV dermal ulcers (vascular, venous, pressure, and diabetic). The Silverlon® Burn Wrap, Silverlon® Burn Glove, Silverlon® Burn Sock and Silverlon® Burn Contact Dressing are configured for the local management of partial thickness burns, skin grafts, and donor sites. The Silverlon® Wound Contact Dressing is configured for incisions, skin grafts, donor sites, lacerations, abrasions, and Stage I–IV dermal ulcers (vascular, venous, pressure, and diabetic).

10.1.6 Statement of how the technological characteristics of the device compare to those of the predicate device

The technological characteristics of the silver content, flexibility, elasticity, primary wound contact, permeability to oxygen and fluids, and protection against microbial contamination of the dressing that are substantially equivalent to the predicate devices cited.

10.2 Assessment of Performance Data

Silverlon® Contact Wound Dressings were subjected to standard *in vitro* and *in vivo* biocompatibility tests including cytotoxicity, sensitization, acute intracutaneous reactivity, acute systemic toxicity, and tissue compatibility (muscle implantation study). All tests were performed in accordance with Part-10993 of the International Standard Organization (ISO) Standard (*Biological Evaluation of Medical Devices*) by North American Science Associates, Inc. (NAMSA), Northwood, Ohio. The studies indicated that Silverlon® Contact Wound Dressings are safe for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 4 2003

A. Bart Flick, M.D.
Research Director
Argentum Research, Inc.
P.O. Box 429
36 Lake Rabun Road
Lakemont, Georgia 30552

Re: K023612
Trade/Device Name: Antimicrobial Barrier Wound Contact Dressing
Antimicrobial Barrier Burn Wrap Dressing
Antimicrobial Barrier Burn Contact Dressing
Silverlon® Acute Burn Glove
Regulatory Class: Unclassified
Product Code: FRO
Dated: October 28, 2002
Received: October 28, 2002

Dear Dr. Flick:

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 (301) 594-4659. 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,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. INDICATIONS FOR USE

510(k) Number: # K023612

Device Name: Antimicrobial Barrier Wound Contact Dressing

Antimicrobial Barrier Burn Wrap Dressing

Antimicrobial Barrier Burn Contact Dressing

Silverlon® Acute Burn Glove

For over-the-counter use, Silverlon® Wound Contact Dressing may be used for:

First aid to help in minor abrasions, minor cuts, lacerations, scrapes, minor scalds and burns.

Under the supervision of a health care professional, Silverlon® Wound Contact Dressing may be used for the management of:

Silverlon® Wound Contact Dressings provide an effective barrier to bacterial penetration and are intended for local management of partial thickness burns, incisions, skin grafts, donor sites, lacerations, abrasions, and Stage I–IV dermal ulcers (vascular, venous, pressure, and diabetic).

Miriam C. Provost

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

510(k) Number K023612

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___ OR Over-The-Counter Use___
(Per 21 CFR 801.109)
(Optional Format 1-2-96)