K023609

10. 510(k) Summary

10.1 Summary Information

JAN 17 2003

10.1.1 Submitter's Name and Address

Argentum Medical LLC

#36 Lake Rabun Road

Lakemont, Georgia 30552

Contact person and telephone number:

A. Bart Flick, M.D., Research Director

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Date summary was prepared:

15 November 2002

10.1.2 Device Name

OTC Name:	Silver Strips™
Professional Trade Name:	Silverlon® Adhesive Strip
Common Name:	Silver-nylon adhesive strip
Classification Name:	Wound and burn dressing

10.1.3 Identification of predicate device to which substantial equivalence is being claimed

Silverlon® Adhesive Strip is substantially equivalent with respect to function, intended use, and composition to:

1. Qualtex Island Dressing (K910657);
2. Silverlon® Contact Wound Dressing (K981299).

10.1.4 Device Description

Explanation of how the device functions:

Silver nylon strips are designed to intimately contact the wound as a primary dressing. They provide a microbial barrier, permit the passage of wound fluids, are absorbent, and provide effective protection of the dressing against microbial contamination.

Basic scientific concepts that form the basis for the device:

The silver plated nylon fabric that comprises the wound contact layer permits the passage of oxygen and fluids to and from the wound. The surface of the nylon fibers in silver nyon strips consists of a thin layer of metallic silver containing approximately 1% silver oxide and 99% metallic silver that provides an effective microbial barrier and protection of the dressing against microbial contamination.

Significant physical and performance characteristics of the device such as device design, materials used, and physical properties:

Silver nylon strips are multi-layer, sterile, non-adherent, absorbent composite dressings with an attached adhesive tape or pad. The dressings are composed of three distinct layers:

- Layer 1 is a polymeric silver coated fabric circumferential covered with a uniform layer of metallic silver.
- Layer 2 is a needle-punched non-woven rayon web that absorbs drainage from the wound site.
- Layer 3 is a latex free skin adhesive and tape.

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

Professional Indications:

Indicated for vascular access, central, arterial and venous IV sites, IM injection sites, abrasions, lacerations, partial thickness burns, wound drain sites and surgical incisions.

Over-The-Counter Indications:

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

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

The technological characteristics of the device are substantially equivalent to Qualtex Island Dressing (K910657) as far as the absorbent pad, and the tape backing with release liners. The only physical difference between the Qualtex Island Dressing and the silver nylon strip is the wound contact layer. In the Qualtex Island Dressing this layer is reported to be a "non-adherent net", whereas in the silver nylon adhesive strip this layer is composed of silver-coated nylon. The primary difference between the silver nylon strip and the Silverlon® Contact Wound Dressing is that the silver nylon strip is a composite dressing that contains the Silverlon® Contact Wound Dressing as the layer that comes in contact with the wound.

10.2 Assessment of Performance Data

The silver nylon strip was tested in a full thickness animal (pig) wound model that showed no local cytotoxicity of the wound site and no absorption (to +/- 2.0 PPB) into systemic circulation of metallic silver or silver ions. Biocompatability tests, including cytotoxicity, sensitization, and acute intracutaneous reactivity studies, were conducted on the Silverlon® Island Wound Dressing. The Silverlon® Island Wound Dressing is identical to the silver nylon strip in composition; both are multilayer composite dressings with similar layers. Only the shapes and thickness of the absorbency pad differ. Therefore, the results of biocompatibility tests conducted with the Silverlon® Island Wound Dressing are applicable to the silver nylon strip.

All tests were performed in accordance with Part-10993 of the International Standard Organization (ISO) Standard (*Biological Evaluation of Medical Devices*) by North America Science Associates, Inc. (NAmSA), Northwood, Ohio. The studies indicated that Silverlon® Island Wound Dressing, and therefore silver nylon strip, is safe for its intended use.

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Silver nylon strips are multi-layer, sterile, non-adherent, absorbent composite dressings with an attached adhesive tape or pad. The dressings are composed of three distinct layers:

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2003

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

Re: K023609
Trade/Device Name: Silverlon® Adhesive Strip
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. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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: # K023609

Device Name: Silverlon® Adhesive Strip

Professional Indications:

Indicated for vascular access, central, arterial and venous IV sites, IM injection sites, abrasions, lacerations, partial thickness burns, wound drain sites and surgical incisions.

Over-The-Counter Indications:

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

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

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

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

510(k) Number K023609

1.2.03