10. 510(k) SUMMARY

10.1 Summary Information

10.1.1 Submitter's Name and Address

Argentum International LLC
#36 Lake Rabun Road
Lakemont, Georgia 30552

Contact person and telephone number:

A. Bart Flick, M.D., Research Director
Telephone: (706) 782-6700
Telefax: (706) 782-3903

Date summary was prepared:
24 November 1998

10.1.2 Device Name

Trade Name: Silverlon™ Island Wound Dressing and Silverlon™ Island Pad

Common Name: Silver-nylon island wound dressing

Classification Name: Wound and Burn Dressing

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

Silverlon™ Island Wound Dressing 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: Silverlon™ Island Wound Dressings are designed to intimately contact the wound as a primary dressing. They provide a protective, moist healing environment for the wound, permit the passage of wound fluids, are highly absorbent, and provide effective protection of the dressing against microbial contamination.

Basic scientific concepts that form the basis for the device: the nylon fabric that comprises the wound contact layer permits the passage of oxygen and fluids from the wound. The surface of the nylon fibers in Silverlon™ Island Wound Dressings consists of a thin layer of metallic silver containing approximately 1% silver oxide and 99% metallic silver 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™ Island

Wound Dressings are multi-layer, sterile, non-adherent, absorbent composite dressings with an attached adhesive tape or pad. The dressings are composed of five distinct layers:

- Layer 1 is a non-adherent wound contact layer that consists of 1 or 4 layers of knitted continuous nylon fiber substrate with a metallic silver surface (Silverlon™). The layers of Silverlon™ are sewn together with silver nylon thread that is plated in an identical fashion to the silver nylon utilized to make the Silverlon™ knitted fabric. The silver coating is a uniform 1-micron thick layer that completely covers the nylon.
- Layer 2 is Delnet P530N
- Layer 3 is a needle punched non-woven 8-ounce rayon web that absorbs drainage from the wound site.
- Layer 4 is polyurethane film that keeps external contaminants out and maintains a moist wound healing environment.
  (Note: Layers 2, 3, and 4 are manufactured as a laminate by AET).
- Layer 5 is a non-woven polyester fabric coated with a skin contact pressure sensitive acrylic adhesive backed with a one sided poly coated lay flat release liner. The pressure sensitive acrylic adhesive is H-566 a hypoallergenic adhesive that meets USP Class 6 standard and satisfies tripartite guidelines for skin contact devices. The Silverlon Island Pad does not have the tape layer.

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™ Island Wound Dressings are multi-layer, sterile, non-adherent, absorbent, composite, antimicrobial barrier wound dressings indicated for local management of superficial wounds, minor burns, and abrasions and lacerations. A health care professional may be consulted prior to the first use of this product to determine whether these conditions exist. Silverlon™ Island Wound Dressings may also be used under the care of a health care professional for wounds such as vascular access or peripheral IV sites, orthopaedic external pin sites, wound drain sites, surgical wounds (donor and graft sites, incisions), and partial to full thickness dermal ulcers (pressure sores, venous stasis ulcers, arterial ulcers, diabetic ulcers). Topical application of Silverlon™ Island Wound Dressings protects the wound area and the open weave of the silver-nylon fabric wound contact layer permits passage of wound fluid through the product to be absorbed by an overlying absorbent material. The silver provides effective protection of the dressing against microbial contamination.

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

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

Dressing (K981299) is that the Island wound dressing is a composite dressing that contains the Contact Wound Dressing as the layer that comes in contact with the wound.

10.2 Assessment of Performance Data

Silverlon™ Island Wound Dressing was subjected to standard *in vitro* and *in vivo* biocompatibility tests including cytotoxicity, sensitization, and acute intracutaneous reactivity. 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 22 1999

Mr. A. Bart Flick
Research Director
Argentum International LLC
36 Lake Rabun Road
Lakemont, Georgia 30552

Re: K984208
Trade Name: Silverlon™ Island Wound Dressing
Regulatory Class: Unclassifed
Product Code: KMF
Dated: November 24, 1998
Received: November 24, 1998

Dear Mr. Flick:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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 (the Act). You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. This device may not be labeled for use on third degree burns.

2. This device may not be labeled as having any accelerating effect on the rate of wound healing or epithelization.

3. This device may not be labeled as a long-term, permanent, or no-change dressing, or as an artificial (synthetic) skin.

4. This device may not be labeled as a treatment or a cure for any type of wound.

The labeling claims listed above would be considered a major modification in the intended use of the device and would require a premarket notification submission (21 CFR 807.81).

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) for Medical Devices: General GMP regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or 301-443-6597 or at its internet address http://www.fda.gov/cdrh/dsmamain.html.

Sincerely yours,

Neil R.P. Ogden for

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

Enclosure

K984208

2. INDICATIONS FOR USE

510(k) Number (if known): K984208

Device Name: Silverlon™ Island Wound Dressing

Silverlon™ Island Wound Dressings are multi-layer, sterile, non-adherent, antimicrobial barrier wound dressings.

The Over-The-Counter indications:

Local management of superficial wounds, minor burns, abrasions and lacerations.

The Prescription Professional indications:

Wounds such as vascular access or peripheral IV sites, orthopaedic external pin sites, wound drain sites, surgical wounds (donor and graft sites, incisions), and partial to full thickness dermal ulcers (Stage I–IV pressure sores, venous stasis ulcers, arterial ulcers, diabetic ulcers).

NRO

(Division Sign-Off)
Division of General Restorative Devices K984208
510(k) Number

(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 X
(Per 21 CFR 801.109)

(Optional Format 1-2-96)