SEP 2 4 1999

K984210

10.1 Summary Information

10.1.1 Submitter's Name and Address

Argentum Research
Post Office Box 429
Lakemont, GA 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 Name of Device

Trade Name: Silverlon™ Wound Packing Strips
Common Name: Silver-nylon wound packing strips
Classification Name: Wound and Burn dressing

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

Silverlon™ Wound Packing Strips are substantially equivalent in function and intended use to: Argentum Research's Silverlon™ Contact Wound Dressing (K981299) and Johnson and Johnson's Nu Gauze Packing Strips (pre-amendment device).

10.1.4 Device Description

Explanation of how the device functions: Silverlon® Wound Packing Strips 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 Packing Strips consists of a thin layer of metallic silver containing approximately 1% 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® Wound Packing Strips are made of flexible, sterile, r non-adherent fabric of a knitted continuous nylon fiber substrate with a metallic silver surface containing approximately 1% silver oxide.

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™ Wound Packing Strips are sterile, non-adherent, absorbent wound dressings are designed as an interface between the wound and a conventional occlusive dressing. Indications are for control of local wound bleeding and nasal hemorrhage, to encourage draining by wicking fluids from a body cavity, infected area, or abscess, and to help remove necrotic tissue from ulcers or other infected wounds when used as a "wet-to-dry" packing. Topical application of Silverlon® Wound Packing Strips protects the wound area and the open weave of Silverlon® Wound Packing Strips permits passage of wound fluid through the product to be absorbed by an overlying absorbent material. The silver coating 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 such as flexible primary contact wound dressing, permeability to oxygen and fluids, and protection against microbial contamination of the dressing are substantially equivalent to the predicate devices cited.

10.2 Assessment of Performance Data

The fabric that constitutes the Silverlon™ Wound Packing Strips 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® Packing Strips are safe for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 24 1999

A. Bart Flick, M.D.
Chief Executive Officer and Research Director
Argentum International LLC
P.O. Box 429
Lakemont, Georgia 30552

Re: K984210
Trade Name: Silverlon™ Wound Packing Strips
Regulatory Class: Unclassified
Product Code: FRO
Dated: July 14, 1999
Received: July 26, 1999

Dear Dr. Flick:

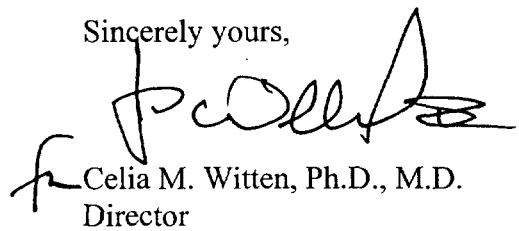
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). 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 (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, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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,



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

K984210

2. INDICATIONS FOR USE

510(k) Number (if known): K984210

Device Name: Silverlon™ Wound Packing Strips

Indications for Use:

Silverlon™ Wound Packing Strips are sterile, non-adherent, silver wound dressings.

The Prescription Professional indications:

Control of local wound bleeding and nasal hemorrhage, to encourage draining by wicking fluids from a body cavity, infected area, or abscess, and to help remove necrotic tissue from ulcers or other infected wounds when used as a "wet-to-dry" packing.

(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___

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984210