10. 510(K) SUMMARY

10.1 Summary Information

10.1.1 Submitter's Name and Address

Argentum International LLC
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:

September 23, 1998

10.1.2 Name of Device

Trade Name:	Silverlon™ Contact Wound Dressing (1- and 4-Layer)
Common Name:	Silver-nylon contact wound dressing
Classification Name:	Contact wound dressing

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

Silverlon™ Contact Wound Dressings are substantially equivalent in function and intended use to the following cleared contact wound dressings: Arglaes Film Dressing (K970566), Acticoat Silver Coated Dressing (K955453), and Tegapore™ Wound Contact Material (K890354).

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™ Contact Wound Dressings 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™ Contact Wound Dressings are made of flexible, sterile, non-adherent fabric consisting of 1 or 4 layers 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™ Contact Wound Dressings are external wound dressings that are designed as an interface between the wound and a conventional occlusive dressing. Silverlon™ Contact Wound Dressings are sterile, non-adherent dressings 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).

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 that are substantially equivalent to the predicate devices cited.

10.2 Assessment of Performance Data

Silverlon™ 1-Layer and 4-Layer 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™ 1-Layer and 4-Layer 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

SEP 25 1998

A. Bart Flick, M.D.
Argentum International, LLC
P.O. Box 429
Lakemont, Georgia 30552

Re: K981299
Trade Name: Silverlon™ Contact Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: July 8, 1998
Received: July 8, 1998

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 (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.

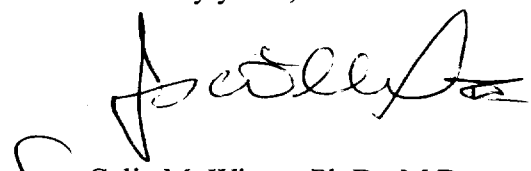
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations (CFR), Title 21, Parts 800 to 895. A substantially 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,



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

K981299

2. INDICATIONS FOR USE

510(k) Number (if known): K981299

Device Name: Silverlon™ Contact Wound Dressing

Indications for Use:

Silverlon™ Contact Wound Dressings are sterile, non-adherent dressings 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).

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

Prescription Use X
(Per 21 CFR 801.109)
(Optional Format 1-2-96)

OR

Over-The-Counter Use_____

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981299