2/22/99 K984204

10.1 510(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 Name of Device

Trade Name:	Silverlon™ DP Wound Closure Strips
Common Name:	Tape Skin Closures
Classification Name:	Strip, adhesive, closure, skin

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

Silverlon™ DP Wound Closure Strip is substantially equivalent with respect to function, intended use, and composition to:

(1) 3M Company, Steri-strip Antimicrobial barrier Skin (K813265);

(2) Genetic Laboratories, Suture Strip™ Wound Closure Strip (K842621);

(3) Silverlon™ Contact Wound Dressing (K981299)

10.1.4 Device Description

Explanation of How the Device Functions: Silverlon™ DP Wound Closure Strips are designed to provide a balanced relief of tensions at the wound edges by exerting a compressive and downward force on the wound surface through the antimicrobial barrier multilaminate composite portion of the strip. Without impairment of microcirculation, the elastasticity of the non latex elastic component provides a stabilizing force to the wound edge reapproximation. The Silverlon™ component provides effective protection of the dressing against microbial contamination. The dressing maintains a moist wound environment which promotes wound healing. The design of the elastic component allows for the wound edges to be pulled together while minimizing the irritation, blistering and skin shearing associated with mechanical trauma. As the patient goes through the activities of daily living, the antimicrobial barrier composite laminate pad experiences minimal motion and therefore minimal disruption of the wound margins. The pattern of the elastic design of the DP portion of the closure

strip provides the minimal motion and intimate contact between the antimicrobial barrier laminate and the wound margins as the edema subsides. The design of the relief holes in the elastic non latex elastic component allow: (1) minimum movement of the laminate and the wound edges as the surrounding skin moves; and (2) the physician to vary the compression on the wound surface after the dressing is applied by cutting bands.

Basic Scientific Concepts that Form the Basis for the Device: The basic scientific concepts of the Silverlon™ DP Wound Closure Strip are:

- **Maintains Antimicrobial barrier Environment:**

The surface of the multilaminate composite pad is silver-plated nylon fibers similar to the silver nylon in the Silverlon™ Contact Wound Dressing. The silver-plated nylon consists of a thin layer of autocatalytic plated metallic silver (1 micron) containing approximately 99% metallic silver and 1% silver oxide to provide an antimicrobial barrier against a broad range of microbial species. The silver provides effective protection of the dressing against microbial contamination.

- **Maintains Moist Wound Environment:**

Moist wound healing is provided by the 8 ounce and 4 ounce rayon pad laminate with polyurethane film. The polyurethane film provides a semipermeable membrane allowing the passage of oxygen but partially restricting the passage of fluids.

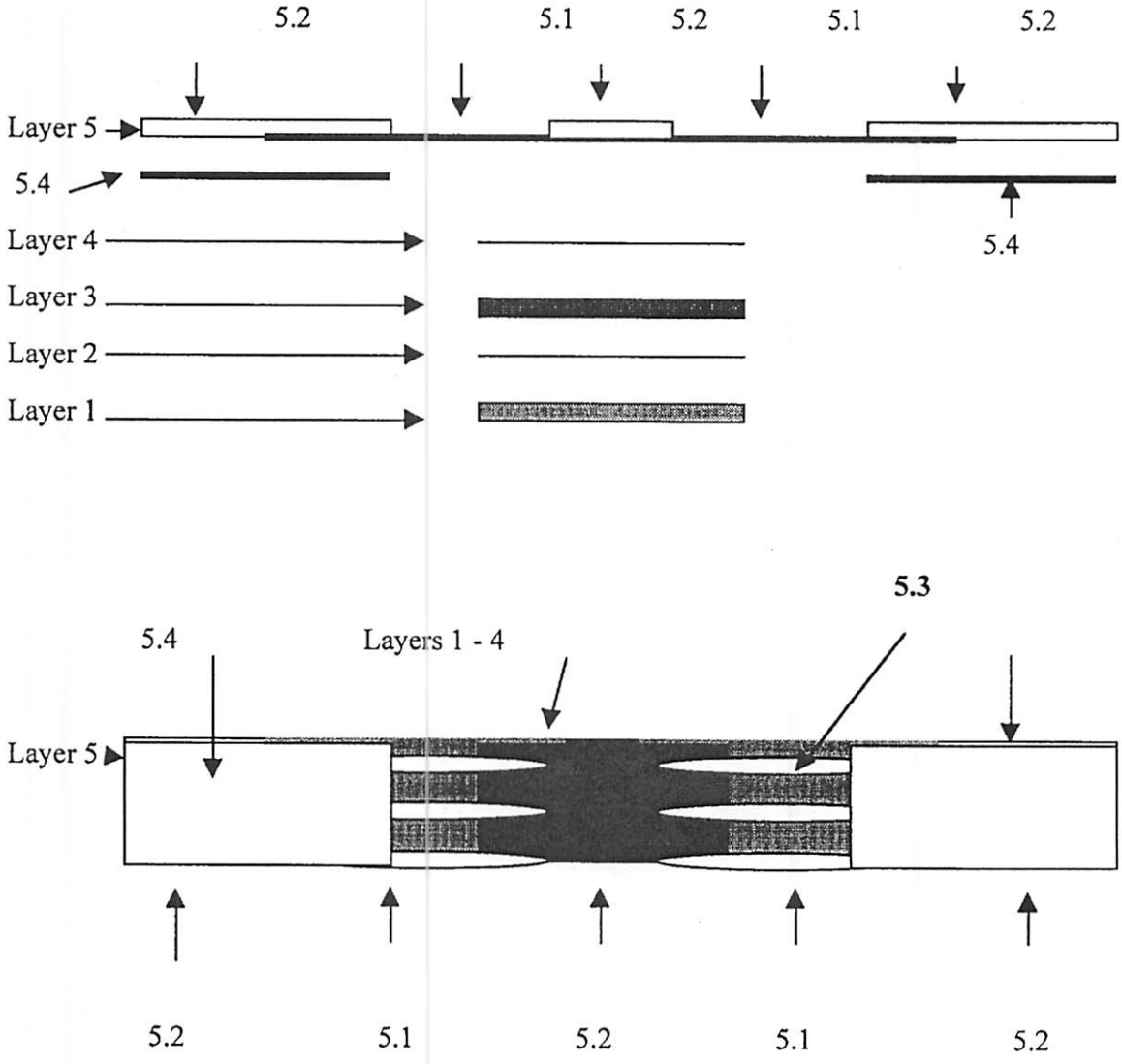
- **Maintains Dynamic Lateral and Downward Compression of the Wound Margins:**

The design of the elastic component allows for lateral and downward compression of the wound margins. The wound edges are pulled together while minimizing the irritation, blistering and skin shearing associated with mechanical trauma. The elastic design provides balanced relief of tensions at the wound edges by exerting a compressive and downward force on the wound surface. The direct pressure (DP) elastic design provides minimal motion and intimate contact between the antimicrobial barrier laminate and the wound margins. This is most noticeable as the edema surrounding the wound edges subsides. The design of the relief holes in the elastic non latex component allow: (1) minimum movement of the laminate and the wound edges as the surrounding skin moves; and (2) the physician to vary the compression on the wound surface after the dressing is applied by cutting bands.

Significant physical and performance characteristics of the device such as device design, materials used, and physical properties: Silverlon™ DP Wound Closure Strips are multi-layer, sterile, elastic, antimicrobial barrier absorbent composite wound closure strips. The dressings are composed of five distinct layers outlined in Figure 1 below:

Figure 1

Side View



- Layer 1 is a non-adherent wound contact layer that consists of 1 or 4 layers of continuous nylon fiber substrate with a metallic silver surface (Silverlon™). Layer 1, Layer 2, Layer 3, and Layer 4 are sewn together with silver nylon

thread that is plated in an identical fashion to the silver nylon utilized to make the Silverlon™ 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 or 4-ounce rayon wed 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 composite laminate of non-woven polyester fabric (5.2, Figure 1) coated with a skin contact pressure sensitive acrylic adhesive (5.4, Figure 1) backed with a one sided poly coated lay flat release liner and non latex elastic. The pressure sensitive acrylic adhesive H-566, is a hypoallergenic adhesive that meets USP Class 6 standard and satisfies tripartite guidelines for skin contact devices. The non-woven polyester tape is interrupted by a section of elastomeric non latex (5.1, Figure 1). Holes are punched out in the non latex elastic (5.3, Figure 1) to allow adjustability of the elastic component of the Silverlon™ DP Wound Closure Strip.

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™ DP Wound Closure Strip are multi-layer, sterile, elastic, wound closure strips with a central antimicrobial barrier absorbent composite laminate, indicated for local management of superficial wounds and tears and minor lacerations. A health care professional may be consulted prior to the first use of this product to determine whether these conditions exist. Silverlon™ DP Wound Closure Strips may also be used under the care of a health care professional for primary or secondary closure following surgery, supplementary-support to sutures, staples or sealants, wound support following suture removal, and wound sites where suturing would aggravate bleeding.

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

The 3M Company, Steri-strip Antimicrobial barrier Skin Closure (K 813265) and Genetic Laboratories, Suture Strip™ Wound Closure Strip (K842621) are composites of a non-woven fabric coated tape with a skin contact pressure sensitive adhesive coated on one side capable of intimately adhering the substrate to human skin. The Genetic Laboratories, Suture Strip™ Wound Closure Strip claim "Dynamic Adherence" with increased elongation at breakage. The dynamic adherence

allows increased compliance, which allows for movement without stress and reduces irritation, blistering and skin shearing associated with mechanical trauma. The 3M Company, Steri-strip Antimicrobial Skin Closure 510(k) has deleted all references to the specifics of the antimicrobial agent utilized, only that the "antimicrobial has been evaluated for safety *in vitro*, on animals and on humans." The Silverlon™ Wound Contact Dressing (K981299), 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 and provides effective protection of the dressing against microbial contamination.

All three products are supplied sterile. The 3M Company, Steri-strip Antimicrobial b Skin and Genetic Laboratories, Suture Strip™ Wound Closure Strip are used as a primary non-suture skin closure, or as a adjunct to suture closure, or as a reinforcement for wounds after early suture or staple removal. The Silverlon™ Wound Contact Dressing is a non-adhering dressing providing effective protection of the dressing against microbialcontamination.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 19 2007

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

Re: K984204
Trade Name: Silverlon™ DP Wound Closure Strip
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 24, 1998
Received: November 24, 1998

Dear Mr. Flick:

This letter corrects our substantially equivalent letter of February 22, 1999.

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 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 (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act including requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration 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).

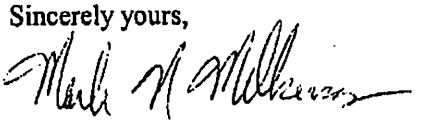
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 continue 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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

2. INDICATIONS FOR USE

510(k) Number (if known): K984204

DeviceName: Silverlon™ DP Wound Closure Strip

Silverlon™ Direct Pressure (DP) Wound Closure Strips are absorbent antimicrobial barrier dressings.

The Over-The-Counter (OTC) indications:

Local management of superficial wounds and skin tears and minor lacerations.

The Prescription Professional indications:

Primary or secondary closure following surgery, supplementary-support to sutures, staples or sealants, wound support following suture removal, and wound sites where suturing would aggravate bleeding.

MRO

(Division Sign-Off)
Division of General Restorative Devices K984204
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 ✓
(Per 21 CFR 801.109)
(Optional Format 1-2