MAY 0 1 2014

5.0 **510(k) Summary**
[As required by 21 CFR 807.92]

5.1. **Submitted by**

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5.3. **Date prepared**

4/23/2014

5.4. **Device trade name**

Silverlon® Island Wound Dressing

5.5. **Common name**

Dressing, Wound, Drug

5.6. **Classification name**

Unclassified: Pre-Amendment
21 CFR Number: None
Product code FRO

5.7. **Substantially Equivalent Devices (Predicates):**

Primary Predicate:
AQUACEL HYDROFIBER WOUND DRESSING AND AG HYDROFIBER DRESSING (K080383) cleared 05/02/2008

Other predicates:
ACTICOAT FLEX 7 DRESSING (K083113) cleared 07/22/2009
Silverlon Island Wound Dressing and Silverlon Island Pad (K984208) cleared 02/22/1999

5.8. **Description of Device**

Silverlon® Island Wound Dressing is a self-adhesive, elastomeric wound dressing composed of 5 distinct layers (in innermost to outermost order):

- Layer 1 is a non-adherent wound contact layer that consists of a single layer of knitted continuous nylon fiber coated with metallic silver at the rate of 5.05 mg/cm (50.5 g/m^2); the silver surface coating is approximately 0.8 – 1.0 μm thick and contains approximately 1% silver oxide).
- Layer 2 is a polyethylene film used to bond the nylon substrate to the pad layer described below;
- Layer 3 is a laminate pad with an absorptive capacity of 65 oz/yd^2 to absorb wound exudate;
- Layer 4 is an apertured high density polyethylene film that bonds the pad to the outer polyester fabric described below; and,
- layer 5 is a non-woven, medical grade polyester fabric coated on the skin-contacting side with a self-curing acrylic, pressure-sensitive, medical grade adhesive covered with a silicone-coated (one side) paper liner.

Layer 1 delivers antimicrobial silver ions in the dressing when activated by moisture. The silver ions in the dressing kill wound bacteria held in the dressing and provides an antimicrobial barrier to protect the wound bed. This dressing absorbs high amounts of wound fluid and the dressing intimately conforms to the wound surface.

Under the direction of a healthcare professional, Silverlon® Island Wound Dressing may be used for wounds such as vascular access or peripheral IV sites, orthopedic 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) or traumatic wounds left to heal by secondary intent, and management of painful wounds.

Silverlon® Island Wound Dressing is indicated for the management of infected wounds, as the silver in the dressing provides an antimicrobial barrier that may be helpful in managing these wounds. In addition, the moist wound healing environment and control of wound bacteria within the Silverlon Island Wound Dressing is indicated for the management of infected wounds, as the silver in the dressing provides an antimicrobial barrier that, may be helpful in managing these wounds.

A majority of postoperative surgical incisions are sutured, stapled or glued and are covered with some form of dressing. This first dressing, frequently referred to as the primary dressing, acts to absorb drainage, maintain a clean environment and serve as a barrier against further trauma to the delicate incision surface. Careful selection of non-adherent, absorptive dressings that do not become incorporated within the incision serves greatly to reduce the potential of surgical incision injury, and reduce pain upon dressing change when the time comes for the initial dressing to be removed.

Silverlon® Island Wound Dressing can be used safely and effectively as primary dressings on surgical incisions which heal by primary intent.

5.9. **Technological Characteristics**

The technological characteristics have not changed from the previously cleared Silverlon® Island Wound Dressing and Silverlon Pad (K984208) cleared 02/22/1999. Silverlon® Island Wound Dressing has substantially the same characteristics as AQUACEL HYDROFIBER WOUND DRESSING AND AG HYDROFIBER DRESSING (K080383) cleared 05/02/2008 and the primary wound contact layer has substantially the same technological characteristics as ACTICOAT FLEX 7 DRESSING (K083113).Any technological differences do not raise new questions of safety and effectiveness.

5.10. **Indications for Use**

Silverlon® Island Wound Dressings is a multi-layer, sterile, non-adherent, antimicrobial barrier wound dressing.

5.10.1. **The Over-The-Counter Indications:**

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

5.10.2. **Prescription Indications:**

Under the supervision of a healthcare professional Silverlon Island Wound Dressings are intended for up to 7 day use for wounds such as vascular access or peripheral IV sites, orthopedic external pin sites, wound drain sites, surgical wounds (donor and graft sites, incisions), and partial to fill thickness dermal ulcers (stage I-IV pressure sores, venous stasis ulcers, arterial ulcers, diabetic ulcers).

Silverlon Island Wound Dressing is indicated for the management of infected wounds[1], as the silver in the dressing provides an antimicrobial barrier that may be helpful in managing these wounds. In addition, the moist wound healing environment and control of wound bacteria within the Silverlon Island Wound Dressing may help reduce the risk of wound infection and support the body's healing process.

Silverlon® Island Wound Dressing may be used for the management of painful wounds[1] Silverlon® Island Wound Dressing's non-adherent wound contact layer reduces pain during dressing changes and evaporation of moisture in the dressing may sooth the wound.

[1]Clarified/New Indication, not previously included in this format under K984208.

Silverlon® Island Wound Dressing may be used for the management of:

- Management of painful wounds[1] Silverlon® Island Wound Dressing's non-adherent wound contact layer reduces pain during dressing changes and evaporation of moisture in the dressing may sooth the wound.

[1]Clarified/New Indication, not previously included in this format under K984208.

5.11. **Preclinical and Clinical Studies**

5.11.1 Silverlon® Island Dressings have been subjected to independent standard in vitro and in vivo biocompatibility tests, including cytotoxicity, sensitization and intracutaneous reactivity. All tests were performed in accordance with the International Standard Organization (ISO) 10993 Standard Series for Biological Evaluation of Medical Devices.

5.11.2 In vitro accelerated stability testing for antimicrobial effectiveness, equivalent to 5 years.

5.11.3 Kirby-Bauer Standard Antimicrobial Susceptibility Test.

5.11.4 Microbiological Consultants - ASTM E2315 Time Kill Assay for Antimicrobial Agents Report.

5.12. **Performance Standards**

No applicable performance standards have been established under Section 514 of the FD&C Act. In vitro testing, animal testing, and clinical investigations have been completed to demonstrate the safe and effectiveness of Silverlon Island Wound Dressing.

5.13. **Substantial Equivalence**

Silverlon Dressings have the 1) same intended use, 2) same technological characteristics, and 3) do not raise new questions of safety or effectiveness to the predicates AQUACEL HYDROFIBER WOUND DRESSING AND AG HYDROFIBER DRESSING (K080383), ACTICOAT FLEX 7 DRESSING (K083113) and several other secondary predicates; which are supported by product specifications, testing, and scientific studies. This is further reflected in the summary documents submitted by the predicate manufacturers (required by 21 CFR 807.92), labeled indications and directions for use of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 1, 2014

Argentum Medical, LLC
% Mr. Walt Brittle
FDAImports.Com, LLC
810 Landmark Drive, Suite 126
Glen Burnie, Maryland 21061

Re: K122817
Trade/Device Name: Silverlon Island Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: February 20, 2014
Received: February 26, 2014

Dear Mr. Brittle:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Binita S. Ashar -S
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Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122817

Device Name: Silverlon® Island Wound Dressings

Silverlon® Island Wound Dressings is a multi-layer, sterile, non-adherent, antimicrobial barrier wound dressing.

The Over-The-Counter Indications:

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Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S

Page 1 of ____