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

August 28, 2014

Argentum Medical
Mr. Richard C. Foster
Director of Quality and Regulatory Affairs
2571 Kaneville Court
Geneva, Illinois 60134

Re: K141573
Trade/Device Name: Silverlon Island Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: August 11, 2014
Received: August 12, 2014

Dear Mr. Foster:

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,

David Krause -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141573

Device Name

Silverlon® Island Wound Dressing

Indications for Use *(Describe)*

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

The Over-The-Counter Indications:
Local management of superficial wounds, minor burns, abrasions and lacerations.

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, 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, Silverlon® Island Wound Dressing's non-adherent wound contact layer reduces pain during dressing changes and evaporation of moisture in the dressing may soothe the wound.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

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5.0 510(k) Summary

[As required by 21 CFR 807.92]

5.1. Submitted by

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5.2. Contact person

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5.3. Date prepared

08/25/2014

55.4. 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):

Predicate: SILVERLON ISLAND WOUND DRESSING (K122817)

510(k) Summary

Argentum Medical

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 (Layer 3);
- 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 (Layer 5) described below; and,
- Layer 5 is a tape layer comprised of a widely used, commercially available foam tape component with natural color that is coated with a non-latex medical grade acrylic adhesive on the skin-contacting side. The side of the dressing away from the body is covered by a medical grade polyurethane film that is bonded to the foam membrane by an acrylic adhesive.

All materials are biocompatible per irritation, sensitization and cytotoxicity testing results.

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

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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

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/m2); the silver surface coating is approximately 0.8 – 1.0 µm thick and contains approximately 1% silver oxide. 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.

5.10. Indications for Use

Silverlon® Island Wound Dressing 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:

The Over-The-Counter Indications:
Local management of superficial wounds, minor burns, abrasions and lacerations.

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, 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, Silverlon® Island Wound Dressing's non-adherent wound contact layer reduces pain during dressing changes and evaporation of moisture in the dressing may soothe the wound.

510(k) Summary

Argentum Medical

5.11. Preclinical and Clinical Studies

Silverlon® Island Dressing 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. Summary of Technological Characteristics of device compared to predicate device

The technological characteristics have not changed from the previously cleared Silverlon® Island Wound Dressing (K122817) cleared 05/01/2014. The tape layer adheres to the body in the same manner as the predicate. Antimicrobial is not affected. The minor changes in design do not influence the technological differences, so there are no new questions of safety and effectiveness.

5.13 Summary of Nonclinical testing

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

5.14 Summary of Clinical testing

No clinical testing was necessary.

5.15 Substantial Equivalence

Silverlon Island Wound Dressing with new tape layer has the 1) same intended use, 2) same technological characteristics, and 3) does not raise new questions of safety or effectiveness to the predicate device, Silverlon Island Wound Dressing, cleared in K122817. This is reflected in labeled indications and directions for use of the predicate device.