January 14, 2019

Argentum Medical, LLC
Kartik Patel
Associate Director, Quality and Regulatory Affairs
2571 Kaneville Court
Geneva, IL 60134

Re: K180570
Trade/Device Name: Silverlon Island Wound Dressing, Silverlon Wound Pad Dressing (also known as Silverlon Burn Pad Dressing)
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 29, 2018
Received: December 3, 2018

Dear Kartik Patel:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kimberly Ferlin -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180570

Device Name
Silverlon® Island Wound Dressing, Silverlon® Wound Pad Dressing (also known as Silverlon® Burn Pad Dressing)

Indications for Use *(Describe)*

Silverlon® Island Wound Dressing and Silverlon® Wound Pad Dressing are multi-layer, sterile, non-adherent, antimicrobial barrier wound dressings.

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 and Silverlon® Wound Pad 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 full thickness dermal ulcers (stage I-IV pressure sores, venous stasis ulcers, arterial ulcers, diabetic ulcers).

Silverlon® Island Wound Dressings and Silverlon® Wound Pad Dressings are 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 and Silverlon® Wound Pad Dressing may help reduce the risk of wound infection and support the body's healing process.

Silverlon® Island Wound Dressings and Silverlon® Wound Pad Dressings may be used for the management of painful wounds, Silverlon® Island Wound Dressings and Silverlon® Wound Pad 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

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510(k) Summary

[As required by 21 CFR 807.92]

1.0 Submitted by

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Phone 630.232.2507
Fax 630.232.8005

2.0 Contact Person

Kartik Patel
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Geneva, IL 60134
Phone 630.232.2510
Fax 630.232.8005
kpatel@silverlon.com

3.0 Date Prepared

November 29, 2018

4.0 Device Trade Name

Silverlon® Island Wound Dressing, Silverlon® Wound Pad Dressing (also known as Silverlon® Burn Pad Dressing)

5.0 Common Name

Dressing, Wound, Drug

6.0 Classification Name

Unclassified: Pre-Amendment

21 CFR Number: None

Product code: FRO

7.0 Substantially Equivalent Devices (Predicate Devices):

Silverlon Island Wound Dressing, Silverlon Wound Pad Dressing (K143001)

7.1. Reference Device:

Silverlon Island Wound Dressing (K122817)

8.0 Device Description

Silverlon Island Wound Dressing is a self-adhesive, elastomeric wound dressing composed of 5 distinct layers (in innermost to outermost order): The Silverlon Wound Pad Dressing is comprised of Layers 1 – 4, they are not supplied with Layer 5 (adhesive tape layer).

- 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. The Silverlon Wound Pad dressings do not have a tape layer.

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 provide 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 and Silverlon Wound Pad 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 Dressings and Silverlon Wound Pad Dressings are 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 Dressings and Silverlon Wound Pad Dressings are 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 nonadherent, 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 Dressings and Silverlon Wound Pad Dressings can be used safely and effectively as primary dressings on surgical incisions which heal by primary intent.

9.0 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/m^2); 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.

10.0 Indications for Use

Silverlon® Island Wound Dressings and Silverlon Wound Pad Dressings are multi-layer, sterile, non-adherent, antimicrobial barrier wound dressings.

10.1. The Over-The-Counter Indications:

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

10.2. Prescription Indications:

Under the supervision of a healthcare professional Silverlon Island Wound Dressings and Silverlon Wound Pad 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 full thickness dermal ulcers (stage I-IV pressure sores, venous stasis ulcers, arterial ulcers, diabetic ulcers).

Silverlon Island Wound Dressings and Silverlon Wound Pad Dressings are 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 and Silverlon Wound Pad Dressing may help reduce the risk of wound infection and support the body's healing process.

Silverlon Island Wound Dressings and Silverlon Wound Pad Dressings may be used for the management of painful wounds, Silverlon Island Wound Dressings and Silverlon Wound Pad Dressing’s non-adherent wound contact layer reduces pain during dressing changes and evaporation of moisture in the dressing may soothe the wound.

11.0 Summary of Technological Characteristics of Device Compared to Predicate Device

The technological characteristics have not changed from the previously cleared Silverlon Island Wound Dressing and Silverlon Wound Pad Dressing (K143001) cleared November 7, 2014. Antimicrobial activity due to the Silverlon pad is not affected. The Silverlon Island Wound Dressing has a tape layer supplied with the dressing and Silverlon Wound Pad Dressing is supplied without the tape layer. The labeling change to MR Conditional does not impact the product design or technological characteristics. There are no new questions of safety and effectiveness.

12.0 Summary of Nonclinical Testing

Silverlon Island Wound Dressings (K122817) 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, including:

- In vitro accelerated stability testing for antimicrobial effectiveness, equivalent to 5 Years;
- Kirby-Bauer Standard Antimicrobial Susceptibility Test; and
- Microbiological Consultants - ASTM E2315 Time Kill Assay for Antimicrobial Agents Report.

The expanded labeling for use of the Silverlon Island Wound Dressings and Silverlon Wound Pad Dressings in the Magnetic Resonance environment is supported by completed testing of:

- Magnetically Induced Displacement Force in accordance with ASTM F2052;
- Magnetically Induced Torque in accordance with ASTM F2213;
- Heating by RF Fields in accordance with ASTM F2182; and
- Image Artifacts in accordance with ASTM F2119.

These tests were completed in accordance with FDA guidance, “Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment” (December 11, 2014).

13.0 Summary of Clinical Testing

No clinical testing was necessary for this submission.

14.0 Substantial Equivalence

The subject device, Silverlon Island Wound Dressings (with a tape layer) and the Silverlon Wound Pad Dressings (pad without a tape layer), and the predicate device, Silverlon Island Wound Dressing and Silverlon Wound Pad Dressing (K143001), have the 1) same intended use and 2) same technological characteristics, and 3) the expanded labeling for use in an MR environment does not raise different questions of safety or effectiveness or significantly affect the safety and effectiveness in comparison to the predicate device.