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

April 30, 2015

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

Re: K150256
Trade/Device Name: Silverlon ®Wound Contact, Burn Contact Dressings
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 30, 2015
Received: February 3, 2015

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

APPENDIX F: Silverlon Island Wound Dressing – Wound Pad Dressing Indications for Use

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)*

K150256

Device Name
Silverlon® Wound Contact, Burn Contact Dressings

Indications for Use *(Describe)*

Silverlon® Wound Contact, Burn Contact Dressings are comprised of a single layer of knitted nylon fiber substrate coated with metallic silver.

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

Prescription Indications:
Silverlon® Wound Contact, Burn Contact Dressings are indicated for use up to 7 days for partial and full thickness wounds including traumatic wounds, surgical wounds (donor and graft sites, incisions), 1st and 2nd degree burns, as well as dermal ulcers (stage I-IV pressure sores, venous stasis ulcers, arterial ulcers, diabetic ulcers), vascular access or peripheral IV sites, orthopedic external pin sites and wound drain sites.

Silverlon® 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® Dressings may help reduce the risk of wound infection and support the body's healing process.

Silverlon® Wound Contact, Burn Contact Dressings may be used for the management of painful wounds. Silverlon® Wound Contact, Burn Contact Dressings is a non-adherent wound contact layer that reduces pain during dressing changes and evaporation of moisture in the dressing may sooth 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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APPENDIX G: 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

12/11/2014

5.4. Device trade name

Silverlon® Wound Contact Dressings,
Silverlon® Burn Contact Dressings

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):

K023612; Silverlon® Antimicrobial Barrier Wound Contact Dressing, Antimicrobial Barrier Burn Wrap Dressing, Antimicrobial Barrier Burn Contact Dressing, SilverlonB Acute Burn Glove
K073213; TheraBond Antimicrobial Barrier Systems
K122817; Silverlon® Island Wound Dressing

APPENDIX G: 510(k) Summary

5.8. Description of Device

Silverlon® Wound Contact, Burn Contact Dressings are sterile, porous, non-adherent, knitted nylon plated with 99% elemental silver and 1% silver oxide. Silverlon® Wound Contact, Burn Contact Dressings 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.

The Silverlon® Wound Contact, Burn Contact Dressings are used as the primary wound contact layer and is placed under reticulated foam, gauze, or other wound fillers. Silverlon® Wound Contact, Burn Contact Dressings are non-adherent, wound care dressings designed to be used up to seven (7) days.

5.9. Technological Characteristics

Silverlon® Wound Contact, Burn Contact Dressings are composed of a single layer of woven nylon fiber substrate plated with metallic silver. The dressing facilitates the body's wound healing process by:

- covering the wound and acting as a barrier to the ingress of foreign objects;
- providing silver ions for an antimicrobial effect in the dressing: and,
- permitting the passage of oxygen and fluids to the wound.

5.9.1. How the device functions

Silverlon® Wound Contact, Burn Contact Dressings deliver 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 for bacterial penetration of the dressing which may help reduce infection.

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

5.10. Indications for Use

Silverlon® Wound Contact, Burn Contact Dressings are comprised of a single layer of knitted nylon fiber substrate coated with metallic silver.

5.10.1. The Over-The-Counter Indications:

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

5.10.2. Prescription Indications:

Silverlon® Wound Contact, Burn Contact Dressings are indicated for use up to 7 days for partial and full thickness wounds including traumatic wounds, surgical wounds (donor and graft sites, incisions), 1st and 2nd degree burns, as well as dermal ulcers (stage I-IV pressure sores, venous stasis ulcers, arterial ulcers, diabetic ulcers), vascular access or peripheral IV sites, orthopedic external pin sites and wound drain sites.

Silverlon® 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® Dressings may help reduce the risk of wound infection and support the body's healing process.

Silverlon® Wound Contact, Burn Contact Dressings may be used for the management of painful wounds. Silverlon® Wound Contact, Burn Contact Dressings is a non-adherent wound contact layer that reduces pain during dressing changes and evaporation of moisture in the dressing may soothe the wound.

5.11. Preclinical and Clinical Studies

APPENDIX G: 510(k) Summary

Silverlon® Dressings have been tested to independent standards for biocompatibility. In vitro and in vivo biocompatibility tests were conducted. These included cytotoxicity, sensitization and intracutaneous reactivity, per the guidance of International Standard Organization (ISO) 10993 Standard Series for Biological Evaluation of Medical Devices. Other in vitro testing included the following:

- In vitro accelerated stability testing for antimicrobial effectiveness on samples aged to the equivalent of 5 years.
- Kirby-Bauer Standard Antimicrobial Susceptibility Test.
- ASTM E2315 Time Kill Assay for Antimicrobial Agents Report.

5.12. Summary of Technological Characteristics of device compared to predicate device

There is no technological difference between the subject devices and the Silverlon® Barrier Wound Contact, Burn Wrap, Burn Contact, Burn Glove Dressing. The technological characteristics have not changed from the previously cleared K023612; Silverlon® Barrier Wound Contact, Burn Wrap, Burn Contact, Burn Glove Dressing. Therefore the subject device also remains unchanged from the cleared predicate K073213; TheraBond Antimicrobial Barrier Systems. The Silverlon® Wound Contact, Burn Contact Dressings have the same technological characteristics cleared in other Silverlon® dressings' 510(k)s including K122817; Silverlon® Island Wound Dressing. .Any technological differences are minor and do not raise 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® Wound Contact, Burn Contact Dressings.

The metallic silver provides antimicrobial protection of the dressing. When the dressing is exposed to moisture in the form of water, water vapor, blood, saline, and other forms of liquid it produces silver ions to minimize/reduce the growth of bacteria within the dressing. Antimicrobial effectiveness in the dressing was addressed in separate in-vitro laboratory evaluations using licensed commercial reference laboratories.

5.14 Summary of Clinical testing

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No clinical studies were conducted to support this premarket notification.

5.15 Substantial Equivalence

Based on the information presented above it is concluded that the Silverlon® Wound Contact and Burn Contact Dressings have the 1) same intended use, 2) same technological characteristics, and 3) do not raise new questions of safety or effectiveness to the listed predicates. This is further reflected in the summary documents submitted by the predicate manufacturers (required by 21 CFR 807.92) and labeled indications.