July 18, 2019

Argentum Medical, LLC
Aftab Ahmad
Director, Quality and Regulatory Affairs
2571 Kaneville CT
Geneva, Illinois 60134

Re: K190343
Trade/Device Name: Silverlon Wound Contact, Burn Contact Dressings
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 17, 2019
Received: April 19, 2019

Dear Aftab Ahmad:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Cynthia Chang, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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)*
K190343

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.

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), first and second degree thermal 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® Wound Contact, Burn Contact Dressings are indicated for use up to 7 days for decontaminated stable unroofed first and second degree mustard-induced vesicant injuries not requiring skin grafting.

Silverlon® Wound Contact, Burn Contact 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® Wound Contact, Burn Contact 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, Wound Burn Dressings are a non-adherent wound contact layer that 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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Section 4: 510(k) Summary

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4.0 510(k) Summary

[As required by 21 CFR 807.92]

4.1. Submitted by

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Phone 630.232.2507
Fax 630.232.8005

4.2. Contact Person

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4.3. Date Prepared

July 18, 2019

4.4. Device Trade Name

Silverlon® Wound Contact, Burn Contact Dressings

4.5. Common Name

Dressing, Wound, Drug

4.6. Classification Name

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

4.7. Substantially Equivalent Device (Predicate Device):

Silverlon Wound Contact, Burn Contact Dressings (K150256)

4.8. Device Description

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.

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

4.9. 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.

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.

4.10. Technological Characteristics Compared to Predicate Device

Silverlon Wound Contact, Burn Contact Dressings have the same technological characteristics as the predicate device. The expanded indications for use has no impact on the product design or technological characteristics.

4.10. Indications for Use

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

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), first and second degree thermal 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 Wound Contact, Burn Contact Dressings are indicated for use up to 7 days for decontaminated stable unroofed first and second degree mustard-induced vesicant injuries not requiring skin grafting.

Silverlon Wound Contact, Burn Contact 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 Wound Contact, Burn Contact 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 are a non-adherent wound contact layer that reduces pain during dressing changes and evaporation of moisture in the dressing may soothe the wound.

4.11. Indications for Use Compared to Predicate Device

Silverlon® Wound Contact, Burn Contact Dressings shares the same intended use and nearly the same indications for use as the predicate device, although the subject device revises the indications for use to clarify first and second degree thermal burns and expands the indications for use to include use up to 7 days for decontaminated stable unroofed first and second degree mustard-induced vesicant injuries not requiring skin grafting, defined as:

• Decontaminated: a mustard vapor injury that has received sufficient debridement to remove all traces of the mustard agent.

• Stable: a mustard vapor injury that has not become deeper or larger during the preceding 2-4 days.

• Unroofed: a mustard vapor injury in which debridement of all appropriate blisters has been performed.

This modification does not result in a new intended use in comparison to the predicate device, and the submitted testing demonstrates that Silverlon Wound Contact, Burn Contact Dressings are substantially equivalent to the predicate device in terms of performance.

4.12. Summary of Bench Testing

No bench studies were conducted to support this premarket notification.

4.13. Summary of Animal Testing

A GLP nonclinical study was conducted comparing use of the subject device and standard of care on vesicant-induced sulfur mustard injuries in 165 Gottingen minipigs. Superficial partial thickness (SD) and moderate partial thickness (DD) depth wounds were induced by sulfur mustard vapor followed by wet-to-wet debridement 48 hours post-injury and daily thereafter for 7 days. The wounds were then covered for 30 days with either the subject device or standard of care followed by 7 days of no wound coverage. The primary endpoint for the study was the histopathology composite score (total score of up to 15) of dermal wounds obtained at the end of the study (Study Day 46). The non-inferiority margin for the total histopathology score is 1.5 (or 10% of maximum possible score). In the DD depth injuries, those covered with the subject device had a mean composite histopathology score 0.36 points higher than those covered with standard of care. In the SD depth injuries, those covered with the subject device had a mean composite histopathology score 0.01 points higher than those covered with standard of care. Dressing moistening was performed three times daily with the subject device and once daily with standard of care. The study demonstrated that the Silverlon Wound Contact, Burn Contact Dressing is non-inferior to standard of care when it is changed every 7 days on moderate partial thickness depth decontaminated stable unroofed mustard-induced vesicant injuries not requiring skin grafting on Gottingen minipigs. The study also demonstrated that the Silverlon Wound Contact Burn Contact Dressing is non-inferior to standard of care when it is changed every 4 days on superficial thickness depth decontaminated stable unroofed mustard-induced vesicant injuries not requiring skin grafting on Gottingen minipigs. There were no device-related adverse events during the study. The results of this study demonstrated that the new indication does not raise different questions of safety and effectiveness and does not significantly increase any concerns of safety or effectiveness in comparison to use of the wound dressings on the other specified burn types in the predicate labeling.

4.14. Summary of Clinical Testing

No clinical studies were conducted to support this premarket notification.

4.14. Substantial Equivalence

Based on the information presented above and further detailed within this premarket notification, Silverlon Wound Contact, Burn Contact Dressings are substantially equivalent to the predicate device. Silverlon Wound Contact, Burn Contact Dressings have the same intended use and same technological characteristics as the predicate device, and do not raise different questions of safety or effectiveness in comparison to the predicate device.