July 31, 2024

Argentum Medical LLC
% Kathy Herzog
Sr Regulatory, Quality, and Compliance Consultant
DuVal & Associates, P.A.
1820 Medical Arts Building
825 Nicollet Mall
Minneapolis, Minnesota 55402

Re: K241225
Trade/Device Name: Silverlon® Wound Contact, Burn Contact Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 1, 2024
Received: May 2, 2024

Dear Kathy Herzog:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Mustafa A. Mazher -S

For Yu-Chieh Chiu, PhD
Assistant Director
DHT4B: Division of Plastic and
Reconstructive 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241225

Device Name
Silverlon® Wound Contact, Burn Contact Dressing

Indications for Use *(Describe)*

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

RX Use
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 use up to 7 days for radiation dermatitis.

Silverlon® Wound Contact, Burn Contact Dressings are indicated for use up to 7 days for acute cutaneous radiation injury including moist desquamation without full thickness skin ulceration and/or necrosis.

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.

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

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510(k) Summary

K241225

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92.

I. SUBMITTER

Argentum Medical, LLC
2571 Kaneville Court
Geneva, IL 60134
Phone: 630.345.4038
JFitzgerald@BravidaMedical.com

Date Prepared: July 30, 2024

II. DEVICE

Trade/Proprietary Names:	Silverlon® Wound Contact, Burn Contact Dressing
Common Name:	Wound Dressing
Regulation Number:	Unclassified
Regulation Name:	NA
Device Class:	Unclassified
Product Code:	FRO
Panel:	General & Plastic Surgery

III. PREDICATE DEVICE

Silverlon® Wound Contact, Burn Contact Dressings, K221218
This predicate has not been subject to a design-related recall.
No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Silverlon® Wound Contact, Burn Contact Dressings (WCD/BCD) are sterile, single use, single layer, non-adherent antimicrobial barrier wound dressings for up to seven day use. The dressings are comprised of Silverlon knitted nylon material plated with 99% elemental silver and 1% silver oxide. When Silverlon® dressings are moistened, the silver ions are activated, which kill wound bacteria held in the dressing which may help to reduce wound infection.

The dressings are used as primary dressings that conform to the wound surface. The dressings are available in several configurations (e.g., rectangular, chest/trunk aprons, wraps, and gloves) and sizes.

V. INTENDED USE/INDICATIONS FOR USE

The Silverlon® Wound Contact, Burn Contact Dressings are indicated for the following:

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

RX Use
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 use up to 7 days for radiation dermatitis.

Silverlon® Wound Contact, Burn Contact Dressings are indicated for use up to 7 days for acute cutaneous radiation injury including moist desquamation without full thickness skin ulceration and/or necrosis.

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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject and predicate Silverlon Wound Contact, Burn Contact Dressings (K221218) have the same intended use as antimicrobial barrier dressings that provide a moist environment for wound healing. The subject and predicate Silverlon Wound Contact, Burn Contact Dressings are identical products and thus have identical technological characteristics (design, materials, configurations, sizes, manufacturing process, packaging materials, sterilization).

VII. PERFORMANCE DATA

Non-Clinical Performance

The subject and predicate Silverlon Wound Contact, Burn Contact Dressings are identical products. Therefore, previously completed non-clinical bench testing (e.g., biocompatibility, sterilization, packaging integrity, shelf-life, and antimicrobial effectiveness) remain valid and applicable to the subject device as the expansion in indications for use does not affect the technological characteristics of the device.

Pre-Clinical Performance

Argentum Medical sponsored a GLP-compliant study in swine to evaluate the safety and effectiveness of Silverlon Wound Contact, Burn Contact Dressings ("Silverlon BCD") on cutaneous radiation injuries (CRI). The 12-week study included 40 swine and 1% silver sulfadiazine (SSD) on gauze as the treatment comparator. The study was divided into toxicology and comparator arms and included analysis of 640 radiation injury wounds at radiation doses of 37 Gy or 47 Gy.

The toxicology results demonstrated that Silverlon BCD are safe for use on CRI wounds. For the comparator arm of the study, the mean difference of histopathology composite scores was within the predefined inferiority margin comparing Silverlon BCD-treated versus silver sulfadiazine-treated wounds.

The results of the animal study are applicable to expected performance of Silverlon BCD in humans as swine and human skin share similar skin structure and similar clinical symptoms of radiation-induced skin injuries resulting from the same damage mechanism of the same biological targets. The animal study results build on the predicate device prior clearance for radiation dermatitis and cutaneous radiation injury through dry desquamation supported by clinical evaluation of Silverlon BCD use on human patients receiving radiation treatment for breast cancer. Collectively, these results demonstrate the safety and performance of Silverlon BCD across a range of radiation dermatitis and cutaneous radiation injury severities.

VIII. CONCLUSIONS

The subject Silverlon Wound Contact, Burn Contact Dressing have the same intended use and are identical products to the predicate Silverlon Wound Contact, Burn Contact Dressings. The preclinical evaluation of the subject device for the management of CRI wounds including moist desquamation demonstrated that the subject device is as safe, and as effective, as the predicate Silverlon Wound Contact, Burn Contact Dressings (K221218).