October 26, 2022

Argentum Medical, Inc.
Kathy Herzog
Regulatory Consutlant
2571 Kaneville Ct
Geneva, Illinois 60134

Re: K221218
Trade/Device Name: Silverlon Wound Contact, Burn Contact Dressings
Regulatory Class: Unclassified
Product Code: FRO
Dated: September 28, 2022
Received: September 29, 2022

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 (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,

Julie Morabito, 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K221218

Device Name

Silverlon Wound Contact, Burn Contact Dressings

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 and cutaneous radiation injury through dry desquamation.

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.

K221218 510(k) Summary

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

Contact Person: Jim Fitzgerald
Phone: 630-232-2507, ext. 119
JFitzgerald@curasurgical.com

Date Prepared: October 26, 2022

II. DEVICE

Trade/Proprietary Names:	Silverlon® Wound Contact, Burn Contact Dressings
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, K190343 and HEALADEX®-P, K063517.

The predicate devices have 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, face masks, 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 and cutaneous radiation injury through dry desquamation.

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

A comparison of the subject Silverlon WCD/BCD to the primary and secondary predicate devices is provided in Table 1.

The subject, primary, and secondary predicate dressings all have the same intended use as wound dressings that provide a moist environment for wound healing. All of the dressings are sterile, single use dressings that are indicated for a variety of cutaneous wounds, including ulcers and first and second degree burns. The subject and secondary predicate dressings are both indicated to manage radiation-induced skin injury

The subject and primary predicate devices are identical and thus have identical technological characteristics. The expanded indications for use has no impact on the product design or technological characteristics.

The subject and secondary predicate, HEALADEX®-P, differ in construction and materials, however, these differences are not expected to raise different questions of safety and effectiveness as both devices are occlusive dressings and have the same principle of operation to allow exchange of oxygen and fluid through the dressing and provide a protective barrier to a wound.

Table 1: Subject and Predicate Device Comparison

Feature	Silverlon WCD/BCD (Subject Dressings)	Silverlon WCD/BCD (Primary Predicate)	HEALADEX®-P* (Secondary Predicate)
K number	K221218	K190343	K063517
Classification	Unclassified	Same	Same
Product Code	FRO	Same	Same primary (FRO) Subsequent code (KGN)
Dressing Description	Sterile, single layer non-adherent antimicrobial barrier dressing	Same	Sterile, hydrogel island wound dressing
Intended Use	Antimicrobial barrier dressings	Same	Wound Dressing
Indications for Use (OTC)	Local management of superficial wounds, minor burns, abrasions, and lacerations.	Same	Not applicable
Indications for Use (Prescription)	Silverlon® Wound Contact, Burn Contact Dressings are indicated for use up to 7 days for partial and full thickness	Same, except does not include the new indication for use of RD and CRI as noted in	HEALADEX®-P Wound Dressing provides a moist environment that is supportive of wound healing. HEALADEX-P

Feature	Silverlon WCD/BCD (Subject Dressings)	Silverlon WCD/BCD (Primary Predicate)	HEALADEX®-P* (Secondary Predicate)
	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	bolded italic text for the subject device	is indicated for dry, light and moderately exudating partial and full thickness wounds such as: • First and second degree burns • Severe sunburns • Superficial injuries, superficial lacerations, cuts, abrasions, incisions/surgical wounds, and skin tears HEALADEX-P dressing should be used under health care professional direction for the following indications: • Pressure ulcers, Stage I-IV • Lower extremity ulcers • Venous ulcers • Arterial ulcers • Ulcers of mixed etiology • Diabetic ulcers • Donor sites and skin grafts • Burns caused by radiation oncology procedures

Feature	Silverlon WCD/BCD (Subject Dressings)	Silverlon WCD/BCD (Primary Predicate)	HEALADEX®-P* (Secondary Predicate)
	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. ***Silverlon® Wound Contact, Burn Contact Dressings are indicated for use up to 7 days for radiation dermatitis and cutaneous radiation injury through dry desquamation.***		
Type of Use	OTC and Prescription	Same	Prescription
User	**OTC**: Public **Prescription**: Healthcare professional	**OTC**: Public **Prescription**: Healthcare professional	Healthcare professional
Intended Use Environment	**OTC:** Home use **Prescription:** Healthcare facility	**OTC:** Home use **Prescription:** Healthcare facility	Healthcare environment
Principle of Operation	The silver coated nylon fabric permits the passage of oxygen and fluids to and from the wound and when activated by	Same	The permeable moisture vapor adhesive film dressing sheet permits the passage of oxygen and

Feature	Silverlon WCD/BCD (Subject Dressings)	Silverlon WCD/BCD (Primary Predicate)	HEALADEX®-P* (Secondary Predicate)
	moisture, silver ions kill wound bacteria held in the dressings which may help reduce infection.		moisture vapor to and from the wound.
Use	Single Use	Same	Same
Duration of Use	Up to 7 days	Same	Not stated
Construction	Single layer	Same	Multi-layer
Materials	**WCD Dressings:** Nylon and elastane substrate. The nylon yarn is circumferentially coated with 99% metallic silver and 1% silver oxide. **BCD, BWD, DS, SL, ABG :** Nylon and elastane substrate. The nylon yarn is circumferentially coated with 99% metallic silver and 1% silver oxide.	Same. Same.	Carboxymethylcellulose and lyophilized formulated porcine plasma (hydrogel) mounted on moisture vapor permeable adhesive film dressing sheet coated with acrylic adhesive and a polyurethane protective film
Packaging	Tyvek film	Same	Foil pouch
Sterilization Method	Ethylene oxide	Same	Not stated
Sterility Assurance Level (SAL)	10^{-6}	Same	Not stated
Shelf Life	5 years	5 years	Not stated

*Information for HEALADEX®-P is limited to that provided in the 510(k) Summary (K063517).

VII. PERFORMANCE DATA

Non-Clinical Performance

The subject and primary predicate Silverlon® Wound Contact, Burn Contact Dressings are identical. Therefore, previously completed non-clinical bench testing remains valid and applicable to the subject device.

Pre-Clinical Performance

No additional animal studies were considered necessary or conducted specifically for the expanded indication for use up to seven days for radiation dermatitis and cutaneous radiation injury through dry desquamation.

Clinical Performance

Argentum Medical sponsored an open label, single site, single arm, unblinded, interventional clinical study to evaluate the safety and feasibility of Silverlon Burn Contact Dressings for the management of radiation dermatitis (RD) of patients receiving external beam radiation therapy (RT) for breast cancer (ClinicalTrials.gov Identifier: NCT04238728). Thirty (30) patients were enrolled and wore Silverlon® Burn Contact Dressings during prescribed RT and for two weeks post RT. The study sample size was not sufficiently powered to draw any statistical conclusions.

The primary analyses demonstrated the safety of Silverlon® Burn Contact Dressings for management of RD as no adverse events related to the dressing were reported during or post RT.

The secondary analyses demonstrated the feasibility of using Silverlon® Burn Contact Dressings for the management of RD for a period of 7 days during RT and for 2 weeks post-RT. The daily wear compliance was 99.9% and the average wear time was 22 hours/day. Of the 28 patients who completed a 90-day follow-up assessment, 100% would recommend Silverlon dressing to other patients.

Each clinical trial subject was matched with three historical patients within a four-year window of the clinical trial at the same study sites for a total of 90 patients. Matched patients received external radiation therapy for breast cancer and RD was managed with standard-of-care treatment (e.g. creams, lotions). Inclusion of historical patients was based solely on the eligibility criteria defined for the clinical study and matching was completed per pre-specified matching rules. The matching criteria included age (±10 years), race, ethnicity, BMI (±6), total prescribed radiation dose and fractionation dose (±5%), and total number of radiation treatment sessions (±5%).

Documented radiation dermatitis (RD) grades (either RTOG or CTCAE) were available for a subset (N=71) of the 90 matched cohort patients. RTOG scores were available for all clinical trial subjects. The RT characteristics for these two groups with documented RD grades are shown in Table 2.

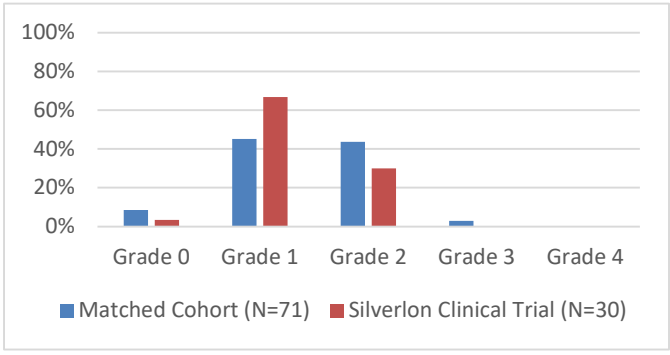
Table 2: RT Characteristics: Matched Cohort vs. Silverlon Clinical Trial Subjects

RT Characteristic	Matched Cohort (N=71)	Clinical Trial (N=30)
RT Type, N (%)		
3D Conformal	60 (96.8)	25 (83.3)
IMRT	2 (3.2)	5 (16.7)
Bolus Use N (%)		
Yes	31 (43.7)	1 (3.3)
No	40 (56.3)	29 (96.7)
Total Prescribed Dose (Gy)		
Mean (SD)	51.8 (4.94)	50.85 (4.42)
Total # of Sessions		
Mean (SD)	22.4 (4.73)	22.1 (4.60)

A comparison of RD grades for these two groups is provided in Table 3. RD grade 3 was observed in 2.8% of the matched cohort patients. No Silverlon clinical study patients were excluded from analysis nor withdrawn from the study due to a RTOG grade of 3 or more. The mean RD grade for each group is provided in Table 4.

Table 3: RD Grade: Matched Cohort vs. Silverlon Clinical Trial Subjects

RD Grade	Matched Cohort (N=71)*	Clinical Trial (N=30)†
Grade 0	8.5%	3.3%
Grade 1	45.1%	66.7%
Grade 2	43.7%	30.0%
Grade 3	2.8%	0.0%
Grade 4	0%	0.0%



*RTOG or CTCAE scale
†RTOG scale

Table 4: Mean RD Grade: Matched Cohort vs. Clinical Trial Subjects

RD Grade	Matched Cohort (N=71)*	Clinical Trial (N=30)†
Mean (SD)	1.41 (0.69)	1.27 (0.52)
Range	0-3	0-2
95% CI	[1.25, 1.57]	[1.07, 1.46]

*RTOG or CTCAE scale
†RTOG scale

Six (6) of 30 study subjects (20%) used topical treatments in the RT field covered by the Silverlon dressing. Twenty of the 30 subjects (67%) used topical treatments in the RT field outside of the Silverlon dressing.

The clinical symptoms and pathology of skin injury from therapeutic radiation (such as seen in cancer patients) have similarities to lower severity CRI.[1, 2] Hence, the clinical results achieved with Silverlon® Burn Contact Dressings in the RD clinical study would be expected to be equivalent in management of CRI through dry desquamation.

The clinical trial results demonstrated that Argentum Medical's Silverlon Burn Contact Dressing (BCD) is a safe and feasible modality for the routine management of radiation dermatitis. The primary analyses showed no adverse events related to use of the Silverlon BCD. The secondary analyses demonstrated the feasibility of using Silverlon dressing as daily wear compliance during and two-weeks post RT was 99.9% with an average wear time of 22 hours per day. At the 90-day post RT follow-up, 100% of the patients surveyed stated they would recommend the use of the Silverlon dressing during RT to other patients. Additional analyses further showed that Silverlon dressings did not increase the severity of radiation dermatitis compared to the historical cohort. Furthermore, the radiation-induced skin injury symptoms (e.g. erythema, dry/moist desquamation and sensations such as tenderness, itchy, burning) assessed in the Silverlon clinical study are shared symptoms for radiation injuries termed either radiation dermatitis or cutaneous radiation injuries.

VIII. CONCLUSIONS

The subject Silverlon WCD/BCD have the same intended use and are identical product to the primary predicate Silverlon WCD/BCD. The clinical evaluation of the subject dressings for the management of RD in breast cancer patients undergoing external beam radiation treatment demonstrated the subject dressings do not raise different questions of safety and effectiveness compared to use of the primary predicate Silverlon WCD/BCD to manage cleared wound indications. The Silverlon WCD/BCD also have the same intended use as the secondary predicate, HEALDEX®-P, and both are indicated to manage radiation-induced skin injury (radiation dermatitis). The differences in dressing construction and materials of Silverlon WCD/BCD as compared to HEALADEX®-P are not expected to raise different questions of safety and effectiveness as both devices are occlusive dressings that have the same principle of operation. Therefore, the subject Silverlon WCD/BCD is as safe, and as effective, as the primary predicate Silverlon WCD/BCD (K190343) and the secondary predicate device HEALADEX®-P (K063517).

[1] DiCarlo, A. L., Bandremer, A. C., Hollingsworth, B. A., Kasim, S., Laniyonu, A., Todd, N. F., ... & Rios, C. I. (2020). Cutaneous radiation injuries: Models, assessment and treatments. Radiation research, 194(3), 315-344.

[2] https://remm.hhs.gov/