



Food and Drug Administration
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September 12, 2014

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

Re: K141033

Trade/Device Name: Silverlon[®] Antimicrobial Wound Contact Negative Pressure Dressing
and Silverlon[®] Easy Ag[™] Antimicrobial Wound Contact
Negative Pressure Dressing

Regulation Number: 21 CFR 878.4780

Regulation Name: Powered suction pump

Regulatory Class: Class II

Product Code: OMP

Dated: August 8, 2014

Received: August 11, 2014

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

Indications for Use

510(k) Number (if known)
K141033

Device Name

Silverlon® Fenestrated Wound Contact Dressings: -

Silverlon® Antimicrobial Wound Contact Negative Pressure Dressing and Silverlon® Easy Ag™ Antimicrobial Wound Contact Negative Pressure Dressing

Indications for Use (Describe)

Silverlon® Antimicrobial Wound Contact Negative Pressure Dressing and the Silverlon® Easy Ag™ Antimicrobial Wound Contact Negative Pressure Dressing are intended to provide moist wound environment and are used for the management of chronic, acute, surgical, traumatic, sub-acute and dehisced wounds, ulcers (such as pressure or diabetic), partial-thickness burns, flaps and grafts; when used in conjunction with an NPWT pump that is intended to be used for negative pressure wound therapy (NPWT), the NPWT system is indicated for patients who benefit from wound management therapy via the application of negative pressure wound therapy for removal of fluids and excess exudates, infectious material, and tissue debris which may promote wound healing. It provides a non-adherent, conformable, antimicrobial barrier and may help reduce infection when placed under reticulated foam, gauze, or other wound fillers. Silverlon® Fenestrated Wound Contact Dressings may be cut or overlapped to fit any wound size.

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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AI Appendix-9: 510(k) Summary2571 Kaneville Court
Geneva, IL 60134PH: (630) 232.2507
TF: (888) 551-0188**5. 510(k) Summary**

[As required by 21 CFR 807.92]

5.1. Submitted byArgentum Medical, LLC
2571 Kaneville CT. Geneva, IL 60134
Phone 630.232.2507
Fax 630.232.8005**5.2. Contact person**C. Richard Foster
Argentum Medical, LLC
2571 Kaneville CT. Geneva, IL 60134
Phone 630.232.2507
Fax 630.232.8005**5.3. Date prepared**

09/08/2014

5.4. Device trade name(s)Silverlon® Fenestrated Wound Contact Dressing
Silverlon® Antimicrobial Wound Contact Negative Pressure Dressing
Silverlon® Easy Ag™ Antimicrobial Wound Contact Negative Pressure Dressing**5.5. Common name**

Negative pressure antimicrobial wound contact layer dressing

5.6. Classification name

Powered suction pump (accessory)

5.7. Substantially Equivalent Devices (Predicates):

K050261; V.A.C. GranuFoam Silver Protection Dressing

K041642; V.A.C. GranuFoam™ Silver Dressing

K080275; Kalypto Medical's NPD 1000 (*Wound Dressing Set*)

K981299; Silverlon Contact Wound Dressing (1 and 4 Layer)

K122817; SILVERLON ISLAND WOUND DRESSING

5.8. Description of Device

Silverlon® Fenestrated Wound Contact Dressings—Models Silverlon® Antimicrobial Wound Contact Negative Pressure Dressing and Silverlon® Easy Ag™ Antimicrobial Wound Contact Negative Pressure Dressing are sterile, porous, non-adherent, knitted nylon plated with 99% elemental silver and 1% silver oxide. The dressings may promote wound healing via assisting the removal of fluids, including body fluids, wound exudates and infectious materials. The Silverlon® Fenestrated Wound Contact Dressing 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® Fenestrated Wound Contact Dressings are used as the primary wound contact layer for NPWT dressing sets and is placed under reticulated foam, gauze, or other wound fillers.

Silverlon® Antimicrobial Wound Contact Negative Pressure Dressing are non-adherent, wound care dressings designed to be used in negative pressure wound therapy dressing sets up to seven (7) days.

Silverlon® Easy Ag™ Antimicrobial Wound Contact Negative Pressure Dressing is a non-adherent, wound care dressings designed to be used in negative pressure wound therapy dressing sets up to three (3) days.

5.9. Technological Characteristics

Silverlon® Fenestrated Wound 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 (e.g. foam particles, etc.);
- providing an antimicrobial effect in the dressing;
- permitting the passage of oxygen and fluids to the wound; and,
- permitting the removal under vacuum of wound exudate from the wound (negative pressure wound therapy).

5.9.1. How the device functions

Silverlon® Fenestrated Wound Contact Dressing functions as an antimicrobial barrier preventing materials and microbes in the dressing set from entering the wound. Silverlon® Fenestrated Wound Contact Dressing 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 for bacterial penetration of the dressing which may help reduce infection.

Bench testing using simulated wound exudate demonstrate the porous single layer structure of the dressing allows substantially the same amount of fluid removal when compared to NPWT dressing sets currently on the market. The metallic silver functions as an antimicrobial in the dressing. When the dressing is exposed to moisture in the form of water, water vapor, blood, saline, and other forms of liquids it releases silver ions that are responsible for the antimicrobial effect. Antimicrobial effectiveness in the dressing was addressed in separate in-vitro laboratory evaluations using licensed commercial reference laboratories.

5.10. Indications for Use

Silverlon® Antimicrobial Wound Contact Negative Pressure Dressing and the Silverlon® Easy Ag™ Antimicrobial Wound Contact Negative Pressure Dressing are intended to provide moist wound environment and are used for the management of chronic, acute, surgical, traumatic, sub-acute and dehisced wounds, ulcers (such as pressure or diabetic), partial-thickness burns, flaps and grafts; when used in conjunction with an NPWT pump that is intended to be used for negative pressure wound therapy (NPWT), the NPWT system is indicated for patients who benefit from wound management therapy via the application of negative pressure wound therapy for removal of fluids and

excess exudates, infectious material, and tissue debris which may promote wound healing. It provides a non-adherent, conformable, antimicrobial barrier and may help reduce infection when placed under reticulated foam, gauze, or other wound fillers. Silverlon® Fenestrated Wound Contact Dressings may be cut or overlapped to fit any wound size.

5.11. Preclinical Clinical Studies

Silverlon® Fenestrated Wound Contact Dressing has 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 device and the Silverlon Island dressing. The only technological difference between the V.A.C. GranuFoam dressing and the subject device is that the predicate has the silver-coated nylon adhered to a substrate, while the subject device is simply the silver-coated nylon without the substrate. The other predicate devices also have very similar technological characteristics.

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® Fenestrated Wound Contact Dressing.

Bench testing using simulated wound exudate demonstrated that the porous single layer structure of the dressing allows substantially the same amount of fluid removal when compared to NPWT dressing sets currently on the market. 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

No clinical studies were conducted to support premarket notification..

5.15. Substantial Equivalence

Based on the information presented above it is concluded that the Silverlon® Fenestrated Wound 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.