December 10, 2018

Vomaris Wound Care, Inc.
Charmaine Sutton
Head of Regulatory and Quality
1911 East Fifth Street
Tempe, Arizona 85281

Re: K180533
Trade/Device Name: Procellera Composite Antibacterial Wound Dressing (also Helix Composite Antibacterial Wound Dressing and Jumpstart Composite Antibacterial Wound Dressing)
Regulatory Class: Unclassified
Product Code: FRO
Dated: September 7, 2018
Received: September 10, 2018

Dear Charmaine Sutton:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lixin Liu -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

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)*
K180533

Device Name
Procellera Composite Antibacterial Wound Dressing (also Helix Composite Antibacterial Wound Dressing and Jumpstart Composite Antibacterial Wound Dressing)

Indications for Use *(Describe)*

Rx Indications for Use:

For professional use, Procellera Composite Antibacterial Wound Dressing is intended for the management of wounds to provide a moist wound environment and is indicated for partial and full-thickness wounds such as pressure ulcers, venous ulcers, diabetic ulcers, first and second degree burns, surgical incisions, donor and recipient graft sites, etc.

OTC Indications for Use:

For over-the-counter use, Procellera Composite Antibacterial Wound Dressing is intended for the management of wounds to provide a moist wound environment and is indicated for superficial wounds such as minor cuts, scrapes, irritations, abrasions, blisters, etc.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary for Procellera® Composite Antibacterial Wound Dressing

Prepared December 7, 2018

## Submitter


| Manufacturer: | Contact Person: |
|---|---|
| Vomaris Wound Care, Inc.<br>1911 East Fifth Street<br>Tempe, AZ 85281<br>480-921-4948 | Charmaine Sutton<br>Head of Regulatory and Quality<br>(480) 921-4948 Ext. 2253<br>e-mail: regulatory@vomaris.com |


## General Information

| | |
|---|---|
| Trade Name: | Procellera Composite Antibacterial Wound Dressing<br>(also Helix Composite Antibacterial Wound Dressing and Jumpstart Composite Antibacterial Wound Dressing) |
| Common / Usual Name: | Wound Dressing |
| Classification Name: | Dressing, Wound, Drug |
| Product Code and Classification: | FRO, Unclassified |
| Primary Predicate Device: | Procellera Antimicrobial Wound Dressing<br>(K160783, K130350, K081977, K060237) |
| Secondary Predicate Device: | Silverlon Island Wound Dressing (K143001) |

## Intended Use

For professional use, Procellera Composite Antibacterial Wound Dressing is intended for the management of wounds to provide a moist wound environment and is indicated for partial and full-thickness wounds such as pressure ulcers, venous ulcers, diabetic ulcers, first and second degree burns, surgical incisions, donor and recipient graft sites, etc.

For over-the-counter use, Procellera Composite Antibacterial Wound Dressing is intended for the management of wounds to provide a moist wound environment and is indicated for superficial wounds such as minor cuts, scrapes, irritations, abrasions, blisters, etc.

## Device Description

Procellera Composite Antibacterial Wound Dressing is a three-layer dressing comprising a broad-spectrum antibacterial contact layer (Procellera), a polyester-based absorbent layer, and a polyurethane semi-occlusive outer adhesive layer to keep the dressing in place and help maintain a moist wound environment. The dressing is offered in various shapes and sizes; the knee and elbow/shoulder dressings are prescription use only, while the square, rectangular and round shaped dressings are for both prescription and over-the-counter use.

Embedded in the dressing are microcell batteries made of elemental silver and elemental zinc applied in a dot-matrix pattern to a polyester substrate. In the presence of a conductive medium such as wound exudate, water-based wound hydrogels, saline, or water, microcurrents are generated at the dressing surface due to its inherent design. Silver and zinc in the dressing help to preserve it and minimize or prevent the growth of bacteria within the dressing.

Procellera Composite Antibacterial Wound Dressing may be used with other common wound treatment products such as sutures, staples, liquid skin adhesives, or steri-strips as an adjunct to local clinical protocols.

## Technological Characteristics

Procellera Composite Antibacterial Wound Dressing is a multi-layer wound dressing with built-in polyester-based absorbent and polyurethane adhesive layers to keep it in place and help maintain a moist wound environment. The wound contact layer of the subject device is identical to the Procellera Antimicrobial Wound Dressing. Elemental silver and elemental zinc are bound to the surface of a polyester substrate in a well-characterized dot matrix pattern. In the presence of a conductive medium, such as wound exudate, water-based wound hydrogels, saline, or water, microcurrents are generated at the surface of the device, and this occurs because it is inherent to the design.

## Safety and Performance Data

Procellera Composite Antibacterial Wound Dressing was tested in accordance with applicable parts of the ISO 10993: Biological Evaluation of Medical Devices standard and found to be biocompatible. Additional tests recommended by FDA guidance Use of International Standard ISO 10993-1 were also performed. Testing included: cytotoxicity, intracutaneous irritation, sensitization, acute systemic toxicity, material-mediated pyrogenicity, subchronic toxicity and implantation.

Procellera Composite Antibacterial Wound Dressing was tested per AATCC TM 100: Assessment of Antibacterial Finishes on Textile Materials and demonstrated broad-spectrum antibacterial effectiveness within the dressing.

## Substantial Equivalence Discussion

The intended use, wound contact layer and antibacterial technology of Procellera Composite Antibacterial Wound Dressing are identical to the primary predicate single layer Procellera Antimicrobial Wound Dressing cleared under K160783 and its predecessors. The composite configuration with multiple functional layers is equivalent to the secondary predicate Silverlon Island Wound Dressing. The impact of the new materials in Procellera Composite Antibacterial Wound Dressing were evaluated through standardized test methods. The tests raised no new questions of safety or effectiveness. Key characteristics of the subject and predicate devices are compared in the table below. Procellera Composite Antibacterial Wound Dressing is substantially equivalent to the legally marketed predicate devices.

**Table: Substantial Equivalence Comparison of Key Characteristics**

| | **Subject Device**<br>Procellera Composite Antibacterial Wound Dressing<br>(K180533)<br>Vomaris Wound Care, Inc.<br>Phoenix, AZ, USA | **Primary Predicate**<br>Procellera Antimicrobial Wound Dressing<br>(K160783)<br>Vomaris Wound Care, Inc.<br>Phoenix, AZ, USA | **Secondary Predicate**<br>Silverlon Island Wound Dressing<br>(K143001)<br>Argentum Medical, LLC.<br>Geneva, IL, USA |
|---|---|---|---|
| Indications for Use (Rx) | Intended for the management of wounds to provide a moist wound environment and indicated for partial and full-thickness wounds such as pressure ulcers, venous ulcers, diabetic ulcers, first and second degree burns, surgical incisions, donor and recipient graft sites, etc. | Intended for the management of wounds to provide a moist wound environment and indicated for partial and full-thickness wounds such as pressure ulcers, venous ulcers, diabetic ulcers, first and second degree burns, surgical incisions, donor and recipient graft sites, etc. | Under the supervision of a healthcare professional Silverlon® Island Wound Dressings and Silverlon® Wound Pad Dressings are intended for up to 7 day use for wounds such as vascular access or peripheral IV sites, orthopedic external pin sites, wound drain sites, surgical wounds (donor and graft sites, incisions), and partial to full thickness dermal ulcers (stage I-IV pressure sores, venous stasis ulcers, arterial ulcers, diabetic ulcers).<br>Silverlon® Island Wound Dressings and Silverlon® Wound Pad 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® Island Wound Dressing and Siverlon® Wound Pad Dressing may help reduce the risk of wound infection and support the body's healing process.<br>Silverlon® Island Wound Dressings and Silverlon® Wound Pad Dressings may be used for the management of painful wounds. Silverlon® Island Wound Dressings and Silverlon® Wound Pad Dressing's non-adherent wound contact layer reduces pain during dressing changes and evaporation of moisture in the dressing may soothe the wound. |

| | **Subject Device**<br>Procellera Composite Antibacterial Wound Dressing<br>(K180533)<br>Vomaris Wound Care, Inc.<br>Phoenix, AZ, USA | **Primary Predicate**<br>Procellera Antimicrobial Wound Dressing<br>(K160783)<br>Vomaris Wound Care, Inc.<br>Phoenix, AZ, USA | **Secondary Predicate**<br>Silverlon Island Wound Dressing<br>(K143001)<br>Argentum Medical, LLC.<br>Geneva, IL, USA |
|---|---|---|---|
| Indications for Use (OTC) | Intended for the management of wounds to provide a moist wound environment and indicated for superficial wounds such as minor cuts, scrapes, irritations, abrasions, blisters, etc. | Intended for the management of wounds to provide a moist wound environment and indicated for superficial wounds such as minor cuts, scrapes, irritations, abrasions, blisters, etc. | Local management of superficial wounds, minor burns, abrasions and lacerations. |
| Materials | Procellera polyester substrate containing elemental silver and elemental zinc.<br>Absorbent polyester- based material.<br>Outer polyurethane layer with acrylate adhesive. | Procellera polyester substrate containing elemental silver and elemental zinc. | Knitted continuous nylon fiber coated with metallic silver.<br>Absorbent laminate pad.<br>Polyester layer with acrylic adhesive.<br>Polyethylene / HDPE films. |
| Configuration | Multi-layered; primary layer that contacts the wound bed, followed by an absorbent layer, then an adhesive tape layer. | Single layer that contacts the wound bed. Used in combination with secondary dressing(s) selected by the user to absorb and fix the dressing in place. | Multi-layered; primary layer that contacts the wound bed, followed by an absorbent layer, then an adhesive tape layer. Two films are used to bond these functional layers together. |
| Sterility | Provided sterilized by irradiation (gamma). | Provided sterilized by irradiation (e-beam). | Provided sterile. |
| Shapes and Sizes (inches) | Square: 4 x 4<br>Rectangular: 5 x 6, 4.5 x 10<br>Round: 4 D, 2.5 D<br>Knee: 6 x 11.5<br>Elbow / Shoulder: 4.2 x 7.5, 4.4 x 9.6 | Square: 1 x 1, 2 x 2, 3 x 3, 4 x 4, 8 x 8, 12 x 12<br>Rectangular: 1.5 x 8, 1.5 x 10, 2 x 5, 4 x 8 | Square: 4 x 4, 6 x 6<br>Rectangular: 4 x 6, 4 x 10, 4 x 12, 4 x 14 |
| Duration of Use | Up to 7 days | Up to 7 days | Up to 7 days |
| Safety | Biocompatible in compliance with ISO 10993 | Biocompatible in compliance with ISO 10993 | Biocompatible in compliance with ISO 10993 |
| Performance Characteristics | Antibacterial effectiveness (AATCC TM 100)<br>Fluid management<br>Conformability<br>Adhesion | Antimicrobial effectiveness (AATCC TM 100) | Antimicrobial effectiveness (Kirby-Bauer; ASTM E2315)<br>Fluid management<br>Conformability<br>Adhesion |