DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 7, 2016

Vomaris Innovations, Inc.
Mr. Timothy Joiner
Head Of Quality And Regulatory
1911 E. 5th St
Tempe, Arizona 85281

Re: K160783
Trade/Device Name: Procellera Antimicrobial Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: July 26, 2016
Received: July 28, 2016

Dear Mr. Joiner:

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" (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 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160783

Device Name
Procellera Antimicrobial Wound Dressing

Indications for Use *(Describe)*
For professional use, Procellera® antimicrobial 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160783

Device Name
Procellera Antimicrobial Wound Dressing

Indications for Use *(Describe)*
For over-the-counter use, Procellera® antimicrobial 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.

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www.procellera.com
Phone: 480-921-4948 Fax: 480-921-0948

510(k) Summary for Procellera® Device

Date: July 11, 2016

Device Name: Procellera®

Trade Name: Procellera® Antimicrobial Wound Dressing

Common Name: Wound Dressing

Product Code: FRO

Predicate Device(s):

- Procellera® Antimicrobial Wound Dressing (K130350)
- Procellera® Antimicrobial Wound Dressing (K081977)
- CMB™ Antimicrobial Dressing (K060237)

Reference Device(s):

- K062212, Silver Shield Antimicrobial Skin and Wound Gel
- K070333, AcryDerm OTC Silver Antimicrobial Wound Gel
- K083103, AcryDerm Antimicrobial Silver Wound Gel

Device Description:

Procellera® is a single layer, broad-spectrum antimicrobial wound dressing; it consists of a polyester substrate containing elemental silver and elemental zinc bound to the surface by a biocompatible binder in a well-characterized dot matrix pattern.

In the presence of a conductive fluid, such as wound exudate or moisture, a small amount of current is produced at the surface of the device, due to its inherent design. The device is self-contained and has no accessories.

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Procellera® contains Silver and Zinc as preservatives to the dressing, to minimize or prevent the growth of microorganisms within the dressing, not at the wound site, and to help preserve the dressing.

Procellera® is a primary contact layer dressing and it should be used under a secondary dressing or bandage, which keeps it in place and helps maintain a moist wound environment. Procellera® may be used with other common wound treatment products such as, sutures, staples, liquid skin adhesives, or steri-strips as an adjunct to the local clinical protocols.

Intended Use:

For professional use, Procellera® antimicrobial 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® antimicrobial 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.

Technological Characteristics:

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 fluid, such as wound exudate or moisture, a small amount of current is produced at the surface of the device, and it occurs because it is inherent to its design.

Performance Data:

Performance data was gathered through in-vitro antimicrobial efficacy testing and voltage potential testing.

Broad-Spectrum in-vitro antimicrobial efficacy testing previously submitted to FDA resulted in clearance of Procellera® Antimicrobial Wound Dressing for prescription use

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with an Antimicrobial claim. Silver and zinc in the dressing inhibit growth of microorganisms within the dressing. Neither the silver nor zinc preservatives provide any antimicrobial action in or on the wound.

The same data and results are applicable to Procellera® Antimicrobial Wound Dressing for OTC use as the products are identical and indistinguishable prior to labeling.

Voltage potential testing confirmed that a sustained, measurable voltage is generated on the surface of the device for up to 30 days when immersed in a conductive fluid. However, Procellera may only be left in place for up to 7 days (or longer, at the discretion and instruction of the treating clinician) and the safety of daily Procellera use for longer than 28 days has not been studied.

Biocompatibility Data:

Procellera® Antimicrobial Wound Dressing was tested per ISO 10993 and found to be biocompatible. Testing included: cytotoxicity, irritation, sensitization, pyrogenicity, and 28-day subcutaneous implantation.

Conclusion:

Based on the information provided herein, we conclude that Procellera® Antimicrobial Wound Dressing is as safe, as effective, and performs as well as the predicate devices, which are identical, and thus is substantially equivalent to the existing legally marketed devices under the Federal Food, Drug and Cosmetic Act.

Contact:

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