VOMARIS

Vomaris Innovations, Inc.
3100 W. Ray Rd, Suite 148, Chandler, AZ 85226
www.procellera.com
Phone: 480-921-4948 Fax: 480-921-0948

510(k) Summary for Procellera® Device for Over-The-Counter Use

510(k) # K130350

JUL 2 2013

Device Name: Procellera® Wound Dressing

Trade Name: Procellera®

Common Name: Wound Dressing

Product Code: FRO

Predicate Devices:

Procellera® wound dressing (K081977)

CMB™ dressing (K060237)

Device Description:

Procellera® is a single layer 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, and it occurs because it is inherent to its design. The device is self-contained and has no accessories.

Silver and zinc in the dressing produce microcurrent which helps the dressing to be preserved and to minimize or prevent growth of microorganisms within 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.

Intended Use:

For over-the-counter use, Procellera® 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.

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Technological Characteristics:

Procellera® device is identical to the device cleared under 510(k) K060237 and K081977.

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:

Voltage potential testing was performed in-house and 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.

Biocompatibility Data

The device 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® device 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:

Jeffry B. Skiba – CTO Vomaris Innovations, Inc.
3100 W. Ray Rd, Suite 148, Chandler, AZ 85226
Phone: 480-921-4948 Fax: 480-921-0948

Date: June 19th, 2013

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Vomaris Innovations, Inc.
% Mr. Jeff Skiba
Chief Technology Officer
3100 West Ray Road, Suite 148
Chandler, Arizona 85226

July 2, 2013

Re: K130350
Trade/Device Name: Procellera Antimicrobial Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 12, 2013
Received: April 22, 2013

Dear Mr. Skiba:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

FOR Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use – Procellera® Prescription Use Device

510(k) Number: K130350

Device Name: **Procellera®** Antimicrobial Wound Dressing

Indications for Use:

For prescription 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/or recipient graft sites, etc.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K130350

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Indications for Use – Procellera® Over-The-Counter Use Device

510(k) Number: K130350

Device Name: **Procellera®** Wound Dressing

Indications for Use:

For over-the-counter use, Procellera® 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.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S

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