Procellera™ (for Professional Use)
510(k) Summary of Safety and Effectiveness

510(K) Summary	Procellera™ is a single layer dressing consisting of a woven absorbent polyester fabric containing elemental silver and zinc which are held in position on the polyester with a biocompatible binder. For professional use, Procellera™ antimicrobial wound dressing is indicated for partial and full-thickness wounds such as: pressure ulcers, venous ulcers, diabetic ulcers, burns, surgical incisions, and donor and/or recipient graft sites. New Device Name: Procellera™ Predicate Device Name: CMB Antimicrobial Dressing (K060237)
Device Description	Procellera™ is a single layer dressing consisting of a woven absorbent polyester fabric containing elemental silver and zinc which are held in position on the polyester with a biocompatible binder. The polyester fabric is single ply and is made from multi-filament spun threads woven together. A small amount of current is produced and it occurs because it is inherent to the design. In the presence of exudate, the device should be used with an appropriate secondary barrier to maintain a moist wound healing environment.
Indications Statement	For professional use, Procellera™ antimicrobial wound dressing is indicated for partial and full-thickness wounds such as: pressure ulcers, venous ulcers, diabetic ulcers, burns, surgical incisions, and donor and/or recipient graft sites.
Technological Characteristics	Technologically, Procellera™ and the predicate device (CMB™ Antimicrobial Wound Dressing) are identical. Procellera™ is the same device as the predicate CMB™. A small amount of current is produced and it occurs because it is inherent to the design.
Performance Data	Performance data were gathered via antimicrobial, animal, bench and biocompatibility testing. Biocompatibility tests performed on the Procellera™: included cytotoxicity, irritation, sensitization, pyrogenicity, systemic injection, and 28 day subcutaneous implantation.
Conclusions	Based on the 510(k) summaries and the 510(k) statements (21 CFR 807) and the information and performance data provided herein, we conclude that the Procellera™ is substantially equivalent to the existing legally marketed devices under the Federal Food, Drug and Cosmetic Act.
Contact	Jeffry Skiba Vomaris Innovations Inc. 3100 W Ray Rd, Suite 148 Chandler, AZ 85226 Phone: 480-921-4948 Fax: 480-921-0948
Date	November 19, 2008

Procellera™ (for Over The Counter Use)

510(k) Summary of Safety and Effectiveness

510(K) Summary	Procellera™ is a single layer dressing consisting of a woven absorbent polyester fabric containing elemental silver and zinc which are held in position on the polyester with a biocompatible binder. For over-the-counter use, Procellera™ wound dressing is indicated for minor cuts, scrapes, irritations, and abrasions. New Device Name: Procellera™ Predicate Device Name: CMB Antimicrobial Dressing (K060237)
Device Description	Procellera™ is a single layer dressing consisting of a woven absorbent polyester fabric containing elemental silver and zinc which are held in position on the polyester with a biocompatible binder. The polyester fabric is single ply and is made from multi-filament spun threads woven together. A small amount of current is produced and it occurs because it is inherent to the design. In the presence of exudate, the device should be used with an appropriate secondary barrier to maintain a moist wound healing environment.
Indications Statement	For over-the-counter use, Procellera™ wound dressing is indicated for minor cuts, scrapes, irritations, and abrasions.
Technological Characteristics	Technologically, Procellera™ and the predicate device (CMB™ Antimicrobial Wound Dressing) are identical. Procellera™ is the same device as the predicate CMB™. A small amount of current is produced and it occurs because it is inherent to the design.
Performance Data	Performance data were gathered via antimicrobial, animal, bench and biocompatibility testing. Biocompatibility tests performed on the Procellera™: included cytotoxicity, irritation, sensitization, pyrogenicity, systemic injection, and 28 day subcutaneous implantation.
Conclusions	Based on the 510(k) summaries and the 510(k) statements (21 CFR 807) and the information and performance data provided herein, we conclude that the Procellera™ is substantially equivalent to the existing legally marketed devices under the Federal Food, Drug and Cosmetic Act.
Contact	Jeffry Skiba Vomaris Innovations Inc. 3100 W Ray Rd, Suite 148 Chandler, AZ 85226 Phone: 480-921-4948 Fax: 480-921-0948
Date	November 19, 2008

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 01 2008

Vomaris Innovations, Inc.
% Mr. Jeff Skiba
President
3100 W Ray Road, Suite 148
Chandler, Arizona 85226

Re: K081977
Trade/Device Name: Procellera™
Regulatory Class: Unclassified
Product Code: FRO
Dated: October 23, 2008
Received: October 24, 2008

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K081977

Device Name: Procellera™

Indications for Use:

For professional use, Procellera™ antimicrobial wound dressing is indicated for partial and full-thickness wounds such as pressure ulcers, venous ulcers, diabetic ulcers, burns, surgical incisions, and donor and/or recipient graft sites.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over-The-Counter Use _____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K081977

Statement of Indications for Use

510(k) Number (if known): K081977

Device Name: Procellera™

Indications for Use:

For over-the-counter use, Procellera™ wound dressing is indicated for minor cuts, scrapes, irritations, and abrasions.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ or Over-The-Counter Use X

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K081977