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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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6. 510(K) SUMMARY

The purpose of this Premarket Notification is to request the addition of the word "antimicrobial" to the Procellera® over-the-counter product, previously cleared through K081977 and K130350.

Procellera® device described in this Traditional 510(k) is identical to the Procellera® device cleared in 2013 (K130350), 2008 (K081977) and in 2006 (K060237). There are no changes to the original device design, characteristics, or to the manufacturing process.

The prescription device and the over-the-counter device cleared in 2013 (K130350) are identical in every way. Only during the labeling process, which is performed after pouching and sterilization, are the products distinguished between prescription use and over-the-counter use.

The Rx product was cleared with the word "antimicrobial" while the OTC product was not cleared with the word "antimicrobial".

The following are the **cleared** "Indications for Use" for each of the respective 510(k)'s:

K081977 (Rx)	K081977 (OTC)
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.	For over-the-counter use, Procellera® wound dressing is indicated for minor cuts, scrapes, irritations, and abrasions.

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K130350 (Rx)	K130350 (OTC)
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.	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.

The requested change is the addition of antimicrobial to the OTC "Indications for Use" such that the wording for both the Rx and OTC would include the word antimicrobial. The following is the proposed language.

Rx – this document	OTC – this document
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.

The 510(k) summary for the Procellera® device subject to this submission is provided in the following pages.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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510(k) Summary for Procellera® Device

Date: July 11, 2016

Device Name: Procellera®

Trade Name: Procellera® Antimicrobial Bioelectric 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, and it occurs because it is inherent to its 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, steri-strips, negative pressure wound therapy, 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:

(b)(4) Confidential and Proprietary Information

[redacted]

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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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.

(b)(4) Confidential and Proprietary Information

[redacted]

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:

Timothy Joiner
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16. SHELF LIFE

Both Procellera® Antimicrobial Wound Dressing RX and OTC single-layer products have a 5-year shelf life.

The shelf life is identified to the user by the use of an expiration date symbol followed by the date.

	Format: the year (yyyy), month (mm); day (dd), each separated by hyphens. Example, January 2, 2014, is presented as 2014-01-02.

The shelf life in the previous 510(k) K130350 we indicated for 3 years. At the time of that submission, only one (1) lot of product was available for testing due to the low production volume. However, since submitting and received clearance for 510(k) K130350, Vomaris has completed 5-year real time studies on two (2) production lots of product (lot 031001, lot 061001) and 5-year accelerated studies on three (3) lots of production product (lot 031001, lot 061001 and lot 041102). The final real-time time point for lot 041102 will be taken in October 2016.

Based on the data from the completion of three lots of 5-year accelerated studies and two lots of 5-year real time studies, Vomaris has set the shelf life date as five (5) years.

The results of these studies are included as attachments listed below:

- 16-01 TS-12 5-Year Accelerated Aging Report Lot 031001
- 16-02 TS-11 5-Year Real Time Report Lot 031001
- 16-03 TS-11 5-Year Accelerated Aging Report Lot 041102
- 16-04 TS-11 5-Year Real Time Aging Report Lot 061001
- 16-05 Summary Report

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Shelf Life Verification - Procellera single layer devices

Test report at the completion of Year 5 Real Time Aging (T6)

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[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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10. Declaration of Conformity and Summary Reports

This section does not apply to this 510(k) submission.

The Performance Standards information presented in this submission is unchanged from those presented in K060237, K081977, and K130350. There are no mandatory performance standards promulgated by the FDA for wound dressings. Procellera® is an unclassified, pre-amendment device that is not exempt from the Quality System Regulation (QSR).

Verification and validation activities were performed by designated individuals and results demonstrate that predetermined acceptance criteria were met.

Manufacturing facilities are in conformance with design control procedure requirements as specified in 21 CFR 820.30.

I certify that, in my capacity as Head of R&D of Vomaris Innovations, Inc., I believe to the best of my knowledge that all design and development activities associated with this product were conducted in compliance with 21 CFR 820.

Signature

04.11.2016
Date

Troy Paluszcyk
Head of R&D
Vomaris, Innovations, Inc.
1911 East Fifth Street
Tempe, AZ 85281

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Shelf Life Verification - Procellera single layer devices

Test report at the completion of Year 5 Real Time Aging (T2A)

(b)(4) Confidential and Proprietary Information

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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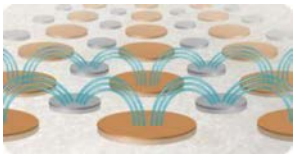
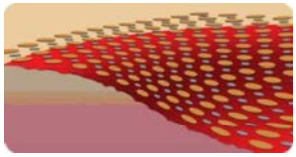
Procellera | Elite™
Wound Care with Advanced Microcurrent Technology

Instructions for OTC Use

Product Description

Procellera® is a single layer antimicrobial wound dressing. Imbedded in the dressing are microcell batteries made of elemental silver and zinc applied in a dot-matrix pattern. In the presence of a conductive medium such as wound exudate, water-based hydrogels or saline, microcurrents are generated at the dressing surface, due to its inherent design. Silver and zinc in the dressing produce microcurrents, to minimize or prevent the growth of microorganisms within the dressing and help the dressing to be preserved.

Procellera is a primary contact layer dressing; it should be used under a secondary dressing or bandage (not provided), to keep it in place and help maintain a moist wound environment.

Advanced Microcurrent Technology™

Indications

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.

Contraindications

- Do not use on individuals with sensitivity or allergy to silver or zinc;
- MRI Non-Compatible: Neither MRI-Safe nor MRI-Compatible and should be removed prior to an MRI procedure. A new dressing may be applied after the procedure.

Warnings

Frequent or prolonged use of this product may result in permanent discoloration of the skin (i.e., argyria).

Precautions

- Single use only.
- Do not use if the pouch is open or damaged prior to use.
- For external use only. Do not use Procellera with topical agents such as antimicrobial ointments, enzymatic debriders, antibiotic creams, silver or zinc containing creams, oxidizing agents, petroleum based products, etc..
- Secondary dressings should be used as stated in their Instructions for Use.
- Stop using the dressing and consult a physician if an allergy, irritation, increased pain, maceration or irregular skin discoloration occurs.
- Procellera is not intended to be used on wounds with uncontrolled bleeding.
- Remove Procellera dressing during energy-based procedures (such as electricity, radiofrequencies, ultrasound, radiation, etc.) where the dressing may interfere with delivery.
- Avoid contact with electrodes or conductive gels during electronic measurements; e.g., EEG (electroencephalogram) or ECG (electrocardiogram).
- Procellera may be used on infected wounds that are being managed in accordance with institutional clinical protocols for infection abatement as an adjunct to the standard treatment regimen.
- The safety of daily Procellera use for longer than 28 days has not been studied.

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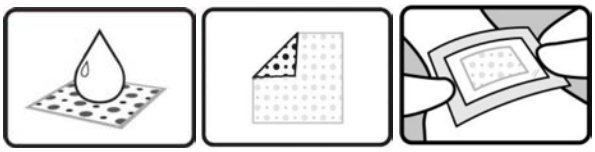
Instructions for OTC Use

Preparation

Follow local hygiene procedures prior to, during and following dressing application and change.

Application



1. Cleanse the wound area with an appropriate wound cleanser.
2. Remove Procellera from package and if needed, cut to a shape that will extend beyond wound edges 1 to 2 cm (1/2 inch to 1 inch). **Caution:** cutting may result in fraying of the dressing.
3. Moisten Procellera with sterile saline, water or a thin, even layer of water-based hydrogel (not included).
4. Apply Procellera dressing to the wound site, **with the dotted side down**, in direct contact with the wound surface.
5. Cover Procellera with an appropriate secondary sterile dressing (such as a waterproof dressing) which will keep it in place and help maintain a moist wound environment. If needed, secure in place with an additional fixation dressing, using care not to restrict blood flow.
6. Keep the dressing moist by re-moistening as necessary (once a day, for dry wounds). Avoid over-soaking.
   Note: It is not necessary to remove Procellera while showering.

(b)(4) Confidential and Proprietary Information

[redacted]

Site Care and Dressing Change

- Procellera may be left in place for up to 7 days. Earlier and/or more frequent changes may be required, depending on the amount of exudate present, the condition of the wound and surrounding skin. Inspect the wound site periodically.
- To remove the Procellera dressing, gently pull it back. If it adheres to the wound surface, do not force it off; moisten or soak the dressing with sterile saline or sterile water until it can be removed without tissue damage.
- Consult a physician if any of the following occur: infection, bleeding, maceration (skin whitening and softening), hypergranulation (excessive tissue formation), irritation at the wound site or the skin surrounding the dressing, or if the wound increases in size after a few dressing changes.

Dressing Components

- The dressing is not made with natural rubber latex.
- The dressing consists of a polyester substrate containing 0.9 mg of elemental silver and 0.3 mg of elemental zinc per square centimeter of dressing. Silver in the dressing acts as a preservative and inhibits growth of microorganisms within the dressing.

Storage and Disposal

- Store in dry conditions at room temperature. Protect from light.
- Dispose of according to local environmental procedures.

Made in the USA by:

Vomaris Wound Care, Inc.
1911 East Fifth Street, Tempe, AZ 85281, USA
(866) 496-8743 (480) 921-4948
www.procellera.com

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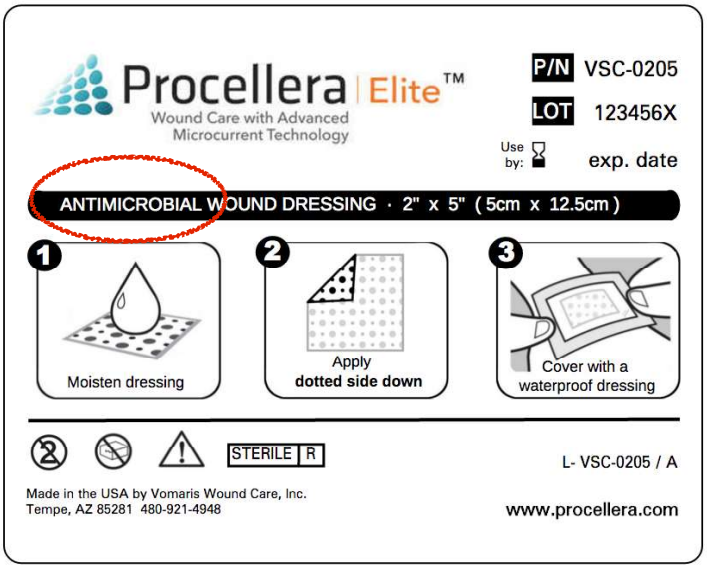
Pouch Label



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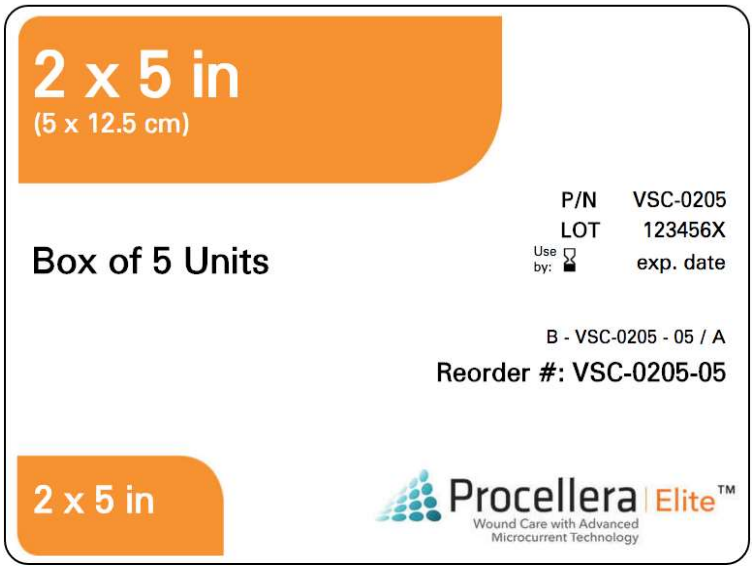
Box Label



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Pouch label on pouch

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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:

(b)(4) Confidential and Proprietary Information

[redacted]

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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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.

(b)(4) Confidential and Proprietary Information

[redacted]

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.

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VOMARIS

Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, AZ 85281
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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

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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:

(b)(4) Confidential and Proprietary Information

[redacted]

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.

(b)(4) Confidential and Proprietary Information

[redacted]

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:

Timothy Joiner
Director, Quality Assurance & Regulatory Affairs
1911 East Fifth Street, Tempe, Arizona, 85281
480-921-4948
Timothy.Joiner@Vomaris.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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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

Vomaris Innovations, Inc.
Mr. Timothy Joiner
Head of Quality and Regulatory
1911 E. 5th St.
Tempe, AZ 85281

Re: K160783
Trade/Device Name: Procellera Antimicrobial Wound Dressing

Dear Mr. Joiner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require responses to the following questions and comments:

(b)(4) Confidential and Proprietary Information

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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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:

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

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Food and Drug Administration

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

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Premarket Notification 510(k) Review

Post-Review Reminders

- ☐ Final Check: Ensure your documentation accurately reflects the final recommendation prior to signature (e.g., Review Summary, data in the Device Description section, the Labeling section, etc)
- ☐ For SE Decisions: Upload SE Letter, and PDFs of IFU form and 510(k) Summary (if included) in DocMan.

To add reminders, type the reminder in the text field to the left then press the Tab key.

Date: June 7, 2016

Reviewer: Charles Durfor

Subject: Traditional 510(k)# K160783

Applicant: Vomaris Innovations, Inc.

Contact Name: Timothy Joiner

Correspondent Firm: Vomaris Innovations, Inc.

Received Date: April 5, 2016

Pro Code(s): FRO **Class:** Unclassified **Reg #:**

Device Trade Name: Procellera Antimicrobial Wound Dressing

Contact Title: Head Of Quality And Regulatory

Phone: (480) 921-4948 **Email:** timothy.joiner@vomaris.com

Due Date: May 5, 2016

Reg Name: Wound Dressing, Drug

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Owner
K130350	FRO	Procellera	Vomaris Innovations Inc.
K081977	FRO	Prosit Wound Treatment Device	Silverleaf Medical Products, Inc.
K060237	FRO	Cmb Antimicrobial Dressing	Silverleaf Medical Products, Inc.

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Recommendation
I recommend that the Procellera Antimicrobial Wound Dressing is/are
in need of Additional Information (AINN)

Review Team
Lead Reviewer
Charles Durfor PRSB-2/DSD/ODE/CDRH

I. Purpose and History

Previously cleared products that are identified by the sponsor.

- K130350 – Vomaris Innovations, Inc.
  - Procellera antimicrobial wound dressing - Rx Use
  - Procellera wound dressing - OTC Use
- K081977 – Vomaris Innovations, Inc.
  - Procellera antimicrobial wound dressing - Rx Use
  - Procellera wound dressing - OTC Use
- K060237 – Silverleaf Medical Products, Inc.
  - CMB Antimicrobial Dresssing - Rx Use

II. 510(k) Summary/Statement

510(k) Summary/Statement		
Was a 510(k) Summary or Statement provided?	Summary	Undo

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

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(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Reviewer Recommendation

The 510(k) Summary/Statement is **[not]** acceptable.

III. Device/System Description

Device Characteristics		Inadequate Or Marked
Is the intended use or fundamental technology new?	No	☐
Is the device life-supporting or life sustaining?	No	☐
Are there any direct or indirect patient contacting components?	Yes	☐
• Is the device or a component an implant?	No	☐
Does the device use software/firmware?	No	☐
Does the device or a component need sterilization (by manufacturer or user)?	Yes	☐
The device/system uses or is…	a single use device(s) (SUD)	☐
The environment for use of the device/system includes…	Home, Hospital	☐
Is the device a combination product?	4 - Device Coated/Impregnated/Combined Drug	☐
Is the device/system electrical (battery or wall powered)?	Yes, it is battery powered Only	☐

Check the attributes that are applicable to this submission.

	Nanotechnology	Reprocessed SUD	Companion Diagnostic	Medical Counter Measures
Yes	☐	☐	☐	☐
No	☒	☒	☒	☒
Unknown	☐	☐	☐	☐

Device Description Table: Summary of important device characteristics is presented below.

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(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Reviewer Recommendation

The Device Description is acceptable.

IV. Comparison of Indications for Use to Predicate Devices

Comparison of Indications for Use	
Subject	
510(k) #: K160783	Rx/OTC: Rx and OTC

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Comparison of Indications for Use

Intended Population	Adults Only	Adults and Pediatrics	Transitional Adolescent A	Transitional Adolescent B	Adolescent	Child	Infant	Neonate/ Newborn
Yes	☐	☒	☐	☐	☐	☐	☐	☐
No	☒	☐	☒	☒	☒	☒	☒	☒
	☐	☐	☐	☐	☐	☐	☐	☐

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

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[redacted]

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(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Reviewer Recommendation

Minor revisions to the Indication for Use form should be made.

V. Comparison of Technology to Predicate Devices

Device & Predicate Device(s):	K160783	K130350	K081977	K060237
General Device Characteristics	[redacted]			

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Product Comparison Table in Section 12 Device Description

Characteristic	Rx (K130350)	OTC (K160783)
Configuration	Elemental silver and zinc are applied on a polyester substrate in a dot matrix pattern.	Identical
Elemental Ag to Zn concentration	(b)(4) Confidential and Proprietary Information and [redacted]	Identical
Surface area	1 in^2 – 144 in^2 6.5 cm^2 – 77.4 cm^2	Identical
Packaging	Mylar / Mylar pouch	Identical
Sterilization – irradiation	E-beam	Identical
Biocompatibility – ISO 10993-1	Cytotoxicity, irritation, sensitization, pyrogenicity, systemic injection and 28 day s.c. implantation data were submitted in K081977 (Rx) and K130350 (Rx & OTC)	Identical
Antimicrobial testing	Provided in K081977 for Rx additionally provided in K130350	Identical

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[redacted]

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Reviewer Recommendation

The Comparison of the Technology to Predicate Devices is acceptable.

VI. Labeling

Labeling Review Needed?	**Yes**	Undo
Usability Consult Needed?	Undo	**No**

A General Labeling Requirements

General Labeling Requirements		Inadequate or Marked
Is the prescription statement (or "Rx only") included?	Inapplicable	☐
Adequate instructions for OTC use?	No	☒
The indications for use are consistent with the IFU page?	Yes	☐
Appropriate contraindications, warnings, precautions and adverse events provided?	Yes	☐
Instructions are in accordance with the guidance (if applicable)?	Inapplicable	☐
Appropriate labeling inside device?	Yes	☒
Appropriate label/indicator outside device?	No	☒
Appropriate Manual labeling?	Inapplicable	☐
Is appropriate home use information included in the labeling?	No	☒
What MRI safety information does the labeling contain?	MR Unsafe	☐

Labeling Table: A summary of the adequacy of several labeling requirements.

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[redacted]

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Reviewer Recommendation

The Labeling is **[not]** acceptable.

VII. Reprocessing, Sterilization, and Shelf-Life

Sterility Review Needed?	Yes	No
Sterility Consult Needed?	Yes	No

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

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(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Reviewer Recommendation
Cleaning, Sterilization, Shelf-Life and Reuse descriptions are **[not]** acceptable.

VIII. Biocompatibility

Biocompatibility Review Needed?	Undo	**No**
Biocompatibility Consult Needed?	Undo	**No**

The FDA review of the previous 510(k), K130350 stated:

Test Performed	Result
Cytotoxicity	Non-cytotoxic
Closed Patch Test for Delayed Hypersensitivity (ISO)	Not a potential to be a contact sensitizer
Skin Irritation Test (ISO)	Non-irritating, no erythema, no edema
Material-mediated Rabbit Pyrogenicity test	No evidence of pyrogenicity was observed in any animal
Determination of Zn and Ag in the blood of rabbits following 28-days subcutaneous implantation Inductively-coupled plasma-Mass Spec (ICP-MS) used for metal detection	No detectable level increase of silver or zinc in the bloodstream after 28 days implantation

Since the products are indistinguishable, Biocompatibility testing results are applicable to both the Rx and OTC products. **No additional data are needed.**

Reviewer Recommendation
The Biocompatibility is acceptable.

IX. Software/Firmware

Reviewer Recommendation
The Software is acceptable.

X. EMC & Electrical, Mechanical and Thermal Safety & Risk Analysis

EMC Review Needed?	Undo	**No**
EMC Consult Needed?	Yes	No

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Reviewer Recommendation

The EMC, EMT and Risk Analysis are acceptable.

XI. Performance Testing

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Reviewer Recommendation

The Performance Testing [Verification & Validation] is **[not]** acceptable.

XII. Kit Certification

N/A

XIII. Manufacturing Information

The manufacturing process for Procellera Antimicrobial Wound Dressing Rx and OTC has been previously submitted and cleared in the aforementioned 510(k)'s. In those documents, the manufacturing process was explained and described in greater detail. The manufacturing process for Procellera Antimicrobial Wound Dressing Rx and OTC is not only the same, but indistinguishable because the product becomes Rx or OTC during the labeling process.

XIV. References

XV. SE Flowchart Questions

Substantial Equivalence Determination	Yes	No
Is the predicate device legally marketed?	☒	☐
Do the devices have the same intended use?	☐	☐

XVI. Original Deficiencies

The sponsor should receive a AINN letter with the following deficiencies:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require responses to the following questions and comments:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

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[redacted]

Digital Signature Concurrence Table	
Reviewer Sign-Off	

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Premarket Notification 510(k) Review

Date: August 22, 2016

Reviewer: Charles Durfor

Subject: Traditional 510(k)# K160783

Applicant: Vomaris Innovations, Inc.

Contact Name: Timothy Joiner

Correspondent Firm: Vomaris Innovations, Inc.

Received Date: April 5, 2016

Pro Code(s): FRO **Class:** Unclassified **Reg #:**

Device Trade Name: Procellera Antimicrobial Wound Dressing

Contact Title: Head Of Quality And Regulatory

Phone: (480) 921-4948 **Email:** timothy.joiner@vomaris.com

Due Date: May 5, 2016

Reg Name: Wound Dressing, Drug

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Owner
K130350	FRO	Procellera	Vomaris Innovations Inc.
K081977	FRO	Prosit Wound Treatment Device	Silverleaf Medical Products, Inc.
K060237	FRO	Cmb Antimicrobial Dressing	Silverleaf Medical Products, Inc.

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Recommendation
I recommend that the Procellera Antimicrobial Wound Dressing is/are Substantially Equivalent (SESE)

Review Team

Lead Reviewer	Charles Durfor	PRSB-2/DSD/ODE/CDRH

I. Purpose and History

Previously cleared products that are identified by the sponsor.

- K130350 – Vomaris Innovations, Inc.
  - Procellera antimicrobial wound dressing - Rx Use
  - Procellera wound dressing - OTC Use
- K081977 – Vomaris Innovations, Inc.
  - Procellera antimicrobial wound dressing - Rx Use
  - Procellera wound dressing - OTC Use
- K060237 – Silverleaf Medical Products, Inc.
  - CMB Antimicrobial Dresssing - Rx Use

II. 510(k) Summary/Statement

510(k) Summary/Statement		
Was a 510(k) Summary or Statement provided?	Summary	Undo
The 510(k) Summary is complete.		

Reviewer Recommendation
The 510(k) Summary/Statement is acceptable.

III. Device/System Description

Device Characteristics		Inadequate Or Marked
Is the intended use or fundamental technology new?	No	☐
Is the device life-supporting or life sustaining?	No	☐

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Device Characteristics		Inadequate Or Marked
Are there any direct or indirect patient contacting components?	Yes	☐
• Is the device or a component an implant?	No	☐
Does the device use software/firmware?	No	☐
Does the device or a component need sterilization (by manufacturer or user)?	Yes	☐
The device/system uses or is…	a single use device(s) (SUD)	☐
The environment for use of the device/system includes…	Home, Hospital	☐
Is the device a combination product?	4 - Device Coated/Impregnated/Combined Drug	☐
Is the device/system electrical (battery or wall powered)?	Yes, it is battery powered Only	☐

Check the attributes that are applicable to this submission.

[redacted]	Nanotechnology	Reprocessed SUD	Companion Diagnostic	Medical Counter Measures
Yes	☐	☐	☐	☐
No	☒	☒	☒	☒
Unknown	☐	☐	☐	☐

Device Description Table: Summary of important device characteristics is presented below.

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

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(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Reviewer Recommendation

The Device Description is acceptable.

IV. Comparison of Indications for Use to Predicate Devices

Comparison of Indications for Use

Subject

510(k) #: K160783 Rx/OTC: Rx and OTC

Intended Population	Adults Only	Adults and Pediatrics	Transitional Adolescent A	Transitional Adolescent B	Adolescent	Child	Infant	Neonate/ Newborn
Yes	☐	☒	☐	☐	☐	☐	☐	☐
No	☒	☐	☒	☒	☒	☒	☒	☒
Unknown	☐	☐	☐	☐	☐	☐	☐	☐

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

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(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Reviewer Recommendation

The Indication for Use form is acceptable.

V. Comparison of Technology to Predicate Devices

Device & Predicate Device(s):	K160783	K130350	K081977	K060237
General Device Characteristics				

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Product Comparison Table in Section 12 Device Description

Characteristic	Rx (K130350)	OTC (K160783)
Configuration	Elemental silver and zinc are applied on a polyester substrate in a dot matrix pattern.	Identical
Elemental Ag to Zn concentration	(b)(4) Confidential and Proprietary Information [redacted]	Identical
Surface area	1 in – 144 in 6.5 cm^2 – 77.4 cm^2	Identical
Packaging	Mylar / Mylar pouch	Identical
Sterilization –	E-beam	Identical

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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irradiation		
Biocompatibility – ISO 10993-1	Cytotoxicity, irritation, sensitization, pyrogenicity, systemic injection and 28 day s.c. implantation data were submitted in K081977 (Rx) and K130350 (Rx & OTC)	Identical
Antimicrobial testing	Provided in K081977 for Rx additionally provided in K130350	Identical

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Reviewer Recommendation

The Comparison of the Technology to Predicate Devices is acceptable.

VI. Labeling

Labeling Review Needed?	**Yes**	Undo
Usability Consult Needed?	Undo	**No**

A General Labeling Requirements

General Labeling Requirements		Inadequate or Marked
Is the prescription statement (or "Rx only") included?	Inapplicable	☐
Adequate instructions for OTC use?	No	☒
The indications for use are consistent with the IFU page?	Yes	☐
Appropriate contraindications, warnings, precautions and adverse events provided?	Yes	☐
Instructions are in accordance with the guidance (if applicable)?	Inapplicable	☐
Appropriate labeling inside device?	Yes	☒
Appropriate label/indicator outside device?	No	☒
Appropriate Manual labeling?	Inapplicable	☐
Is appropriate home use information included in the labeling?	No	☒
What MRI safety information does the labeling contain?	MR Unsafe	☐

Labeling Table: A summary of the adequacy of several labeling requirements.

- Attachment 14-01 – Rx Instructions for Use – Review of this document finds it acceptable.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Reviewer Recommendation

The Labeling is acceptable.

VII. Reprocessing, Sterilization, and Shelf-Life

Sterility Review Needed?	Undo	**No**
Sterility Consult Needed?	Undo	**No**

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Reviewer Recommendation

Cleaning, Sterilization, Shelf-Life and Reuse descriptions are acceptable.

VIII. Biocompatibility

Biocompatibility Review Needed?	Undo	**No**
Biocompatibility Consult Needed?	Undo	**No**

The FDA review of the previous 510(k), K130350 stated:

Test Performed	Result
Cytotoxicity	Non-cytotoxic
Closed Patch Test for Delayed Hypersensitivity (ISO)	Not a potential to be a contact sensitizer
Skin Irritation Test (ISO)	Non-irritating, no erythema, no edema
Material-mediated Rabbit Pyrogenicity test	No evidence of pyrogenicity was observed in any animal
Determination of Zn and Ag in the blood of rabbits following 28-days subcutaneous implantation Inductively-coupled plasma-Mass Spec (ICP-MS) used for metal detection	No detectable level increase of silver or zinc in the bloodstream after 28 days implantation

Since the products are indistinguishable, Biocompatibility testing results are applicable to both the Rx and OTC products. **No additional data are needed.**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Reviewer Recommendation

The Biocompatibility is acceptable.

IX. Software/Firmware

Reviewer Recommendation

The Software is acceptable.

X. EMC & Electrical, Mechanical and Thermal Safety & Risk Analysis

EMC Review Needed?	Undo	**No**
EMC Consult Needed?	Undo	**No**

Reviewer Recommendation

The EMC, EMT and Risk Analysis are acceptable.

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

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[redacted]

This response is acceptable.

Reviewer Recommendation
The Performance Testing is acceptable.

XII. Kit Certification

N/A

XIII. Manufacturing Information

The manufacturing process for Procellera Antimicrobial Wound Dressing Rx and OTC has been previously submitted and cleared in the aforementioned 510(k)'s. In those documents, the manufacturing process was explained and described in greater detail. The manufacturing process for Procellera Antimicrobial Wound Dressing Rx and OTC is not only the same, but indistinguishable because the product becomes Rx or OTC during the labeling process.

XIV. References

XV. SE Flowchart Questions

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Substantial Equivalence Determination	Yes	No
Is the predicate device legally marketed?	☒	☐
Do the devices have the same intended use?	☒	☐
Please explain how the intended use of the subject device is similar to or different from the predicate device: The only difference sought in this 510(k) is the addition of the term "antimicrobial" to the name of the OTC product. The sponsor has previously submitted data supporting this claim. In this 510(k), the sponsor identified the name of multiple other OTC Woudn Dressings cleared through the 510(k) process with the same term.		
Do the devices have the same technological characteristics?	☒	☐

XVI. Other Information

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

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[redacted]

Digital Signature Concurrence Table	
Reviewer Sign-Off	

Branch Sign-off

for Jiyoung Dang

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

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,

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

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September 7, 2016

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

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Sincerely yours,

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Reorder # AAA-XXXX-XX

Procellera® Single Layer
Antimicrobial Wound Dressing

X x X in / X x X cm

Expiration Date
2017-08-20

Box of X Unit(s)

REF AAA-XXXX LOT 123456X

Contains silver and zinc as preservatives

060700200 Rev A

(01) 0 0614141 99999 6 (17) 170820 (10) 123456X

X x X in / X x X cm

Procellera® Single Layer
Antimicrobial Wound Dressing

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Procellera®
Antimicrobial Wound Dressing

Instructions for OTC Use

Product Description

Procellera® is a single layer, broad-spectrum antimicrobial wound dressing. Embedded in the dressing are microcell batteries made of elemental silver and zinc applied in a dot-matrix pattern (Figure 1). In the presence of a conductive medium such as wound exudate, water-based hydrogels or saline, microcurrents are generated at the dressing surface, due to its inherent design.

Procellera® is a primary contact layer dressing (Figure 2); it should be used under a secondary dressing or bandage (not provided), to keep it in place and help maintain a moist wound environment.

Silver and zinc in the dressing minimize or prevent the growth of microorganisms within the dressing, not at the wound site, and help preserve the dressing.

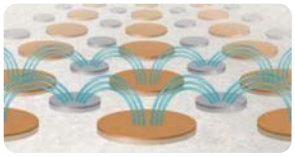


Figure 1

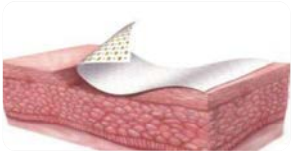


Figure 2

Indications

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.

Contraindications

- **Do not use on individuals with sensitivity or allergy to silver or zinc;**

Warnings

Frequent or prolonged use of this product may result, in rare occasions, in temporary discoloration of the skin.

Precautions

- **Single use only.**
- **Do not use if the pouch is open or damaged prior to use.**
- **For external use only.**
- **Do not apply Procellera dressing when using topical agents such as antimicrobial ointments, enzymatic debriders, antibiotic creams, silver or zinc containing creams, oxidizing agents, or petroleum based products**
- **Secondary dressings should be used as stated in their Instructions for Use.**
- **Stop using the Procellera dressing and consult a physician if an allergy, irritation, increased pain, maceration or irregular skin discoloration occurs.**
- **Procellera is not intended to be used on wounds with uncontrolled bleeding.**
- **Remove Procellera dressing during energy-based procedures (such as radiofrequencies, ultrasound, or radiation) where the dressing may interfere with delivery.**
- **Avoid contact with electrodes or conductive gels during electronic measurements; e.g., EEG** (electroencephalogram) **or ECG** (electrocardiogram)**.**
- Infected wounds should be treated under a physician's **supervision.**
- **The safety of daily Procellera use for longer than 28 days has not been studied.**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

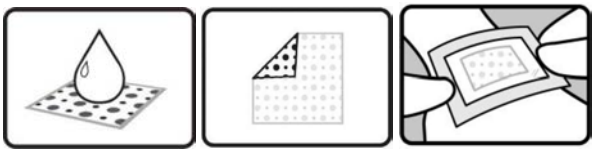
Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Instructions for OTC Use

Preparation

Follow local hygiene procedures prior to, during and following dressing application and change.

Application



1. **Cleanse the wound area with an appropriate wound cleanser.**
2. **Remove Procellera from package and if needed, cut to a shape that will extend beyond wound edges 1 to 2 cm** (1⁄2 inch to 1 inch). **Caution: cutting may result in fraying of the dressing.**
3. **Moisten Procellera with sterile saline, water or a thin, even layer of water-based hydrogel (not included).**
4. **Apply Procellera dressing to the wound site, with the dotted side down, in direct contact with the wound surface.**
5. **Cover Procellera with an appropriate secondary sterile dressing (such as a waterproof dressing) which will keep it in place and help maintain a moist wound environment. If needed, secure in place with an additional fixation dressing, using care not to restrict blood flow.**
6. **Keep Procellera moist by re-moistening as necessary (once a day, for dry wounds). Avoid over-soaking.**
   Note: It is not necessary to remove Procellera while showering.

Site Care and Dressing Change

- **Procellera may be left in place for up to 7 days. Earlier and/or more frequent changes may be required, depending on the amount of exudate present, the condition of the wound and surrounding skin.** Inspect the wound site periodically.
- **To remove the Procellera dressing, gently pull it back. If it adheres to the wound surface, do not force it off; moisten or soak the dressing with sterile saline or sterile water until it can be removed without tissue damage.**
- Consult a physician if any of the following occur: **infection, bleeding, maceration (skin whitening and softening), hypergranulation (excessive tissue formation), irritation at the wound site or the skin surrounding the Procellera dressing, or if the wound increases in size after a few dressing changes.**

Dressing Components

- **The Procellera dressing is not made with natural rubber latex.**
- **The Procellera dressing consists of a polyester substrate containing 0.9 mg of elemental silver and 0.3 mg of elemental zinc per square centimeter of dressing.**

Storage and Disposal

- **Store in dry conditions at controlled room temperature. Controlled room temperature is 20°C to 25°C (68°F to 77°F). Excursions are permitted between 15°C and 30°C (59°F and 86°F). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F), however, such exposure should be minimized.**
- **Protect from light.**
- **Dispose of according to local environmental procedures**

Made in the USA by:

Vomaris Wound Care, Inc.
1911 East Fifth Street, Tempe, AZ 85281, USA
(866) 496-8743 (480) 921-4948
www.vomaris.com

© 2016 Vomaris. All rights reserved. Procellera and Advanced Microcurrent Technology are all registered trademarks of Vomaris Innovations, Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

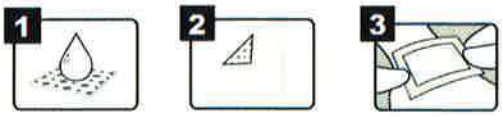
Procellera® Single Layer

Antimicrobial Wound Dressing

X x X in / X x X cm

Expiration Date
2017-08-20

REF AAA-XXXX LOT 123456X



Single Use Only

Do not use if package is damaged or open

See Instructions for Use

Manufactured by:
Vomaris Wound Care, Inc., Tempe, AZ 85281
Made in the U.S.A.

STERILE R

+77°F
+25°C
+68°F
+20°C

060700100 Rev A

(01) 0 0614141 99999 6 (17) 170820 (10) 123456X

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017

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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

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."

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

VOMARIS

Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, AZ 85281
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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

VOMARIS
Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, AZ 85281
www.procellera.com
Phone: 480-921-4948 Fax: 480-921-0948

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:

(b)(4) Confidential and Proprietary Information

[redacted]

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

VOMARIS
Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, AZ 85281
www.procellera.com
Phone: 480-921-4948 Fax: 480-921-0948

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.

(b)(4) Confidential and Proprietary Information

[redacted]

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:

Timothy Joiner
Director, Quality Assurance & Regulatory Affairs
1911 East Fifth Street, Tempe, Arizona, 85281
480-921-4948
Timothy.Joiner@Vomaris.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Record to the Memo
K160783/s01
Procellera Antimicrobial Bioelectric Wound Dressing

Date: April 22, 2016

Subject: K160783/s01 - Procellera Antimicrobial Bioelectric Wound Dressing

Contact: FDA - Charles Durfor, Ph.D.
PRSB-2/DSD/ODE/CDRH/FDA
301-796-6970 or charles.durfor@fda.hhs.gov

Sponsor - Timothy Joiner
Vomaris Innovations, Inc.
(480) 921-4948 or timothy.joiner@vomaris.com

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Digital Signature Concurrence Table	
Reviewer Sign-Off	
Branch Chief Sign-Off (optional)	
Division Sign-Off (optional)	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

MEMO TO THE RECORD
K160783/s02

DATE: August 10, 2016 **OFFICE**: HFZ-410
FROM: Charles N. Durfor **DIVISION**: DSD/PRSB-2

RE: K160783/s02 – Procellera Antimicrobial Wound Dressing by Vomaris Innovations, Inc.

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

MEMO TO THE RECORD
K160783/s02

DATE: August 10, 2016 **OFFICE**: HFZ-410
FROM: Charles N. Durfor **DIVISION**: DSD/PRSB-2

RE: K160783/s02 – Procellera Antimicrobial Wound Dressing by Vomaris Innovations, Inc.

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Telephone Record

Date: August 9, 2016

Subject: K160783/s02 - Procellera Antimicrobial Bioelectric Wound Dressing

Contact: FDA - Charles Durfor, Ph.D.
PRSB-2/DSD/ODE/CDRH/FDA
301-796-6970 or charles.durfor@fda.hhs.gov

Sponsor - Timothy Joiner
Vomaris Innovations, Inc.
(480) 921-4948 or timothy.joiner@vomaris.com

Background: Subsequent to a review of Supplement 2 the sponsor was contacted to request the following additional information:

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6865; Released by CDRH on 03-13-2017

Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K160783 Date Received by DCC: Apr 21, 2016

Lead Reviewer: Charles Durfor

Branch: PRSB2 Division: DSD Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Decision: ◉ Accept ○ Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant electronically and include a copy of this checklist.

Digital Signature Concurrence Table	
Reviewer Sign-Off	Charle[redacted] 2016.0[redacted]-04'00'
Branch Chief Sign-Off (digital signature optional)*	Cynthi[redacted] 2016.0[redacted]-04'00'
Division Sign-Off (digital signature optional)*	

* Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Food and Drug Administration
Office Location
Business Address
Phone Number

Premarket Notification 510(k) Review

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

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Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6865; Released by CDRH on 03-13-2017

Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Special 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K160783 Date Received by DCC: Apr 5, 2016

Lead Reviewer: Charles Durfor

Branch: PRSB2 Division: DSD Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during the substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Digital Signature Concurrence Table	
Reviewer Sign-Off	Charles N. Durfor -S 2016.04.07 15:37:36 -04'00'
Branch Chief Sign-Off	
Division Sign-Off	

Records processed under FOIA Request #2016-6865; Released by CDRH on 03-13-2017

Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K160783 Date Received by DCC: Apr 5, 2016

Lead Reviewer: Charles Durfor

Branch: PRSB2 Division: DSD Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

(b)(4) Confidential and Proprietary Information and (b)(5)

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(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

on 03-13-2017.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017

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K160783/A001

FDA/CDRH/DCC
AUG 12 2016
RECEIVED

eCopy Cover Letter

August 9, 2016

To:
Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – W066-G609
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

RE: eCopy Procellera Device - 510(k) Notification

Dear Madam/Sir:

The eCopy is an exact duplicate of the paper copy.

Please do not hesitate to contact me for any questions you may have:

Timothy Joiner, Director of QA/RA
Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, Arizona, 85281
Office: 480-921-0948 (b) (6) [redacted] Fax: 480-921-0948
Email: Timothy.Joiner@Vomaris.com

Sincerely,

Timothy Joiner, Director of QA/RA

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

36

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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3. COVER LETTER

August 9, 2016

To:
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center
10903 New Hampshire Ave., Bldg. 66, Rm G609
Silver Spring, MD 20993-0002

RE: Procellera Device - 510(k) Notification – Replacement Copy

Dear Mr. Durfor:

This is a partial replacement copy of 510(k) K160783/S001.

Sections 36 and 37 were removed since submitting supplement 002 and replaced with sections 36 through 40 as attachments to section 16. Attachments 014_ATT_14-01 and 014_ATT_14-05 have been updated to support the change made in response to FDA communications; however, Vomaris elects to keep the Indication for Use statements previously cleared in 510(k) K130350. Additionally, Vomaris has elected to return some IFU statements to those cleared in 510(k) K130350. A full summary of the changes made to this submission since supplement 002, specifically to the above documents, is included in this cover letter as Addendum 3.1

Vomaris Innovations, Inc. hereby submits this revised Traditional 510(k) Premarket Notification Submission for Procellera® Antimicrobial Wound Dressing device.

The device described in this 510(k) is identical to that currently cleared on February 4, 2013 under K130350 and to that cleared on December 1, 2008 under K081977 and June 15, 2006 under K060237. There are no changes to the original device design characteristics or to the manufacturing methods.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

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The reason for this submission is to request the addition of the word "antimicrobial" to the Procellera OTC product, previously cleared through K081977 and K130350.

- The Rx device cleared by K060237, K081977 and K130350 included an antimicrobial claim.
- The OTC device submission K130350 originally included an antimicrobial claim, because the product design, raw materials, production process, facilities and personnel are identical and indistinguishable.
    - During the FDA review of K130350, the antimicrobial claim was removed based on correspondence from FDA instructing Vomaris to remove the antimicrobial indication. At the time of submission K130350, Vomaris did not completely understand the reasoning behind the FDA instruction to remove the antimicrobial indication from the OTC product and was not in a position to pursue the issue due to business obligations.
- Additional clinical and scientific data reviews have now been performed to support the safe and effective claim of Antimicrobial for the OTC product. This information is included in sections 022 Post Market Surveillance, 034 Scientific Data and Clinical Summary and 035 Barakat Clinical Summary Report.
    - NOTE: 035 Barakat Clinical Summary Report is only included to demonstrate the safety of Procellera. Although Vomaris reserves the right to pursue any potential claims in the future; at this time no additional claims are being made other than those indicated in 005 Rx and OTC 510(k) Indications for Use.

The enclosed submission was compiled in accordance with 21 CFR 807, Subpart E and with applicable guidance documents for Industry and FDA Staff.

This submission contains information required for demonstrating substantial equivalence of the proposed device to legally marketed predicate devices, in accordance with the Safe Medical Device Act of 1990.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

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We consider our intent to market this device and the information contained within this submission confidential commercial information that is exempt from public disclosure.

Table 3.1 Administrative information

Type of Submission:	Traditional 510(k) Notification
Device Type:	Wound Dressing
Proprietary Name:	Procellera® Antimicrobial Bioelectric Wound Dressing
Classification Name:	Wound Dressing Device
510(k) Submitter:	Vomaris Innovations, Inc. 3100 W Ray Rd, Suite 148, Chandler, AZ 85226 Phone: 480-921-4948, Fax: 480-921-0948
Establishment Registration #:	3005803853
Contact information:	Timothy Joiner, Director of QA/RA Office: 480-921-4948 (b) (6) [redacted] Timothy.Joiner@Vomaris.com
Confidentiality:	We prefer continued confidentiality in accordance with 21 CFR 807.95
Classification Regulation:	Unclassified
Product Code:	FRO
Panel:	General & Plastic Surgery

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Basis of Submission:	New Indication for Use
Prior 510k Submissions:	K060237, K081977, K130350

Table 3.2 Design and Use of the Device

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	Y	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?	Y	
Does the device contain components derived from a tissue or other biologic source?		N
Is the device provided sterile?	Y	
Is the device intended for single use?	Y	
Is the device a reprocessed single use device?		N
If yes, does this device type require reprocessed validation data?	NA	NA
Does the device contain a drug?		N
Does the device contain a biologic?		N
Does the device use software?		N
Does the submission include clinical information?		N
Is the device implanted?		N

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

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I understand that the submission to the U.S. Government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Please do not hesitate to contact me for any questions you may have:

Timothy Joiner, Director of QA/RA
Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, Arizona, 85281
Office: 480-921-0948 (b) (6) [redacted] Fax: 480-921-0948
Email: Timothy.Joiner@Vomaris.com

Sincerely,

Timothy Joiner, Director of QA/RA

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Addendum 3.1 Changes to 510(k) K160783 Supplement 0002

Document	Section / Page	Added Information
3. Cover Letter	Page 1	Sections 36 and 37 were removed since submitting supplement 002 and replaced with sections 36 through 40 as attachments to section 16. Attachments 014_ATT_14-01 and 014_ATT_14-05 have been updated to support the change made in response to FDA communications; however, Vomaris elects to keep the Indication for Use statements previously cleared in 510(k) K130350. Additionally, Vomaris has elected to return some IFU statements to those cleared in 510(k) K130350. A full summary of the changes made to this submission since supplement 002, specifically to the above documents, is included in this cover letter as Addendum 3.1
4. Table of Contents	Page 2	16-01 Attachment ……36
	Page 2	16-02 Attachment……37
	Page 2	16-03 Attachment……38
	Page 2	16-04 Attachment……39
	Page 2	16-05 Attachment……40
6. 510(k) Summary	Page 4-5	<u>Performance Data:</u> (b)(4) Confidential and Proprietary Information [redacted] Broad-Spectrum in-vitro antimicrobial efficacy testing previously submitted to FDA resulted in clearance of Procellera® Antimicrobial Wound Dressing for prescription use 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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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		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. (b)(4) Confidential and Proprietary Information [redacted]
16. Shelf Life	Page 1	The shelf life in the previous 510(k) K130350 we indicated for 3 years. At the time of that submission, only one (1) lot of product was available for testing due to the low production volume. However, since submitting and received clearance for 510(k) K130350, Vomaris has completed 5-year real time studies on two (2) production lots of product (lot 031001, lot 061001) and 5-year accelerated studies on three (3) lots of production product (lot 031001, lot 061001 and lot 041102). The final real-time time point for lot 041102 will be taken in October 2016. Based on the data from the completion of three lots of 5-year accelerated studies and two lots of 5-year real time studies, Vomaris has set the shelf life date as five (5) years. The results of these studies are included as attachments listed below: • 16-01 TS-12 5-Year Accelerated Aging Report Lot 031001 • 16-02 TS-11 5-Year Real Time Report Lot 031001 • 16-03 TS-11 5-Year Accelerated Aging Report Lot 041102 • 16-04 TS-11 5-Year Real Time Aging Report Lot 061001 • 16-05 Summary Report

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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36-40	Attachments	Added Attachments 16-01, 16-02, 16-03, 16-04, and 16-05

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

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6. 510(K) SUMMARY

The purpose of this Premarket Notification is to request the addition of the word "antimicrobial" to the Procellera® over-the-counter product, previously cleared through K081977 and K130350.

Procellera® device described in this Traditional 510(k) is identical to the Procellera® device cleared in 2013 (K130350), 2008 (K081977) and in 2006 (K060237). There are no changes to the original device design, characteristics, or to the manufacturing process.

The prescription device and the over-the-counter device cleared in 2013 (K130350) are identical in every way. Only during the labeling process, which is performed after pouching and sterilization, are the products distinguished between prescription use and over-the-counter use.

The Rx product was cleared with the word "antimicrobial" while the OTC product was not cleared with the word "antimicrobial".

The following are the **cleared** "Indications for Use" for each of the respective 510(k)'s:

K081977 (Rx)	K081977 (OTC)
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.	For over-the-counter use, Procellera® wound dressing is indicated for minor cuts, scrapes, irritations, and abrasions.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

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K130350 (Rx)	K130350 (OTC)
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.	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.

The requested change is the addition of antimicrobial to the OTC "Indications for Use" such that the wording for both the Rx and OTC would include the word antimicrobial. The following is the proposed language.

Rx – this document	OTC – this document
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.

The 510(k) summary for the Procellera® device subject to this submission is provided in the following pages.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

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510(k) Summary for Procellera® Device

Date: July 11, 2016

Device Name: Procellera®

Trade Name: Procellera® Antimicrobial Bioelectric 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, and it occurs because it is inherent to its design. The device is self-contained and has no accessories.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

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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, steri-strips, negative pressure wound therapy, 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:

(b)(4) Confidential and Proprietary Information

[redacted]

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-15-2017.

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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.

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:

Timothy Joiner
Director, Quality Assurance & Regulatory Affairs
1911 East Fifth Street, Tempe, Arizona, 85281
480-921-4948
Timothy.Joiner@Vomaris.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Procellera®
Wound Care with Advanced Microcurrent Technology

Instructions for Prescription Use

Product Description

Procellera® is a single layer, broad-spectrum antimicrobial wound dressing featuring Advanced Microcurrent Technology®. Embedded in the dressing are microcell batteries made of elemental silver and zinc applied in a dot-matrix pattern (Figure 1). In the presence of a conductive medium such as wound exudate, water-based hydrogels or saline, microcurrents are generated at the dressing surface, due to its inherent design.

Procellera is a primary contact layer dressing (Figure 2); it should be used under a secondary dressing or bandage (not provided), to keep it in place and help maintain a moist wound environment.

Silver and zinc in the dressing minimize or prevent the growth of microorganisms within the dressing, not at the wound site, and help preserve the dressing.

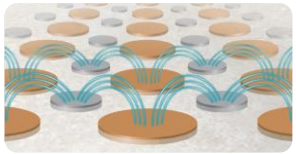


Figure 1

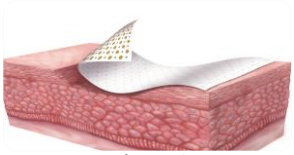


Figure 2

Indications

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.

Contraindications

- Do not use on individuals with sensitivity or allergy to silver or zinc.

Warnings

- Frequent or prolonged use of this product may result, in rare occasions, in temporary discoloration of the skin.

Precautions

Caution: Federal law restricts this device to sale by or on the order of a physician.

- Single use only.
- Electron beam irradiation sterilized. Opening the dressing pack compromises the sterile barrier. Do not use if the pouch is open or damaged prior to use.
- Remove Procellera dressing prior to an MRI or HBOT procedure and apply a new dressing after the procedure.
- For external use only.
- Do not apply Procellera dressing when using topical agents such as antimicrobial ointments, enzymatic debriders, antibiotic creams, silver or zinc containing creams, oxidizing agents, or petroleum-based products.
- Secondary dressings should be used as stated in their Instructions for Use.
- The patient should stop using the dressing and consult a physician if allergy, irritation, increased pain, maceration, or any irregular skin discoloration occurs.
- Procellera is not intended to be used on wounds with uncontrolled bleeding.
- Remove Procellera dressing during energy-based procedures (such as radiofrequencies, ultrasound, or radiation) where the dressing may interfere with delivery.
- Avoid direct contact with electrodes or conductive gels during electronic measurements; e.g., EEG or ECG.
- Procellera may be used on infected wounds being clinically managed, as an adjunct to the local clinical protocol.
- The safety of daily Procellera use for longer than 28 days has not been studied.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

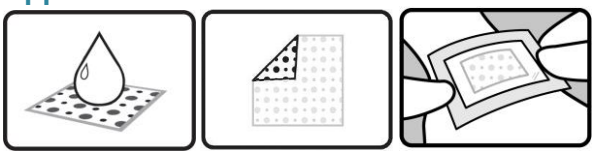
Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Instructions for Prescription Use

Preparation

Follow local hygiene procedures prior to, during and following dressing application and change.

Application



1. Cleanse the wound area with an appropriate wound cleanser according to local clinical protocol.
2. Remove Procellera from package and if needed, cut to a shape that will extend beyond wound edges 1 to 2 cm (1⁄2 inch to 1 inch). **Caution:** cutting may result in fraying of the dressing.
3. Moisten Procellera with sterile saline, water, or a thin, even layer of water-based hydrogel (not included).
4. Apply Procellera dressing **with the dotted side down**, in direct contact with the wound.
5. Cover Procellera with an appropriate secondary sterile dressing to help maintain a moist wound environment. The choice of secondary dressing should be determined by the amount of wound exudate, for example:
   - For DRY wounds; waterproof, semi-permeable, or hydrogel-like dressings are recommended to ensure prolonged moisture.
   - For EXUDATING wounds; cover Procellera with layer(s) of sterile gauze or foam dressing to absorb excessive moisture and prevent maceration. Then apply a semi-permeable or hydrogel-like dressing.
     If needed, secure in place with an additional fixation dressing, using care not to restrict blood flow.
6. Keep the dressing moist by re-moistening as necessary. Avoid over-soaking, for example:
   - DRY wounds may require more frequent dressing re-moistening.
   - EXUDATING wounds may require dressing re-moistening only if exudate decreases and the dressing becomes dry.

Site Care and Dressing Change

- Procellera may be left in place for up to 7 days (or longer, at the discretion and instruction of the treating clinician). Earlier and/or more frequent changes may be required, depending on the amount of exudate present and the condition of the wound and/or the surrounding skin. Inspect the wound site periodically.
- To remove the Procellera dressing, gently pull it back. If it adheres to the wound surface, do not force it off; moisten or soak the dressing with sterile saline or water until it can be removed without tissue disruption.
- The patient should consult a physician if any of the following occur: infection, bleeding, maceration, hypergranulation, irritation at the wound and/or the surrounding skin, or if the wound increases in size after a few dressing changes.

Dressing Components

- The dressing is not made with natural rubber latex.
- The dressing consists of a polyester substrate containing 0.9 mg of elemental silver and 0.3 mg of elemental zinc per square centimeter of dressing.

Storage and Disposal

- Store in dry conditions at controlled room temperature. Controlled room temperature is 20°C to 25°C (68°F to 77°F). Excursions are permitted between 15°C and 30°C (59°F and 86°F). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F), however, such exposure should be minimized.
- Protect from light.
- Dispose of according to local environmental procedures.

Made in the USA by:

Vomaris Wound Care, Inc.
1911 East Fifth Street, Tempe, AZ 85281, USA
(866) 496-8743 (480) 921-4948
www.procellera.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Procellera®
Wound Care with Advanced Microcurrent Technology

Instructions for OTC Use

Product Description

Procellera® is a single layer, broad-spectrum antimicrobial wound dressing. Embedded in the dressing are microcell batteries made of elemental silver and zinc applied in a dot-matrix pattern (Figure 1). In the presence of a conductive medium such as wound exudate, water-based hydrogels or saline, microcurrents are generated at the dressing surface, due to its inherent design.

Procellera® is a primary contact layer dressing (Figure 2); it should be used under a secondary dressing or bandage (not provided), to keep it in place and help maintain a moist wound environment.

Silver and zinc in the dressing minimize or prevent the growth of microorganisms within the dressing, not at the wound site, and help preserve the dressing.

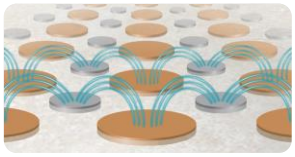


Figure 1

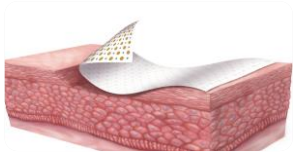


Figure 2

Indications

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.

Contraindications

- Do not use on individuals with sensitivity or allergy to silver or zinc;

Warnings

Frequent or prolonged use of this product may result, in rare occasions, in temporary discoloration of the skin.

Precautions

- Single use only.
- Do not use if the pouch is open or damaged prior to use.
- For external use only.
- Do not apply Procellera dressing when using topical agents such as antimicrobial ointments, enzymatic debriders, antibiotic creams, silver or zinc containing creams, oxidizing agents, or petroleum based products
- Secondary dressings should be used as stated in their Instructions for Use.
- Stop using the dressing and consult a physician if an allergy, irritation, increased pain, maceration or irregular skin discoloration occurs.
- Procellera is not intended to be used on wounds with uncontrolled bleeding.
- Remove Procellera dressing during energy-based procedures (such as radiofrequencies, ultrasound, or radiation) where the dressing may interfere with delivery.
- Avoid contact with electrodes or conductive gels during electronic measurements; e.g., EEG (electroencephalogram) or ECG (electrocardiogram).
- Infected wounds should be treated under a physician's supervison.
- The safety of daily Procellera use for longer than 28 days has not been studied.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

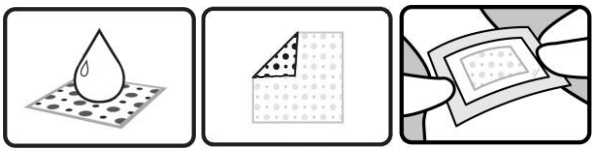
Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Instructions for OTC Use

Preparation

Follow local hygiene procedures prior to, during and following dressing application and change.

Application



1. Cleanse the wound area with an appropriate wound cleanser.
2. Remove Procellera from package and if needed, cut to a shape that will extend beyond wound edges 1 to 2 cm (1⁄2 inch to 1 inch). **Caution:** cutting may result in fraying of the dressing.
3. Moisten Procellera with sterile saline, water or a thin, even layer of water-based hydrogel (not included).
4. Apply Procellera dressing to the wound site, **with the dotted side down**, in direct contact with the wound surface.
5. Cover Procellera with an appropriate secondary sterile dressing (such as a waterproof dressing) which will keep it in place and help maintain a moist wound environment. If needed, secure in place with an additional fixation dressing, using care not to restrict blood flow.
6. Keep the dressing moist by re-moistening as necessary (once a day, for dry wounds). Avoid over-soaking.
   Note: It is not necessary to remove Procellera while showering.

Site Care and Dressing Change

- Procellera may be left in place for up to 7 days. Earlier and/or more frequent changes may be required, depending on the amount of exudate present, the condition of the wound and surrounding skin. Inspect the wound site periodically.
- To remove the Procellera dressing, gently pull it back. If it adheres to the wound surface, do not force it off; moisten or soak the dressing with sterile saline or sterile water until it can be removed without tissue damage.
- Consult a physician if any of the following occur: infection, bleeding, maceration (skin whitening and softening), hypergranulation (excessive tissue formation), irritation at the wound site or the skin surrounding the dressing, or if the wound increases in size after a few dressing changes.

Dressing Components

- The dressing is not made with natural rubber latex.
- The dressing consists of a polyester substrate containing 0.9 mg of elemental silver and 0.3 mg of elemental zinc per square centimeter of dressing.

Storage and Disposal

- Store in dry conditions at controlled room temperature. Controlled room temperature is 20°C to 25°C (68°F to 77°F). Excursions are permitted between 15°C and 30°C (59°F and 86°F). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F), however, such exposure should be minimized.
- Protect from light.
- Dispose of according to local environmental procedures

Made in the USA by:

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1911 East Fifth Street, Tempe, AZ 85281, USA
(866) 496-8743 (480) 921-4948
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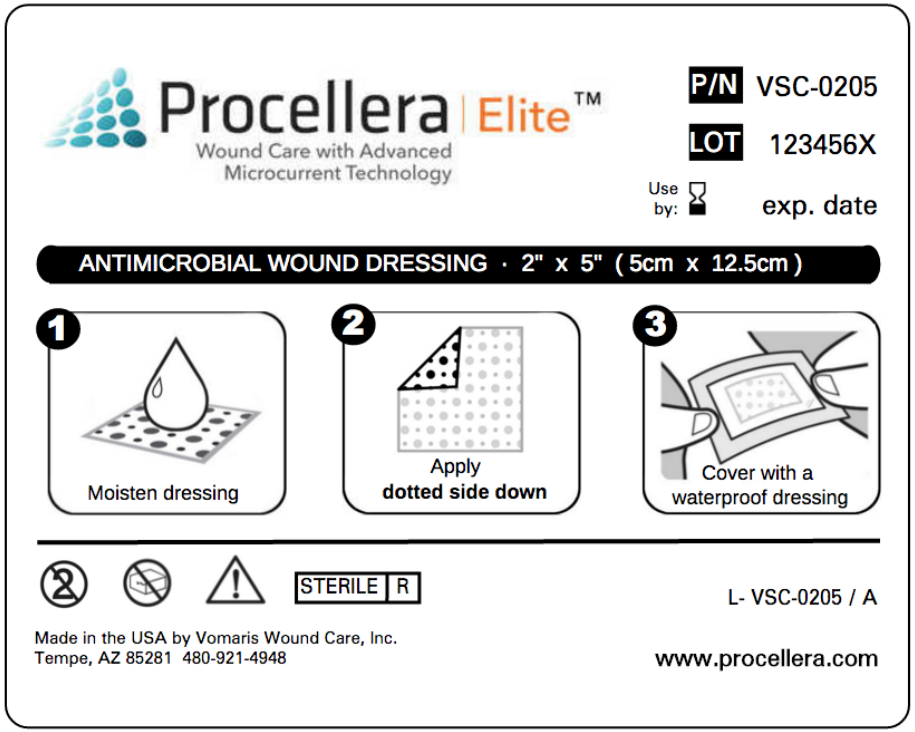
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Pouch Label



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16. SHELF LIFE

Both Procellera® Antimicrobial Wound Dressing RX and OTC single-layer products have a 5-year shelf life.

The shelf life is identified to the user by the use of an expiration date symbol followed by the date.

	Format: the year (yyyy), month (mm); day (dd), each separated by hyphens. Example, January 2, 2014, is presented as 2014-01-02.

The shelf life in the previous 510(k) K130350 we indicated for 3 years. At the time of that submission, only one (1) lot of product was available for testing due to the low production volume. However, since submitting and received clearance for 510(k) K130350, Vomaris has completed 5-year real time studies on two (2) production lots of product (b)(4) Confidential and Proprietary Information [redacted]

(b)(4) Confidential and Proprietary Information [redacted]

The results of these studies are included as attachments listed below:

- 16-01 TS-12 5-Year Accelerated Aging Report Lot 031001
- 16-02 TS-11 5-Year Real Time Report Lot 031001
- 16-03 TS-11 5-Year Accelerated Aging Report Lot 041102
- 16-04 TS-11 5-Year Real Time Aging Report Lot 061001
- 16-05 Summary Report

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Shelf Life Verification - Procellera devices in Amcor pouches

Summary Report at the Completion of the Accelerated Aging

(b)(4) Confidential and Proprietary Information

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) Confidential and Proprietary Information

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Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Shelf Life Verification - Procellera single layer devices

Test report at the completion of Year 5 Real Time Aging (T2A)

(b)(4) Confidential and Proprietary Information

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) Confidential and Proprietary Information

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SHELF LIFE VERIFICATION SUMMARY– ACCELERATED AND REAL TIME AGING PROCELLERA DEVICES IN AMCOR POUCHES

(b)(4) Confidential and Proprietary Information

[redacted]

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(b)(4) Confidential and Proprietary Information

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K160783/A002

VOMARIS

Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, AZ 85281
www.procellera.com
Phone: 480-921-4948 Fax: 480-921-0948

FDA/CDRH/DCC
AUG 31 2016
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ECOPY COVER LETTER

August 29, 2016

To:
Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – W066-G609
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

RE: eCopy Procellera Device - 510(k) Notification

Dear Madam/Sir:

The eCopy is an exact duplicate of the paper copy.

Please do not hesitate to contact me for any questions you may have:

Timothy Joiner, Director of QA/RA
Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, Arizona, 85281
Office: 480-921-0948 (b) (6) [redacted] Fax: 480-921-0948
Email: Timothy.Joiner@Vomaris.com

Sincerely,

Timothy Joiner, Director of QA/RA

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

65

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3. COVER LETTER

August 29, 2016

To:
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center
10903 New Hampshire Ave., Bldg. 66, Rm G609
Silver Spring, MD 20993-0002

RE: Procellera Device - 510(k) Notification – Replacement Copy

Dear Mr. Durfor:

This is a partial replacement copy of 510(k) K160783/S001. Section 006 was updated based on your email comments dated August 27, 2016.

Vomaris Innovations, Inc. hereby submits this revised Traditional 510(k) Premarket Notification Submission for Procellera® Antimicrobial Wound Dressing device.

The device described in this 510(k) is identical to that currently cleared on February 4, 2013 under K130350 and to that cleared on December 1, 2008 under K081977 and June 15, 2006 under K060237. There are no changes to the original device design characteristics or to the manufacturing methods.

The reason for this submission is to request the addition of the word "antimicrobial" to the Procellera OTC product, previously cleared through K081977 and K130350.

- The Rx device cleared by K060237, K081977 and K130350 included an antimicrobial claim.
- The OTC device submission K130350 originally included an antimicrobial claim, because the product design, raw materials, production process, facilities and personnel are identical and indistinguishable.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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- o During the FDA review of K130350, the antimicrobial claim was removed based on correspondence from FDA instructing Vomaris to remove the antimicrobial indication. At the time of submission K130350, Vomaris did not completely understand the reasoning behind the FDA instruction to remove the antimicrobial indication from the OTC product and was not in a position to pursue the issue due to business obligations.

- Additional clinical and scientific data reviews have now been performed to support the safe and effective claim of Antimicrobial for the OTC product. This information is included in sections 022 Post Market Surveillance, 034 Scientific Data and Clinical Summary and 035 Barakat Clinical Summary Report.
  - o NOTE: 035 Barakat Clinical Summary Report is only included to demonstrate the safety of Procellera. Although Vomaris reserves the right to pursue any potential claims in the future; at this time no additional claims are being made other than those indicated in 005 Rx and OTC 510(k) Indications for Use.

The enclosed submission was compiled in accordance with 21 CFR 807, Subpart E and with applicable guidance documents for Industry and FDA Staff.

This submission contains information required for demonstrating substantial equivalence of the proposed device to legally marketed predicate devices, in accordance with the Safe Medical Device Act of 1990.

We consider our intent to market this device and the information contained within this submission confidential commercial information that is exempt from public disclosure.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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1911 East Fifth Street, Tempe, AZ 85281
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Table 3.1 Administrative information

Type of Submission:	Traditional 510(k) Notification
Device Type:	Wound Dressing
Proprietary Name:	Procellera® Antimicrobial Bioelectric Wound Dressing
Classification Name:	Wound Dressing Device
510(k) Submitter:	Vomaris Innovations, Inc. 3100 W Ray Rd, Suite 148, Chandler, AZ 85226 Phone: 480-921-4948, Fax: 480-921-0948
Establishment Registration #:	3005803853
Contact information:	Timothy Joiner, Director of QA/RA Office: 480-921-4948 (b) (6) [redacted] Timothy.Joiner@Vomaris.com
Confidentiality:	We prefer continued confidentiality in accordance with 21 CFR 807.95
Classification Regulation:	Unclassified
Product Code:	FRO
Panel:	General & Plastic Surgery
Basis of Submission:	New Indication for Use
Prior 510k Submissions:	K060237, K081977, K130350

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Table 3.2 Design and Use of the Device

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	Y	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?	Y	
Does the device contain components derived from a tissue or other biologic source?		N
Is the device provided sterile?	Y	
Is the device intended for single use?	Y	
Is the device a reprocessed single use device?		N
If yes, does this device type require reprocessed validation data?	NA	NA
Does the device contain a drug?		N
Does the device contain a biologic?		N
Does the device use software?		N
Does the submission include clinical information?		N
Is the device implanted?		N

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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I understand that the submission to the U.S. Government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Please do not hesitate to contact me for any questions you may have:

Timothy Joiner, Director of QA/RA
Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, Arizona, 85281
Office: 480-921-0948 (b) (6) [redacted] Fax: 480-921-0948
Email: Timothy.Joiner@Vomaris.com

Sincerely,

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eCOPY COVER LETTER

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Timothy Joiner, Director of QA/RA

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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August 29, 2016

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- During the FDA review of K130350, the antimicrobial claim was removed based on correspondence from FDA instructing Vomaris to remove the antimicrobial indication. At the time of submission K130350, Vomaris did not completely understand the reasoning behind the FDA instruction to remove the antimicrobial indication from the OTC product and was not in a position to pursue the issue due to business obligations.

- Additional clinical and scientific data reviews have now been performed to support the safe and effective claim of Antimicrobial for the OTC product. This information is included in sections 022 Post Market Surveillance, 034 Scientific Data and Clinical Summary and 035 Barakat Clinical Summary Report.
  - NOTE: 035 Barakat Clinical Summary Report is only included to demonstrate the safety of Procellera. Although Vomaris reserves the right to pursue any potential claims in the future; at this time no additional claims are being made other than those indicated in 005 Rx and OTC 510(k) Indications for Use.

The enclosed submission was compiled in accordance with 21 CFR 807, Subpart E and with applicable guidance documents for Industry and FDA Staff.

This submission contains information required for demonstrating substantial equivalence of the proposed device to legally marketed predicate devices, in accordance with the Safe Medical Device Act of 1990.

We consider our intent to market this device and the information contained within this submission confidential commercial information that is exempt from public disclosure.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, AZ 85281
www.procellera.com
Phone: 480-921-4948 Fax: 480-921-0948

Table 3.1 Administrative information

Type of Submission:	Traditional 510(k) Notification
Device Type:	Wound Dressing
Proprietary Name:	Procellera® Antimicrobial Bioelectric Wound Dressing
Classification Name:	Wound Dressing Device
510(k) Submitter:	Vomaris Innovations, Inc. 3100 W Ray Rd, Suite 148, Chandler, AZ 85226 Phone: 480-921-4948, Fax: 480-921-0948
Establishment Registration #:	3005803853
Contact information:	Timothy Joiner, Director of QA/RA Office: 480-921-4948 (b) (6) [redacted] Timothy.Joiner@Vomaris.com
Confidentiality:	We prefer continued confidentiality in accordance with 21 CFR 807.95
Classification Regulation:	Unclassified
Product Code:	FRO
Panel:	General & Plastic Surgery
Basis of Submission:	New Indication for Use
Prior 510k Submissions:	K060237, K081977, K130350

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Table 3.2 Design and Use of the Device

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	Y	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?	Y	
Does the device contain components derived from a tissue or other biologic source?		N
Is the device provided sterile?	Y	
Is the device intended for single use?	Y	
Is the device a reprocessed single use device?		N
If yes, does this device type require reprocessed validation data?	NA	NA
Does the device contain a drug?		N
Does the device contain a biologic?		N
Does the device use software?		N
Does the submission include clinical information?		N
Is the device implanted?		N

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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I understand that the submission to the U.S. Government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Please do not hesitate to contact me for any questions you may have:

Timothy Joiner, Director of QA/RA
Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, Arizona, 85281
Office: 480-921-0948 (b) (6) [redacted] Fax: 480-921-0948
Email: Timothy.Joiner@Vomaris.com

Sincerely,

Timothy Joiner, Director of QA/RA

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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6. 510(K) SUMMARY

The purpose of this Premarket Notification is to request the addition of the word "antimicrobial" to the Procellera® over-the-counter product, previously cleared through K081977 and K130350.

Procellera® device described in this Traditional 510(k) is identical to the Procellera® device cleared in 2013 (K130350), 2008 (K081977) and in 2006 (K060237). There are no changes to the original device design, characteristics, or to the manufacturing process.

The prescription device and the over-the-counter device cleared in 2013 (K130350) are identical in every way. Only during the labeling process, which is performed after pouching and sterilization, are the products distinguished between prescription use and over-the-counter use.

The Rx product was cleared with the word "antimicrobial" while the OTC product was not cleared with the word "antimicrobial".

The following are the **cleared** "Indications for Use" for each of the respective 510(k)'s:

K081977 (Rx)	K081977 (OTC)
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.	For over-the-counter use, Procellera® wound dressing is indicated for minor cuts, scrapes, irritations, and abrasions.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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K130350 (Rx)	K130350 (OTC)
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.	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.

The requested change is the addition of antimicrobial to the OTC "Indications for Use" such that the wording for both the Rx and OTC would include the word antimicrobial. The following is the proposed language.

Rx – this document	OTC – this document
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.

The 510(k) summary for the Procellera® device subject to this submission is provided in the following pages.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

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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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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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:

(b)(4) Confidential and Proprietary Information

[redacted]

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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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:

Timothy Joiner
Director, Quality Assurance & Regulatory Affairs
1911 East Fifth Street, Tempe, Arizona, 85281
480-921-4948
Timothy.Joiner@Vomaris.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

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.

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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."

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

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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Department of Health and Human Services
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Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017

VOMARIS

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Phone: 480-921-4948 Fax: 480-921-0948

K160783/A003

FDA/CDRH/DCC
SEP 02 2016
RECEIVED

eCopy Cover Letter

September 1, 2016

To:
Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – W066-G609
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

RE: eCopy Procellera Device - 510(k) Notification

Dear Madam/Sir:

The eCopy is an exact duplicate of the paper copy.

Please do not hesitate to contact me for any questions you may have:

Timothy Joiner, Director of QA/RA
Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, Arizona, 85281
Office: 480-921-0948 (b) (6) [redacted] Fax: 480-921-0948
Email: Timothy.Joiner@Vomaris.com

Sincerely,

Timothy Joiner, Director of QA/RA

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

17

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Procellera®
Wound Care with Advanced Microcurrent Technology

Instructions for Prescription Use

Product Description

Procellera® is a single layer, broad-spectrum antimicrobial wound dressing featuring Advanced Microcurrent Technology®. Embedded in the dressing are microcell batteries made of elemental silver and zinc applied in a dot-matrix pattern (Figure 1). In the presence of a conductive medium such as wound exudate, water-based hydrogels or saline, microcurrents are generated at the dressing surface, due to its inherent design.

Procellera is a primary contact layer dressing (Figure 2); it should be used under a secondary dressing or bandage (not provided), to keep it in place and help maintain a moist wound environment.

Silver and zinc in the dressing minimize or prevent the growth of microorganisms within the dressing, not at the wound site, and help preserve the dressing.

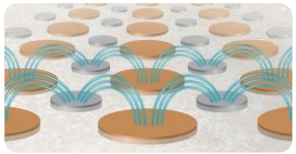
Figure 1

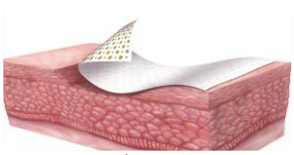
Figure 2

Indications

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.

Contraindications

- Do not use on individuals with sensitivity or allergy to silver or zinc.

Warnings

- Frequent or prolonged use of this product may result, in rare occasions, in temporary discoloration of the skin.

Precautions

Caution: Federal law restricts this device to sale by or on the order of a physician.

- Single use only.
- Electron beam irradiation sterilized. Opening the dressing pack compromises the sterile barrier. Do not use if the pouch is open or damaged prior to use.
- Remove Procellera dressing prior to an MRI or HBOT procedure and apply a new dressing after the procedure.
- For external use only.
- Do not apply Procellera dressing when using topical agents such as antimicrobial ointments, enzymatic debriders, antibiotic creams, silver or zinc containing creams, oxidizing agents, or petroleum-based products.
- Secondary dressings should be used as stated in their Instructions for Use.
- The patient should stop using the dressing and consult a physician if allergy, irritation, increased pain, maceration, or any irregular skin discoloration occurs.
- Procellera is not intended to be used on wounds with uncontrolled bleeding.
- Remove Procellera dressing during energy-based procedures (such as radiofrequencies, ultrasound, or radiation) where the dressing may interfere with delivery.
- Avoid direct contact with electrodes or conductive gels during electronic measurements; e.g., EEG or ECG.
- Procellera may be used on infected wounds being clinically managed, as an adjunct to the local clinical protocol.
- The safety of daily Procellera use for longer than 28 days has not been studied.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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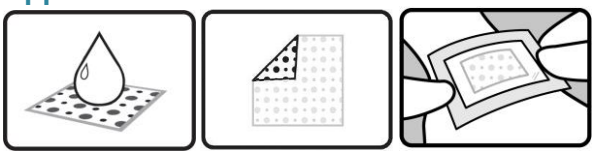
Instructions for Prescription Use

Preparation

Follow local hygiene procedures prior to, during and following dressing application and change.

Application



1. Cleanse the wound area with an appropriate wound cleanser according to local clinical protocol.
2. Remove Procellera from package and if needed, cut to a shape that will extend beyond wound edges 1 to 2 cm (1⁄2 inch to 1 inch). **Caution:** cutting may result in fraying of the dressing.
3. Moisten Procellera with sterile saline, water, or a thin, even layer of water-based hydrogel (not included).
4. Apply Procellera dressing **with the dotted side down**, in direct contact with the wound.
5. Cover Procellera with an appropriate secondary sterile dressing to help maintain a moist wound environment. The choice of secondary dressing should be determined by the amount of wound exudate, for example:
   - For DRY wounds; waterproof, semi-permeable, or hydrogel-like dressings are recommended to ensure prolonged moisture.
   - For EXUDATING wounds; cover Procellera with layer(s) of sterile gauze or foam dressing to absorb excessive moisture and prevent maceration. Then apply a semi-permeable or hydrogel-like dressing.
     If needed, secure in place with an additional fixation dressing, using care not to restrict blood flow.
6. Keep the dressing moist by re-moistening as necessary. Avoid over-soaking, for example:
   - DRY wounds may require more frequent dressing re-moistening.
   - EXUDATING wounds may require dressing re-moistening only if exudate decreases and the dressing becomes dry.

Site Care and Dressing Change

- Procellera may be left in place for up to 7 days (or longer, at the discretion and instruction of the treating clinician). Earlier and/or more frequent changes may be required, depending on the amount of exudate present and the condition of the wound and/or the surrounding skin. Inspect the wound site periodically.
- To remove the Procellera dressing, gently pull it back. If it adheres to the wound surface, do not force it off; moisten or soak the dressing with sterile saline or water until it can be removed without tissue disruption.
- The patient should consult a physician if any of the following occur: infection, bleeding, maceration, hypergranulation, irritation at the wound and/or the surrounding skin, or if the wound increases in size after a few dressing changes.

Dressing Components

- The dressing is not made with natural rubber latex.
- The dressing consists of a polyester substrate containing 0.9 mg of elemental silver and 0.3 mg of elemental zinc per square centimeter of dressing.

Storage and Disposal

- Store in dry conditions at controlled room temperature. Controlled room temperature is 20°C to 25°C (68°F to 77°F). Excursions are permitted between 15°C and 30°C (59°F and 86°F). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F), however, such exposure should be minimized.
- Protect from light.
- Dispose of according to local environmental procedures.

Made in the USA by:

Vomaris Wound Care, Inc.
1911 East Fifth Street, Tempe, AZ 85281, USA
(866) 496-8743 (480) 921-4948
www.procellera.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Procellera | Rx™
Wound Care with Advanced Microcurrent Technology

P/N VSR-0404
LOT 131101A
Use by: 2019-01-28

ANTIMICROBIAL WOUND DRESSING · 4" x 4" (10cm x 10cm)

1. Moisten dressing
2. Apply **dotted side down**
3. Cover with a waterproof dressing

Rx ONLY · STERILE R · L- VSR-0404 / A

Made in the USA by Vomaris Wound Care, Inc.
Tempe, AZ 85281 480-921-4948

www.procellera.com

Procellera | Rx™
Wound Care with Advanced Microcurrent Technology

P/N VSR-0404
LOT 131101A
Use by: 2019-01-28

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Rx ONLY · STERILE R · L- VSR-0404 / A

Made in the USA by Vomaris Wound Care, Inc.
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Procellera | Rx™
Wound Care with Advanced Microcurrent Technology

P/N VSR-0404
LOT 131101A
Use by: 2019-01-28

ANTIMICROBIAL WOUND DRESSING · 4" x 4" (10cm x 10cm)

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Rx ONLY · STERILE R · L- VSR-0404 / A

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Procellera | Rx™
Wound Care with Advanced Microcurrent Technology

P/N VSR-0404
LOT 131101A
Use by: 2019-01-28

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Procellera | Rx™
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Procellera | Rx™
Wound Care with Advanced Microcurrent Technology

P/N VSR-0404
LOT 131101A
Use by: 2019-01-28

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1. Moisten dressing
2. Apply **dotted side down**
3. Cover with a waterproof dressing

Rx ONLY · STERILE R · L- VSR-0404 / A

Made in the USA by Vomaris Wound Care, Inc.
Tempe, AZ 85281 480-921-4948

www.procellera.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

4 x 4 in
(10 x 10 cm)

Rx ONLY

P/N VSR-0404
LOT 123456X
Use by: exp. date

Box of 10 Units

Reorder #: VSR-0404-10

B - VSR-0404 - 10 / A

(01) 3 0381780 25796 1 (17) 160616 (10) 123456X

4 x 4 in

Procellera | Rx™
Wound Care with Advanced Microcurrent Technology

4 x 4 in
(10 x 10 cm)

Rx ONLY

P/N VSR-0404
LOT 123456X
Use by: exp. date

Box of 10 Units

Reorder #: VSR-0404-10

B - VSR-0404 - 10 / A

(01) 3 0381780 25796 1 (17) 160616 (10) 123456X

4 x 4 in

Procellera | Rx™
Wound Care with Advanced Microcurrent Technology

4 x 4 in
(10 x 10 cm)

Rx ONLY

P/N VSR-0404
LOT 123456X
Use by: exp. date

Box of 10 Units

Reorder #: VSR-0404-10

B - VSR-0404 - 10 / A

(01) 3 0381780 25796 1 (17) 160616 (10) 123456X

4 x 4 in

Procellera | Rx™
Wound Care with Advanced Microcurrent Technology

4 x 4 in
(10 x 10 cm)

Rx ONLY

P/N VSR-0404
LOT 123456X
Use by: exp. date

Box of 10 Units

Reorder #: VSR-0404-10

B - VSR-0404 - 10 / A

(01) 3 0381780 25796 1 (17) 160616 (10) 123456X

4 x 4 in

Procellera | Rx™
Wound Care with Advanced Microcurrent Technology

4 x 4 in
(10 x 10 cm)

Rx ONLY

P/N VSR-0404
LOT 123456X
Use by: exp. date

Box of 10 Units

Reorder #: VSR-0404-10

B - VSR-0404 - 10 / A

(01) 3 0381780 25796 1 (17) 160616 (10) 123456X

4 x 4 in

Procellera | Rx™
Wound Care with Advanced Microcurrent Technology

4 x 4 in
(10 x 10 cm)

Rx ONLY

P/N VSR-0404
LOT 123456X
Use by: exp. date

Box of 10 Units

Reorder #: VSR-0404-10

B - VSR-0404 - 10 / A

(01) 3 0381780 25796 1 (17) 160616 (10) 123456X

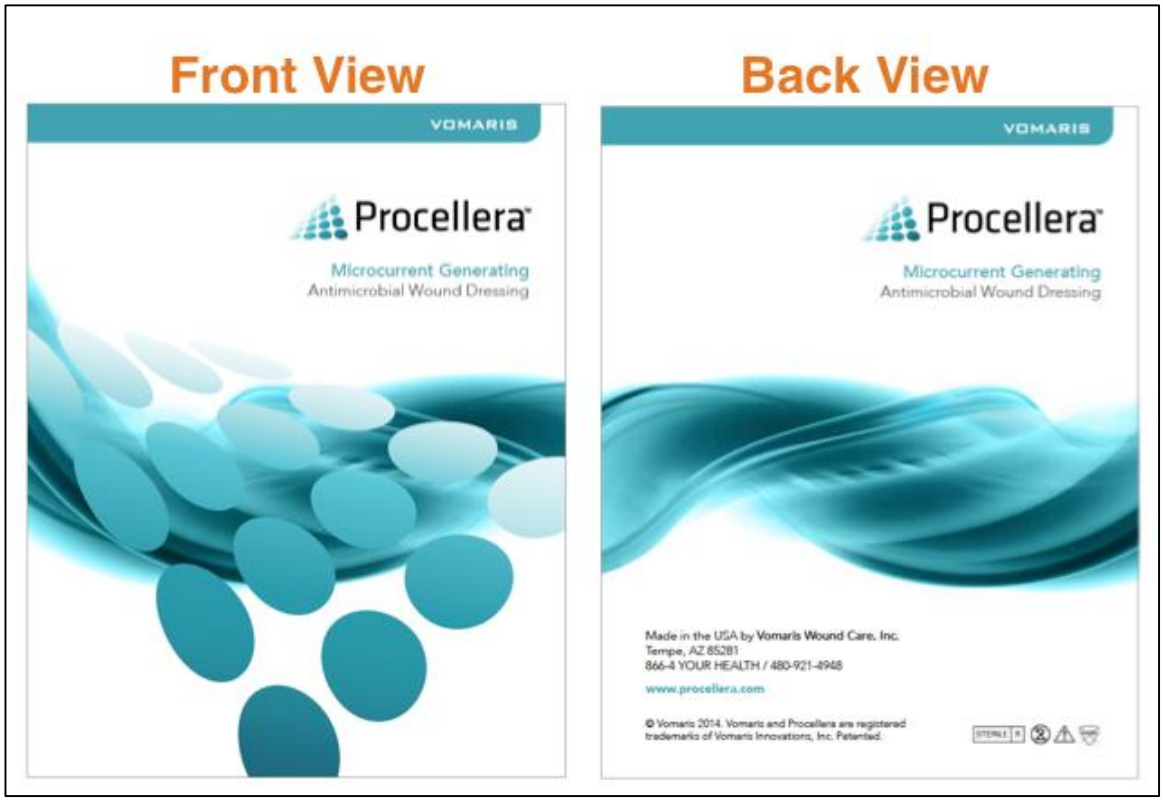
4 x 4 in

Procellera | Rx™
Wound Care with Advanced Microcurrent Technology

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Rx and OTC outer box with non-variable information



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Procellera®
Wound Care with Advanced Microcurrent Technology

Instructions for OTC Use

Product Description

Procellera® is a single layer, broad-spectrum antimicrobial wound dressing. Embedded in the dressing are microcell batteries made of elemental silver and zinc applied in a dot-matrix pattern (Figure 1). In the presence of a conductive medium such as wound exudate, water-based hydrogels or saline, microcurrents are generated at the dressing surface, due to its inherent design.

Procellera® is a primary contact layer dressing (Figure 2); it should be used under a secondary dressing or bandage (not provided), to keep it in place and help maintain a moist wound environment.

Silver and zinc in the dressing minimize or prevent the growth of microorganisms within the dressing, not at the wound site, and help preserve the dressing.

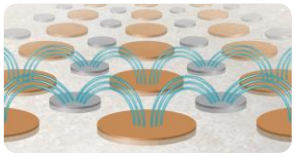


Figure 1

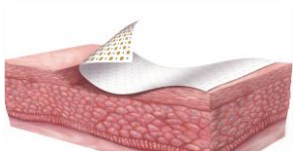


Figure 2

Indications

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.

Contraindications

- Do not use on individuals with sensitivity or allergy to silver or zinc;

Warnings

Frequent or prolonged use of this product may result, in rare occasions, in temporary discoloration of the skin.

Precautions

- Single use only.
- Do not use if the pouch is open or damaged prior to use.
- For external use only.
- Do not apply Procellera dressing when using topical agents such as antimicrobial ointments, enzymatic debriders, antibiotic creams, silver or zinc containing creams, oxidizing agents, or petroleum based products
- Secondary dressings should be used as stated in their Instructions for Use.
- Stop using the dressing and consult a physician if an allergy, irritation, increased pain, maceration or irregular skin discoloration occurs.
- Procellera is not intended to be used on wounds with uncontrolled bleeding.
- Remove Procellera dressing during energy-based procedures (such as radiofrequencies, ultrasound, or radiation) where the dressing may interfere with delivery.
- Avoid contact with electrodes or conductive gels during electronic measurements; e.g., EEG (electroencephalogram) or ECG (electrocardiogram).
- Infected wounds should be treated under a physician's supervison.
- The safety of daily Procellera use for longer than 28 days has not been studied.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

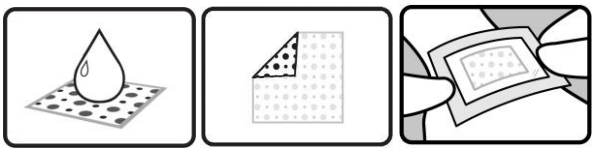
Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Instructions for OTC Use

Preparation

Follow local hygiene procedures prior to, during and following dressing application and change.

Application



1. Cleanse the wound area with an appropriate wound cleanser.
2. Remove Procellera from package and if needed, cut to a shape that will extend beyond wound edges 1 to 2 cm (1⁄2 inch to 1 inch). **Caution:** cutting may result in fraying of the dressing.
3. Moisten Procellera with sterile saline, water or a thin, even layer of water-based hydrogel (not included).
4. Apply Procellera dressing to the wound site, **with the dotted side down**, in direct contact with the wound surface.
5. Cover Procellera with an appropriate secondary sterile dressing (such as a waterproof dressing) which will keep it in place and help maintain a moist wound environment. If needed, secure in place with an additional fixation dressing, using care not to restrict blood flow.
6. Keep the dressing moist by re-moistening as necessary (once a day, for dry wounds). Avoid over-soaking.
   Note: It is not necessary to remove Procellera while showering.

Site Care and Dressing Change

- Procellera may be left in place for up to 7 days. Earlier and/or more frequent changes may be required, depending on the amount of exudate present, the condition of the wound and surrounding skin. Inspect the wound site periodically.
- To remove the Procellera dressing, gently pull it back. If it adheres to the wound surface, do not force it off; moisten or soak the dressing with sterile saline or sterile water until it can be removed without tissue damage.
- Consult a physician if any of the following occur: infection, bleeding, maceration (skin whitening and softening), hypergranulation (excessive tissue formation), irritation at the wound site or the skin surrounding the dressing, or if the wound increases in size after a few dressing changes.

Dressing Components

- The dressing is not made with natural rubber latex.
- The dressing consists of a polyester substrate containing 0.9 mg of elemental silver and 0.3 mg of elemental zinc per square centimeter of dressing.

Storage and Disposal

- Store in dry conditions at controlled room temperature. Controlled room temperature is 20°C to 25°C (68°F to 77°F). Excursions are permitted between 15°C and 30°C (59°F and 86°F). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F), however, such exposure should be minimized.
- Protect from light.
- Dispose of according to local environmental procedures

Made in the USA by:

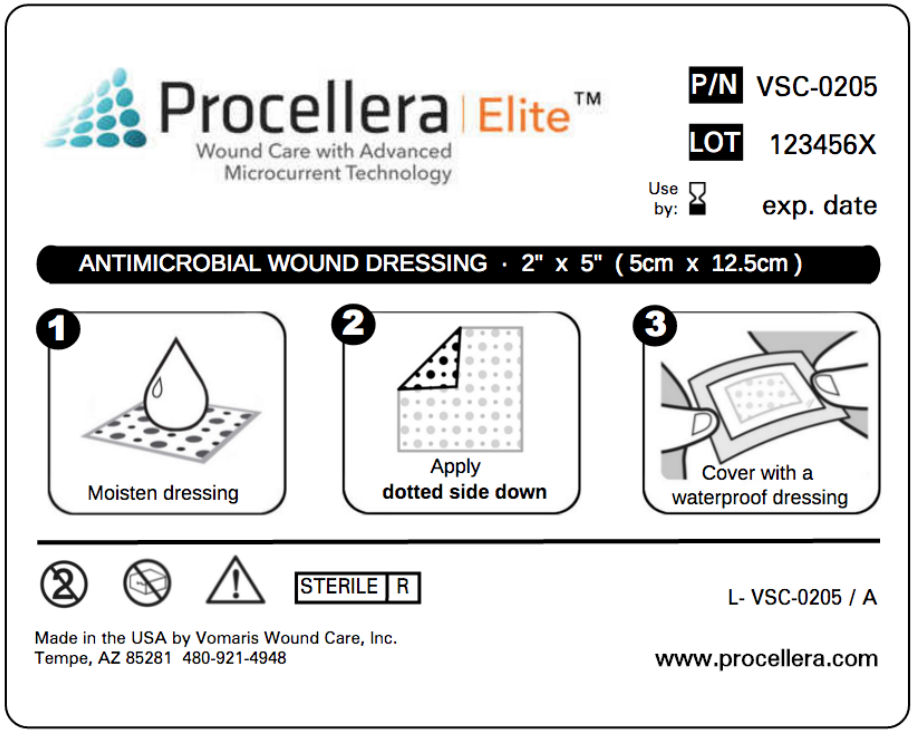
Vomaris Wound Care, Inc.
1911 East Fifth Street, Tempe, AZ 85281, USA
(866) 496-8743 (480) 921-4948
www.procellera.com

© 2016 Vomaris. All rights reserved., Procellera, Procellera Helix, Procellera Elite, Procellera with logo and Advanced Microcurrent Technology are all trademarks of Vomaris Innovations, Inc. All other trademarks are the property of their respective owners.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Pouch Label



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

2 x 5 in
(5 x 12.5 cm)

P/N VSC-0205
LOT 123456X
Use by: exp. date

Box of 5 Units
Reorder #: VSC-0205-05

Contains silver and zinc as preservatives
B - VSC-0205 - 05 / A

(01) 3 0381780 25796 1 (17) 160616 (10) 123456X

2 x 5 in

Procellera | Elite™
Wound Care with Advanced Microcurrent Technology

2 x 5 in
(5 x 12.5 cm)

P/N VSC-0205
LOT 123456X
Use by: exp. date

Box of 5 Units
Reorder #: VSC-0205-05

Contains silver and zinc as preservatives
B - VSC-0205 - 05 / A

(01) 3 0381780 25796 1 (17) 160616 (10) 123456X

2 x 5 in

Procellera | Elite™
Wound Care with Advanced Microcurrent Technology

2 x 5 in
(5 x 12.5 cm)

P/N VSC-0205
LOT 123456X
Use by: exp. date

Box of 5 Units
Reorder #: VSC-0205-05

Contains silver and zinc as preservatives
B - VSC-0205 - 05 / A

(01) 3 0381780 25796 1 (17) 160616 (10) 123456X

2 x 5 in

Procellera | Elite™
Wound Care with Advanced Microcurrent Technology

2 x 5 in
(5 x 12.5 cm)

P/N VSC-0205
LOT 123456X
Use by: exp. date

Box of 5 Units
Reorder #: VSC-0205-05

Contains silver and zinc as preservatives
B - VSC-0205 - 05 / A

(01) 3 0381780 25796 1 (17) 160616 (10) 123456X

2 x 5 in

Procellera | Elite™
Wound Care with Advanced Microcurrent Technology

2 x 5 in
(5 x 12.5 cm)

P/N VSC-0205
LOT 123456X
Use by: exp. date

Box of 5 Units
Reorder #: VSC-0205-05

Contains silver and zinc as preservatives
B - VSC-0205 - 05 / A

(01) 3 0381780 25796 1 (17) 160616 (10) 123456X

2 x 5 in

Procellera | Elite™
Wound Care with Advanced Microcurrent Technology

2 x 5 in
(5 x 12.5 cm)

P/N VSC-0205
LOT 123456X
Use by: exp. date

Box of 5 Units
Reorder #: VSC-0205-05

Contains silver and zinc as preservatives
B - VSC-0205 - 05 / A

(01) 3 0381780 25796 1 (17) 160616 (10) 123456X

2 x 5 in

Procellera | Elite™
Wound Care with Advanced Microcurrent Technology

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Pouch label on pouch

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

VOMARIS

Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, AZ 85281
www.procellera.com
Phone: 480-921-4948 Fax: 480-921-0948

K160783/A4

FDA/CDRH/DCC
SEP 06 2016
RECEIVED

eCopy Cover Letter

September 2, 2016

To:
Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – W066-G609
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

RE: eCopy Procellera Device - 510(k) Notification

Dear Madam/Sir:

The eCopy is an exact duplicate of the paper copy.

Please do not hesitate to contact me for any questions you may have:

Timothy Joiner, Director of QA/RA
Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, Arizona, 85281
Office: 480-921-0948 (b) (6) [redacted] Fax: 480-921-0948
Email: Timothy.Joiner@Vomaris.com

Sincerely,

Timothy Joiner, Director of QA/RA

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

50

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Procellera®
Antimicrobial Wound Dressing

Instructions for OTC Use

Product Description

Procellera® is a single layer, broad-spectrum antimicrobial wound dressing. Embedded in the dressing are microcell batteries made of elemental silver and zinc applied in a dot-matrix pattern (Figure 1). In the presence of a conductive medium such as wound exudate, water-based hydrogels or saline, microcurrents are generated at the dressing surface, due to its inherent design.

Procellera® is a primary contact layer dressing (Figure 2); it should be used under a secondary dressing or bandage (not provided), to keep it in place and help maintain a moist wound environment.

Silver and zinc in the dressing minimize or prevent the growth of microorganisms within the dressing, not at the wound site, and help preserve the dressing.

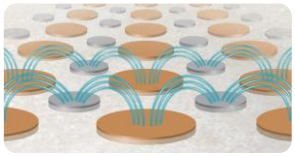


Figure 1

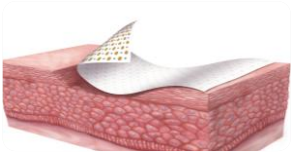


Figure 2

Indications

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.

Contraindications

- **Do not use on individuals with sensitivity or allergy to silver or zinc;**

Warnings

Frequent or prolonged use of this product may result, in rare occasions, in temporary discoloration of the skin.

Precautions

- **Single use only.**
- **Do not use if the pouch is open or damaged prior to use.**
- **For external use only.**
- **Do not apply Procellera dressing when using topical agents such as antimicrobial ointments, enzymatic debriders, antibiotic creams, silver or zinc containing creams, oxidizing agents, or petroleum based products**
- **Secondary dressings should be used as stated in their Instructions for Use.**
- **Stop using the Procellera dressing and consult a physician if an allergy, irritation, increased pain, maceration or irregular skin discoloration occurs.**
- **Procellera is not intended to be used on wounds with uncontrolled bleeding.**
- **Remove Procellera dressing during energy-based procedures (such as radiofrequencies, ultrasound, or radiation) where the dressing may interfere with delivery.**
- **Avoid contact with electrodes or conductive gels during electronic measurements; e.g., EEG (**electroencephalogram) **or ECG (**electrocardiogram)**.**
- Infected wounds should be treated under a physician's **supervision.**
- **The safety of daily Procellera use for longer than 28 days has not been studied.**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

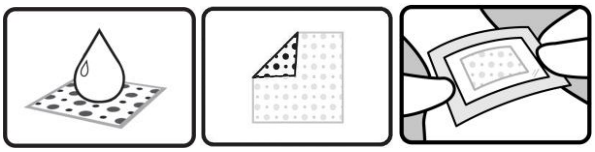
Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Instructions for OTC Use

Preparation

Follow local hygiene procedures prior to, during and following dressing application and change.

Application



1. **Cleanse the wound area with an appropriate wound cleanser.**
2. **Remove Procellera from package and if needed, cut to a shape that will extend beyond wound edges 1 to 2 cm** (1⁄2 inch to 1 inch). **Caution: cutting may result in fraying of the dressing.**
3. **Moisten Procellera with sterile saline, water or a thin, even layer of water-based hydrogel (not included).**
4. **Apply Procellera dressing to the wound site, with the dotted side down, in direct contact with the wound surface.**
5. **Cover Procellera with an appropriate secondary sterile dressing (such as a waterproof dressing) which will keep it in place and help maintain a moist wound environment. If needed, secure in place with an additional fixation dressing, using care not to restrict blood flow.**
6. **Keep Procellera moist by re-moistening as necessary (once a day, for dry wounds). Avoid over-soaking.**
   Note: It is not necessary to remove Procellera while showering.

Site Care and Dressing Change

- **Procellera may be left in place for up to 7 days. Earlier and/or more frequent changes may be required, depending on the amount of exudate present, the condition of the wound and surrounding skin.** Inspect the wound site periodically.
- **To remove the Procellera dressing, gently pull it back. If it adheres to the wound surface, do not force it off; moisten or soak the dressing with sterile saline or sterile water until it can be removed without tissue damage.**
- Consult a physician if any of the following occur: **infection, bleeding, maceration (skin whitening and softening), hypergranulation (excessive tissue formation), irritation at the wound site or the skin surrounding the Procellera dressing, or if the wound increases in size after a few dressing changes.**

Dressing Components

- **The Procellera dressing is not made with natural rubber latex.**
- **The Procellera dressing consists of a polyester substrate containing 0.9 mg of elemental silver and 0.3 mg of elemental zinc per square centimeter of dressing.**

Storage and Disposal

- **Store in dry conditions at controlled room temperature. Controlled room temperature is 20°C to 25°C (68°F to 77°F). Excursions are permitted between 15°C and 30°C (59°F and 86°F). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F), however, such exposure should be minimized.**
- **Protect from light.**
- **Dispose of according to local environmental procedures**

Made in the USA by:

Vomaris Wound Care, Inc.
1911 East Fifth Street, Tempe, AZ 85281, USA
(866) 496-8743 (480) 921-4948
www.vomaris.com

© 2016 Vomaris. All rights reserved. Procellera and Advanced Microcurrent Technology are all registered trademarks of Vomaris Innovations, Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

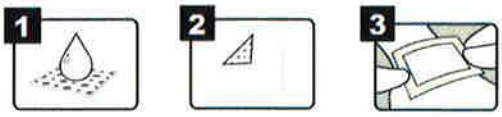
Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Procellera® Single Layer
Antimicrobial Wound Dressing

X x X in / X x X cm

Expiration Date
2017-08-20

REF AAA-XXXX LOT 123456X



Single Use Only

Do not use if package is damaged or open

See Instructions for Use

Manufactured by:
Vomaris Wound Care, Inc., Tempe, AZ 85281
Made in the U.S.A.

STERILE R

+77°F
+25°C
+68°F
+20°C

060700100 Rev A

(01) 0 0614141 99999 6 (17) 170820 (10) 123456X

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Reorder # AAA-XXXX-XX

Procellera® Single Layer
Antimicrobial Wound Dressing

X x X in / X x X cm

Expiration Date
2017-08-20

Box of X Unit(s)

REF AAA-XXXX LOT 123456X

Contains silver and zinc as preservatives

060700200 Rev A

(01) 0 0614141 99999 6 (17) 170820 (10) 123456X

X x X in / X x X cm

Procellera® Single Layer
Antimicrobial Wound Dressing

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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VOMARIS

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

K160783

FDA/CDRH/DCC
APR 05 2016
RECEIVED

eCopy Cover Letter

March 31, 2016

To:
Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – W066-G609
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

RE: eCopy Procellera Device - 510(k) Notification

Dear Madam/Sir:

The eCopy is an exact duplicate of the paper copy.

Please do not hesitate to contact me for any questions you may have:

Timothy Joiner, Director of QA/RA
Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, Arizona, 85281
Office: 480-921-0948 (b) (6) [redacted] Fax: 480-921-0948
Email: Timothy.Joiner@Vomaris.com

Sincerely,

Timothy Joiner, Director of QA/RA

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

78

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017

VOMARIS

Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, AZ 85281
www.procellera.com
Phone: 480-921-4948 Fax: 480-921-0948

K160783

3. COVER LETTER

March 14, 2016

FDA/CDRH/DCC
MAR 30 2016
RECEIVED

To:
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center
10903 New Hampshire Ave., Bldg. 66, Rm G609
Silver Spring, MD 20993-0002

RE: Procellera Device - 510(k) Notification

Dear Madam/Sir:

Vomaris Innovations, Inc. hereby submits this Special 510(k) Premarket Notification Submission for Procellera® Antimicrobial Wound Dressing device.

The device described in this 510(k) is identical to that currently cleared on February 4, 2013 under K130350 and to that cleared on December 1, 2008 under K081977 and June 15, 2006 under K060237. There are no changes to the original device design characteristics or to the manufacturing methods.

The main reason for this submission is to request the addition of the word "antimicrobial" to the Procellera OTC product, previously cleared through K081977 and K130350.

- The Rx device cleared by K060237, K081977 and K130350 included an antimicrobial claim.
- The OTC device cleared by K130350 did not include an antimicrobial claim, although the product design, raw materials, production process, facilities and personnel are identical.

The enclosed submission was compiled in accordance with 21 CFR 807, Subpart E and with applicable guidance documents for Industry and FDA Staff.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017

VOMARIS

Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, AZ 85281
www.procellera.com
Phone: 480-921-4948 Fax: 480-921-0948

This submission contains information required for demonstrating substantial equivalence of the proposed device to legally marketed predicate devices, in accordance with the Safe Medical Device Act of 1990.

We consider our intent to market this device and the information contained within this submission confidential commercial information that is exempt from public disclosure.

Table 3.1 Administrative information

Type of Submission:	Special 510(k) Notification
Device Type:	Wound Dressing
Proprietary Name:	Procellera® Antimicrobial Bioelectric Wound Dressing
Classification Name:	Wound Dressing Device
510(k) Submitter:	Vomaris Innovations, Inc. 3100 W Ray Rd, Suite 148, Chandler, AZ 85226 Phone: 480-921-4948, Fax: 480-921-0948
Establishment Registration #:	3005803853
Contact information:	Timothy Joiner, Director of QA/RA Office: 480-921-4948 (b) (6) [redacted] Timothy.Joiner@Vomaris.com
Confidentiality:	We prefer continued confidentiality in accordance with 21 CFR 807.95
Classification Regulation:	Unclassified

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017
Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, AZ 85281
www.procellera.com
Phone: 480-921-4948 Fax: 480-921-0948

Product Code:	FRO
Panel:	General & Plastic Surgery
Basis of Submission:	New Indication for Use
Prior 510k Submissions:	K060237, K081977, K130350

Table 3.2 Design and Use of the Device

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?	X	
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		NA
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017

VOMARIS

Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, AZ 85281
www.procellera.com
Phone: 480-921-4948 Fax: 480-921-0948

Does the submission include clinical information?		X
Is the device implanted?		X

I understand that the submission to the U.S. Government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Please do not hesitate to contact me for any questions you may have:

Timothy Joiner, Director of QA/RA
Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, Arizona, 85281
Office: 480-921-0948 (b) (6) [redacted] Fax: 480-921-0948
Email: Timothy.Joiner@Vomaris.com

Sincerely,

Timothy Joiner, Director of QA/RA

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

K160783

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

VOMARIS

Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, AZ 85281
www.procellera.com
Phone: 480-921-4948 Fax: 480-921-0948

eCopy Cover Letter

March 24, 2016

FDA/CDRH/DCC
MAR 25 2016
RECEIVED

To:
Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – W066-G609
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

RE: eCopy Procellera Device - 510(k) Notification

Dear Madam/Sir:

The eCopy is an exact duplicate of the paper copy.

Please do not hesitate to contact me for any questions you may have:

Timothy Joiner, Director of QA/RA
Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, Arizona, 85281
Office: 480-921-0948 (b) (6) [redacted] Fax: 480-921-0948
Email: Timothy.Joiner@Vomaris.com

Sincerely,

Timothy Joiner, Director of QA/RA

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

94

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

VOMARIS

Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, AZ 85281
www.procellera.com
Phone: 480-921-4948 Fax: 480-921-0948

FDA/CDRH/DCC
MAR 25 2016
RECEIVED

3. COVER LETTER

March 14, 2016

To:
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center
10903 New Hampshire Ave., Bldg. 66, Rm G609
Silver Spring, MD 20993-0002

RE: Procellera Device - 510(k) Notification

Dear Madam/Sir:

Vomaris Innovations, Inc. hereby submits this Special 510(k) Premarket Notification Submission for Procellera® Antimicrobial Wound Dressing device.

The device described in this 510(k) is identical to that currently cleared on February 4, 2013 under K130350 and to that cleared on December 1, 2008 under K081977 and June 15, 2006 under K060237. There are no changes to the original device design characteristics or to the manufacturing methods.

The main reason for this submission is to request the addition of the word "antimicrobial" to the Procellera OTC product, previously cleared through K081977 and K130350.

- The Rx device cleared by K060237, K081977 and K130350 included an antimicrobial claim.
- The OTC device cleared by K130350 did not include an antimicrobial claim, although the product design, raw materials, production process, facilities and personnel are identical.

The enclosed submission was compiled in accordance with 21 CFR 807, Subpart E and with applicable guidance documents for Industry and FDA Staff.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

94

Records processed under FOIA Request #2016-8865; Release Date: 03-13-2017
Vomaris Innovations, Inc.
901 East 8th Street, Tempe, AZ 85281
www.procellera.com
Phone: 480-921-4948 Fax: 480-921-0948

This submission contains information required for demonstrating substantial equivalence of the proposed device to legally marketed predicate devices, in accordance with the Safe Medical Device Act of 1990.

We consider our intent to market this device and the information contained within this submission confidential commercial information that is exempt from public disclosure.

Table 3.1 Administrative information

Type of Submission:	Special 510(k) Notification
Device Type:	Wound Dressing
Proprietary Name:	Procellera® Antimicrobial Bioelectric Wound Dressing
Classification Name:	Wound Dressing Device
510(k) Submitter:	Vomaris Innovations, Inc. 3100 W Ray Rd, Suite 148, Chandler, AZ 85226 Phone: 480-921-4948, Fax: 480-921-0948
Establishment Registration #:	3005803853
Contact information:	Timothy Joiner, Director of QA/RA Office: 480-921-4948 (b) (6) [redacted] Timothy.Joiner@Vomaris.com
Confidentiality:	We prefer continued confidentiality in accordance with 21 CFR 807.95
Classification Regulation:	Unclassified

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, AZ 85281
www.procellera.com
Phone: 480-921-4948 Fax: 480-921-0948

Product Code:	FRO
Panel:	General & Plastic Surgery
Basis of Submission:	New Indication for Use
Prior 510k Submissions:	K060237, K081977, K130350

Table 3.2 Design and Use of the Device

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?	X	
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		NA
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-03-2017

VOMARIS

Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, AZ 85281
www.procellera.com
Phone: 480-921-4948 Fax: 480-921-0948

Does the submission include clinical information?		X
Is the device implanted?		X

I understand that the submission to the U.S. Government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Please do not hesitate to contact me for any questions you may have:

Timothy Joiner, Director of QA/RA
Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, Arizona, 85281
Office: 480-921-0948 (b) (6) [redacted] Fax: 480-921-0948
Email: Timothy.Joiner@Vomaris.com

Sincerely,

Timothy Joiner, Director of QA/RA

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

VOMARIS

Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, AZ 85281
www.procellera.com
Phone: 480-921-4948 Fax: 480-921-0948

3. COVER LETTER

K160783

March 14, 2016

To:
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center
10903 New Hampshire Ave., Bldg. 66, Rm G609
Silver Spring, MD 20993-0002

FDA/CDRH/DCC
MAR 22 2016
RECEIVED

RE: Procellera Device - 510(k) Notification

Dear Madam/Sir:

Vomaris Innovations, Inc. hereby submits this Special 510(k) Premarket Notification Submission for Procellera® Antimicrobial Wound Dressing device.

The device described in this 510(k) is identical to that currently cleared on February 4, 2013 under K130350 and to that cleared on December 1, 2008 under K081977 and June 15, 2006 under K060237. There are no changes to the original device design characteristics or to the manufacturing methods.

The main reason for this submission is to request the addition of the word "antimicrobial" to the Procellera OTC product, previously cleared through K081977 and K130350.

- The Rx device cleared by K060237, K081977 and K130350 included an antimicrobial claim.
- The OTC device cleared by K130350 did not include an antimicrobial claim, although the product design, raw materials, production process, facilities and personnel are identical.

The enclosed submission was compiled in accordance with 21 CFR 807, Subpart E and with applicable guidance documents for Industry and FDA Staff.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, AZ 85281
www.procellera.com
Phone: 480-921-4948 Fax: 480-921-0948

This submission contains information required for demonstrating substantial equivalence of the proposed device to legally marketed predicate devices, in accordance with the Safe Medical Device Act of 1990.

We consider our intent to market this device and the information contained within this submission confidential commercial information that is exempt from public disclosure.

Table 3.1 Administrative information

Type of Submission:	Special 510(k) Notification
Device Type:	Wound Dressing
Proprietary Name:	Procellera® Antimicrobial Bioelectric Wound Dressing
Classification Name:	Wound Dressing Device
510(k) Submitter:	Vomaris Innovations, Inc. 3100 W Ray Rd, Suite 148, Chandler, AZ 85226 Phone: 480-921-4948, Fax: 480-921-0948
Establishment Registration #:	3005803853
Contact information:	Timothy Joiner, Director of QA/RA Office: 480-921-4948 (b) (6) [redacted] Timothy.Joiner@Vomaris.com
Confidentiality:	We prefer continued confidentiality in accordance with 21 CFR 807.95
Classification Regulation:	Unclassified

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, AZ 85281
www.procellera.com
Phone: 480-921-4948 Fax: 480-921-0948

Product Code:	FRO
Panel:	General & Plastic Surgery
Basis of Submission:	New Indication for Use
Prior 510k Submissions:	K060237, K081977, K130350

Table 3.2 Design and Use of the Device

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?	X	
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		NA
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

VOMARIS

Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, AZ 85281
www.procellera.com
Phone: 480-921-4948 Fax: 480-921-0948

Does the submission include clinical information?		X
Is the device implanted?		X

I understand that the submission to the U.S. Government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Please do not hesitate to contact me for any questions you may have:

Timothy Joiner, Director of QA/RA
Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, Arizona, 85281
Office: 480-921-0948 (b) (6) [redacted] Fax: 480-921-0948
Email: Timothy.Joiner@Vomaris.com

Sincerely,

Timothy Joiner, Director of QA/RA

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

VOMARIS

Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, AZ 85281
www.procellera.com
Phone: 480-921-4948 Fax: 480-921-0948

FDA/CDRH/DCC
MAR 22 2016
RECEIVED

0. eCopy Cover Letter

March 14, 2016

To:
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center
10903 New Hampshire Ave., Bldg. 66, Rm G609
Silver Spring, MD 20993-0002

RE: eCopy Procellera Device - 510(k) Notification

Dear Madam/Sir:

The eCopy is an exact duplicate of the paper copy.

Please do not hesitate to contact me for any questions you may have:

Timothy Joiner, Director of QA/RA
Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, Arizona, 85281
Office: 480-921-0948 (b) (6) [redacted] Fax: 480-921-0948
Email: Timothy.Joiner@Vomaris.com

Sincerely,

Timothy Joiner, Director of QA/RA

58

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b) (4) [redacted]
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

VOMARIS INNOVATIONS INC
1911 E. 5th Street
Tempe
Maricopa
AZ 85281
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
[redacted] (b) (4)

2. CONTACT NAME
Lumi Skiba

2.1 E-MAIL ADDRESS
lumi.skiba@vomaris.com

2.2 TELEPHONE NUMBER (include Area code)
480-9214948 2236

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
480-9210948

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[X] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number: SBD165312

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville Road,

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

COLE-14-14253 Silver Spring, MD 20993-0002
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b) (4) [redacted] 11-Mar-2016

Form FDA 3601 (05/13)

"Close Window" Print Cover sheet

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

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For more assistance with Adobe Reader visit http://www.adobe.com/go/acrreader.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

VOMARIS

Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, AZ 85281
www.procellera.com
Phone: 480-921-4948 Fax: 480-921-0948

3. COVER LETTER

March 31, 2016

To:
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center
10903 New Hampshire Ave., Bldg. 66, Rm G609
Silver Spring, MD 20993-0002

RE: Procellera Device - 510(k) Notification

Dear Madam/Sir:

This is a replacement copy of 510(k) K160783. All of the information is the same. The Table of Contents and order of the attachment documents have been changed to comply with the eCopy requirements.

Vomaris Innovations, Inc. hereby submits this Special 510(k) Premarket Notification Submission for Procellera® Antimicrobial Wound Dressing device.

The device described in this 510(k) is identical to that currently cleared on February 4, 2013 under K130350 and to that cleared on December 1, 2008 under K081977 and June 15, 2006 under K060237. There are no changes to the original device design characteristics or to the manufacturing methods.

The main reason for this submission is to request the addition of the word "antimicrobial" to the Procellera OTC product, previously cleared through K081977 and K130350.

- The Rx device cleared by K060237, K081977 and K130350 included an antimicrobial claim.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, AZ 85281
www.procellera.com
Phone: 480-921-4948 Fax: 480-921-0948

- The OTC device cleared by K130350 did not include an antimicrobial claim, although the product design, raw materials, production process, facilities and personnel are identical.

The enclosed submission was compiled in accordance with 21 CFR 807, Subpart E and with applicable guidance documents for Industry and FDA Staff.

This submission contains information required for demonstrating substantial equivalence of the proposed device to legally marketed predicate devices, in accordance with the Safe Medical Device Act of 1990.

We consider our intent to market this device and the information contained within this submission confidential commercial information that is exempt from public disclosure.

Table 3.1 Administrative information

Type of Submission:	Special 510(k) Notification
Device Type:	Wound Dressing
Proprietary Name:	Procellera® Antimicrobial Bioelectric Wound Dressing
Classification Name:	Wound Dressing Device
510(k) Submitter:	Vomaris Innovations, Inc. 3100 W Ray Rd, Suite 148, Chandler, AZ 85226 Phone: 480-921-4948, Fax: 480-921-0948
Establishment Registration #:	3005803853
Contact information:	Timothy Joiner, Director of QA/RA Office: 480-921-4948 (b) (6) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, AZ 85281
www.procellera.com
Phone: 480-921-4948 Fax: 480-921-0948

	Timothy.Joiner@Vomaris.com
Confidentiality:	We prefer continued confidentiality in accordance with 21 CFR 807.95
Classification Regulation:	Unclassified
Product Code:	FRO
Panel:	General & Plastic Surgery
Basis of Submission:	New Indication for Use
Prior 510k Submissions:	K060237, K081977, K130350

Table 3.2 Design and Use of the Device

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?	X	
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		NA

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

VOMARIS

Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, AZ 85281
www.procellera.com
Phone: 480-921-4948 Fax: 480-921-0948

Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

I understand that the submission to the U.S. Government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Please do not hesitate to contact me for any questions you may have:

Timothy Joiner, Director of QA/RA
Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, Arizona, 85281
Office: 480-921-0948 (b) (6) [redacted] Fax: 480-921-0948
Email: Timothy.Joiner@Vomaris.com

Sincerely,

Timothy Joiner, Director of QA/RA

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-15-2017.

VOMARIS
Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, AZ 85281
www.procellera.com
Phone: 480-921-4948 Fax: 480-921-0948

4. Table of Contents

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14-02 Attachment 24
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14-06 Attachment 28
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14-08 Attachment 30

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-15-2017.

VOMARIS

Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, AZ 85281
www.procellera.com
Phone: 480-921-4948 Fax: 480-921-0948

19-01 Attachment **31**

19-02 Attachment **32**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017

VOMARIS

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1911 East Fifth Street, Tempe, AZ 85281
www.procellera.com
Phone: 480-921-4948 Fax: 480-921-0948

5. INDICATIONS FOR USE

Indications for Use – Procellera® Rx Prescription Use Device

510(k) Number: TBD

Device Names:

- **Procellera®** Antimicrobial Wound Dressing (Rx)

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)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017

VOMARIS

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1911 East Fifth Street, Tempe, AZ 85281
www.procellera.com
Phone: 480-921-4948 Fax: 480-921-0948

Indications for Use – Procellera® OTC

510(k) Number: TBD

Device Names:

- **Procellera®** Antimicrobial Wound Dressing (OTC)

Indications for Use:

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.

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)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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6. 510(K) SUMMARY

The purpose of this Premarket Notification is to request the addition of the word "antimicrobial" to the Procellera® over-the-counter product, previously cleared through K081977 and K130350.

Procellera® device described in this Special 510(k) is identical to the Procellera® device cleared in 2013 (K130350), 2008 (K081977) and in 2006 (K060237). There are no changes to the original device design, characteristics, or to the manufacturing process.

The prescription device and the over-the-counter device cleared in 2013 (K130350) are identical in every way. Only during the labeling process, which is performed after pouching and sterilization, are the products distinguished between prescription use and over-the-counter use.

The Rx product was cleared with the word "antimicrobial" while the OTC product was not cleared with the word "antimicrobial".

The following are the **cleared** "Indications for Use" for each of the respective 510(k)'s:

K081977 (Rx)	K081977 (OTC)
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.	For over-the-counter use, Procellera® wound dressing is indicated for minor cuts, scrapes, irritations, and abrasions.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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K130350 (Rx)	K130350 (OTC)
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.	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.

The requested change is the addition of antimicrobial to the OTC "Indications for Use" such that the wording for both the Rx and OTC would include the word antimicrobial. The following is the proposed language.

Rx – no change	OTC – this document
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.	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.

The 510(k) summary for the Procellera® device subject to this submission is provided in the following pages.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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510(k) Summary for Procellera® Device

Date: February 9, 2016

Device Name: Procellera®

Trade Name: Procellera® Antimicrobial Bioelectric 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)

Device Description:

Procellera® Antimicrobial Wound Dressing, described in K081977 for Rx and K130350 for OTC, is a single layer non-adhesive dressing that requires secondary materials to (1) retain moisture necessary for Procellera® function and (2) hold the dressing in-place. The secondary components are described in their respective IFU and previously provided to FDA in the above referenced 510(k) Premarket Notifications.

Intended 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.

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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:

Procellera® Antimicrobial Wound Dressing is an electroceutical device. It is a single layer microcurrent-generating antimicrobial wound dressing. Embedded in the dressing are microcell batteries made of elemental silver and zinc applied in a well-characterized dot-matrix pattern to a polyester substrate.

Performance Data:

(b)(4) Confidential and Proprietary Information

[redacted]

Antimicrobial efficacy testing previously submitted to FDA resulted in clearance of Procellera® Antimicrobial Wound Dressing for prescription use with an Antimicrobial claim. 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.

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,

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which are identical, and thus is substantially equivalent to the existing legally marketed devices under the Federal Food, Drug and Cosmetic Act.

Contact:

Timothy Joiner
Director, Quality Assurance & Regulatory Affairs
1911 East Fifth Street, Tempe, Arizona, 85281
480-921-4948
Timothy.Joiner@Vomaris.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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7. TRUTHFUL AND ACCURATE STATEMENT

I certify that, in my capacity as Director of Quality Assurance & Regulatory Affairs of Vomaris Innovations, Inc., I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

(Signature)

Timothy J. Joiner
(Typed Name)

March 31, 2016
(Date)

K160783
*(Premarket Notification [510(k)]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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8. CLASS III SUMMARY AND CERTIFICATION

This section does not apply to this 510(k) submission.

Procellera® is not a Class III device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-10-2017.

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9. FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT

This section does not apply to this 510(k) submission.

No clinical studies information is included in this submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

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10. DECLARATION OF CONFORMITY AND SUMMARY REPORTS

This section does not apply to this 510(k) submission.

The Performance Standards information presented in this submission is unchanged from those presented in K060237, K081977, and K130350. There are no mandatory performance standards promulgated by the FDA for wound dressings. Procellera® is an unclassified, pre-amendment device that is not exempt from the Quality System Regulation (QSR).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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11. Device Classification

	Predicate – Single Layer Rx	Predicate – Single Layer OTC
Proprietary Name	Procellera; Procellera Antimicrobial Wound Dressing; Procellera Elite Wound Dressing; Procellera Rx Antimicrobial Wound Dressing	Procellera OTC
Classification Name	DRESSING, WOUND, DRUG	DRESSING, WOUND, DRUG
Product Code	FRO	FRO
Device Class	U (Unclassified; reason Pre-Amendment)	U (Unclassified; reason Pre-Amendment)
Registered Establishment Name	Vomaris Wound Care, Inc.	Vomaris Wound Care, Inc.
Registered Establishment Number	3005803853	3005803853
Premarket Submission Number	K130350 (both Rx and OTC device)	K130350 (both Rx and OTC device)
Owner/Operator	Vomaris Innovations Inc.	Vomaris Innovations Inc.
Owner/Operator Number	9079581	9079581
Establishment Operations	Manufacturer	Manufacturer

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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12. Device Description

Procellera® Antimicrobial Wound Dressing, described in K081977 for Rx and K130350 for OTC, is a single layer non-adhesive dressing that requires secondary materials to (1) retain moisture necessary for Procellera function and (2) hold the dressing in-place. The secondary components are described in their respective IFU and previously provided to FDA in the above referenced 510(k) Premarket Notifications.

The following is a graphic of the product. The Rx or OTC products are indistinguishable, since, until labeled, they are identical. In actual clinical use their performance would also be indistinguishable since they are identical.

Product Comparison Table

Characteristic	Rx	OTC
Configuration	Elemental silver and zinc are applied on a polyester substrate in a dot matrix pattern.	Identical
Elemental silver to elemental zinc concentration	(b)(4) Confidential and Proprietary Information [redacted]	Identical
Surface area	1 in^2 – 144 in^2 6.5 cm^2 – 77.4 cm^2	Identical
Packaging	Mylar / Mylar pouch	Identical
Sterilization – irradiation	ebeam	Identical

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Characteristic	Rx	OTC
Biocompatibility – ISO 10993-1	• Body Contact • Breached or compromised surfaces • 24 Hours – 30 Days) Provided in K081977 (Rx) and K130350 (Rx & OTC)	Identical
Antimicrobial testing	Provided in K081977 for Rx additionally provided in K130350	Identical

(b)(4) Confidential and Proprietary Information

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4) Confidential and Proprietary Information

[redacted]

Product Table

The table below lists the current sizes of Procellera® Antimicrobial Wound Dressing followed by the products. The Procellera product surface area ranges from 1 in^2 – 144 in^2.

Dressing Size (inches)	Rx Part Number	OTC Part Number
4x4	VSR-0404	VSC-0404
1x1 Slit	VSR-0101F	VSC-0101F
1.5x8	VSR-1508	VSC-1508
1.5x10	VSR-1510	VSC-1510
2x2	VSR-0202	VSC-0202
2x5	VSR-0205	VSC-0205
3x3	VSR-0303	VSC-0303
8x8	VSR-0808	VSC-0808
12x12	VSR-1212	VSC-1212

Device Description and Operating Principle

Procellera® Antimicrobial Wound Dressing device description and operating principles were previously discussed and explained in cleared 510(k) K060237, K081977, and K130350.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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13. DESIGN CONTROL

The Design Control process is the same for Procellera® Antimicrobial Wound Dressing RX and

(b)(4) Confidential and Proprietary Information

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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14. LABELING

Attached are copies of draft OTC Procellera IFU's, and examples of applicable pouch and carton labels with antimicrobial added. The Rx labels are currently cleared labels and labeling.

- Physical sizes for both Rx and OTC are the same.
- The labeling and labels are the same except for the Rx and OTC specific language.
- Examples of the labels and labeling are identified below:

Attachment		Description	Document ID
14-01	Rx	Rx Instruction for Use	Rx IFU-01 rev J Oct 13 2015.pdf
14-02	Rx	Pouch label	Rx Pouch L_VSR_0404_A_Lot_131101A.pdf
14-03	Rx	Box label	Rx Box L_VSR_0101F_A_NBO_LOT_130401A.pdf
14-04	Rx & OTC	Box Carton	Rx and OTC Outer box with non-variable information.docx
14-05	OTC	OTC Instruction for Use	OTC DRAFT IFU-02.docx
14-06	OTC	OTC Pouch label	OTC Pouch Label L-VSC-0205.docx
14-07	OTC	OTC Box label	OTC Box Label B-VSC-0205.docx
14-08	OTC	Pouch label on pouch example	OTC Pouch label on pouch L-VSC-0205.docx

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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15. MANUFACTURING

The manufacturing process for Procellera® Antimicrobial Wound Dressing Rx and OTC has been previously submitted and cleared in the aforementioned 510(k)'s. In those documents, the manufacturing process was explained and described in greater detail.

The manufacturing process for Procellera® Antimicrobial Wound Dressing Rx and OTC is not only the same, but indistinguishable because the product becomes Rx or OTC during the labeling process.

Manufacturing Locations and Activities

Establishment	Vomaris Wound Care, Inc. 1911 E 5Th St Tempe, AZ 85281
Activities	• Manufactures Procellera single-layer • Labels, packages, and distributes product
Registration Number	3005803853
Owner/Operator Number	9079581
Official Correspondent	Tim Joiner 1911 E 5Th Street Tempe, AZ 85281 (480) 9214948-2239

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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16. SHELF LIFE

Both Procellera® Antimicrobial Wound Dressing RX and OTC single-layer products have a 5-year shelf life.

The shelf life is identified to the user by the use of an expiration date symbol followed by the date.

	Format: the year (yyyy), month (mm); day (dd), each separated by hyphens. Example, January 2, 2014, is presented as 2014-01-02.

The shelf life is that same as previous cleared in the 510(k)'s. It is not being changed.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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17. LIFETIME

The Lifetime for Procellera® Antimicrobial Wound Dressing Rx and OTC are the same in this submission as in the aforementioned 510(k)'s submitted to and cleared by the FDA. They are as follows:

There are two (2) "lifetimes" of the devices: Time of Use and Shelf Life; Shelf Life is also known as and denoted by expiration date, or use before date.

Time of Use

Upon opening, Time of Use is up to seven (7) days in situ use as a wound care device. The time starts from opening the product and continues for 7 days. If needed, the device may be removed and replaced by another device of the same or different size.

This may continue for up to twenty-eight (28) days. Longer than 28 days has not been evaluated, thus the company does not recommend its use past 28 days.

Shelf Life

The shelf life is currently five (5) years.

The shelf life is identified to the user by the use of the applicable expiration date symbol followed by the date.

The date format is: the year, using four digits; followed by the month, using two digits; followed by the day, using two digits; each separated by hyphens.

For example, January 2, 2014, is presented as 2014-01-02.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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18. BIOCOMPATIBILITY

Since the products are indistinguishable, Biocompatibility testing results are applicable to both the Rx and OTC products.

The results demonstrated that the product is safe. These reports were previously provided in the aforementioned 510(k) submissions. They are not being provided herein.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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19. RISK MANAGEMENT

Risk Management occurs throughout the product lifecycle and is an active component of the Vomaris Quality System.

There has been no change to the Risk profile for either the Rx or OTC product.

Risk Analysis files for the Procellera single-layer products are attached as

(b)(4) Confidential and Proprietary Information

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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20. STERILIZATION

The sterilization method and facility has not changed. It is the same as previously reported to FDA in the aforementioned 510(k) submissions.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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21. SOFTWARE

This section does not apply to this 510(k) submission.

Procellera Rx and Procellera OTC do not contain nor use software.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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22. POST MARKET SUMMARY AND POST MARKET CLINICAL FOLLOW-UP

Complaint History Summary

- Procellera device has been marketed in the US market since July 2006, when it was initially cleared by US Food and Drug Administration.
- There have been no field safety corrective actions or recalls since the July 2006 clearance.
- Regulatory reporting requirements are based on FDA 21CFR803 Medical Device Reporting.

(b)(4) Confidential and Proprietary Information

[redacted]

Post Market Clinical Follow-up

At this time, Vomaris does not have any studies that require clinical follow-up.
At this time, there are no complaints specific to the OT.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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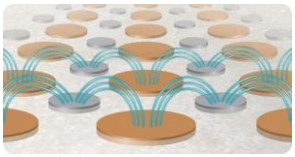
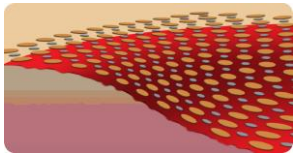
Procellera | Rx™
Wound Care with Advanced Microcurrent Technology

Instructions for Prescription Use

Product Description

Procellera® is a single layer antimicrobial wound dressing. Imbedded in the dressing are microcell batteries made of elemental silver and zinc applied in a dot-matrix pattern. In the presence of a conductive medium such as wound exudate, water-based hydrogels or saline, microcurrents are generated at the dressing surface, due to its inherent design. Silver and zinc in the dressing produce microcurrent, to minimize or prevent the growth of microorganisms within the dressing and help the dressing to be preserved.

Procellera is a primary contact layer dressing; it should be used under a secondary dressing or bandage (not provided), to keep it in place and help maintain a moist wound environment.

Advanced Microcurrent Technology™

Indications

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.

Contraindications

- Do not use on individuals with sensitivity or allergy to silver or zinc.
- MRI Non-Compatible: Neither MRI-Safe nor MRI-Compatible and should be removed prior to an MRI procedure. A new dressing may be applied after the procedure.

Warnings

Frequent or prolonged use of this product may result in permanent discoloration of the skin (i.e., argyria).

Precautions

- **Caution:** Federal law restricts this device to sale by or on the order of a physician.
- Single use only.
- Do not use if the pouch is open or damaged prior to use.
- For external use only. Do not use Procellera with topical agents such as antimicrobial ointments, enzymatic debriders, antibiotic creams, silver or zinc containing creams, oxidizing agents, petroleum based products, etc.
- Secondary dressings should be used as stated in their Instructions for Use.
- The patient should stop using the dressing and consult a physician if allergy, irritation, increased pain, maceration or any irregular skin discoloration occurs.
- Procellera is not intended to be used on wounds with uncontrolled bleeding.
- Remove Procellera dressing during energy-based procedures (such as electricity, radiofrequencies, ultrasound, radiation, etc.) where the dressing may interfere with delivery.
- Avoid contact with electrodes or conductive gels during electronic measurements; e.g., EEG or ECG.
- Procellera may be used on infected wounds that are being managed in accordance with institutional clinical protocols for infection abatement as an adjunct to the standard treatment regimen.
- The safety of daily Procellera use for longer than 28 days has not been studied.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

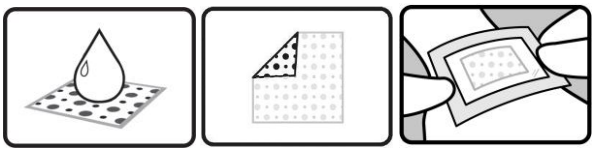
Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Instructions for Prescription Use

Preparation

Follow local hygiene procedures prior to, during and following dressing application and change.

Application



1. Cleanse the wound area with an appropriate wound cleanser according to local clinical protocol.
2. Remove Procellera from package and if needed, cut to a shape that will extend beyond wound edges 1 to 2 cm (1⁄2 inch to 1 inch). **Caution:** cutting may result in fraying of the dressing.
3. Moisten Procellera with sterile saline, water or a thin, even layer of water-based hydrogel (not included).
4. Apply Procellera dressing to the wound site, **with the dotted side down**, in direct contact with the wound surface.
5. Cover Procellera with an appropriate secondary sterile dressing which will help maintain a moist wound environment. The choice of secondary dressing should be determined by the degree of exudate produced by the wound, for example:
   - For DRY wounds: waterproof, semi-permeable or hydrogel-like dressings are recommended to ensure prolonged moisture.
   - For EXUDATING wounds: cover Procellera with layer(s) of sterile gauze or foam dressing to absorb excessive moisture and prevent maceration. Then apply a semi-permeable or hydrogel-like dressing.
     If needed, secure in place with an additional fixation dressing, using care not to restrict blood flow.
6. Keep the dressing moist by re-moistening as necessary. Avoid over-soaking. Example:
   - DRY wounds may require more frequent re-moistening of the dressing(s).
   - EXUDATING wounds require dressing re-moistening only if exudate decreases and the dressing becomes dry.

Site Care and Dressing Change

- Procellera may be left in place for up to 7 days. Earlier and/or more frequent changes may be required, depending on the amount of exudate present, the condition of the wound and the surrounding skin. Inspect the wound site periodically.
- To remove the Procellera dressing, gently pull it back. If it adheres to the wound surface, do not force it off; moisten or soak the dressing with sterile saline or sterile water until it can be removed without tissue damage.
- The patient should consult a physician if any of the following occur: infection, bleeding, maceration (skin whitening and softening), hypergranulation (excessive tissue formation), irritation at the wound site or the skin surrounding the dressing, or if the wound increases in size after a few dressing changes.

Dressing Components

- The dressing is not made with natural rubber latex.
- The dressing consists of a polyester substrate containing 0.9 mg of elemental silver and 0.3 mg of elemental zinc per square centimeter of dressing. Silver in the dressing acts as a preservative and inhibits growth of microorganisms within the dressing.

Storage and Disposal

- Store in dry conditions at room temperature. Protect from light.
- Dispose of according to local environmental procedures.

Made in the USA by:

Vomaris Wound Care, Inc.
1911 East Fifth Street, Tempe, AZ 85281, USA
(866) 496-8743 (480) 921-4948
www.procellera.com

© 2015 Vomaris. All rights reserved. Procellera, Procellera with logo and Advanced Microcurrent Technology are all trademarks of Vomaris Innovations, Inc. All other trademarks are the property of their respective owners.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Procellera | Rx™
Wound Care with Advanced Microcurrent Technology

P/N VSR-0404
LOT 131101A
Use by: 2019-01-28

ANTIMICROBIAL WOUND DRESSING · 4" x 4" (10cm x 10cm)

1. Moisten dressing
2. Apply **dotted side down**
3. Cover with a waterproof dressing

Rx ONLY · STERILE R · L- VSR-0404 / A

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Tempe, AZ 85281 480-921-4948

www.procellera.com

Procellera | Rx™
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Procellera | Rx™
Wound Care with Advanced Microcurrent Technology

P/N VSR-0101F LOT 130401A

Use by: 2018-07-05

ANTIMICROBIAL WOUND DRESSING 1" x 1" (2.5cm x 2.5cm) Fenestrated

1 Moisten dressing

2 Apply **dotted side down**

3 Cover with a waterproof dressing

Rx ONLY STERILE R

L-VSR-0101F/A

Made in the USA by Vomaris Wound Care, Inc.
Tempe, AZ 85281 480-921-4948

www.procellera.com

Procellera | Rx™
Wound Care with Advanced Microcurrent Technology

P/N VSR-0101F LOT 130401A

Use by: 2018-07-05

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Rx ONLY STERILE R

L-VSR-0101F/A

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Procellera | Rx™
Wound Care with Advanced Microcurrent Technology

P/N VSR-0101F LOT 130401A

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L-VSR-0101F/A

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Procellera | Rx™
Wound Care with Advanced Microcurrent Technology

P/N VSR-0101F LOT 130401A

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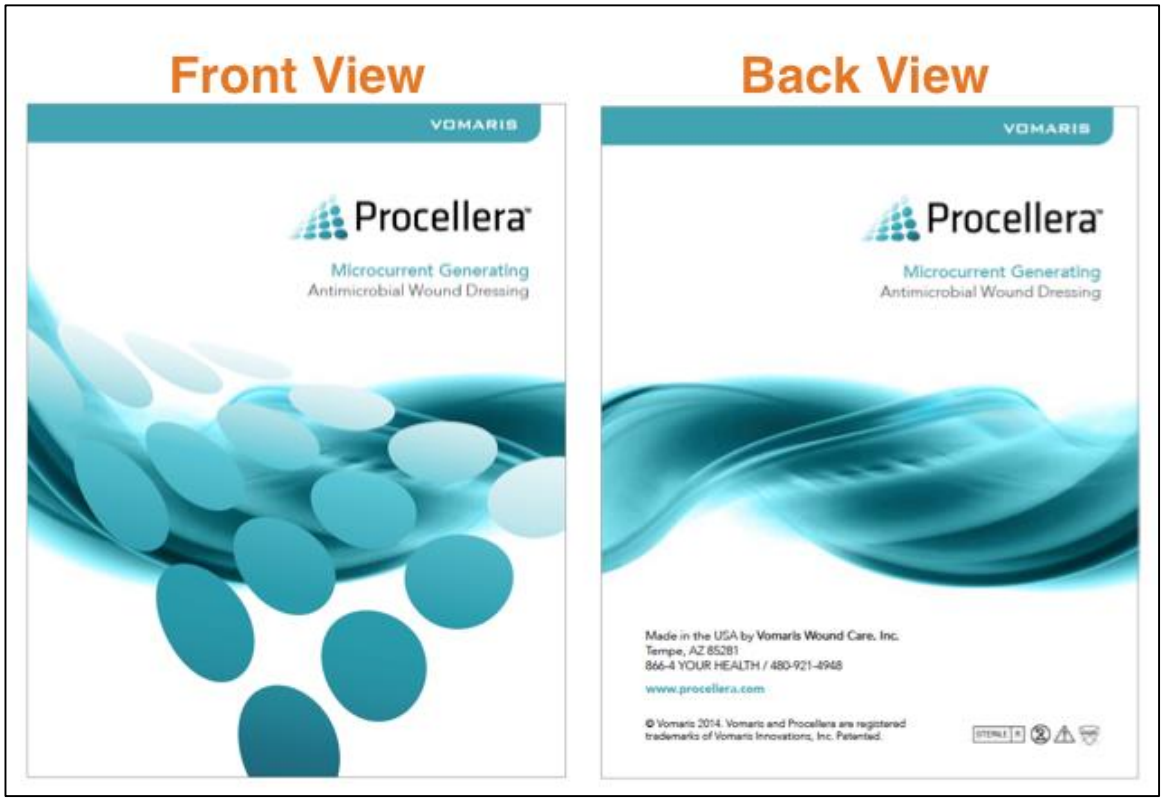
Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Rx and OTC outer box with non-variable information



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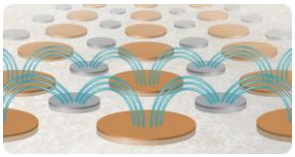
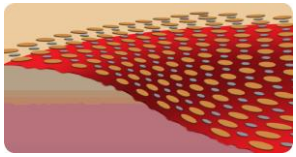
Procellera | Elite™
Wound Care with Advanced Microcurrent Technology

Instructions for OTC Use

Product Description

Procellera® is a single layer antimicrobial wound dressing. Imbedded in the dressing are microcell batteries made of elemental silver and zinc applied in a dot-matrix pattern. In the presence of a conductive medium such as wound exudate, water-based hydrogels or saline, microcurrents are generated at the dressing surface, due to its inherent design. Silver and zinc in the dressing produce microcurrents, to minimize or prevent the growth of microorganisms within the dressing and help the dressing to be preserved.

Procellera is a primary contact layer dressing; it should be used under a secondary dressing or bandage (not provided), to keep it in place and help maintain a moist wound environment.

Advanced Microcurrent Technology™

Indications

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.

Contraindications

- Do not use on individuals with sensitivity or allergy to silver or zinc;
- MRI Non-Compatible: Neither MRI-Safe nor MRI-Compatible and should be removed prior to an MRI procedure. A new dressing may be applied after the procedure.

Warnings

Frequent or prolonged use of this product may result in permanent discoloration of the skin (i.e., argyria).

Precautions

- Single use only.
- Do not use if the pouch is open or damaged prior to use.
- For external use only. Do not use Procellera with topical agents such as antimicrobial ointments, enzymatic debriders, antibiotic creams, silver or zinc containing creams, oxidizing agents, petroleum based products, etc..
- Secondary dressings should be used as stated in their Instructions for Use.
- Stop using the dressing and consult a physician if an allergy, irritation, increased pain, maceration or irregular skin discoloration occurs.
- Procellera is not intended to be used on wounds with uncontrolled bleeding.
- Remove Procellera dressing during energy-based procedures (such as electricity, radiofrequencies, ultrasound, radiation, etc.) where the dressing may interfere with delivery.
- Avoid contact with electrodes or conductive gels during electronic measurements; e.g., EEG (electroencephalogram) or ECG (electrocardiogram).
- Procellera may be used on infected wounds that are being managed in accordance with institutional clinical protocols for infection abatement as an adjunct to the standard treatment regimen.
- The safety of daily Procellera use for longer than 28 days has not been studied.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

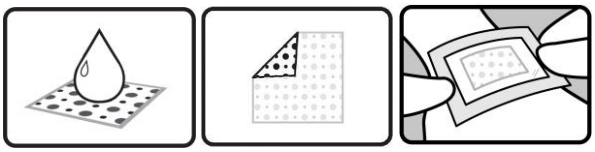
Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Instructions for OTC Use

Preparation

Follow local hygiene procedures prior to, during and following dressing application and change.

Application



1. Cleanse the wound area with an appropriate wound cleanser.
2. Remove Procellera from package and if needed, cut to a shape that will extend beyond wound edges 1 to 2 cm (1⁄2 inch to 1 inch). **Caution:** cutting may result in fraying of the dressing.
3. Moisten Procellera with sterile saline, water or a thin, even layer of water-based hydrogel (not included).
4. Apply Procellera dressing to the wound site, **with the dotted side down**, in direct contact with the wound surface.
5. Cover Procellera with an appropriate secondary sterile dressing (such as a waterproof dressing) which will keep it in place and help maintain a moist wound environment. If needed, secure in place with an additional fixation dressing, using care not to restrict blood flow.
6. Keep the dressing moist by re-moistening as necessary (once a day, for dry wounds). Avoid over-soaking.
   Note: It is not necessary to remove Procellera while showering.

Site Care and Dressing Change

- Procellera may be left in place for up to 7 days. Earlier and/or more frequent changes may be required, depending on the amount of exudate present, the condition of the wound and surrounding skin. Inspect the wound site periodically.
- To remove the Procellera dressing, gently pull it back. If it adheres to the wound surface, do not force it off; moisten or soak the dressing with sterile saline or sterile water until it can be removed without tissue damage.
- Consult a physician if any of the following occur: infection, bleeding, maceration (skin whitening and softening), hypergranulation (excessive tissue formation), irritation at the wound site or the skin surrounding the dressing, or if the wound increases in size after a few dressing changes.

Dressing Components

- The dressing is not made with natural rubber latex.
- The dressing consists of a polyester substrate containing 0.9 mg of elemental silver and 0.3 mg of elemental zinc per square centimeter of dressing. Silver in the dressing acts as a preservative and inhibits growth of microorganisms within the dressing.

Storage and Disposal

- Store in dry conditions at room temperature. Protect from light.
- Dispose of according to local environmental procedures.

Made in the USA by:

Vomaris Wound Care, Inc.
1911 East Fifth Street, Tempe, AZ 85281, USA
(866) 496-8743 (480) 921-4948
www.procellera.com

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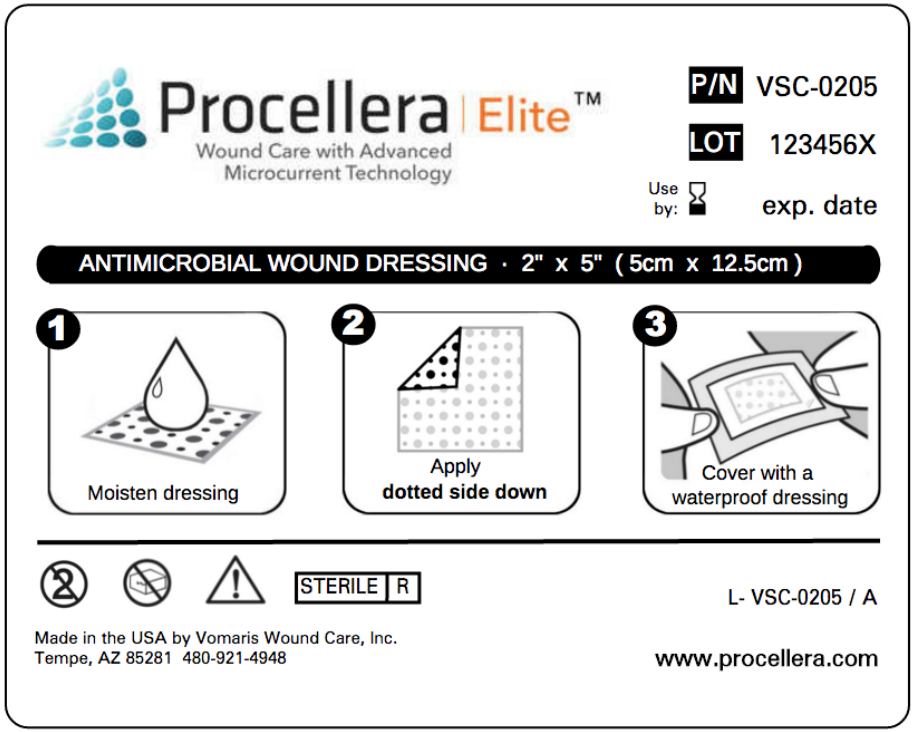
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Pouch Label



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Box Label

2 x 5 in
(5 x 12.5 cm)

P/N VSC-0205
LOT 123456X
Use by: exp. date

Box of 5 Units

B - VSC-0205 - 05 / A
Reorder #: VSC-0205-05

2 x 5 in

Procellera | Elite™
Wound Care with Advanced Microcurrent Technology

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Pouch label on pouch

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

(b)(4) Confidential and Proprietary Information

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) Confidential and Proprietary Information

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VOMARIS

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

K160783/S1

FDA/CDRH/DCC
APR 21 2016
RECEIVED

3. COVER LETTER

April 20, 2016

To:
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center
10903 New Hampshire Ave., Bldg. 66, Rm G609
Silver Spring, MD 20993-0002

RE: Procellera Device - 510(k) Notification – Replacement Copy

Dear Madam/Sir:

This is a replacement copy of 510(k) K160783.

Sections 33, 34 and 35 have been added to support the Traditional 510(k) process and in response to FDA communications. Sections 4 and 22 have been updated for the same reasons.

Vomaris Innovations, Inc. hereby submits this Special 510(k) Premarket Notification Submission for Procellera® Antimicrobial Wound Dressing device.

The device described in this 510(k) is identical to that currently cleared on February 4, 2013 under K130350 and to that cleared on December 1, 2008 under K081977 and June 15, 2006 under K060237. There are no changes to the original device design characteristics or to the manufacturing methods.

The reason for this submission is to request the addition of the word "antimicrobial" to the Procellera OTC product, previously cleared through K081977 and K130350.

- The Rx device cleared by K060237, K081977 and K130350 included an antimicrobial claim.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 05-15-2017.

VOMARIS

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1911 East Fifth Street, Tempe, AZ 85281
www.procellera.com
Phone: 480-921-4948 Fax: 480-921-0948

- The OTC device submission K130350 originally included an antimicrobial claim, because the product design, raw materials, production process, facilities and personnel are identical and indistinguishable.
    - During the FDA review of K130350, the antimicrobial claim was removed based on correspondence from FDA instructing Vomaris to remove the antimicrobial indication. At the time of submission K130350, Vomaris did not completely understand the reasoning behind the FDA instruction to remove the antimicrobial indication from the OTC product and was not in a position to pursue the issue due to business obligations.
- Additional clinical and scientific data reviews have now been performed to support the safe and effective claim of Antimicrobial for the OTC product.

The enclosed submission was compiled in accordance with 21 CFR 807, Subpart E and with applicable guidance documents for Industry and FDA Staff.

This submission contains information required for demonstrating substantial equivalence of the proposed device to legally marketed predicate devices, in accordance with the Safe Medical Device Act of 1990.

We consider our intent to market this device and the information contained within this submission confidential commercial information that is exempt from public disclosure.

Table 3.1 Administrative information

Type of Submission:	Special 510(k) Notification
Device Type:	Wound Dressing
Proprietary Name:	Procellera® Antimicrobial Bioelectric Wound Dressing
Classification Name:	Wound Dressing Device

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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1911 East Fifth Street, Tempe, AZ 85281
www.procellera.com
Phone: 480-921-4948 Fax: 480-921-0948

510(k) Submitter:	Vomaris Innovations, Inc. 3100 W Ray Rd, Suite 148, Chandler, AZ 85226 Phone: 480-921-4948, Fax: 480-921-0948
Establishment Registration #:	3005803853
Contact information:	Timothy Joiner, Director of QA/RA Office: 480-921-4948 (b) (6) [redacted] Timothy.Joiner@Vomaris.com
Confidentiality:	We prefer continued confidentiality in accordance with 21 CFR 807.95
Classification Regulation:	Unclassified
Product Code:	FRO
Panel:	General & Plastic Surgery
Basis of Submission:	New Indication for Use
Prior 510k Submissions:	K060237, K081977, K130350

Table 3.2 Design and Use of the Device

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?	X	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		NA
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

I understand that the submission to the U.S. Government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Please do not hesitate to contact me for any questions you may have:

Timothy Joiner, Director of QA/RA
Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, Arizona, 85281
Office: 480-921-0948 (b) (6) [redacted] Fax: 480-921-0948
Email: Timothy.Joiner@Vomaris.com

Sincerely,

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Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, AZ 85281
www.procellera.com
Phone: 480-921-4948 Fax: 480-921-0948

Timothy Joiner, Director of QA/RA

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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eCOPY COVER LETTER

FDA/CDRH/DCC
APR 21 2016
RECEIVED

April 20, 2016

To:
Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – W066-G609
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

RE: eCopy Procellera Device - 510(k) Notification

Dear Madam/Sir:

The eCopy is an exact duplicate of the paper copy.

Please do not hesitate to contact me for any questions you may have:

Timothy Joiner, Director of QA/RA
Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, Arizona, 85281
Office: 480-921-0948 (b) (6) [redacted] Fax: 480-921-0948
Email: Timothy.Joiner@Vomaris.com

Sincerely,

Timothy Joiner, Director of QA/RA

67

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b) (4) [redacted]
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

VOMARIS INNOVATIONS INC
1911 E. 5th Street
Tempe
Maricopa
AZ 85281
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
(b) (4) [redacted]

2. CONTACT NAME
Lumi Skiba

2.1 E-MAIL ADDRESS
lumi.skiba@vomaris.com

2.2 TELEPHONE NUMBER (include Area code)
480-9214948 2236

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
480-9210948

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[X] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number: SBD165312

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville Road,

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COLE-14-14253 Silver Spring, MD 20993-0002
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b) (4) [redacted] 11-Mar-2016

Form FDA 3601 (05/13)

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3. COVER LETTER

April 20, 2016

To:
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center
10903 New Hampshire Ave., Bldg. 66, Rm G609
Silver Spring, MD 20993-0002

RE: Procellera Device - 510(k) Notification – Replacement Copy

Dear Madam/Sir:

This is a replacement copy of 510(k) K160783.

Sections 33, 34 and 35 have been added to support the Traditional 510(k) process and in response to FDA communications. Sections 4 and 22 have been updated for the same reasons.

Vomaris Innovations, Inc. hereby submits this Special 510(k) Premarket Notification Submission for Procellera® Antimicrobial Wound Dressing device.

The device described in this 510(k) is identical to that currently cleared on February 4, 2013 under K130350 and to that cleared on December 1, 2008 under K081977 and June 15, 2006 under K060237. There are no changes to the original device design characteristics or to the manufacturing methods.

The reason for this submission is to request the addition of the word "antimicrobial" to the Procellera OTC product, previously cleared through K081977 and K130350.

- The Rx device cleared by K060237, K081977 and K130350 included an antimicrobial claim.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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- The OTC device submission K130350 originally included an antimicrobial claim, because the product design, raw materials, production process, facilities and personnel are identical and indistinguishable.
    - During the FDA review of K130350, the antimicrobial claim was removed based on correspondence from FDA instructing Vomaris to remove the antimicrobial indication. At the time of submission K130350, Vomaris did not completely understand the reasoning behind the FDA instruction to remove the antimicrobial indication from the OTC product and was not in a position to pursue the issue due to business obligations.
- Additional clinical and scientific data reviews have now been performed to support the safe and effective claim of Antimicrobial for the OTC product.

The enclosed submission was compiled in accordance with 21 CFR 807, Subpart E and with applicable guidance documents for Industry and FDA Staff.

This submission contains information required for demonstrating substantial equivalence of the proposed device to legally marketed predicate devices, in accordance with the Safe Medical Device Act of 1990.

We consider our intent to market this device and the information contained within this submission confidential commercial information that is exempt from public disclosure.

Table 3.1 Administrative information

Type of Submission:	Special 510(k) Notification
Device Type:	Wound Dressing
Proprietary Name:	Procellera® Antimicrobial Bioelectric Wound Dressing
Classification Name:	Wound Dressing Device

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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510(k) Submitter:	Vomaris Innovations, Inc. 3100 W Ray Rd, Suite 148, Chandler, AZ 85226 Phone: 480-921-4948, Fax: 480-921-0948
Establishment Registration #:	3005803853
Contact information:	Timothy Joiner, Director of QA/RA Office: 480-921-4948 (b) (6) [redacted] Timothy.Joiner@Vomaris.com
Confidentiality:	We prefer continued confidentiality in accordance with 21 CFR 807.95
Classification Regulation:	Unclassified
Product Code:	FRO
Panel:	General & Plastic Surgery
Basis of Submission:	New Indication for Use
Prior 510k Submissions:	K060237, K081977, K130350

Table 3.2 Design and Use of the Device

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?	X	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		NA
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

I understand that the submission to the U.S. Government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Please do not hesitate to contact me for any questions you may have:

Timothy Joiner, Director of QA/RA
Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, Arizona, 85281
Office: 480-921-0948 (b) (6) [redacted] Fax: 480-921-0948
Email: Timothy.Joiner@Vomaris.com

Sincerely,

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Timothy Joiner, Director of QA/RA

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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5. INDICATIONS FOR USE

Indications for Use – Procellera® Rx Prescription Use Device

510(k) Number: 160783

Device Names:

- **Procellera®** Antimicrobial Wound Dressing (Rx)

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)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Indications for Use – Procellera® OTC

510(k) Number: 160783

Device Names:

- **Procellera®** Antimicrobial Wound Dressing (OTC)

Indications for Use:

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.

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)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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6. 510(K) SUMMARY

The purpose of this Premarket Notification is to request the addition of the word "antimicrobial" to the Procellera® over-the-counter product, previously cleared through K081977 and K130350.

Procellera® device described in this Special 510(k) is identical to the Procellera® device cleared in 2013 (K130350), 2008 (K081977) and in 2006 (K060237). There are no changes to the original device design, characteristics, or to the manufacturing process.

The prescription device and the over-the-counter device cleared in 2013 (K130350) are identical in every way. Only during the labeling process, which is performed after pouching and sterilization, are the products distinguished between prescription use and over-the-counter use.

The Rx product was cleared with the word "antimicrobial" while the OTC product was not cleared with the word "antimicrobial".

The following are the **cleared** "Indications for Use" for each of the respective 510(k)'s:

K081977 (Rx)	K081977 (OTC)
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.	For over-the-counter use, Procellera® wound dressing is indicated for minor cuts, scrapes, irritations, and abrasions.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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K130350 (Rx)	K130350 (OTC)
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.	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.

The requested change is the addition of antimicrobial to the OTC "Indications for Use" such that the wording for both the Rx and OTC would include the word antimicrobial. The following is the proposed language.

Rx – no change	OTC – this document
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.	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.

The 510(k) summary for the Procellera® device subject to this submission is provided in the following pages.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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510(k) Summary for Procellera® Device

Date: February 9, 2016

Device Name: Procellera®

Trade Name: Procellera® Antimicrobial Bioelectric 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)

Device Description:

Procellera® Antimicrobial Wound Dressing, described in K081977 for Rx and K130350 for OTC, is a single layer non-adhesive dressing that requires secondary materials to (1) retain moisture necessary for Procellera® function and (2) hold the dressing in-place. The secondary components are described in their respective IFU and previously provided to FDA in the above referenced 510(k) Premarket Notifications.

Intended 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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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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:

Procellera® Antimicrobial Wound Dressing is an electroceutical device. It is a single layer microcurrent-generating antimicrobial wound dressing. Embedded in the dressing are microcell batteries made of elemental silver and zinc applied in a well-characterized dot-matrix pattern to a polyester substrate.

Performance Data:

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

Antimicrobial efficacy testing previously submitted to FDA resulted in clearance of Procellera® Antimicrobial Wound Dressing for prescription use with an Antimicrobial claim. 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.

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,

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which are identical, and thus is substantially equivalent to the existing legally marketed devices under the Federal Food, Drug and Cosmetic Act.

Contact:

Timothy Joiner
Director, Quality Assurance & Regulatory Affairs
1911 East Fifth Street, Tempe, Arizona, 85281
480-921-4948
Timothy.Joiner@Vomaris.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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7. TRUTHFUL AND ACCURATE STATEMENT

I certify that, in my capacity as Director of Quality Assurance & Regulatory Affairs of Vomaris Innovations, Inc., I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

_

(Signature)

Timothy J. Joiner___ _____
(Typed Name)

April 20, 2016_____
(Date)

K160783_____
*(Premarket Notification [510(k)]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-19-2017.

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8. CLASS III SUMMARY AND CERTIFICATION

This section does not apply to this 510(k) submission.

Procellera® is not a Class III device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-10-2017.

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9. FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT

This section does not apply to this 510(k) submission.

No clinical studies information is included in this submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-16-2017.

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10. Declaration of Conformity and Summary Reports

This section does not apply to this 510(k) submission.

The Performance Standards information presented in this submission is unchanged from those presented in K060237, K081977, and K130350. There are no mandatory performance standards promulgated by the FDA for wound dressings. Procellera® is an unclassified, pre-amendment device that is not exempt from the Quality System Regulation (QSR).

Verification and validation activities were performed by designated individuals and results demonstrate that predetermined acceptance criteria were met.

Manufacturing facilities are in conformance with design control procedure requirements as specified in 21 CFR 820.30.

I certify that, in my capacity as Head of R&D of Vomaris Innovations, Inc., I believe to the best of my knowledge that all design and development activities associated with this product were conducted in compliance with 21 CFR 820.

Signature

04.11.2016
Date

Troy Paluszcyk
Head of R&D
Vomaris, Innovations, Inc.
1911 East Fifth Street
Tempe, AZ 85281

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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11. Device Classification

	Predicate – Single Layer Rx	Predicate – Single Layer OTC
Proprietary Name	Procellera; Procellera Antimicrobial Wound Dressing; Procellera Elite Wound Dressing; Procellera Rx Antimicrobial Wound Dressing	Procellera OTC
Classification Name	DRESSING, WOUND, DRUG	DRESSING, WOUND, DRUG
Product Code	FRO	FRO
Device Class	U (Unclassified; reason Pre-Amendment)	U (Unclassified; reason Pre-Amendment)
Registered Establishment Name	Vomaris Wound Care, Inc.	Vomaris Wound Care, Inc.
Registered Establishment Number	3005803853	3005803853
Premarket Submission Number	K130350 (both Rx and OTC device)	K130350 (both Rx and OTC device)
Owner/Operator	Vomaris Innovations Inc.	Vomaris Innovations Inc.
Owner/Operator Number	9079581	9079581
Establishment Operations	Manufacturer	Manufacturer

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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VOMARIS

Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, AZ 85281
www.procellera.com
Phone: 480-921-4948 Fax: 480-921-0948

12. Device Description

Procellera® Antimicrobial Wound Dressing, described in K081977 for Rx and K130350 for OTC, is a single layer non-adhesive dressing that requires secondary materials to (1) retain moisture necessary for Procellera function and (2) hold the dressing in-place. The secondary components are described in their respective IFU and previously provided to FDA in the above referenced 510(k) Premarket Notifications.

The following is a graphic of the product. The Rx or OTC products are indistinguishable, since, until labeled, they are identical. In actual clinical use their performance would also be indistinguishable since they are identical.

Product Comparison Table

Characteristic	Rx	OTC
Configuration	Elemental silver and zinc are applied on a polyester substrate in a dot matrix pattern.	Identical
Elemental silver to elemental zinc concentration	(b)(4) Confidential and Proprietary Information [redacted]	Identical
Surface area	1 in^2 – 144 in^2 6.5 cm^2 – 77.4 cm^2	Identical
Packaging	Mylar / Mylar pouch	Identical
Sterilization – irradiation	ebeam	Identical

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Characteristic	Rx	OTC
Biocompatibility – ISO 10993-1	• Body Contact • Breached or compromised surfaces • 24 Hours – 30 Days) Provided in K081977 (Rx) and K130350 (Rx & OTC)	Identical
Antimicrobial testing	Provided in K081977 for Rx additionally provided in K130350	Identical

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[redacted]

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[redacted]

Product Table

The table below lists the current sizes of Procellera® Antimicrobial Wound Dressing followed by the products. The Procellera product surface area ranges from 1 in^2 – 144 in^2.

Dressing Size (inches)	Rx Part Number	OTC Part Number
4x4	VSR-0404	VSC-0404
1x1 Slit	VSR-0101F	VSC-0101F
1.5x8	VSR-1508	VSC-1508
1.5x10	VSR-1510	VSC-1510
2x2	VSR-0202	VSC-0202
2x5	VSR-0205	VSC-0205
3x3	VSR-0303	VSC-0303
8x8	VSR-0808	VSC-0808
12x12	VSR-1212	VSC-1212

Device Description and Operating Principle

Procellera® Antimicrobial Wound Dressing device description and operating principles were previously discussed and explained in cleared 510(k) K060237, K081977, and K130350.

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14. LABELING

Attached are copies of draft OTC Procellera IFU's, and examples of applicable pouch and carton labels with antimicrobial added. The Rx labels are currently cleared labels and labeling.

- Physical sizes for both Rx and OTC are the same.
- The labeling and labels are the same except for the Rx and OTC specific language.
- Examples of the labels and labeling are identified below:

Attachment		Description	Document ID
14-01	Rx	Rx Instruction for Use	Rx IFU-01 rev J Oct 13 2015.pdf
14-02	Rx	Pouch label	Rx Pouch L_VSR_0404_A_Lot_131101A.pdf
14-03	Rx	Box label	Rx Box L_VSR_0101F_A_NBO_LOT_130401A.pdf
14-04	Rx & OTC	Box Carton	Rx and OTC Outer box with non-variable information.docx
14-05	OTC	OTC Instruction for Use	OTC DRAFT IFU-02.docx
14-06	OTC	OTC Pouch label	OTC Pouch Label L-VSC-0205.docx
14-07	OTC	OTC Box label	OTC Box Label B-VSC-0205.docx
14-08	OTC	Pouch label on pouch example	OTC Pouch label on pouch L-VSC-0205.docx

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15. MANUFACTURING

The manufacturing process for Procellera® Antimicrobial Wound Dressing Rx and OTC has been previously submitted and cleared in the aforementioned 510(k)'s. In those documents, the manufacturing process was explained and described in greater detail.

The manufacturing process for Procellera® Antimicrobial Wound Dressing Rx and OTC is not only the same, but indistinguishable because the product becomes Rx or OTC during the labeling process.

Manufacturing Locations and Activities

Establishment	Vomaris Wound Care, Inc. 1911 E 5Th St Tempe, AZ 85281
Activities	• Manufactures Procellera single-layer • Labels, packages, and distributes product
Registration Number	3005803853
Owner/Operator Number	9079581
Official Correspondent	Tim Joiner 1911 E 5Th Street Tempe, AZ 85281 (480) 9214948-2239

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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16. SHELF LIFE

Both Procellera® Antimicrobial Wound Dressing RX and OTC single-layer products have a 5-year shelf life.

The shelf life is identified to the user by the use of an expiration date symbol followed by the date.

	Format: the year (yyyy), month (mm); day (dd), each separated by hyphens. Example, January 2, 2014, is presented as 2014-01-02.

The shelf life is that same as previous cleared in the 510(k)'s. It is not being changed.

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17. LIFETIME

The Lifetime for Procellera® Antimicrobial Wound Dressing Rx and OTC are the same in this submission as in the aforementioned 510(k)'s submitted to and cleared by the FDA. They are as follows:

There are two (2) "lifetimes" of the devices: Time of Use and Shelf Life; Shelf Life is also known as and denoted by expiration date, or use before date.

Time of Use

Upon opening, Time of Use is up to seven (7) days in situ use as a wound care device. The time starts from opening the product and continues for 7 days. If needed, the device may be removed and replaced by another device of the same or different size.

This may continue for up to twenty-eight (28) days. Longer than 28 days has not been evaluated, thus the company does not recommend its use past 28 days.

Shelf Life

The shelf life is currently five (5) years.

The shelf life is identified to the user by the use of the applicable expiration date symbol followed by the date.

The date format is: the year, using four digits; followed by the month, using two digits; followed by the day, using two digits; each separated by hyphens.

For example, January 2, 2014, is presented as 2014-01-02.

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18. BIOCOMPATIBILITY

Since the products are indistinguishable, Biocompatibility testing results are applicable to both the Rx and OTC products.

The results demonstrated that the product is safe. These reports were previously provided in the aforementioned 510(k) submissions. They are not being provided herein.

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19. RISK MANAGEMENT

Risk Management occurs throughout the product lifecycle and is an active component of the Vomaris Quality System.

There has been no change to the Risk profile for either the Rx or OTC product.

Risk Analysis files for the Procellera single-layer products are attached as

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[redacted]

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20. STERILIZATION

The sterilization method and facility has not changed. It is the same as previously reported to FDA in the aforementioned 510(k) submissions.

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21. SOFTWARE

This section does not apply to this 510(k) submission.

Procellera Rx and Procellera OTC do not contain nor use software.

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22. POST MARKET SUMMARY AND POST MARKET CLINICAL FOLLOW-UP

Complaint History Summary

- Procellera device has been marketed in the US market since July 2006, when it was initially cleared by US Food and Drug Administration.
- There have been no field safety corrective actions or recalls since the July 2006 clearance.
- Regulatory reporting requirements are based on FDA 21CFR803 Medical Device Reporting.

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[redacted]

Post Market Clinical Follow-up

At this time, Vomaris does not have any studies that require clinical follow-up.

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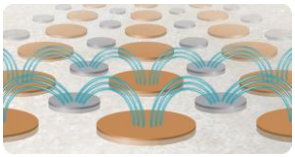
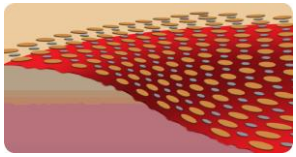
Procellera | Rx™
Wound Care with Advanced Microcurrent Technology

Instructions for Prescription Use

Product Description

Procellera® is a single layer antimicrobial wound dressing. Imbedded in the dressing are microcell batteries made of elemental silver and zinc applied in a dot-matrix pattern. In the presence of a conductive medium such as wound exudate, water-based hydrogels or saline, microcurrents are generated at the dressing surface, due to its inherent design. Silver and zinc in the dressing produce microcurrent, to minimize or prevent the growth of microorganisms within the dressing and help the dressing to be preserved.

Procellera is a primary contact layer dressing; it should be used under a secondary dressing or bandage (not provided), to keep it in place and help maintain a moist wound environment.

Advanced Microcurrent Technology™

Indications

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.

Contraindications

- Do not use on individuals with sensitivity or allergy to silver or zinc.
- MRI Non-Compatible: Neither MRI-Safe nor MRI-Compatible and should be removed prior to an MRI procedure. A new dressing may be applied after the procedure.

Warnings

Frequent or prolonged use of this product may result in permanent discoloration of the skin (i.e., argyria).

Precautions

- **Caution:** Federal law restricts this device to sale by or on the order of a physician.
- Single use only.
- Do not use if the pouch is open or damaged prior to use.
- For external use only. Do not use Procellera with topical agents such as antimicrobial ointments, enzymatic debriders, antibiotic creams, silver or zinc containing creams, oxidizing agents, petroleum based products, etc.
- Secondary dressings should be used as stated in their Instructions for Use.
- The patient should stop using the dressing and consult a physician if allergy, irritation, increased pain, maceration or any irregular skin discoloration occurs.
- Procellera is not intended to be used on wounds with uncontrolled bleeding.
- Remove Procellera dressing during energy-based procedures (such as electricity, radiofrequencies, ultrasound, radiation, etc.) where the dressing may interfere with delivery.
- Avoid contact with electrodes or conductive gels during electronic measurements; e.g., EEG or ECG.
- Procellera may be used on infected wounds that are being managed in accordance with institutional clinical protocols for infection abatement as an adjunct to the standard treatment regimen.
- The safety of daily Procellera use for longer than 28 days has not been studied.

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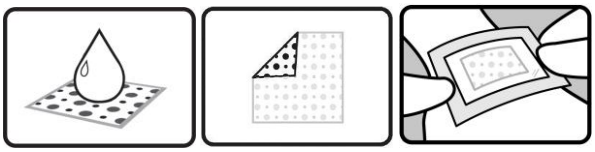
Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Instructions for Prescription Use

Preparation

Follow local hygiene procedures prior to, during and following dressing application and change.

Application



1. Cleanse the wound area with an appropriate wound cleanser according to local clinical protocol.
2. Remove Procellera from package and if needed, cut to a shape that will extend beyond wound edges 1 to 2 cm (1⁄2 inch to 1 inch). **Caution:** cutting may result in fraying of the dressing.
3. Moisten Procellera with sterile saline, water or a thin, even layer of water-based hydrogel (not included).
4. Apply Procellera dressing to the wound site, **with the dotted side down**, in direct contact with the wound surface.
5. Cover Procellera with an appropriate secondary sterile dressing which will help maintain a moist wound environment. The choice of secondary dressing should be determined by the degree of exudate produced by the wound, for example:
   - For DRY wounds: waterproof, semi-permeable or hydrogel-like dressings are recommended to ensure prolonged moisture.
   - For EXUDATING wounds: cover Procellera with layer(s) of sterile gauze or foam dressing to absorb excessive moisture and prevent maceration. Then apply a semi-permeable or hydrogel-like dressing.
     If needed, secure in place with an additional fixation dressing, using care not to restrict blood flow.
6. Keep the dressing moist by re-moistening as necessary. Avoid over-soaking. Example:
   - DRY wounds may require more frequent re-moistening of the dressing(s).
   - EXUDATING wounds require dressing re-moistening only if exudate decreases and the dressing becomes dry.

Site Care and Dressing Change

- Procellera may be left in place for up to 7 days. Earlier and/or more frequent changes may be required, depending on the amount of exudate present, the condition of the wound and the surrounding skin. Inspect the wound site periodically.
- To remove the Procellera dressing, gently pull it back. If it adheres to the wound surface, do not force it off; moisten or soak the dressing with sterile saline or sterile water until it can be removed without tissue damage.
- The patient should consult a physician if any of the following occur: infection, bleeding, maceration (skin whitening and softening), hypergranulation (excessive tissue formation), irritation at the wound site or the skin surrounding the dressing, or if the wound increases in size after a few dressing changes.

Dressing Components

- The dressing is not made with natural rubber latex.
- The dressing consists of a polyester substrate containing 0.9 mg of elemental silver and 0.3 mg of elemental zinc per square centimeter of dressing. Silver in the dressing acts as a preservative and inhibits growth of microorganisms within the dressing.

Storage and Disposal

- Store in dry conditions at room temperature. Protect from light.
- Dispose of according to local environmental procedures.

Made in the USA by:

Vomaris Wound Care, Inc.
1911 East Fifth Street, Tempe, AZ 85281, USA
(866) 496-8743 (480) 921-4948
www.procellera.com

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Procellera | Rx™
Wound Care with Advanced Microcurrent Technology

P/N VSR-0404
LOT 131101A
Use by: 2019-01-28

ANTIMICROBIAL WOUND DRESSING · 4" x 4" (10cm x 10cm)

1. Moisten dressing
2. Apply **dotted side down**
3. Cover with a waterproof dressing

Rx ONLY · STERILE R · L- VSR-0404 / A

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Procellera | Rx™
Wound Care with Advanced Microcurrent Technology

P/N VSR-0101F LOT 130401A

Use by: 2018-07-05

ANTIMICROBIAL WOUND DRESSING 1" x 1" (2.5cm x 2.5cm) Fenestrated

1 Moisten dressing

2 Apply **dotted side down**

3 Cover with a waterproof dressing

Rx ONLY STERILE R

L-VSR-0101F/A

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Procellera | Rx™
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Rx ONLY STERILE R

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Procellera | Rx™
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Rx ONLY STERILE R

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P/N VSR-0101F LOT 130401A

Use by: 2018-07-05

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Rx ONLY STERILE R

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Rx ONLY STERILE R

L-VSR-0101F/A

Made in the USA by Vomaris Wound Care, Inc.
Tempe, AZ 85281 480-921-4948

www.procellera.com

Procellera | Rx™
Wound Care with Advanced Microcurrent Technology

P/N VSR-0101F LOT 130401A

Use by: 2018-07-05

ANTIMICROBIAL WOUND DRESSING 1" x 1" (2.5cm x 2.5cm) Fenestrated

1 Moisten dressing

2 Apply **dotted side down**

3 Cover with a waterproof dressing

Rx ONLY STERILE R

L-VSR-0101F/A

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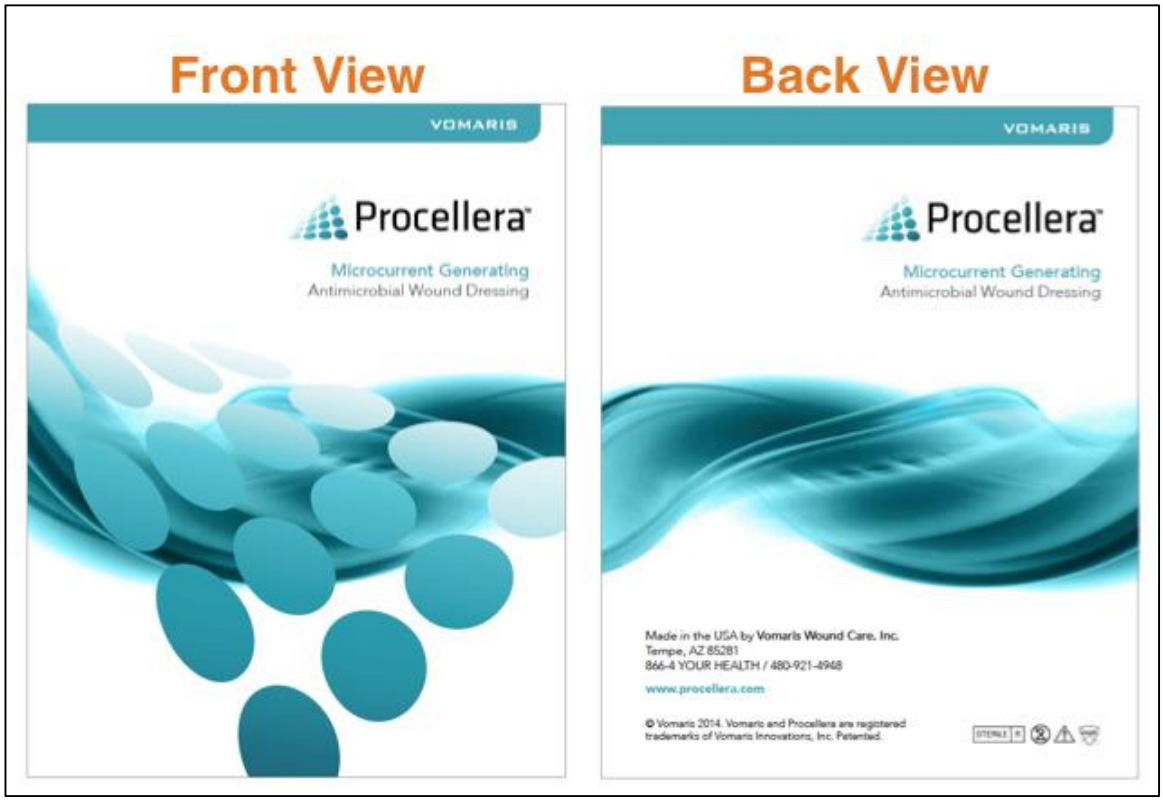
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Rx and OTC outer box with non-variable information



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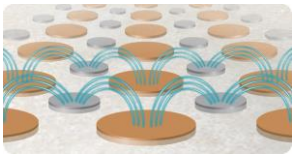
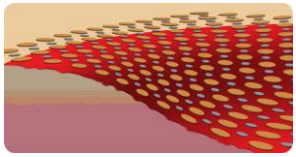
Procellera | Elite™
Wound Care with Advanced Microcurrent Technology

Instructions for OTC Use

Product Description

Procellera® is a single layer antimicrobial wound dressing. Imbedded in the dressing are microcell batteries made of elemental silver and zinc applied in a dot-matrix pattern. In the presence of a conductive medium such as wound exudate, water-based hydrogels or saline, microcurrents are generated at the dressing surface, due to its inherent design. Silver and zinc in the dressing produce microcurrents, to minimize or prevent the growth of microorganisms within the dressing and help the dressing to be preserved.

Procellera is a primary contact layer dressing; it should be used under a secondary dressing or bandage (not provided), to keep it in place and help maintain a moist wound environment.

Advanced Microcurrent Technology™

Indications

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.

Contraindications

- Do not use on individuals with sensitivity or allergy to silver or zinc;
- MRI Non-Compatible: Neither MRI-Safe nor MRI-Compatible and should be removed prior to an MRI procedure. A new dressing may be applied after the procedure.

Warnings

Frequent or prolonged use of this product may result in permanent discoloration of the skin (i.e., argyria).

Precautions

- Single use only.
- Do not use if the pouch is open or damaged prior to use.
- For external use only. Do not use Procellera with topical agents such as antimicrobial ointments, enzymatic debriders, antibiotic creams, silver or zinc containing creams, oxidizing agents, petroleum based products, etc..
- Secondary dressings should be used as stated in their Instructions for Use.
- Stop using the dressing and consult a physician if an allergy, irritation, increased pain, maceration or irregular skin discoloration occurs.
- Procellera is not intended to be used on wounds with uncontrolled bleeding.
- Remove Procellera dressing during energy-based procedures (such as electricity, radiofrequencies, ultrasound, radiation, etc.) where the dressing may interfere with delivery.
- Avoid contact with electrodes or conductive gels during electronic measurements; e.g., EEG (electroencephalogram) or ECG (electrocardiogram).
- Procellera may be used on infected wounds that are being managed in accordance with institutional clinical protocols for infection abatement as an adjunct to the standard treatment regimen.
- The safety of daily Procellera use for longer than 28 days has not been studied.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

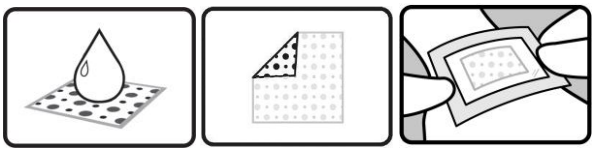
Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Instructions for OTC Use

Preparation

Follow local hygiene procedures prior to, during and following dressing application and change.

Application



1. Cleanse the wound area with an appropriate wound cleanser.
2. Remove Procellera from package and if needed, cut to a shape that will extend beyond wound edges 1 to 2 cm (1⁄2 inch to 1 inch). **Caution:** cutting may result in fraying of the dressing.
3. Moisten Procellera with sterile saline, water or a thin, even layer of water-based hydrogel (not included).
4. Apply Procellera dressing to the wound site, **with the dotted side down**, in direct contact with the wound surface.
5. Cover Procellera with an appropriate secondary sterile dressing (such as a waterproof dressing) which will keep it in place and help maintain a moist wound environment. If needed, secure in place with an additional fixation dressing, using care not to restrict blood flow.
6. Keep the dressing moist by re-moistening as necessary (once a day, for dry wounds). Avoid over-soaking.
   Note: It is not necessary to remove Procellera while showering.

Site Care and Dressing Change

- Procellera may be left in place for up to 7 days. Earlier and/or more frequent changes may be required, depending on the amount of exudate present, the condition of the wound and surrounding skin. Inspect the wound site periodically.
- To remove the Procellera dressing, gently pull it back. If it adheres to the wound surface, do not force it off; moisten or soak the dressing with sterile saline or sterile water until it can be removed without tissue damage.
- Consult a physician if any of the following occur: infection, bleeding, maceration (skin whitening and softening), hypergranulation (excessive tissue formation), irritation at the wound site or the skin surrounding the dressing, or if the wound increases in size after a few dressing changes.

Dressing Components

- The dressing is not made with natural rubber latex.
- The dressing consists of a polyester substrate containing 0.9 mg of elemental silver and 0.3 mg of elemental zinc per square centimeter of dressing. Silver in the dressing acts as a preservative and inhibits growth of microorganisms within the dressing.

Storage and Disposal

- Store in dry conditions at room temperature. Protect from light.
- Dispose of according to local environmental procedures.

Made in the USA by:

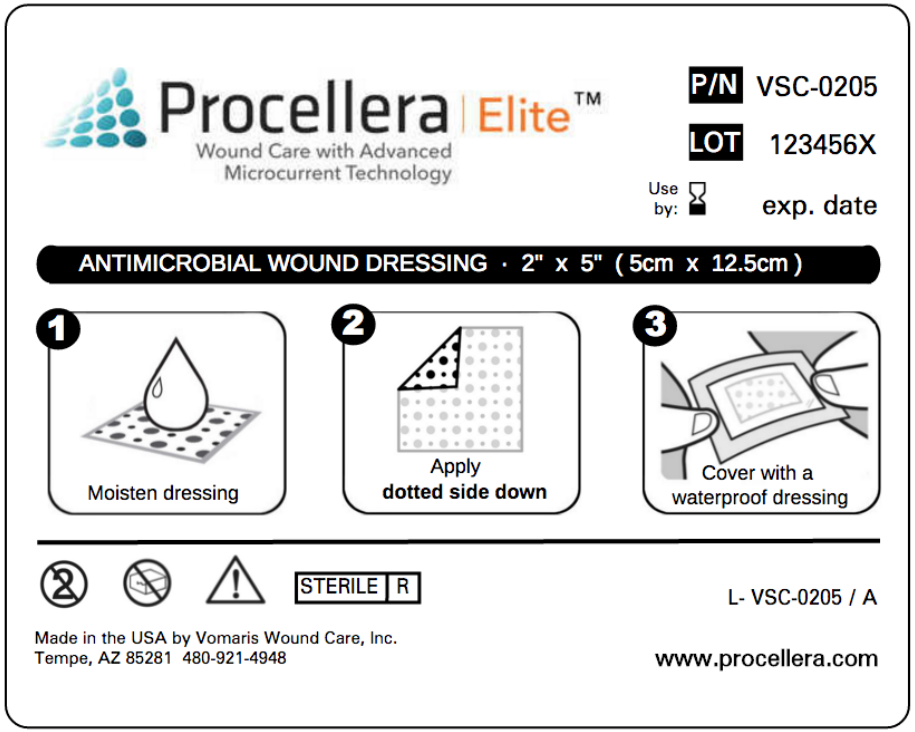
Vomaris Wound Care, Inc.
1911 East Fifth Street, Tempe, AZ 85281, USA
(866) 496-8743 (480) 921-4948
www.procellera.com

© 2015 Vomaris. All rights reserved., Procellera, Procellera Helix, Procellera Elite, Procellera with logo and Advanced Microcurrent Technology are all trademarks of Vomaris Innovations, Inc. All other trademarks are the property of their respective owners.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Pouch Label



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Box Label

2 x 5 in
(5 x 12.5 cm)

P/N VSC-0205
LOT 123456X
Use by: exp. date

Box of 5 Units

B - VSC-0205 - 05 / A
Reorder #: VSC-0205-05

2 x 5 in

Procellera | Elite™
Wound Care with Advanced Microcurrent Technology

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Pouch label on pouch

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Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

(b)(4) Confidential and Proprietary Information

[redacted]

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VOMARIS
Vomaris Innovations, Inc.
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www.procellera.com
Phone: 480-921-4948 Fax: 480-921-0948

33. SUBSTANTIAL EQUIVALENCE AND REFERENCE DEVICE DISCUSSION

SUBSTANTIAL EQUIVALENCE

The device described in this 510(k) is identical to that currently cleared in 2006 under K060237, in 2008 under K081977 and in 2013 under K130350. There are no changes to the original device design, characteristics, or to the manufacturing methods.

Furthermore, the prescription device and the over-the-counter device are identical: the only change outlined in this submission K160783 is the addition of Antimicrobial to the OTC product labeling. The Intended Use of the RX and OTC products included in this submission K160783 are the same as the listed predicate devices. The Indications for Use of the RX and OTC products included in this submission K160783 are the same as the listed predicate devices, with the exception of adding the term Antimicrobial to the OTC product labeling, which is already included in the RX product labeling.

The similarities and the differences between the device subject to this submission and its predicate devices are presented in detail below. Changes are outlined in red text.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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[redacted]

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REFERENCE DEVICE DISCUSSION

Vomaris is electing to use the following cleared 510(k) submissions as Reference Devices for this submission K160783.

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

Our decision for using the above products as reference devices is based on the FDA Guidance Document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] Guidance for Industry and Food & Drug Administration Staff. Issued July 28, 2014"

As discussed by FDA on page 13 of the above document titled Reference Devices, specifically Example 2, Vomaris products included in submission K160783 has the same indication and intended use as the above Reference Devices that are also OTC and identified as antimicrobial. The Vomaris product included in submission K160783 does not raise different (new) questions of safety and/or effectiveness as compared to the above Reference Devices.

The similarities and the differences between the device subject to this submission and its reference devices are presented in detail below:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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K160783/S002

VOMARIS

Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, AZ 85281
www.procellera.com
Phone: 480-921-4948 Fax: 480-921-0948

ECOPY COVER LETTER

FDA/CDRH/DCC
JUL 28 2016
RECEIVED

July 26, 2016

To:
Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – W066-G609
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

RE: eCopy Procellera Device - 510(k) Notification

Dear Madam/Sir:

The eCopy is an exact duplicate of the paper copy.

Please do not hesitate to contact me for any questions you may have:

Timothy Joiner, Director of QA/RA
Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, Arizona, 85281
Office: 480-921-0948 (b) (6) [redacted] Fax: 480-921-0948
Email: Timothy.Joiner@Vomaris.com

Sincerely,

Timothy Joiner, Director of QA/RA

62

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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ECOPY COVER LETTER

K160783/S 2

July 11, 2016

FDA/CDRH/DCC
JUL 26 2016
RECEIVED

To:
Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – W066-G609
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1911 East Fifth Street, Tempe, Arizona, 85281
Office: 480-921-0948 (b) (6) [redacted] Fax: 480-921-0948
Email: Timothy.Joiner@Vomaris.com

Sincerely,

Timothy Joiner, Director of QA/RA

57

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eCOPY COVER LETTER

July 11, 2016

To:
Food and Drug Administration
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1911 East Fifth Street, Tempe, Arizona, 85281
Office: 480-921-0948 (b) (6) [redacted] Fax: 480-921-0948
Email: Timothy.Joiner@Vomaris.com

Sincerely,

Timothy Joiner, Director of QA/RA

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

VOMARIS

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1911 East Fifth Street, Tempe, AZ 85281
www.procellera.com
Phone: 480-921-4948 Fax: 480-921-0948

3. COVER LETTER

July 11, 2016

To:
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center
10903 New Hampshire Ave., Bldg. 66, Rm G609
Silver Spring, MD 20993-0002

RE: Procellera Device - 510(k) Notification – Replacement Copy

Dear Mr. Durfor:

This is a partial replacement copy of 510(k) K160783/S001.

Sections 36 and 37 have been added since submitting supplement 0001 to support the Traditional 510(k) process and in response to FDA communications. Sections 003, 004, 005, 006, 016, 034 and Attachments 014_ATT_14-01 and 014_ATT_14-05 have been updated for the same reasons to support the change made in response to FDA communications; however, Vomaris elects to keep the Indication for Use statements previously cleared in 510(k) K130350. A full summary of the changes made to this submission since supplement 001, specifically to the above documents, is included in this cover letter as Addendum 3.1 In addition, a copy of your most recent response letter in attached as a reference to the changes made in this submission.

Vomaris Innovations, Inc. hereby submits this revised Traditional 510(k) Premarket Notification Submission for Procellera® Antimicrobial Wound Dressing device.

The device described in this 510(k) is identical to that currently cleared on February 4, 2013 under K130350 and to that cleared on December 1, 2008 under K081977 and June 15, 2006 under K060237. There are no changes to the original device design characteristics or to the manufacturing methods.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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The reason for this submission is to request the addition of the word "antimicrobial" to the Procellera OTC product, previously cleared through K081977 and K130350.

- The Rx device cleared by K060237, K081977 and K130350 included an antimicrobial claim.
- The OTC device submission K130350 originally included an antimicrobial claim, because the product design, raw materials, production process, facilities and personnel are identical and indistinguishable.
    - During the FDA review of K130350, the antimicrobial claim was removed based on correspondence from FDA instructing Vomaris to remove the antimicrobial indication. At the time of submission K130350, Vomaris did not completely understand the reasoning behind the FDA instruction to remove the antimicrobial indication from the OTC product and was not in a position to pursue the issue due to business obligations.
- Additional clinical and scientific data reviews have now been performed to support the safe and effective claim of Antimicrobial for the OTC product. This information is included in sections 022 Post Market Surveillance, 034 Scientific Data and Clinical Summary and 035 Barakat Clinical Summary Report.
    - NOTE: 035 Barakat Clinical Summary Report is only included to demonstrate the safety of Procellera. Although Vomaris reserves the right to pursue any potential claims in the future; at this time no additional claims are being made other than those indicated in 005 Rx and OTC 510(k) Indications for Use.

The enclosed submission was compiled in accordance with 21 CFR 807, Subpart E and with applicable guidance documents for Industry and FDA Staff.

This submission contains information required for demonstrating substantial equivalence of the proposed device to legally marketed predicate devices, in accordance with the Safe Medical Device Act of 1990.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, AZ 85281
www.procellera.com
Phone: 480-921-4948 Fax: 480-921-0948

We consider our intent to market this device and the information contained within this submission confidential commercial information that is exempt from public disclosure.

Table 3.1 Administrative information

Type of Submission:	Traditional 510(k) Notification
Device Type:	Wound Dressing
Proprietary Name:	Procellera® Antimicrobial Bioelectric Wound Dressing
Classification Name:	Wound Dressing Device
510(k) Submitter:	Vomaris Innovations, Inc. 3100 W Ray Rd, Suite 148, Chandler, AZ 85226 Phone: 480-921-4948, Fax: 480-921-0948
Establishment Registration #:	3005803853
Contact information:	Timothy Joiner, Director of QA/RA Office: 480-921-4948 (b) (6) [redacted] Timothy.Joiner@Vomaris.com
Confidentiality:	We prefer continued confidentiality in accordance with 21 CFR 807.95
Classification Regulation:	Unclassified
Product Code:	FRO
Panel:	General & Plastic Surgery

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Basis of Submission:	New Indication for Use
Prior 510k Submissions:	K060237, K081977, K130350

Table 3.2 Design and Use of the Device

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	Y	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?	Y	
Does the device contain components derived from a tissue or other biologic source?		N
Is the device provided sterile?	Y	
Is the device intended for single use?	Y	
Is the device a reprocessed single use device?		N
If yes, does this device type require reprocessed validation data?	NA	NA
Does the device contain a drug?		N
Does the device contain a biologic?		N
Does the device use software?		N
Does the submission include clinical information?		N
Is the device implanted?		N

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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I understand that the submission to the U.S. Government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Please do not hesitate to contact me for any questions you may have:

Timothy Joiner, Director of QA/RA
Vomaris Innovations, Inc.
1911 East Fifth Street, Tempe, Arizona, 85281
Office: 480-921-0948 (b) (6) [redacted] Fax: 480-921-0948
Email: Timothy.Joiner@Vomaris.com

Sincerely,

Timothy Joiner, Director of QA/RA

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Addendum 3.1 Changes to 510(k) K160783 Supplement 0002

Document	Section / Page	Added Information
3. Cover Letter	Page 1	Sections 36 and 37 have been added since submitting supplement 0001 to support the Traditional 510(k) process and in response to FDA communications. Sections 003, 004, 005, 006, 016, 034 and Attachments 014_ATT_14-01 and 014_ATT_14-05 have been updated for the same reasons to support the change made in response to FDA communications. A full summary of the changes made to this submission since supplement 0001, specifically to the above documents, is included in this cover letter as Addendum 3.1
	Page 2	- Additional clinical and scientific data reviews have now been performed to support the safe and effective claim of Antimicrobial for the OTC product. This information is included in sections 022 Post Market Surveillance, 034 Scientific Data and Clinical Summary and 035 Barakat Clinical Summary Report. o NOTE: 035 Barakat Clinical Summary Report is only included to demonstrate the safety of Procellera. Although Vomaris reserves the right to pursue any potential claims in the future; at this time no additional claims are being made other than those indicated in 005 Rx and OTC 510(k) Indications for Use.
	Page 6	Addendum 3.1 Changes to 510(k) K160783 Supplement 0002
4. Table of Contents	Page 2	5 Year Accelerated Aging Report ……36
	Page 2	5 Year Real Time Aging Report……37
5 Rx and OTC 510(k) Indications for Use	Page 1	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,

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		diabetic ulcers, first and second degree burns, surgical incisions, donor and recipient graft sites, etc.
	Page 2	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.
6. 510(k) Summary	Page 2	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.
	Page 2	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.
	Page 3	Reference Devices • K062212, Silver Shield Antimicrobial Skin and Wound Gel • K070333, AcryDerm OTC Silver Antimicrobial Wound Gel • K083103, AcryDerm Antimicrobial Silver Wound Gel
	Page 4	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
	Page 4	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,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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		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.
16. Shelf Life	Page 1	In the last submission, K130350, the shelf life was indicated for 3 years. However, additional testing has been performed. The shelf life for this submission, K160783, is 5 years. Shelf life data is included.
34. Scientific Data and Clinical Summary	Page 1	This information is only included to clearly demonstrate the safety of Procellera. Although Vomaris reserves the right to pursue any potential claims in the future; at this time no additional claims are being made other than those indicated in 005 Rx and OTC 510(k) Indications for Use.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Attachment: FDA Response Letter

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

Vomaris Innovations, Inc.
Mr. Timothy Joiner
Head of Quality and Regulatory
1911 E. 5th St.
Tempe, AZ 85281

Re: K160783
Trade/Device Name: Procellera Antimicrobial Wound Dressing

Dear Mr. Joiner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require responses to the following questions and comments:

(b)(4) Confidential and Proprietary Information

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4) Confidential and Proprietary Information

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4) Confidential and Proprietary Information

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4) Confidential and Proprietary Information

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4) Confidential and Proprietary Information

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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5. INDICATIONS FOR USE

Indications for Use – Procellera® Rx Prescription Use Device

510(k) Number: 160783

Device Names:

- **Procellera®** Antimicrobial Wound Dressing (Rx)

Indications for 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.

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)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Indications for Use – Procellera® OTC

510(k) Number: 160783

Device Names:

- **Procellera®** Antimicrobial Wound Dressing (OTC)

Indications for Use:

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.

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)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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6. 510(K) SUMMARY

The purpose of this Premarket Notification is to request the addition of the word "antimicrobial" to the Procellera® over-the-counter product, previously cleared through K081977 and K130350.

Procellera® device described in this Traditional 510(k) is identical to the Procellera® device cleared in 2013 (K130350), 2008 (K081977) and in 2006 (K060237). There are no changes to the original device design, characteristics, or to the manufacturing process.

The prescription device and the over-the-counter device cleared in 2013 (K130350) are identical in every way. Only during the labeling process, which is performed after pouching and sterilization, are the products distinguished between prescription use and over-the-counter use.

The Rx product was cleared with the word "antimicrobial" while the OTC product was not cleared with the word "antimicrobial".

The following are the **cleared** "Indications for Use" for each of the respective 510(k)'s:

K081977 (Rx)	K081977 (OTC)
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.	For over-the-counter use, Procellera® wound dressing is indicated for minor cuts, scrapes, irritations, and abrasions.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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K130350 (Rx)	K130350 (OTC)
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.	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.

The requested change is the addition of antimicrobial to the OTC "Indications for Use" such that the wording for both the Rx and OTC would include the word antimicrobial. The following is the proposed language.

Rx – this document	OTC – this document
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.

The 510(k) summary for the Procellera® device subject to this submission is provided in the following pages.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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510(k) Summary for Procellera® Device

Date: July 11, 2016

Device Name: Procellera®

Trade Name: Procellera® Antimicrobial Bioelectric 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, and it occurs because it is inherent to its design. The device is self-contained and has no accessories.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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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, steri-strips, negative pressure wound therapy, 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:

(b)(4) Confidential and Proprietary Information

[redacted]

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Antimicrobial claim. 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.

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:

Timothy Joiner
Director, Quality Assurance & Regulatory Affairs
1911 East Fifth Street, Tempe, Arizona, 85281
480-921-4948
Timothy.Joiner@Vomaris.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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7. TRUTHFUL AND ACCURATE STATEMENT

I certify that, in my capacity as Director of Quality Assurance & Regulatory Affairs of Vomaris Innovations, Inc., I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

_

(Signature)

Timothy J. Joiner___ _____
(Typed Name)

July 11, 2016
(Date)

K160783_____
*(Premarket Notification [510(k)]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-15-2017.

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14. LABELING

Attached are copies of draft OTC Procellera IFU's, and examples of applicable pouch and carton labels with antimicrobial added. The Rx labels are currently cleared labels and labeling.

- Physical sizes for both Rx and OTC are the same.
- The labeling and labels are the same except for the Rx and OTC specific language.
- Examples of the labels and labeling are identified below:

Attachment		Description	Document ID
14-01	Rx	Rx Instruction for Use	Rx IFU-01 Revision K Draft.pdf
14-02	Rx	Pouch label	Rx Pouch L_VSR_0404_A_Lot_131101A.pdf
14-03	Rx	Box label	Rx Box B_VSR_0404_A.pdf
14-04	Rx & OTC	Box Carton	Rx and OTC Outer box with non-variable information.docx
14-05	OTC	OTC Instruction for Use	OTC DRAFT IFU-02.docx
14-06	OTC	OTC Pouch label	OTC Pouch Label L-VSC-0205.docx
14-07	OTC	OTC Box label	OTC Box Label B-VSC-0205.docx
14-08	OTC	Pouch label on pouch example	OTC Pouch label on pouch L-VSC-0205.docx

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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16. SHELF LIFE

Both Procellera® Antimicrobial Wound Dressing RX and OTC single-layer products have a 5-year shelf life.

The shelf life is identified to the user by the use of an expiration date symbol followed by the date.

	Format: the year (yyyy), month (mm); day (dd), each separated by hyphens. Example, January 2, 2014, is presented as 2014-01-02.

In the last submission, K130350, the shelf life was indicated for 3 years. However, additional testing has been performed. The shelf life for this submission, K160783, is 5 years. Shelf life data is included

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Procellera®
Wound Care with Advanced Microcurrent Technology

Instructions for Prescription Use

Product Description

Procellera® is a single layer, broad-spectrum antimicrobial wound dressing featuring Advanced Microcurrent Technology®. Embedded in the dressing are microcell batteries made of elemental silver and zinc applied in a dot-matrix pattern (Figure 1). In the presence of a conductive medium such as wound exudate, water-based hydrogels or saline, microcurrents are generated at the dressing surface, due to its inherent design.

Procellera is a primary contact layer dressing (Figure 2); it should be used under a secondary dressing or bandage (not provided), to keep it in place and help maintain a moist wound environment.

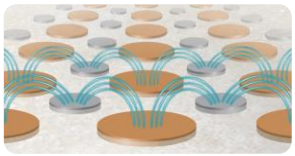


Figure 1

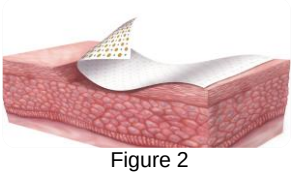


Figure 2

Indications

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, and other wounds of a similar nature.

Contraindications

- Do not use on individuals with sensitivity or allergy to silver or zinc.

Warnings

- Frequent or prolonged use of this product may result, in rare occasions, in temporary discoloration of the skin.

Precautions

Caution: Federal law restricts this device to sale by or on the order of a physician.

- Single use only.
- Electron beam irradiation sterilized. Opening the dressing pack compromises the sterile barrier. Do not use if the pouch is open or damaged prior to use.
- Remove Procellera dressing prior to an MRI or HBOT procedure and apply a new dressing after the procedure.
- For external use only.
- Do not use Procellera with topical agents such as antimicrobial ointments, enzymatic debriders, antibiotic creams, silver or zinc containing creams, oxidizing agents, or petroleum-based products.
- Secondary dressings should be used as stated in their Instructions for Use.
- The patient should stop using the dressing and consult a physician if allergy, irritation, increased pain, maceration, or any irregular skin discoloration occurs.
- Procellera is not intended to be used on wounds with uncontrolled bleeding.
- Remove Procellera dressing during energy-based procedures (such as radiofrequencies, ultrasound, or radiation) where the dressing may interfere with delivery.
- Avoid direct contact with electrodes or conductive gels during electronic measurements; e.g., EEG or ECG.
- Procellera may be used on infected wounds being clinically managed, as an adjunct to the local clinical protocol.
- The safety of daily Procellera use for longer than 28 days has not been studied.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

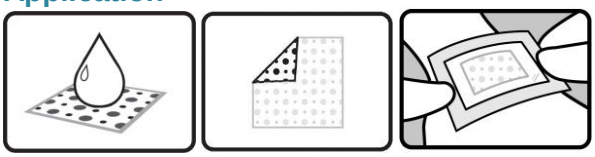
Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Instructions for Prescription Use

Preparation

Follow local hygiene procedures prior to, during and following dressing application and change.

Application



1. Cleanse the wound area with an appropriate wound cleanser according to local clinical protocol.
2. Remove Procellera from package and if needed, cut to a shape that will extend beyond wound edges 1 to 2 cm (1⁄2 inch to 1 inch). **Caution:** cutting may result in fraying of the dressing.
3. Moisten Procellera with sterile saline, water, or a thin, even layer of water-based hydrogel (not included).
4. Apply Procellera dressing **with the dotted side down**, in direct contact with the wound.
5. Cover Procellera with an appropriate secondary sterile dressing to help maintain a moist wound environment. The choice of secondary dressing should be determined by the amount of wound exudate, for example:
   - For DRY wounds; waterproof, semi-permeable, or hydrogel-like dressings are recommended to ensure prolonged moisture.
   - For EXUDATING wounds; cover Procellera with layer(s) of sterile gauze or foam dressing to absorb excessive moisture and prevent maceration. Then apply a semi-permeable or hydrogel-like dressing.
     If needed, secure in place with an additional fixation dressing, using care not to restrict blood flow.
6. Keep the dressing moist by re-moistening as necessary. Avoid over-soaking, for example:
   - DRY wounds may require more frequent dressing re-moistening.
   - EXUDATING wounds may require dressing re-moistening only if exudate decreases and the dressing becomes dry.

Site Care and Dressing Change

- Procellera may be left in place for up to 7 days (or longer, at the discretion and instruction of the treating clinician). Earlier and/or more frequent changes may be required, depending on the amount of exudate present and the condition of the wound and/or the surrounding skin. Inspect the wound site periodically.
- To remove the Procellera dressing, gently pull it back. If it adheres to the wound surface, do not force it off; moisten or soak the dressing with sterile saline or water until it can be removed without tissue disruption.
- The patient should consult a physician if any of the following occur: infection, bleeding, maceration, hypergranulation, irritation at the wound and/or the surrounding skin, or if the wound increases in size after a few dressing changes.

Dressing Components

- The dressing is not made with natural rubber latex.
- The dressing consists of a polyester substrate containing 0.9 mg of elemental silver and 0.3 mg of elemental zinc per square centimeter of dressing.
- Silver and zinc in the dressing minimize or prevent the growth of microorganisms within the dressing, not at the wound site, and help preserve the dressing.

Storage and Disposal

- Store in dry conditions at controlled room temperature. Controlled room temperature is 20°C to 25°C (68°F to 77°F). Excursions are permitted between 15°C and 30°C (59°F and 86°F). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F), however, such exposure should be minimized.
- Protect from light.
- Dispose of according to local environmental procedures.

Made in the USA by:

Vomaris Wound Care, Inc.
1911 East Fifth Street, Tempe, AZ 85281, USA
(866) 496-8743 (480) 921-4948
www.procellera.com

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

4 x 4 in
(10 x 10 cm)

Rx ONLY

P/N VSR-0404
LOT 123456X
Use by: exp. date

Box of 10 Units

Reorder #: VSR-0404-10

B - VSR-0404 - 10 / A

(01) 3 0381780 25796 1 (17) 160616 (10) 123456X

4 x 4 in

Procellera | Rx™
Wound Care with Advanced Microcurrent Technology

4 x 4 in
(10 x 10 cm)

Rx ONLY

P/N VSR-0404
LOT 123456X
Use by: exp. date

Box of 10 Units

Reorder #: VSR-0404-10

B - VSR-0404 - 10 / A

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4 x 4 in

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Wound Care with Advanced Microcurrent Technology

4 x 4 in
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Use by: exp. date

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4 x 4 in

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Wound Care with Advanced Microcurrent Technology

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Procellera®
Wound Care with Advanced Microcurrent Technology

Instructions for OTC Use

Product Description

Procellera® is a single layer, broad-spectrum antimicrobial wound dressing. Embedded in the dressing are microcell batteries made of elemental silver and zinc applied in a dot-matrix pattern (Figure 1). In the presence of a conductive medium such as wound exudate, water-based hydrogels or saline, microcurrents are generated at the dressing surface, due to its inherent design.

Procellera® is a primary contact layer dressing (Figure 2); it should be used under a secondary dressing or bandage (not provided), to keep it in place and help maintain a moist wound environment.

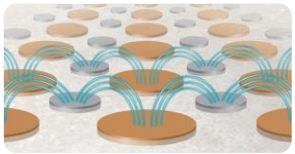


Figure 1

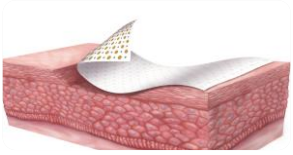


Figure 2

Indications

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 or wounds of a similar nature.

Contraindications

- Do not use on individuals with sensitivity or allergy to silver or zinc;

Warnings

Frequent or prolonged use of this product may result, in rare occasions, in temporary discoloration of the skin.

Precautions

- Single use only.
- Do not use if the pouch is open or damaged prior to use.
- For external use only.
- Do not use Procellera with topical agents such as antimicrobial ointments, enzymatic debriders, antibiotic creams, silver or zinc containing creams, oxidizing agents, or petroleum based products
- Secondary dressings should be used as stated in their Instructions for Use.
- Stop using the dressing and consult a physician if an allergy, irritation, increased pain, maceration or irregular skin discoloration occurs.
- Procellera is not intended to be used on wounds with uncontrolled bleeding.
- Remove Procellera dressing during energy-based procedures (such as radiofrequencies, ultrasound, or radiation) where the dressing may interfere with delivery.
- Avoid contact with electrodes or conductive gels during electronic measurements; e.g., EEG (electroencephalogram) or ECG (electrocardiogram).
- Procellera may be used on infected wounds that are being managed in accordance with institutional clinical protocols for infection abatement as an adjunct to the standard treatment regimen.
- The safety of daily Procellera use for longer than 28 days has not been studied.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

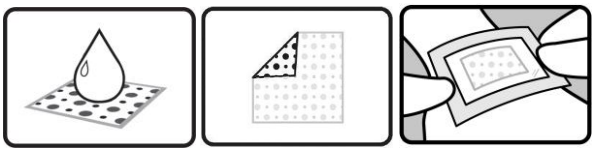
Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Instructions for OTC Use

Preparation

Follow local hygiene procedures prior to, during and following dressing application and change.

Application



1. Cleanse the wound area with an appropriate wound cleanser.
2. Remove Procellera from package and if needed, cut to a shape that will extend beyond wound edges 1 to 2 cm (1⁄2 inch to 1 inch). **Caution:** cutting may result in fraying of the dressing.
3. Moisten Procellera with sterile saline, water or a thin, even layer of water-based hydrogel (not included).
4. Apply Procellera dressing to the wound site, **with the dotted side down**, in direct contact with the wound surface.
5. Cover Procellera with an appropriate secondary sterile dressing (such as a waterproof dressing) which will keep it in place and help maintain a moist wound environment. If needed, secure in place with an additional fixation dressing, using care not to restrict blood flow.
6. Keep the dressing moist by re-moistening as necessary (once a day, for dry wounds). Avoid over-soaking.
   Note: It is not necessary to remove Procellera while showering.

Site Care and Dressing Change

- Procellera may be left in place for up to 7 days. Earlier and/or more frequent changes may be required, depending on the amount of exudate present, the condition of the wound and surrounding skin. Inspect the wound site periodically.
- To remove the Procellera dressing, gently pull it back. If it adheres to the wound surface, do not force it off; moisten or soak the dressing with sterile saline or sterile water until it can be removed without tissue damage.
- Consult a physician if any of the following occur: infection, bleeding, maceration (skin whitening and softening), hypergranulation (excessive tissue formation), irritation at the wound site or the skin surrounding the dressing, or if the wound increases in size after a few dressing changes.

Dressing Components

- The dressing is not made with natural rubber latex.
- The dressing consists of a polyester substrate containing 0.9 mg of elemental silver and 0.3 mg of elemental zinc per square centimeter of dressing.
- Silver and zinc in the dressing minimize or prevent the growth of microorganisms within the dressing, not at the wound site, and help preserve the dressing.

Storage and Disposal

- Store in dry conditions at controlled room temperature. Controlled room temperature is 20°C to 25°C (68°F to 77°F). Excursions are permitted between 15°C and 30°C (59°F and 86°F). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F), however, such exposure should be minimized.
- Protect from light.
- Dispose of according to local environmental procedures

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2 x 5 in
(5 x 12.5 cm)

P/N VSC-0205
LOT 123456X
Use by: exp. date

Box of 5 Units
Reorder #: VSC-0205-05

Contains silver and zinc as preservatives
B - VSC-0205 - 05 / A

(01) 3 0381780 25796 1 (17) 160616 (10) 123456X

2 x 5 in

Procellera | Elite™
Wound Care with Advanced Microcurrent Technology

2 x 5 in
(5 x 12.5 cm)

P/N VSC-0205
LOT 123456X
Use by: exp. date

Box of 5 Units
Reorder #: VSC-0205-05

Contains silver and zinc as preservatives
B - VSC-0205 - 05 / A

(01) 3 0381780 25796 1 (17) 160616 (10) 123456X

2 x 5 in

Procellera | Elite™
Wound Care with Advanced Microcurrent Technology

2 x 5 in
(5 x 12.5 cm)

P/N VSC-0205
LOT 123456X
Use by: exp. date

Box of 5 Units
Reorder #: VSC-0205-05

Contains silver and zinc as preservatives
B - VSC-0205 - 05 / A

(01) 3 0381780 25796 1 (17) 160616 (10) 123456X

2 x 5 in

Procellera | Elite™
Wound Care with Advanced Microcurrent Technology

2 x 5 in
(5 x 12.5 cm)

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LOT 123456X
Use by: exp. date

Box of 5 Units
Reorder #: VSC-0205-05

Contains silver and zinc as preservatives
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www.procellera.com
Phone: 480-921-4948 Fax: 480-921-0948

(b)(4) Confidential and Proprietary Information

[redacted]

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36. 5 Year Accelerated Aging Report

See following pages.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-8865; Released by CDRH on 03-13-2017.

Shelf Life Verification - Procellera devices in Amcor pouches

Summary Report at the Completion of the Accelerated Aging

(b)(4) Confidential and Proprietary Information

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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37. 5 Year Real Time Aging Report

See following pages.

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