November 6, 2019

Hydrofera, LLC
Sean Anderson
Director of Regulatory Affairs and Quality Assurance
340 Progress Drive
Manchester, Connecticut 06042

Re: K190268
Trade/Device Name: Hydrofera Blue READY - Border
Regulatory Class: Unclassified
Product Code: FRO
Dated: October 2, 2019
Received: October 3, 2019

Dear Sean Anderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Cynthia J. Chang, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190268

Device Name
Hydrofera Blue READY - Border

Indications for Use *(Describe)*
Hydrofera Blue READY - Border is intended as an external dressing for use in local management of moderate to heavily exuding wounds such as pressure ulcers, donor sites, venous stasis ulcers, arterial ulcers, diabetic ulcers, abrasions, lacerations, superficial burns, post-surgical incisions, and other external wounds inflicted by trauma.

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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Section 5: 510(k) Summary	Hydrofera Blue READY - Border Traditional 510(k) K190268

Date Prepared: November 6, 2019

The following is a summary of 510(k) safety and effectiveness information in accordance with 21 CFR 807.92(c):

1. Applicant

Company:	Hydrofera, LLC 340 Progress Drive Manchester, CT 06042 USA Telephone: 860-337-7466 Fax: 860-337-7462
Official Correspondent:	John O'Gara Hydrofera, LLC 340 Progress Drive Manchester, CT 06042 USA Telephone: 860-337-7741 Fax: 860-337-7462 Email: johno@hydrof.com

2. Device Details

Common Name:	Absorbent Wound Dressing
Trade Name(s) – Type:	• **Hydrofera Blue READY™ – Border**
Classification Name:	Dressing, Wound, Drug
Regulatory Class:	Unclassified
Product Code:	FRO
Panel:	General & Plastic Surgery

3. Predicate Device(s)

Predicate Device Name:	Hydrofera Blue PU Antibacterial Dressing (K130670)

4. Device Description

Hydrofera Blue READY – Border is a sterile absorptive foam dressings made of polyurethane (PU) foam, with methylene blue and gentian violet concentrations of at least 0.00005 g/g each with a combined total concentration of less than or equal to 0.0007 g/g. The dressings include an outer polyurethane film backing with silicone adhesive border.

5. Intended Use/Indications for Use

Indications for Use:
Hydrofera Blue READY – Border is intended as an external dressing for use in local management of moderate to heavily exuding wounds such as pressure ulcers, donor sites, venous stasis ulcers, arterial ulcers, diabetic ulcers, abrasions, lacerations, superficial burns, post-surgical incisions, and other external wounds inflicted by trauma.

6. Technological/Design Characteristics and Substantial Equivalence

Hydrofera Blue READY – Border is substantially equivalent to the predicate device with respect to material composition, device characteristics, and intended use. Table 5-1 below provides a comparison of the technological/design characteristics of the subject device compared to the predicate device.

Table 5-1. Comparison of Technological/Design Characteristics with the Predicate Device

	Predicate Device K130670, Hydrofera Blue PU Antibacterial Dressing	Modified Device K190268, Hydrofera Blue READY - Border	Substantial Equivalence Comments
Indications for Use	Hydrofera Blue PU antibacterial foam dressings are intended as external dressings for use in local management of wounds such as pressure ulcers, donor sites, venous stasis ulcers, arterial ulcers, diabetic ulcers, abrasions, lacerations, superficial burns, post-surgical incisions, and other external wounds inflicted by trauma.	Hydrofera Blue READY – Border is intended as an external dressing for use in local management of moderate to heavily exuding wounds such as pressure ulcers, donor sites, venous stasis ulcers, arterial ulcers, diabetic ulcers, abrasions, lacerations, superficial burns, post-surgical incisions, and other external wounds inflicted by trauma.	Same as predicate
Where Used	Hospitals, clinics, healthcare facilities, homecare	Hospitals, clinics, healthcare facilities, homecare	Same as predicate

Anatomical Sites	❖ Chronic wounds • Pressure sores/ulcers • Diabetic ulcers • Venous stasis ulcers • Arterial Ulcers ❖ Acute wounds • Traumatic wounds • Surgical wounds • Post-surgical incisions • Donor sites • Superficial burns • Skin abrasions • Lacerations	❖ Chronic wounds • Pressure sores/ulcers • Diabetic ulcers • Venous stasis ulcers • Arterial Ulcers ❖ Acute wounds • Traumatic wounds • Surgical wounds • Post-surgical incisions • Donor sites • Superficial burns • Skin abrasions • Lacerations	Same as predicate

Design/Materials Comparison	Layers: 1. Polyurethane Foam Pad 2. Polyurethane Film (with printed white ink)	Layers: 1. Polyurethane Foam Pad 2. Polyurethane Film (with printed white ink) 3. Silicone Adhesive Border 4. Polycarbonate Release Liner	1. Same as predicate 2. Same as predicate 3. The subject device adds a silicone adhesive border, which has a long history of safe use in wound dressings. 4. The subject device adds a polycarbonate release liner to protect the silicone adhesive prior to application. The liner has a long history of safe use in wound dressings and is removed prior to patient contact.
Primary Mode of Action	Absorption of exudate	Absorption of exudate	Same as predicate

Antibacterial Content	PU Foam Pad contains: • Gentian Violet: less than or equal to 0.00035g/g • Methylene Blue: less than or equal to 0.00035g/g	PU Foam Pad contains: • The combined total of Gentian Violet and Methylene Blue are less than or equal to 0.0007 g/g • Gentian Violet: greater than or equal to 0.00005 g/g • Methylene Blue: greater than or equal to 0.00005 g/g	The subject and predicate devices use the same antibacterial dyes. The maximum combined total of both dyes is the same for the subject and predicate. The subject device adds a minimum dye specification. Overall, a two-sided specification is created that is tighter than, yet falls within, the predicate device's range.
Biocompatibility Testing (per ISO 10993)	• Cytotoxicity • Irritation • Acute Systemic Reactivity • Sensitization • Hemolysis	• Cytotoxicity • Irritation • Acute Systemic Reactivity • Sensitization • Hemolysis • Material-Mediated Pyrogenicity • Implantation • Toxicity Risk Assessment	The subject device adds, material-mediated pyrogenicity, implantation, and a Toxicity Risk Assessment All tests passed.

In Vitro Antibacterial Testing in Simulated Wound Fluid	• NA	• Staphylococcus aureus • Streptococcus pneumoniae • Bacillus subtilis • Pseudomonas aeruginosa • Escherichia coli • Enterobacter cloacae	The subject device adds test data using simulated wound fluid. All tests passed.
In Vitro Antibacterial Testing in Saline	• Methicillin Resistant Staphylococcus Aureus (MRSA) • Staphylococcus aureus • Staphylococcus epidermidis (coagulase neg.) • Pseudomonas aeruginosa • Pseudomonas florescens • Escherichia coli • Enterococcus faecalis • Vancomycin Resistant Enterococcus (VRE) • Streptococcus pyogenes • Klebsiella pneumonaie • Proteus mirabilis • Proteus vulgaris • Enterobacter aerogenes • Enterobacter cloacae • Bacillus subtilis • Yersinia enterocolitica • Serratia marcescens • Streptococcus pneumonaie • Candida albicans • Candida krusei • Candida glabrata	• Methicillin Resistant Staphylococcus Aureus (MRSA) • Staphylococcus aureus • Staphylococcus epidermidis (coagulase neg.) • Pseudomonas aeruginosa • Pseudomonas florescens • Escherichia coli • Enterococcus faecalis • Vancomycin Resistant Enterococcus (VRE) • Streptococcus pyogenes • Klebsiella pneumonaie • Proteus mirabilis • Proteus vulgaris • Enterobacter aerogenes • Enterobacter cloacae • Bacillus subtilis • Yersinia enterocolitica • Serratia marcescens • Streptococcus pneumonaie • Candida albicans • Candida krusei • Candida glabrata	Same as predicate

Sterilization Method	Gamma Radiation	Ethylene Oxide	The subject and predicate devices are both provided sterile and are sterilized using traditional methods. A Sterility Assurance Level (SAL) of 10^{-6} was achieved for the subject device.
Energy Source	No energy sources are utilized	No energy sources are utilized	Same as predicate

7. Performance Data

The following performance data is provided in support of the substantial equivalence determination:

	Parameter Evaluated	Acceptance Criteria	Predicate Device Testing (K130670) (Appendix L)	Subject Device Testing (K190268)
1	Antibacterial Efficacy ASTM E2149-10 (modified)	≥ 4 log reduction over 7 days	20 Organisms tested 20 ≥ 4 log reductions	8 gram + Organisms tested 8 ≥ 6 log reduction 10 gram - Organisms tested 10 ≥ 6 log reduction
2	Zone of Inhibition –AATCC 147-2011	no zone of inhibition	No evidence of growth surrounding the Dressing	No evidence of growth surrounding the Dressing
3	Dye Leachable	< 0.5 ppm for each dye	Leachable amounts were measured at far less than 0.5 ppm for each dye (Methylene Blue and Gentian Violet)	Leachable amounts were measured at far less than 0.5 ppm for each dye (Methylene Blue and Gentian Violet)
4	LAL Endotoxin – ANSI/AAMI ST72:2011	less than 20 EU/device	Device contains less than 0.5 EU/device and meets the requirements of the test for Blood/Lymph Contact and Cerebrospinal Fluid Contact.	Device contains less than 0.5 EU/device and meets the requirements of the test for Blood/Lymph Contact and Cerebrospinal Fluid Contact.
5	Device Performance – Wicking Speed	absorb fluid in less than 30 seconds	Absorbs fluid in ≤ 5 seconds.	Absorbs fluid in <3 seconds
6	Device Performance – Fluid Retention	≥ 30% Fluid Retained	35.20% (σ 1.23)	37.47% (σ 1.35)
7	Device Performance – Border Adhesion	comparable to market leaders	Predicate[1] does not have border. Data for other commercial bordered products are located in K190268, Appendix 18-5, Attachment 3.	The adhesion performance of the perforated silicone adhesive was evaluated for peel strength in comparison to Hollister Triact Foam Dressing with silicone border and Coloplast Biatain silicone (with silicone border). The peel strength met the acceptance criteria.

8	Antibacterial Efficacy Low Specification Dye Limit – Simulated Wound Fluid[2]	≥ 4 log reduction over 7 days	NA	All low specification dye limit test articles evaluated exceeded the antibacterial efficacy acceptance criteria by demonstrating complete kill of the bacteria Staphylococcus aureus, Streptococcus pneumoniae, Bacillus subtilis, Pseudomonas aeruginosa, Escherichia coli and Enterobacter cloacae after 7 days of incubation, following a 7-day pre-conditioning period.
9	Antibacterial Efficacy Lot Consistency – Simulated Wound Fluid[3]	≥ 4 log reduction over 7 days	NA	All lot consistency test articles evaluated exceeded the antibacterial efficacy acceptance criteria by demonstrating complete kill of the bacteria Staphylococcus aureus, Streptococcus pneumoniae, Bacillus subtilis, Pseudomonas aeruginosa, Escherichia coli and Enterobacter cloacae after 7 days of incubation, following a 7-day pre-conditioning period.

Biocompatibility:

Biocompatibility testing for the Hydrofera Blue READY – Border was assessed in accordance with "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices - Part 1: Evaluation and testing within a risk management process,'" issued on June 16, 2016, effective September 14, 2016, as recognized by the FDA. Testing included:

- Cytotoxicity: Performed per ISO 10993-5 (ISO elution method), device is considered non-cytotoxic.
- Sensitization: Performed per ISO 10993-10 (Magnusson-Kligman method), device is considered non-sensitizing.
- Irritation: Performed per ISO 10993-11 (intracutaneous reactivity testing), device is considered non-irritant.
- Pyrogenicity: Performed per ISO 10993-11 and USP <151>, (rabbit pyrogen test) device is considered non-pyrogenic.
- Local effects after implantation: Performed per ISO 10993-6. In the rabbit muscle study, the device was considered passing.
- Acute systemic toxicity: Performed per ISO 10993-11 (implantation in rabbit abdomen), device showed no signs of acute systemic toxicity.
- Hemolysis/Interaction with blood: Performed per ASTM Hemolysis Test and passed
- Toxicology Risk Assessment: Performed per ISO standards 10993-1, 10993-2, 10993-11, 10993-3, 10993-17, 10993-18, 21726, and 14971. Toxicity is not expected from the intended use of the device. However, the product has not been tested or evaluated on the pediatric or neonatal patient populations

No clinical data was required to support substantial equivalence, and the testing performed demonstrates that the Hydrofera Blue READY – Border meets all performance specifications and is as safe and effective as the predicate device .

8. Conclusion

Based on the information provided in this 510(k), Hydrofera, LLC believes that the proposed Hydrofera Blue READY – Border is substantially equivalent to Hydrofera Blue PU Antibacterial Dressing (K130670) in terms of its intended use, design, operational and technological characteristics. The subject device raises no new issues of safety and effectiveness, met all test specifications, and the non-clinical testing performed demonstrates that the subject device is as safe, as effective, and performs as well as the predicate device.