K130670

JAN - 2 2014

510(k) Summary

Manufacture's name: Hydrofera LLC
322 Main Street
Willimantic CT 06226

Phone Number: (860) 456-0677
Fax Number: (860) 456- 0898

Name of Contact Person: Heather S. Somers
Phone Number: (860) 389-4628

Date Summary Prepared: April 23, 2013

Name of Device: Hydrofera Blue Antibacterial PU Dressing
Trade Name or Proprietary Name: Hydrofera Blue Antibacterial PU Dressing

Commom or Usual Name: Absorbent Wound Dressing
Classification Name: Dressing, wound
Product Code: FRO
Classification: Unclassified

The legally marketed device to which we are claiming equivalence (807.92(a) (3):

K#	Applicant	Device Name
K013462	Hydrofera, LLC	Hydrofera Blue
K060832	Retro-Tech, LLC	RTD Dressing

Description of the Device:

Hydrofera Blue PU Antibacterial Dressing is a sterile absorptive foam dressing made of bacteriostatic polyurethane (PU) foam, Methylene blue (less than or equal to 0.00035g/g) and Crystal violet (less than or equal to 0.00035g/g).
The Hydrofera Blue PU dressing is a dry absorbent wound dressing. The foam contains two antimicrobials that provide broad- spectrum antimicrobial protection in the foam:

1. Methylene Blue- a known inorganic antimicrobial/ antifungal, widely accepted to kill gram negative bacteria

2. Gentian Violet (Crystal violet) a known inorganic antimicrobial/antifungal widely accepted to kill gram positive bacteria

Indications:

Hydrofera Blue PU Antibacterial Wound 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 wound inflicted by trauma.

Summary of the technological characteristics of our device compared in the following areas and found to have similar technological characteristics and to be equivalent:

- Indications for Use
- Design
- Materials
- Performance
- Sterility
- Testing Done
- In- vitro Antimicrobial Activity
- Where used
- Anatomical sites

Comparison Table

Hydrofera Blue PU dressing	Hydrofera K# 013462	Retro Tech K#060832
Local Management of wounds including: •Pressure ulcers •Donor sites •Venous stasis ulcers Arterial ulcers •Diabetic ulcers •Abrasions •Lacerations •Superficial burns •Post surgical incisions •Any other wound inflicted by trauma	Local management of wounds including: •Pressure ulcers •Donor sites •Venous stasis ulcers Arterial ulcers •Diabetic ulcers •Abrasions •Lacerations •Superficial burns •Post surgical incisions •Any other wound inflicted by trauma	Indicated for moderately to heavily exudating partial to full thickness wounds including: •Pressure ulcers •Leg ulcers •Diabetic foot ulcers •Graft wound and donor site •Skin tears •Surgical wounds •Post operative wounds •Lacerations and abrasions •Any other wound caused by trauma

In Vitro Antimicrobial Testing

Hydrofera Blue PU dressing	Hydrofera K# 013462	Retro Tech K # 060832
Bacillus subtilis	Bacillus subtilis	Aspergillus niger
E-Coli	E-Coli	Candida albicans
MRSA	MRSA	Bacillus subtilis
VRE	VRE	Clostridium sporogenes
Serratia marcescens	Serratia marcescens	Salmonella cholerasuis
Staph aureus	Staph aureus	E-Coli
Staph epidermidis	Staph epidermidis	Pseudomonas aeruginosa
Pseudomonas aeruginosa		Staph aureus
Pseudomonas florescens		VRE
Enterococcus faecalis		MRSA
Streptococcus pyogenes		
Klebsiella pneumonaie		
Proteus mirabilis		
Proteus vulgaris		
Enterobacter aerogenes		
Yersinia enterocolitica		
Candida albicans		
Candida krusei		
Candida glabrata		

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Anatomical Sites

Hydrofera Blue PU Dressing	Hydrofera k # 013462	Retro Tech k # 060832
Anatomical sites where the following occur: •Pressure ulcers •Donor sites •Venous Stasis ulcers •Arterial ulcers •Diabetic ulcers •Abrasions •Lacerations •Superficial burns •Post surgical incisions	Anatomical sites where the following occur: •Pressure ulcers •Donor sites •Venous stasis ulcers •Arterial ulcers •Diabetic ulcers •Abrasions •Lacerations •Superficial burns •Post surgical incisions	Anatomical sites where the following occur: •Pressure ulcers •Leg ulcers •Diabetic foot ulcers •Graft wound and donor site •Skin tears •Surgical wounds •Post operative wounds •Lacerations and

Any other wound inflicted by trauma	Any other wound inflicted by trauma	abrasions •Any other wound caused by trauma

Where Product is Used

Hydrofera Blue PU Dressing	Hydrofera k # 013462	Retro Tech k # 060832
Hospitals, clinics, healthcare facilities, homecare	Hospitals, clinics, healthcare facilities, homecare	Hospitals, clinics, healthcare facilities, homecare

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Design Comparison

	Hydrofera Blue PU Dressing	Hydrofera k # 013462	Retro Tech k # 060832
Silver sodium Zirconium Phosphate			X
Gentian violet	x	x	x
Methylene Blue	X	X	X
Dressing Flexibility	Flexible	Rigid	flexible
Wound environment	Dry to wet	Wet	Dry to wet
Adhesive	Non adhesive	Non adhesive	Non adhesive

Materials Comparison

Hydrofera Blue PU Dressing	Hydrofera k # 013462	Retro Tech k # 060832
Polyurethane	Polyvinyl alcohol	Polyurethane

Sterility Comparison

Hydrofera Blue PU Dressing	Hydrofera k # 013462	Retro Tech k # 060832
Sterilized by Gamma irradiation or electron beam radiation	Sterilized by Gamma irradiation or electron beam radiation	Unknown

Testing performed

Hydrofera Blue PU Dressing	Hydrofera k # 013462	Retro Tech k # 060832
Biocompatibility per ISO 10993		
Sensitization	Sensitization	Sensitization
Irritation	Irritation	Irritation
Systemic toxicity	Systemic toxicity	Systemic toxicity
Hemocompatibility	Not performed	Hemocompatibility
Sterilization	Sterilization	Sterilization
Pyrogenicity	Pyrogenicity	Pyrogenicity

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The In Vitro Testing shows:

1) The Hydrofera Blue PU Antibacterial Wound Dressing extracts did not cause skin irritation nor did is cause sensitization reactions.
2) The Hydrofera Blue PU Antibacterial Wound Dressing meets the requirements for cytotoxicity (no cell death).
3) The Hydrofera Blue PU Antibacterial Wound Dressing did not cause acute systemic toxicity.
4) The Hydrofera Blue PU Antibacterial Wound Dressing is considered non irritant.

Conclusion:

The above testing demonstrates that the Hydrofera Blue PU Antibacterial Wound Dressing is safe and effective and performs as well as the predicate devices.

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

January 2, 2014

Hydrofera, LLC
Ms. Heather S. Somers
Director International
322 Main Street
Willimantic, Connecticut 06226

Re: K130670
Trade/Device Name: Hydrofera Blue PU Antibacterial Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: December 2, 2013
Received: December 3, 2013

Dear Ms. Somers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Binita S. Ashar -S
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Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

EXHIBIT 2

Premarked Notification 510(k) Hydrofera LLC

K130670

Indications for Use Statement

Indications for Use:

510(k) Number : 130670

Device Name: Hydrofera Blue PU Antibacterial Dressing

Hydrofera Blue PU Antibacterial Wound 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 wound inflicted by trauma.

Prescription Use _____x_____ and/or Over the Counter Use_____
(part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S