**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

December 31, 2014

Blue Ocean Medical Product, LLC
% E.J. Smith
Smith Associates
1468 Harwell Avenue
Crofton, Maryland 21114

Re: K133333
Trade/Device Name: UNI NPWT Foam Dressing Kit
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: December 2, 2014
Received: December 3, 2014

Dear Smith:

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 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" (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 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

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 on last page.*

510(k) Number *(if known)*
K133333

Device Name
UNI NPWT Foam Dressing Kit

Indications for Use *(Describe)*

The UNI NPWT Foam Dressing Kit is intended to be used in conjunction with the Simex Negative Pressure Wound Therapy Pumps (K113291) for the application of negative pressure wound therapy to the wound. When used in conjunction with the Simex Negative Pressure Wound Therapy Pumps, the UNI NPWT Foam Dressing Kit is indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing by removal of excess exudates, infectious material and tissue debris.

The UNI NPWT Foam Dressing Kit is appropriate for use on the following wounds:
- Pressure Ulcers
- Diabetic/Neuropathic Ulcers
- Venous Insufficiency Ulcers
- Traumatic Wounds
- Post-Operative and Dehisced Surgical Wounds
- Skin Flap and Grafts

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

# 510(k) Summary
**807.92(c)**

**SPONSOR** **807.92(a)(1)**


| | |
|---|---|
| Company Name: | Blue Ocean Medical Product, Inc. |
| Company Address | 135 Calkins Rd., Suite 600<br>Rochester, NY 14623 |
| Telephone: | 585.203.7652 |
| Fax: | 866.929.4761 |
| Contact Person: | Dana Ledgerwood |
| Summary Preparation Date: | December 31, 2014 |


**DEVICE NAME** **807.92(a)(2)**

| | |
|---|---|
| Trade Name: | UNI NPWT Foam Dressing Kit (Small, Medium, Large) |
| Common/Usual Name: | Foam Dressing Kit |
| Classification Name: | Powered Suction Pump |
| Regulation Number**:** | 21 CFR 878.4780 |
| Product Code: | OMP |
| Device Class: | Class II |
| Panel: | General & Plastic Surgery |

**PREDICATE DEVICE** **807.92(a)(3)**

Legally Marketed Equivalent Device

| *Company* | *Product* | *510(k) #* |
|---|---|---|
| Genadyne Biotechnologies, Inc. | A4-XLR8 Foam Dressing | K092992 |

**DEVICE DESCRIPTION** **807.92(a)(4)**

The UNI NPWT Foam Dressing Kit without pump is manufactured using a reticulated flexible polyether based polyurethane hydrophobic foam material. The UNI NPWT Foam Dressing Kit includes the (1) foam dressing, (2) occlusive drape and (3) silicon suction dome with (4) negative pressure tubing.

UNI NPWT Foam Dressing Kit is available in three sizes; 1) small, 2) medium and 3) large.

**DEVICE INDICATIONS FOR USE** **807.92(a)(5)**

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**DISCUSSION OF TECHNOLOGICAL CHARACTERISTICS** **807.92(a)(6)**

The UNI NPWT Foam Dressing Kit and the predicate device (Genadyne Biotechnologies, Inc. A4-XLR8 Foam Dressing Kit) have the same indications for use, both use flexible polyether and polyester polyurethane foam dressing material, are hydrophobic, are provided sterile, offer various size dressings, and are used for negative pressure wound therapy.

**NON-CLINICAL PERFORMANCE DATA** **807.92(B)(1)**

The following non-clinical tests and risk management were conducted:

- ISO 10993-5 Cytotoxicity
- ISO 10993-10 Irritation and Sensitization
- ISO 10993-11 Tests for Systemic Toxicity
- ANSI/AAMI/ISO 11137-2 Sterilization of health care products
- USP 35, NF 30 <85> Bacterial Endotoxins Test (LAL)
- USP <151> Pyrogen Test
- ASTM F88-09 Seal Strength Test
- ASTM F1929-98 Dye Penetration Test
- ASTM D3574-11 Standard Test Methods for Flexible Cellular Materials - Slab, Bonded, and Molded Urethane Foams
- ISO 14971 Medical Devices - Application of Risk Management to Medical Devices

A mechanical comparative test was conducted between the UNI NPWT Foam Dressing Kit and that of the predicate. The results of these tests demonstrated that the UNI NPWT Foam

Dressing Kit is substantially equivalent in terms of tensile strength, stress (elongation), ultimate elongation, tear resistance and fluid removal rate.

**CLINICAL PERFORMANCE DATA** **807.92(b)(2)**

No clinical study was conducted.

**Conclusion** **807.92(b)(3)**

The Blue Ocean UNI NPWT Foam Dressing is similar to the predicate device in indications for use, materials, and operating principle as a negative pressure wound therapy foam dressing. The Blue Ocean UNI NPWT Foam Dressing is substantially equivalent to the predicate device and introduced no new issues of safety and effectiveness.