DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 29, 2016

LC Medical Concepts, Inc.
Ms. Dana M. Ledgerwood
Chief Executive Officer
P.O. Box 502
Penfield, New York 14526

Re: K161570
Trade/Device Name: Theia NPWT Foam Wound Dressing Kit
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: May 1, 2016
Received: June 7, 2016

Dear Ms. Ledgerwood:

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" (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

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)*
K161570

Device Name
Theia NPWT Foam Wound Dressing Kit

Indications for Use *(Describe)*
The Theia NPWT Foam Wound 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 Theia NPWT Foam Wound 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 Theia NPWT Foam Wound 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Date Prepared: August 24, 2016

Sponsor**:** LC Medical Concepts, Inc.
PO Box 502
Penfield, NY 14526

510(k) Contact: Ms. Dana Ledgerwood
PO Box 502
Penfield, NY 14526
Telephone: 585-203-7652
e-mail: dm@lcmedicalconcepts.com

Trade Name: Theia NPWT Foam Wound Dressing Kit

Common Name: Foam Dressing Kit

Classification: Powered Suction Pump
21 CFR 878.4780
Class II

Product Code: OMP – Pump, Portable, Aspiration (manual or powered)

Panel: General & Plastic Surgery

Predicate Device: UNI NPWT Foam Dressing Kit **(**K133333)

Indications For Use:

The Theia 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 Theia 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 Theia 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

Device Description:

The Theia NPWT Foam Wound Dressing Kit without the pump includes a foam dressing composed of a reticulated flexible polyether based polyurethane hydrophobic foam material, an

occlusive drape and silicon suction dome with negative pressure tubing. Theia NPWT Foam Wound Dressing Kits are available in three sizes; 1) small, 2) medium and 3) large.

Technical Characteristics:

Feature Comparison Chart

Feature	Theia NPWT Foam Wound Dressing Kit	UNI NPWT Foam Wound Dressing Kit K133333
Indications For Use	The Theia NPWT Foam Wound 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 Theia NPWT Foam Wound 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 Theia NPWT Foam Wound 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	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 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
Product Code	OMP	OMP
Technology	• The foam wound dressing functions as the dressing material used to pack the wound. • The dome aids in removal of fluids/exudate from the wound to the collection canister of the NPWT suction pump. • The tubing as part of the dome assembly aids in the removal of fluids/exudates from the wound to the collection canister while maintaining a sealed application. • The occlusive drape is a semipermeable, transparent sheet applied over the foam dressing to cover the peri wound area and ensure a proper seal.	• The foam wound dressing functions as the dressing material used to pack the wound. • The dome aids in removal of fluids/exudate from the wound to the collection canister of the NPWT suction pump. • The tubing as part of the dome assembly aids in the removal of fluids/exudates from the wound to the collection canister while maintaining a sealed application. • The occlusive drape is a semipermeable, transparent sheet applied over the foam dressing to cover the peri wound area and ensure a proper seal.
Foam Dressing Material	Flexible Polyether Polyurethane Foam	Flexible Polyether Polyurethane Foam
Hydrophobic	Yes	Yes
Dome Assembly:	Consists of Dome, Skirt and Tubing Dome Material: Thermoplastic Elastomer Skirt Material: Polyurethane Medical Tape with Adhesive Backing Tubing Material: PVC	Consists of Dome, Skirt and Tubing Dome Material: Thermoplastic Elastomer Skirt Material: Polyurethane Medical Tape with Adhesive Backing Tubing Material: PVC
Occlusive Drape	Semipermeable, polyurethane (polymeric) transparent film	Semipermeable, polyurethane (polymeric) transparent film
Foam Dressing Dimensions:	Small 10 x 8 x 3 cm Medium 20 x 13 x 3 cm Large 25 x 16 x 3 cm	Small 10 x 8 x 3 cm Medium 20 x 13 x 3 cm Large 25 x 16 x 3 cm
Used in conjunction with NPWT pumps	For use with Simex NPWT Pumps (K113291)	For use with Simex NPWT Pumps (K113291)
NPWT pump provided with	No	No

Dressing Kit		
Provided Sterile	Yes	Yes
Single Use Only	Yes	Yes
Biocompatible	Yes	Yes

Non-clinical Testing:

The non – clinical testing for the Theia NPWT Foam Wound Dressing Kit is identical to the testing conducted in K133333 for the predicate device.

Clinical Performance Data:

No clinical study was conducted.

Substantial Equivalence:

The Theia NPWT Foam Wound Dressing Kit is substantially equivalent to the currently marketed UNI NPWT Foam Wound Dressing Kit, (K133333, Blue Ocean Medical Products, LLC). Both of these NPWT foam wound dressing kits are 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. Both the Theia NPWT Foam Wound Dressing and the UNI NPWT Foam Wound Dressing Kits are 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.

Both the Theia NWPT Foam Wound Dressing Kits and the predicate dressing kits contain the same components, namely a foam wound dressing, a dome assembly consisting of a dome port, skirt and tubing, and an occlusive drape. Each of the kit components in the Theia NPWT dressing kits have the same design and are manufactured of the same materials as the UNI NPWT dressing kit components. The Theia NPWT Foam Wound Dressing kits are provided in Small, Medium and Large, determined by the dimensions of the foam wound dressing contained in the kit, the same sizes provided in the predicate, UNI NPWT Foam Wound Dressing kits.

Conclusion:

The Theia Foam Wound Dressing Kits are substantially equivalent to the currently marketed UNI NPWT Foam Wound Dressing Kit (K133333) having the same indications for use, technological characteristics, design and materials, and do not raise new issues of safety and effectiveness.