May 31, 2022

Zhejiang Longterm Medical Technology Co., LTD
Claudia Zsang
Director of Regulatory Affairs
No. 493 North Huancheng Road
Mogan Mountain National High-Tech District
Deqing, Zhejiang 313200
China

Re: K211571
Trade/Device Name: Small Foam Kit, Medium Foam Kit, Large Foam Kit, Extra Large Foam Kit
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: November 29, 2021
Received: December 7, 2021

Dear Claudia Zsang:

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,

Julie Morabito, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211571

Device Name
Longterm NPWT Foam Dressing Kit

Indications for Use *(Describe)*
Longterm NPWT Foam Dressing Kit is intended to be used along with VCare 1000 -300S pump for wound management via the application of negative pressure to the wound, in order for the removal of fluids, including wound exudates, irrigation fluids, body fluids and infectious materials. The system is intended for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts. Longterm NPWT foam dressing kit is for use in professional healthcare facilities only.

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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510(k) SUMMARY

1 The 510(k) summary information is being submitted in accordance with the requirements of 21 CFR 807. 92(c).

Date Prepared:	May 03, 2022
Applicant:	Zhejiang Longterm Medical Technology Co., LTD No. 493 North Huancheng Road, Mogan Mountain National High-Tech District, Deqing Zhejiang, CHINA 313200
Official Correspondent:	Claudia Zsang Claudia.zsang@gmail.com
Phone Number:	1-416-276-9555
Device Name:	Longterm NPWT Foam Dressing Kit
Common Name:	NPWT System Accessories
FDA Panel:	General & Plastic surgery
Product Code:	OMP
Class:	II
Predicate Devices:	VCare 1000-300S Pump, VCare 1000-300S System, Perme-foam Dressing (K162159) (Primary) KCI USA Inc-V.A.C.® ATS, mini VAC, VAC Freedom (K032310)

2 Device Description:

Longterm NPWT Foam dressing kit is an accessory to VCare 1000-300S pump, manufactured by VR Medical Technology Co., Ltd. The dressing kit is composed of black foam dressing, polyurethane (PU) film drape and suction bell.

The foam dressing is used to pack the wound bed, the PU film drape is used to cover the packed wound bed and peri-wound area to create and maintain a sealed environment, the suction bell is served as a conduit between the wound bed and the negative pressure pump to transfer the wound fluid to the canister attached to the pump.

Longterm NPWT Foam dressing kit consists of hydrophobic, reticulated Polyurethane foam, polyurethane film drape coated with acrylic adhesive, suction bell composed of a polyvinyl chloride (PVC) drainage tubing with a polypropylene pinch clamp, a bell shape dome made of polyvinyl chloride, a transparent polyurethane film coated with acrylic

adhesive. Each component is individually packaged and sterilized. The foam dressing should be changed every 2-3 days depending on the wound condition or according to the local protocol.

The suction bell is comprised of a polyvinyl chloride drainage tubing with a polypropylene pinch clamp, a bell shape dome made of polyvinyl chloride, a transparent poly urethane film coated with acrylic adhesive.

Foam dressing is available in 4 sizes; small (10cmx7.5cmx2.5cm), medium (18cmx12.5cmx2.5cm), large (26cmx15cmx2.5cm) and extra large (45cmx30cmx2.5cm). PU film drape is available in 2 sizes; 30cmx30cm and 45cmx30cm.

3 Indications for Use:

Longterm NPWT Foam Dressing kit is intended to be used along with VCare 1000-300S pump for wound management via the application of negative pressure to the wound, in order for the removal of fluids, including wound exudates, irrigation fluids, body fluids and infectious materials. The system is intended for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.

Longterm NPWT foam dressing kit is for use in professional healthcare facilities only

4 Substantial Equivalence

Parameter	Subject Device	Predicate Device #1 (Primary)	Predicate Device #2
510(k)#	K211571	K162159	K032310
Device name	Longterm NPWT Foam Dressing Kit	VCare 1000-300S Pump, VCare 1000-300S System, Perme-foam Dressing (K162159)	KCI-V.A.C. ATS, mini VAC, VAC Freedom
Note	Accessory to VCare pump (510 (k) K162159)	-	Only foam dressing is used as the predicate
Classification Regulation	878.4780	Same	Same
Product Code	OMP	Same	Same
Skin Contact Materials	- Polyurethane ester foam with 0.1% carbon black colorant - Polyurethane film with acrylic adhesive	- Polyurethane ester foam; - Polyurethane drape	- Black, reticulated, polyurethane foam
Non-Skin Contact Materials	Suction Bell comprised of a polypropylene drainage tubing with a polypropylene pinch clamp, a bell shape dome made of polyvinyl chloride, a transparent poly urethane film coated with acrylic adhesive.	Suction Bell with connecting (drainage) tube and clamp	Non-specific
Mechanism of Action	The foam dressing is used to pack the wound bed, the PU film drape is used to cover the packed wound bed and peri-wound area to create and maintain a sealed environment, the suction bell is served as a conduit between the wound bed and the negative pressure pump to transfer the wound fluid to the canister attached to the pump.	Same	Same
Intended Use	The dressing kit is intended to be used along with VCare 1000-300S pump for wound management via the application of negative pressure to the wound, in order for the removal of fluids, including wound exudates, irrigation fluids, body fluids and infectious materials. The system is intended for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.	The VR Medical VCare 1000-300S Negative Pressure Wound Therapy System is an integrated wound management system, indicated for wound management via the application of negative pressure to the wound, in order for the removal of fluids, including wound exudates, irrigation fluids, body fluids and infectious materials. The system is intended for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness	The **V.A.C.** family of devices are feedback-controlled negative pressure devices used to help promote wound healing, through means including vacuum assisted drainage and removal of infectious material or other fluids, under the influence of continuous *and or* intermittent suction pressures, particularly for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and

Parameter	Subject Device	Predicate Device #1 (Primary)	Predicate Device #2
510(k)#	K211571	K162159	K032310
		burns, ulcers (such as diabetic or pressure), flaps and grafts.	grafts. Feedback control is achieved by measuring the level of negative pressure at the wound site.
Use environment	The foam dressing kit is for use in professional healthcare facilities only.	The device is for use in professional healthcare facilities only.	Non-specific
Biocompatibility (breached skin, prolonged, >24hr to 30days)	Non cytotoxic, non-irritant, non-sensitizing, non-toxic, none- pyrogenic	Non cytotoxic, non-irritant, non-sensitizing, non-toxic, none- pyrogenic	Biocompatible
Sterilization	Each kit components individually sterilized by Ethylene Oxide or Gamma Irradiation	Gamma Irradiation	Gamma irritation
Sterility Assurance Level	SAL of 10^{-6}	SAL of 10^{-6}	SAL of 10^{-6}

5 Non-clinical Testing Summary:

The following tests were performed to support the substantial equivalence of the subject

device: **Biocompatibility Testing:**

- Cytotoxicity – ISO 10993-5:2009
- Irritation – ISO 10993-10:2010
- Sensitization – ISO 10093-10:2010
- Pyrogenicity -ISO 10993-11:2006/USP39-NF34 <151>
- Acute toxicity – ISO 10993-11:2017
- Subacute toxicity – ISO 10993-11:2017/ ISO 10993-6:2016
- Subchronic toxicity – ISO 10993-11: 2017 / ISO 10993-2016
- Muscle implantation – ISO 10993-6:2016

Bench testing:
Longterm NPWT Foam Dressing Kit was evaluated under a number of bench tests to ensure the dressing kit can be used along with VCare 1000-300S pump regarding performance and functionality requirements.

- The foam dressing dimension test under various negative pressure after 72 hours at both continuous and intermittent modes;
- The fluid removal rate under various negative pressure at 72 hours at both continuous and intermittent modes;
- The pressure distribution under the foam dressing in 72 hours at both continuous and intermittent modes;
- The pressure difference under the foam dressing in 72 hours at both continuous and intermittent modes.
- Mechanical properties (tensile strength and elongation, ASTM D3574)

Animal testing:
Porcine wound healing study

6 Clinical Testing:

No clinical testing was required to support substantial equivalence.

7 Conclusion:

The non-clinical tests demonstrate that the subject device is as safe, as effective and performs as well as the legally marked predicate device.