



May 23, 2019

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

Re: K182458
Trade/Device Name: Longterm NPWT Foam Dressing Kit
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: April 14, 2019
Received: April 23, 2019

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/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 David Krause, Ph.D.
Acting 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

Indications for Use

510(k) Number (if known)

K182458

Device Name

Longterm NPWT Foam Dressing Kit

Indications for Use (Describe)

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 dehiscent wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.

The 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.

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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 20, 2019
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 claudiaz@longterm-health.com
Phone Number:	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) Cork Medical Products- Cork Medical Products NPWT Wound Dressing Kit (K132004) V.A.C.® ATS, mini VAC, VAC Freedom (K032310)

2 Device Description:

Longterm NPWT dressing kit is a single use device as an accessory to VCare 1000-300S pump, manufactured by VR Medical Technology Co., Ltd. The 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 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.

The foam dressing is used to pack the wound bed, the 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 suction pump to transfer the wound fluid to the canister attached to the suction pump.

The foam dressing should not be used for more than 24 hours and should be replaced with other dressings compatible with the VCare 1000-300S pump after 24 hours.

3 Indications for 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 dehiscent wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.

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

4 Substantial Equivalence

Parameter	Subject Device	Predicate Device #1	Predicate Device #2	Predicate Device #3
510(k)#	K182458	K162159	K132004	K032310
Device name	Longterm NPWT Foam Dressing Kit	VCare 1000-300S Pump, VCare 1000-300S System, Perme-foam Dressing (K162159)	Cork NPWT Wound Dressing Kit	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	Same
Product Code	OMP	Same	Same	Same
Skin Contact Materials	- Polyurethane ester foam with 0.1% carbon black colorant - Polyurethane film with acrylic adhesive	- Polyurethane ester foam; - Polyurethane drape	- Reticulated polyether based polyurethane foam (30 pores per inch); - Transparent polyurethane film drape with adhesive backing	- 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	port pad comprised of port pad, drainage tubing, luer connector, pinch clamp, transparent film drape with adhesive backing.	Suction bell with drainage tube
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	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	Cork Medical Products NPWT Wound Dressing Kit is intended to be used in conjunction with the Genadyne XLRS Pump to deliver negative pressure wound therapy to the wound. When used in conjunction	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

	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.	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.	with a NPWT pump system, Cork Medical Products NPWT Wound Dressing Kit is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing by the removal of excess exudates, infectious material, and tissue debris.	removal of infectious material or other fluids, under the influence of continuous <i>and or</i> 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 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 subject device is for use in professional healthcare facilities only.	The subject device is for use in professional healthcare facilities only.	The subject device is for use in professional healthcare facilities only.
Biocompatibility (Foam)	Non-cytotoxic, non-irritant, non-sensitizing, non- pyrogenic	Non-cytotoxic, non-irritant, non-sensitizing, non-toxic, non-pyrogenic	Non-cytotoxic, non-irritant, non-sensitizing	Biocompatible
Biocompatibility (Drape)	Non-cytotoxic, non-irritant, non-sensitizing, non-toxic, non-pyrogenic	Non-cytotoxic, non-irritant, non-sensitizing, non-toxic, non-pyrogenic	Non-cytotoxic, non-irritant, non-sensitizing	Biocompatible
Biocompatibility (Suction bell)	Non cytotoxic, non-irritant, non-sensitizing	Biocompatible	Biocompatible	Biocompatible
Sterilization	Each kit components individually sterilized by Ethylene Oxide or Gamma Irradiation	Gamma Irradiation	Individual kit components individually sterilized by Ethylene Oxide or Gamma Irradiation	Gamma irritation

Sterility Assurance Level	SAL of 10 ⁻⁶	SAL of 10 ⁻⁶	SAL of 10 ⁻⁶	SAL of 10 ⁻⁶
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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 (Foam, Drape, Suction bell)
- Irritation – ISO 10993-10:2010 (Foam, Drape, Suction bell)
- Sensitization – ISO 10093-10:2010 (Foam, Drape, Suction bell)
- Pyrogenicity -ISO 10993-11:2006/USP39-NF34 <151> (Foam, Drape)
- Acute systemic toxicity – ISO 10993-11:2017 (Foam, Drape)

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

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 devices.