December 15, 2021

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

Re: K202823
Trade/Device Name: Innomed NPWT Silicone Foam Dressing
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: November 17, 2021
Received: November 17, 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,

For Julie Morabito, PhD, RAC
Assistant Director
DHT4B: Division of 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)*
K202823

Device Name
Innomed NPWT Silicone Foam Dressing

Indications for Use *(Describe)*
Innomed NPWT Silicone Foam Dressing 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.
When used along with VCare 1000-300S pump, Innomed NPWT Silicone Foam Dressing is intended for patients with the following wound types:
- Chronic
- Acute
- Traumatic
- Subacute and dehisced wounds
- Partial-thickness burns,
- Ulcers (such as diabetic or pressure)
- Flaps and grafts

The device 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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:	December 10, 2021
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.zang@gmail.com
Phone Number:	416-276-9555
Device Name:	Innomed NPWT Silicone Foam Dressing
Common Name:	NPWT System Accessories
FDA Panel:	General & Plastic surgery
Product Code:	OMP
Regulation Number:	21 CFR 878.4780
Regulation Name:	Powered Suction Pump
Class:	II
Predicate Devices:	Primary Predicate Device: VCare 1000-300S Pump, VCare 1000-300S System, Perme-foam Dressing (K162159) Secondary Predicate Device: PICO Single Use Negative Pressure Wound Therapy System (K151436)

2 Device Description:

Innomed NPWT Silicone foam dressing is a single-use device, as an accessory to VCare-1000-300S pump, manufactured by VR Medical Technology Co., Ltd. The NPWT Silicone foam dressing consists of silicone adhesive coated foam dressing attached with a suction bell and fixation film strips.

The silicone foam dressing is comprised of PU film, absorbent pad consisting of polyurethane (PU) foam, absorbent fibre and polyester fabric, a layer silicone adhesive is coated onto the entire surface.

The suction bell is comprised of a polyvinyl chloride drainage tubing with a polypropylene pinch clamp, a polypropylene luer taper, a bell shape dome made of polyvinyl chloride, a

transparent poly urethane film coated with acrylic adhesive. The suction bell is attached on the silicone foam dressing surface.
Fixations film strips is composed of PU film coated with acrylic adhesive.
Machnism of Action: The silicone adhesive coated foam dressing is used to pack the wound bed and cover periwound area, and the fixation film strips are applied over the outside edges of the dressing to facilitate hold the silicone foam dressing in place and seal the wound bed area. The other end of the attached suction bell is connected to a canister attached to the negative pressure pump, VCare 1000-300S pump, and served as a conduit to transfer the wound exudate to the canister under negative pressure when the pump is turned on.

Innomed NPWT Silicone Foam Dressing is available in 10 sizes: SNPWT-1010 (10cm X 10cm), SNPWT-1020 (10cm X 20cm), SNPWT-1030 (10cm X 30cm), SNPWT-1040(10cm X 40cm), SNPWT-1515(15cm X 15cm), SNPWT-1520 (15cm X 20cm), SNPWT-1530 (15cm X 30cm), SNPWT-2020 (20cm X 20cm), SNPWT-2025(20cm X 25cm), SNPWT-2525(25cm X 25cm)

3 Indications for Use:

Innomed NPWT Silicone Foam Dressing 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.
When used along with VCare 1000-300S pump, Innomed NPWT Silicone Foam Dressing is intended for patients with the following wound types:

- Chronic
- Acute
- Traumatic
- Subacute and dehisced wounds
- Partial-thickness burns,
- Ulcers (such as diabetic or pressure)
- Flaps and grafts

The device is for use in professional healthcare facilities only.

4 Substantial Equivalence Comparison

Characteristics	Subject Device	Primary Predicate Device	Secondary Predicate Device	Comment
510(k)#	K202823	K162159	K151436	
Device name	Innomed NPWT Silicone Foam Dressing	VCare 1000-300S Pump, Vcare 1000-300S System, Perme-foam Dressing (K162159)	PICO Single Use Negative Pressure Wound Therapy System(K151436)	
Note	Accessory to Vcare pump (510 (k) K162159)	Only the foam dressing is used as the predicate	Only silicone foam dressing is used as the predicate	
Class	Class II	Class II	Class II	Same
Classification Regulation	21CFR 878.4780	21CFR 878.4780	21CFR 878.4780	Same
Product Code	OMP	OMP	OMP	Same
Skin Contact Materials	- Silicone foam dressing - PU film strips coated with acrylic adhesive	- Foam dressing	- Silicone foam dressing - PU film strips with acrylic adhesive	Similar to secondary predicate
Non-Skin Contact Materials	Suction Bell system	Suction Bell system	Suction bell system	Similar to primary /secondary predicates
Mechanism of Action	The silicone foam dressing is used to pack the wound bed and provide a sealed environment. The wound fluid is removed from the wound bed to a canister through the attached suction bell tube under a negative pressure.	The foam dressing is used to pack the wound bed and provide a sealed environment. The wound fluid is removed from the wound bed to a canister through the attached suction bell tube under a negative pressure.	The silicone foam dressing is used to pack the wound bed and provide a sealed environment. The wound fluid is removed from the wound bed to a canister through the attached suction bell tube under a negative pressure.	Similar to primary/ secondary predicates
Indications for Use	Innomed NPWT Silicone Foam Dressing 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. When used along with VCare 1000-300S pump, Innomed NPWT Silicone Foam	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 burns, ulcers (such as diabetic or pressure), flaps and grafts.	PICO is intended for the patients who may benefit from a suction device (Negative Pressure Wound Therapy) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials. Appropriate wound types include: ● Chronic ● Acute ● Traumatic ● Subacute and dehisced wounds	A subset of the primary / secondary predicates

Characteristics	Subject Device	Primary Predicate Device	Secondary Predicate Device	Comment
510(k)#	K202823	K162159	K151436	
	Dressing is intended for patients with the following wound types: • Chronic • Acute • Traumatic • Subacute and dehisced wounds • Partial-thickness burns, • Ulcers (such as diabetic or pressure) • Flaps and grafts The device is for use in professional healthcare facilities only.	The device is for use in professional healthcare facilities only.	● Partial-thickness burns ●Ulcers(such as diabetic or pressure) ● Flaps and grafts ● Closed surgical incisions PICO single use negative pressure wound therapy system is suitable for use both in a hospital and homecare setting.	
Use environment	The device is for use in professional healthcare facilities only.	The device is for use in professional healthcare facilities only.	The device is suitable for use both in a hospital and homecare setting.	Same to primary predicate
Biocompatibility (silicone foam dressing, (breached skin, prolonged, >24hr to 30days)	Non-cytotoxic, non-irritating, non-sensitizing, non-toxic, non-pyrogenic	Non cytotoxic, non-irritant, non-sensitizing, non-toxic, none- pyrogenic	Non cytotoxic, Negligible irritant, non-sensitizing	Same to primary/secondary predicates
Sterilization	Ethylene Oxide	Gamma Irradiation	Ethylene Oxide	Same to secondary predicate
Sterility Assurance Level	SAL of 10^{-6}	SAL of 10^{-6}	SAL of 10^{-6}	Same to primary/secondary predicates
Single Use	Yes	Yes	Yes	Same to primary/secondary predicates

Characteristics	Subject Device	Primary Predicate Device	Secondary Predicate Device	Comment
510(k)#	K202823	K162159	K151436	
Prescription	Yes	Yes	Yes	Same to primary predicate
Shelf-life	3 years	3 years	2 years	Same to primary predicate

5 Non-clinical Testing Summary:

The following tests were performed to support the safety and effectiveness of the subject device:

Biocompatibility Testing:

- Cytotoxicity – ISO 10993-5:2009
- Irritation – ISO 10993-10:2010
- Sensitization – ISO 10093-10:2010
- Acute and subacute systemic toxicity- ISO 10993-11:2017
- Material mediated pyrogenicity – ISO 10993-11:2017/USP<151>
- Implantation – ISO 10993-6:2016

Bench testing:

Innomed NPWT Silicone Foam Dressing was evaluated under a number of bench tests, along with the predicate, to ensure the dressing can be used along with VCare 1000-300S pump regarding performance and functionality requirements and performs similarly as the predicates.

Test Parameters	Subject Device (K202823)	Secondary predicate (K151436)	Comment
Silicone adhesive peel strength (N/25cm)	0.51	0.60	Similar
Water absorption	7	9	Similar
Moisture vapor transmission rate (MVTR)	699	1112	The secondary predicate does not work with a canister, therefore the wound exudate removal is dependent on the MVTR and the ability to retain the wound exudate in the dressing (Fluid Handling Capacity).
Fluid handling capacity	4.7	11	The secondary predicate does not work with a canister, therefore the wound exudate removal is dependent on the MVTR and the ability to retain the wound exudate in the dressing (Fluid Handling Capacity).
Pressure distribution underneath the dressings in 72 hours under various negative pressure conditions	Meet the requirements	Meet the requirements	Similar
Alarming functions	Meet the requirements	Meet the requirements	Similar
Liquid pooling	No	No	Similar

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.