August 19, 2024

Med Way Inc.
% Charles Mack
Principal Engineer
Irc
2950 E Lindrick Drive
Chandler, Arizona 85249

Re: K241023
Trade/Device Name: Negative Pressure Wound Therapy Device (V-Move, V-Grand)
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: March 23, 2024
Received: April 15, 2024

Dear Charles Mack:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Yu-chieh Chiu -S

Yu-Chieh Chiu, Ph.D.
Assistant Director
DHT4B: Division of Plastic and
Reconstructive 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241023

Device Name
Negative Pressure Wound Therapy Device (V-Move, V-Grand)

Indications for Use *(Describe)*

The Negative Pressure Wound Therapy Device is indicated for wound management via the application of negative pressure to the wound by the removal of wound exudate, infectious materials, and tissue debris from the wound bed.

The Negative Pressure Wound Therapy Device is indicated for the following wound types: chronic, acute, traumatic, subacute, and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps, 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.

510(k) SUMMARY
AS REQUIRED BY 21CFR807.92(c)

Preparation Date:	August 19, 2024
Manufacturer's Name and Address:	Med Way Inc. 1650 Horizon Pkwy NE, Suite 450, Buford, GA, USA 30518 Tel: (888) 563-3929
Corresponding Official:	Charles Mack
Telephone Number:	931-625-4938
Email Address:	charliemack@irc-us.com
Trade Name:	Negative Pressure Wound Therapy Device Model: V-Move, V-Grand
Common Name(s):	negative pressure wound therapy powered suction pump
Regulation Name(s):	Powered suction pump
Regulation Number(s):	21CFR878.4780
Primary Product Code:	OMP
Device Class:	Class II
Predicate Device:	K132225
Trade Name:	EXTRICARE
Common Name:	negative pressure wound therapy powered suction pump
Regulation Number(s):	21CFR878.4780
Product Code:	OMP

Device Description:

The Negative Pressure Wound Therapy Device is a portable, rechargeable, battery-powered pump capable of delivering bespoke continuous and/or intermittent negative pressure intended to allow wound management by draining and removing wound exudates, infectious material, and tissue debris from the wound bed. The Negative Pressure Wound Device is packaged and provided with the following components: Negative Pressure Wound Therapy Pump and Collection Canister.

Patients with chronic, acute, traumatic, subacute, and dehisced wounds, partial-thickness burns, diabetic ulcers, neuropathic ulcers, pressure ulcers, flaps, and grafts may benefit from this system.

The Negative Pressure Wound Therapy Device used with wound dressings can produce a negative pressure environment in either intermittent or continuous mode. This allows the user to program the specific pressure ranging from 50mmHg to 200mmHg (V-Move) and 0 to 200 mmHg (V-Grand).

In intermittent mode, the pump will alternate between applying pressure for 5 continuous minutes and reducing pressure to 0 for 2 minutes for V-Move. In intermittent mode, therapy pressure, operating time, and interval time can be adjusted for V-Grand.

The Negative Pressure Wound Therapy Device is compatible with the Longterm NPWT Foam Dressing Kit (K211571).
The device is used in professional medical facilities.

The Negative Pressure Wound Therapy pump accessories that are included in this 510(k) submission and will be commercialized separately are the following:
300cc Collection Canister
500cc Collection Canister
1000cc Collection Canister

Indications for Use

The Negative Pressure Wound Therapy Device is indicated for wound management via the application of negative pressure to the wound by the removal of wound exudate, infectious materials, and tissue debris from the wound bed.

The Negative Pressure Wound Therapy Device is indicated for the following wound types: chronic, acute, traumatic, subacute, and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps, and grafts.

Item	Subject Device	Predicate Device	Reference Device	Comment
510(k)	K241023	K132225	K162159	-
Device	Negative Pressure Wound Therapy Device	Negative Pressure Wound Therapy System	VCare 1000-300S System	-
Model	V-Move, V-Grand	extriCARE 3600	VCare 1000-300S Pump	-
Applicant	MED WAY INC.	Devin Medical, Inc.	VR Medical Technology Company, Ltd.	-
Product code	OMP	OMP	OMP	-
Regulation Number	878.4780	878.4780	878.4780	-
Indication for Use	The Negative Pressure Wound Therapy Device is indicated for wound management via the application of negative pressure to the wound by the removal of wound exudate, infectious materials, and tissue debris from the wound bed. The Negative Pressure Wound Therapy Device is indicated for the following wound types: chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.	The extriCARE 3600 Negative Pressure Wound Therapy System is indicated for wound management via the application of negative pressure to the wound by the removal of wound exudate, infectious materials, and tissue debris from the wound bed. The extriCARE 3600 Negative Pressure Wound Therapy System is indicated for the following wound types: 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 burns, ulcers (such as diabetic or pressure), flaps and grafts.	Identical *Note 1*
Contraindications	- Exposed vessels, organs, or nerves. - Anastomotic sites. - Exposed arteries or veins in a wound. - Fistulas, unexplored or non-enteric. - Untreated osteomyelitis. - Malignancy in the wound. - Excess amount of necrotic tissue with eschar. - Wounds which are too large or too deep to be accommodated by the dressing. - Inability to be followed by a medical professional or to keep scheduled appointments. - Allergy to urethane dressings and adhesives. - Use of topical products which must be applied more frequently than the dressing change schedule allows	- Exposed vessels, organs, or nerves. - Anastomotic sites. - Exposed arteries or veins in a wound. - Fistulas, unexplored or non-enteric. - Untreated osteomyelitis. - Malignancy in the wound. - Excess amount of necrotic tissue with eschar. - Wounds which are too large or too deep to be accommodated by the dressing. - Inability to be followed by a medical professional or to keep scheduled appointments. - Allergy to urethane dressings and adhesives. - Use of topical products which must be applied more frequently than the dressing change schedule allows	- Exposed vessels, organs, or nerves. - Anastomotic sites. - Exposed arteries or veins in a wound. - Fistulas, unexplored or non-enteric. - Untreated osteomyelitis. - Malignancy in the wound. - Excess amount of necrotic tissue with eschar. - Wounds which are too large or too deep to be accommodated by the dressing. - Inability to be followed by a medical professional or to keep scheduled appointments. - Allergy to urethane dressings and adhesives. - Use of topical products which must be applied more frequently than the dressing change schedule allows	Identical

Item	Subject Device	Predicate Device	Reference Device	Comment
Principle of Operation	A vacuum pump generates vacuum. A collection canister is connected to the vacuum pump, and a tubing connecting the wound dressing and the canister brings wound exudate	A vacuum pump generates vacuum. A collection canister is connected to the vacuum pump, and a tubing connecting the wound dressing and the canister brings wound exudate	A vacuum pump generates vacuum. A collection canister is connected to the vacuum pump, and a tubing connecting the wound dressing and the canister brings wound exudate	Identical
Vacuum mode	Continuous and Intermittent	Continuous and Intermittent	Continuous and Intermittent	Identical
Negative Pressure	50~200 mmHg (V-Move) 0~200 mmHg (V-Grand)	40~200 mmHg	20~200 mmHg	*Note 2*
Canister	300cc, 500cc (V-Move) 500cc,1000cc (V-Grand)	400cc, 1000cc	140, 400, 600cc	*Note 2*
Prescription Use	Yes	Yes	Yes	Identical
Sterility	Non-sterile (exclude dressing)	Non-sterile (exclude dressing)	Non-sterile (exclude dressing)	Identical
Weight	1.5 lbs (0.7kg) for V-Move; 8.1 lbs (3.7kg) for V-Grand	2.87 lbs (1.3kg)	0.51 lbs (0.23kg)	*Note 3*
User Life	Indefinite, with routine servicing and repair	Indefinite, with routine servicing and repair	Indefinite, with routine servicing and repair	Identical
Energy source	AC and Battery	AC and Battery	AC and Battery	Identical
Negative Pressure Tubing	PVC	PVC	PVC	Identical
Battery	Lithium battery	Lithium battery	Lithium battery	Identical

Testing

Non-clinical tests were conducted to verify that the proposed devices met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed devices comply with the following standards:

Safety and EMC

- ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]

- IEC60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

Biocompatibility

The Pump and the Cannister are not tissue contacting. No biocompatibility test submitted.

Performance

To ensure the performance of subject device meet the design input, a series of bench tests were conducted which including safety test, environmental test, device performance test, function test etc.

Software

The software validation was conducted according to the FDA guidance “Content of Premarket Submissions for Device Software Functions”. Testing concluded that the subject device met the requirement.

Clinical Study:

No clinical testing was required to support substantial equivalence

Conclusion:

In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Part 807, and based on the information provided in this pre-market notification, the subject device is as safe and as effective as and substantially equivalent to the predicate devices as described herein.