DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 28, 2017

VR Medical Technology Company, Ltd.
Lee Pan
CEO
90 Gaoxin Rd.
Kunshan, CN 215325 Jiangsu

Re: K162159
Trade/Device Name: VCare 1000-300S Pump, VCare 1000-300S System, Perme-foam Dressing
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: March 27, 2017
Received: March 28, 2017

Dear Lee Pan:

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,

FDA 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)*
K162159

Device Name
VCare 1000-300S Pump, VCare 1000-300S System, Perme-foam Dressing

Indications for Use *(Describe)*
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.

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

## I. Submitter Information

VR Medical Technology Co., Ltd.
90 Gaoxin Rd., Zhouzhuang
Kunshan, Jiangsu, CHINA 215325

Contact Person: Lee Pan, Ph.D.
lpan@vrmedical.net
+86 512 5720 0500

Date Prepared: April 22, 2017

## II. Device Information

| | |
|---|---|
| Name of Device: | VCare 1000-300S Pump<br>VCare 1000-300S System<br>Perme-foam Dressing |
| Common Names: | Negative Pressure Wound Therapy Pump<br>Negative Pressure Wound Therapy System |
| Classification Name(s): | Powered Suction Pump (21 CFR 878.4780) |
| Regulatory Class: | II |
| Product Code: | OMP |

## III. Predicated Device

Primary: K140634 Devon Medical Products Inc., ExtriCare 2400 NPWT System with ExtriCare 2400 Pump and ExtriCare NPWT Foam Dressing Kit
This predicate has not been subject to a design-related recall

K112458 Medica-Rents Co., Prospera Pro-II
This predicate has not been subject to a design-related recall

K132252 Devon Medical Inc., ExtriCare Negative Pressure Wound Therapy 100cc, 250cc, and 300cc canisters
This predicate has not been subject to a design-related recall

## IV. Device Description

The VR Medical VCare 1000-300S System is an AC-Powered portable suction device, with battery backup, that provides localized negative pressure when used with the VR Medical Perme-Foam Dressing to remove fluid, irrigation solutions and infectious materials from the wound. The systems consist of a powered suction pump device with a built-in placement holder for the disposable fluid collection canister, and a foam dressing kit. The kit consists of polyurethane foam, suction bell with connecting (drainage) tube and clamp, and

polyurethane drape. The single-use foam dressing kit is packaged in a PE/PET peel pouch bag, which is gamma sterilized.

The Foam Dressing Kit (VR Medical Perme-Foam Dressing) can be sold alone or as a part of the VCare 1000-300S System in two sizes:

- Large foam dressing kit
- Medium foam dressing kit
- The Foam Dressing can be used for up to 72 hours of continuous use.

## V. Intended Use(s)

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.

## VI. Technological Characteristics

The manufacturer believes that the technological characteristics of the VCare 1000-300S System are substantially similar to those of the predicate devices. The subject and predicate devices are based on the following same technical elements:

- Continuous and Intermitted negative pressure treatment modes
- Selectable Pressure Settings from -20 mmHg to -200 mmHg
- AC and rechargeable battery with 48 hour battery life

## VII. Performance Data

*Non-Clinical Tests (Bench)*

Testing has been conducted to verify that the VR Medical VCare 1000-300S System demonstrates substantial equivalence to the predicate devices. The list below summarizes the testing conducted for the VR Medical VCare 1000-300S device.

- Verification that the device delivers negative pressure wound therapy in continuous and intermittent (variable & pulse) operating modes identical to the predicate devices using simulated exudate
- Verification of system performance with foam dressing kits and accessories identical to predicate devices
- Verification of system alarms
- Verification of battery performance

*Electrical Safety and Electromagnetic Compatibility (EMC)*

Electrical safety and EMC testing were conducted on the VR Medical VCare 1000-300S System. The system complies with the IEC 60601-1 and IEC 60601-1-11 standards for safety and the IEC 60601-1-2 standard for EMC.

*Software Verification and Validation Testing*

Software verification and validation testing were conducted and documentation was provided as recommended by the FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Moderate" level of concern, since a failure or latent flaw in the software could directly result in minor injury to the patient or operator.

*Biocompatibility*

The VCare 1000-300S System consists of both the VCare 1000-300S Pump and the VR Medical Perme-Foam Dressing. While the pump has no direct body contact when used as indicated, the Perme-Foam Dressing does have direct body contact. Per ISO-10993 B-prolonged contact (24h-30days) requirements, the Perme-Foam Dressing samples were tested for the following items and all tests were successfully passed.

- In Vitro Cytotoxicity Test per ISO 10993-5:2009
- Skin Sensitization Test per ISO 10993-10:2010
- Intracutaneous Reactivity Test per ISO 10993-10:2010
- Acute Systemic Toxicity Test per ISO 10993-11:2006
- In Vitro Mammalian Cell Gene Mutation test per ISO 10993-3:2009
- Ames Test per ISO 10993-3:2014
- In Vitro Mammalian Chromosome Aberration Test per ISO 10993-3:2014
- Muscle Implantation Test per ISO 10993-6:2007
- In Vitro Hemolytic Test per ISO 10993-4:2002/Amd.1: 2006
- Subchronic Systemic Toxicity Test per ISO 10993-11:2006
- Pyrogen Test per ISO 10993-11:2006 and USP39-NF34<151>

## VIII. Conclusion

The non-clinical tests, electrical safety and EMC, software verification & validation, and biocompatibility, demonstrate that the VR Medical VCare 1000-300S System is equivalent to the predicate device for the intended use.