January 15, 2025

Suzhou Minhua Medical Apparatus Supplies Co., Ltd
Alex Wang
Regulatory Affairs Specialist
You Yi Industrial Park, Songlin Town, Wujiang
Suzhou, Jiangsu 215222
China

Re: K241096
Trade/Device Name: Venera 608 Deep Vein Thrombosis (DVT) Prevention System
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: April 7, 2024
Received: April 22, 2024

Dear Alex Wang:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Eric E. Richardson -S

for Nicole Gillette
Assistant Director
DHT2B: Division of Circulatory Support,
Structural, and Vascular Devices
OHT2: Office of Cardiovascular 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.

Submission Number *(if known)*

K241096

Device Name

Venera 608 Deep Vein Thrombosis (DVT) Prevention System

Indications for Use *(Describe)*

The Venera 608 Series system is a prescription device intended to be used preventatively to increase venous blood flow in patients at risk of deep vein thrombosis due to the associated risk factors for thrombus formation during: trauma, critical care, general medicine, general surgery, as well as neurological, orthopedic, urologic, obstetric conditions and treatments.

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.

K241096 510(k) Summary

Submitter:

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Postal Code: 215222

Tel：+86-0512-63091066

Contact Person: Alex Wang

Date Prepared: January 14, 2025

Device:

Common Name: Intermittent Pneumatic Compression Device

Proprietary Name: Venera^{TM} 608 Deep Vein Thrombosis Prevention System

Regulatory Class: II

Product Code: JOW

Regulation Number: 21 CFR 870.5800

Predicate Device:

The Venera 608 Deep Vein Thrombosis Prevention System is equivalent to the following:

Predicate Device	Manufacturer	510(k)#
Cirona 6200 Deep Vein Thrombosis(DVT) Prevention System	Devon Medical Products	K141578

Device Description

The Venera^{TM} 608 Series deep vein thrombosis prevention system is a pneumatic compression device that noninvasively helps reduce the incidence of deep vein thrombosis, a potentially life-threatening condition. The Venera^{TM} 608 Series system consists of a device and a pair of soft compression cuff(s) (sleeves) and the extension tubing set for the calf, calf-thigh, and foot. The device will alternatively inflate the two cuffs

and mimic the natural walking pace in order to enhance circulation. The device-supplied compression provides a 60-second automatically timed cycle consisting of an approximately 12-second inflation period followed by a 48-second period of relaxation. A pressure of 40mmHg is used for the calf, calf-thigh, and 120mmHg for foot treatments. This pressurization enhances venous flow and fibrinolytic activity in order to ultimately prevent early blood clotting.

Intended Use:

The Venera 608 Series system is a prescription device intended to be used preventatively to increase venous blood flow in patients at risk of deep vein thrombosis due to the associated risk factors for thrombus formation during: trauma, critical care, general medicine, general surgery, as well as neurological, orthopedic, urologic, obstetric conditions and treatments.

Comparison of Technological Characteristics With the Predicate Device:

The technological principle for both the subject and predicate devices is to prevent pooling of blood in a limb by inflating periodically a sleeve around the limb.

At the system construction level, the subject and predicate devices are comprised of the same system set-up, which is a compression pump and a pair of soft compression cuff(s) (sleeves) and the extension tubing set that connects the pump and the cuff. For both subject and predicate devices, a compression pump is used to deliver compressive air to periodically inflate the cuff to achieve the motion of limb massage and circulation enhancement.

At the operation level, the subject and predicate devices are based on the following same technological elements:

- Physical components – both have the same physical components, which are pump, power cord, extension tubing and cuff.
- Device Construct – both pumps have similar form factor in terms of their dimensions
- Device Construct – both have LCD screen the displays therapy setting and key notifications
- Device Construct – the different cuffs from both subject and predicate devices are similar or identical in shape and mode of wear; cuffs from both are made of the same type of plastic or fabric
- Pressure – both the subject and predicate devices have the same operating pressures that are applied to calf or foot, depending on the type of cuff utilized
  Therapy Cycle Length – both the subject and predicate devices have the same programmed therapy cycle length

The following technological differences exist between the subject and predicate devices:

- Materials – Although both devices use the same family of plastic and fabric materials on the cuffs/sleeves, the materials for the subject device are different from of those of the predicate.
- User Interface – subject device contains an optimized user interface that allows more sophisticated functions or buttons such as power on/off button, start/pause button, therapy time reset/mute button,

therapy mode setting button on the LCD screen, whereas the predicate device has limited control capability on its screen.

The manufacturer believes that the technological characteristics of the Venera^{TM} 608 Deep Vein Thrombosis Prevention System are substantially equivalent to those of the predicate device. Venera 608 DVT Prevention System has similar components to its predicate device and identical principles of operation.

Performance Tests

To verify that the device design met its function and performance requirements, samples of the device underwent function and mechanical testing.

The following tests were conducted:

System Level Software Test
Pressure Accuracy Test
Cycle Time Test
Alarm Function Test
Charge and Discharge Test
Cuff Burst Testing (included Leak Testing)

The conclusions drawn from the performance tests demonstrate that the device is performing as intended, and is safe and effective.

Sterilization and Shelf Life

Sterilization and shelf life are not applicable to Venera 608 DVT Prevention System.

Standards

Electrical safety and EMC tests were conducted according to the following standards:

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020 Medical Electrical Equipment Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2:2014+A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013, IEC 60601-1-6:2010/AMD2:2020 Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance -

Collateral standard: Usability for use in conjunction with IEC 62366-1:2015, IEC 62366-1:2015/AMD1:2020, and IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020.

Biocompatibility tests were conducted according to the following standards:

ISO 10993-5: 2009 Biological evaluation of medical devices – Part 5: Tests for In Vitro Cytotoxicity

ISO 10993-23:2021 Biological evaluation of medical devices – Part 23: Tests for irritation

ISO 10993-10: 2021 Biological evaluation of medical devices – Part 10: Tests for skin sensitization

Software Verification and Validation

Software verification and validation were conducted and documentation is provided. The software was considered as a Moderate level of concern, since a failure or latent flaw in the software could directly or indirectly result in minor injury to the patient or operator.

Animal Study and Clinical Study

No animal study or clinical study was conducted.

Statement of Substantial Equivalence

The Venera 608 Deep Vein Thrombosis Prevention System is substantially equivalent in its intended use, technology, function, operating parameters to the predicate device and does not raise any new concerns regarding safety or effectiveness.