June 29, 2018

Suzhou Minhua Medical Apparatus Supplies Co. Ltd.
Alex Wang
Regulatory Affairs Specialist
No.789, Wu Fang Road, Friendship Industrial Zone
Song Ling Town, Wu Jiang
Suzhou, 215222 China

Re: K180389
Trade/Device Name: Venera 508 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: May 15, 2018
Received: June 4, 2018

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 (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.

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,

Nicole M. Gillette -S
2018.06.29 08:28:57
-04'00'

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

The Venera 508 Deep Vein Thrombosis Prevention Therapy System is a portable treatment system intended to help prevent the onset of DVT in patients by stimulating blood flow in the extremities (simulating muscle contractions).

This system can be applied in either home or clinical settings to:

- Aid in the prevention of DVT
- Enhance blood circulation
- Diminish post-operative pain and swelling
- Reduce wound healing time
- Aid in the treatment of: stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency and reduction of edema in the lower limbs
- As a prophylaxis for DVT by persons expecting to be stationary for long periods of time

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.

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510K Summary

**Submitter:**
Suzhou Minhua Medical Apparatus Supplies Co. Ltd.
No.789, Wu Fang Road, Friendship Industrial Zone, Song Ling Town,
Wu Jiang District, Su Zhou City, Jiangsu Province, China
Postal Code: 215222

Tel:  +86-0512-63091066

Contact Person:  Alex Wang
Date Prepared: Jan 15, 2018

**Device:**
Common Names:  Intermittent Pneumatic Compression Device
Proprietary Name:  Venera™ 508 Deep Vein Thrombosis Prevention System
Regulatory Class:  II
Product Code:  JOW

**Predicate Devices:**
The Venera 508 Deep Vein Thrombosis Prevention System is equivalent to the following:

<table>
<thead>
<tr>
<th>Predicate Device</th>
<th>Manufacturer</th>
<th>510(k)#</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cirona 6300 Deep Vein Thrombosis(DVT) Prevention System</td>
<td>Devon Medical Products</td>
<td>K151189</td>
</tr>
</tbody>
</table>

**Device Description**
The Venera™ 508 Deep Vein Thrombosis Prevention System is an easy to use portable pneumatic compression system that noninvasively helps prevent the onset of DVT in patients by
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simulating blood flow in the extremities (simulating muscle contractions). The Venera 508 system consists of a pair of pump and cuff assemblies. The device will alternatively inflate and deflate the garment (cuff) to stimulate blood flow in the extremities (muscle contraction). The device provides a 50mmHg pressure and followed by 50 seconds of deflation period once it reaches the desired pressure.

Indications for Use:
The Venera™ 508 Deep Vein Thrombosis Prevention System is a portable treatment system intended to help prevent the onset of DVT in patients by stimulating blood flow in the extremities (simulating muscle contractions).

This system can be applied in either home or clinical settings to:
- Aid in the prevention of DVT
- Enhance blood circulation
- Diminish post-operative pain and swelling
- Reduce wound healing time
- Aid in the treatment of: stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency and reduction of edema in the lower limbs
- As a prophylaxis for DVT by persons expecting to be stationary for long periods of time

Technological Characteristics:
Below is a table of comparison for the technological characteristics against the predicate device:

<table>
<thead>
<tr>
<th>Predicate</th>
<th>Cirona 6300 DVT System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indication for Use</td>
<td>S</td>
</tr>
<tr>
<td>Components</td>
<td>S</td>
</tr>
<tr>
<td>Material</td>
<td>SE</td>
</tr>
<tr>
<td>Biocompatibility</td>
<td>SE</td>
</tr>
<tr>
<td>Principle of Operation</td>
<td>SE</td>
</tr>
<tr>
<td>Treatment parameters</td>
<td>S</td>
</tr>
<tr>
<td>User Interface</td>
<td>S</td>
</tr>
</tbody>
</table>

*SE – Substantial Equivalent    *S - Same
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The manufacturer believes that the technological characteristics of the Venera™ 508 Deep Vein Thrombosis Prevention System are substantially similar to those of the predicate device. Venera 508 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:

<table>
<thead>
<tr>
<th>Function Performance Tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pressure Accuracy Test Report</td>
</tr>
<tr>
<td>Pressure Switch Test Report</td>
</tr>
<tr>
<td>Venera 508 Cycle Time Test Report</td>
</tr>
<tr>
<td>Alarm Function Test Report</td>
</tr>
<tr>
<td>Battery Life Test Report</td>
</tr>
</tbody>
</table>

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

Biocompatibility

Biocompatibility test evaluation for Venera 508 DVT Prevention System is done in accordance to the FDA Good Laboratory Practice guidelines. The following tests were done:

- Cytotoxicity
- Sensitization
- Irritation

Sterilization and Shelf Life

Sterilization and shelf life are not applicable to Venera 508 DVT Prevention System.

Electrical Safety and Electromagnetic Compatibility (EMC)

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

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- IEC 60601-1-11: 2015 Medical electrical equipment Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

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 508 Deep Vein Thrombosis Prevention System is substantially equivalent in its intended use, technology, function, operating parameters to predicate devices that are currently commercially available and in distribution, and does not raise any new concerns regarding safety or effectiveness.