DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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July 11, 2017

Devon Medical Products (Jiangsu) Ltd.
Julian Chu
Plant Manager
East Half of 1-2f, Appt D2, 1, Qingfeng Road.
Nantong, 226017
China

Re: K170814
Trade/Device Name: Devon 24 Deep Vein Thrombosis Prevention Therapy System
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: April 11, 2017
Received: April 12, 2017

Dear Julian Chu:

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,

Nicole G. Ibrahim -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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)*
K170814

Device Name

Devon 24 Deep Vein Thrombosis Prevention Therapy System

Indications for Use *(Describe)*

The Devon 24 deep vein thrombosis prevention system is intended to be an easy to use portable system, prescribed by a physician, to help prevent the onset of DVT in patients by stimulating blood flow in the extremities (simulating muscle contractions).
This device can be used in the 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.

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Section 5

510K Summary

Submitter:

Devon Medical Products (Jiangsu) Ltd.

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Nantong, Jiangsu, CHINA 226017

Phone: 011-86-531-51080927

Fax: 011-86-531-51080928

Contact Person: Julian Chu

Date Prepared: June 13, 2017

Device:

Common Names: Intermittent Pneumatic Compression Device

Proprietary Name: Devon 24 Deep Vein Thrombosis Prevention Therapy System

Regulation Number: 21 CFR 870.5800

Classification Name: Compressive Limb Sleeve

Regulatory Class: II

Product Code: JOW

Predicate Devices:

The Devon 24 Deep Vein Thrombosis Prevention Therapy System is equivalent to the following:

Predicate Device	Manufacturer	510(k)#
Cirona 6300	Devon Medical Products	K151189

Section 5

Device Description

Premarket notification device:

Devon 24 Deep Vein Thrombosis Prevention Therapy System

The Devon 24 deep vein thrombosis prevention therapy system (referred as Devon 24 below) is an easy to use portable pneumatic compression system that noninvasively helps prevent the onset of DVT in patients by stimulating blood flow in the extremities (simulating muscle contractions). The Devon 24 system consists of a pair of pumps and sleeve assemblies.

The device will alternatively inflate and deflate the garment (sleeve) to stimulate blood flow in the extremities (muscle contraction). The device provides a 40mmHg pressure and followed by a deflation period once it reaches the desired pressure, each cycle time is 50 seconds.

Intended Use:

The Devon 24 deep vein thrombosis prevention system is intended to be an easy to use portable system, prescribed by a physician, to help prevent the onset of DVT in patients by stimulating blood flow in the extremities (simulating muscle contractions).

This device can be used in the 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

Section 5

Technological Characteristics:

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

Predicate	Cirona 6300
Indication for Use	S
Components	S
Material	S
Biocompatibility	S
Principle of Operation	SE
Pressure	D
User Interface	S

*SE – Substantial Equivalent *S – Same *D - Different

The manufacturer believes that the technological characteristics of the Devon 24 Disposable Deep Vein Thrombosis Prevention System are substantially similar to those of the predicate device. Devon 24 has very similar components to its predicate devices and very similar 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:

Function Performance Tests	
TR63.J001	Pressure Accuracy Test Report
TR63.J002	Pressure Sensor Calibration Test Report
TR63.J003	Devon 24 Cycle Time Test Report
TR63.J004	Alarm Function Test Report
TR63.J005	Battery Life Test Report
TR63.J006	Devon 24 Garment Burst Testing Report

The conclusions drawn from the performance tests demonstrate that the device is performing as intended, and is substantially equivalent to the predicate.

Biocompatibility

The Devon 24 uses the exact same sleeve material as its predicate, in the same direct body contact method, and manufactured by the same manufacturer, so new biocompatibility testing was not run. The predicate device underwent the biocompatibility test evaluation in accordance with the FDA Good Laboratory Practice. The following tests were done:

- Cytotoxicity
- Sensitization
- Irritation

Sterilization and Shelf Life

Sterilization and shelf life is not applicable to Devon 24.

Electrical Safety and Electromagnetic Compatibility (EMC)

EMC tests were conducted according to the following standards:

- IEC 60601-1: 2005+C1:2006+C2:2007+A1:2012 Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2014 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 Medical electrical equipment Part 1-6: General requirements for safety - Collateral Standard: Usability including IEC 62366: Application of usability engineering to medical devices
- 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

Section 5

Software Verification and Validation

Software verification and validation was 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 result in serious injury to the patient or operator.

Animal Study and Clinical Study

No animal study or clinical study was conducted.

Statement of Substantial Equivalence

The Devon 24 Disposable Deep Vein Thrombosis Prevention Therapy System is substantially equivalent in technology, function, operating parameters, and intended use to predicate devices that are currently commercially available and in distribution, and does not raise any new questions of safety or effectiveness.