November 27, 2017

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

Re: K172030
Trade/Device Name: Devon 51 Sequential Compression Device
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: October 25, 2017
Received: October 25, 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.

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.

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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172030

Device Name
Devon 51 Sequential Compression Device

Indications for Use *(Describe)*
The Devon 51 Series Sequential Compression Device is a compression device based on sequential pneumatic Compression technique which is intended for the treatment of the following conditions:

- Lymphedema
- Venous stasis ulcers
- Venous insufficiency
- Peripheral edema

The device is intended for both home and hospital use.

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

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Contact Person: Julian Chu

Date Prepared: October 30, 2017

Device:

Common Names: Sequential Pneumatic Compression Device

Proprietary Name: Devon 51 Sequential Compression Device

Regulation Number: 21 CFR 870.5800

Classification Name: Compressive Limb Sleeve

Regulatory Class: II

Product Code: JOW

Predicate Devices:

The Devon 51 Sequential Compression Device is equivalent to the following:

Predicate Device	Manufacturer	510(k)#
CircuFlow 5200	Devon Medical Products	K101523

Device Description

Premarket notification device:

Devon 51 Sequential Compression Device

Section 5

The Devon 51 Sequential Compression device is a gradient compression pneumatic device used for treatment and management of venous or lymphatic disorders. The application of gradient compression is effective by increasing blood flow and encouraging extracellular fluid clearance. The system consists of a pump and a pair of four-chambered garments. The garments are available in different types and sizes. The pump provides cycles of compressed air at certain adjustable pressures and which sequentially inflates the garment from distal to proximal. When activated, air flows into the garment chambers, and the pump provides gradient pressurization to the chambers (with distal chambers inflated to a greater pressure than the proximal ones.)

After each chamber is inflated, the pressure is held constant until all chambers are inflated in order to prevent reverse gradient flow. Once all chambers are inflated, they are then all released simultaneously, and the cycle repeats until the set therapy time is reached.

Indication for Use:

The Devon 51 Series Sequential Compression Device is a compression device based on sequential pneumatic compression technique which is intended for the treatment of the following conditions:

- Lymphedema
- Venous stasis ulcers
- Venous insufficiency
- Peripheral edema

The device is intended for both home and hospital use.

Technological Characteristics:

The manufacturer believes that the technological characteristics of the Devon 51 Sequential Compression Device are substantially equivalent to those of the predicate device. Devon 51 has very similar components to its predicate devices and very similar principles of operation. The device consists of an electrically generated source of compressed air, tubing to convey the pressurized air to the sleeve, like the predicates, pressure is applied cyclically for a specified period of time according to the physician's prescription.

Performance Tests

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

The following tests were conducted:

Function Performance Tests	
TR66.J002	Devon 51 Cycle Time Test Report
TR66.J004	Devon 51 Reverse Pressure Test Report
TR66.J006	Devon 51 Sleeve Integrity Test Report
TR66.J009	Devon 51 Treatment Time Test Report
TR66.J007	Devon 51 Pressure Sensor Calibration Test 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 51 uses the exact same garment material as its predicate, in the same direct body contact method, and manufactured by the same manufacturer. The medical device (Devon 51 Garments) in its final finished form is identical to CircuFlow 5200 garments in formulation, processing, and geometry and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents). Therefore, 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

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and 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

Statement of Substantial Equivalence

The Devon 51 Sequential Compression Device is substantially equivalent in technology, function, operating parameters, and indication for use to predicate devices that are currently commercially available and in distribution, and does not raise any new questions of safety or effectiveness.

Conclusions

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, Devon Medical Products believes that the Devon 51 Sequential Compression Device is substantially equivalent to the predicate device CircuFlow 5200 (K101523) as described herein.