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FEB 2 8 2013

510(K) SUMMARY

Submitter:

Devon Medical Products, Inc.

Contact Person:

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1100 First Avenue, Suite 202
King of Prussia, PA 19406
Phone: 610.757.4103
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Common Classification & Proprietary Names:

Common Names: Sequential Compression Device

Proprietary Name: CircuFlow™ 5150

Date Prepared:

October 31rd, 2012

Classification

The classification name, 21 CFR Part and Paragraph number, product code and classification of the CircuFlow™ 5150.

Classification Name	21 CFR Section	Product Code	Class
Compressible Limb Sleeve	870.5800	JOW	II

Predicate Devices:

The CircuFlow™ 5150 Sequential Compression Device is substantially equivalent to the following.

Predicate Device	Manufacturer	510(k)#
CircuFlow™ 5200	Devon Medical, Inc.	K101523
CircuFlow™ 5100	Devon Medical, Inc.	K100446

Device Description

The CircuFlow™ 5150 is a digitally controlled sequential pneumatic compression device designed to apply compression to a limb. The CircuFlow™ 5150 enables different treatment pressures and treatment times that should be used according to physician prescription. When activated, air flows into the garment chambers, and the pump provides gradient pressurization to the chambers (sequential inflation of distal to proximal, 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

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prevent reverse gradient flow. Once all chambers are inflated, they are then all released simultaneously, and the cycle repeats. Pressure within in the first chamber can be programmed, with each successive chamber having its pressure be 7% less than the previous chamber.

Intended Use:

The CircuFlow™ 5150 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 CircuFlow™ 5150 are substantially equivalent to those of the predicate devices.

The CircuFlow™ 5150 has very similar components to its predicate devices and has 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 Testing

Bench and laboratory testing was performed and assures that the product meets its specifications. The manufacturer believes that the technological characteristics of the CircuFlow™ 5150 are substantially similar to those of the predicate devices. The performance testing includes the following tests:

List of Performance Tests	
Test 1	Pressure Accuracy Test
Test 2	Cycle Time Test
Test 3	Reverse Pressure Test
Test 4	Treat Time Performance
Test 5	Pressure Sensor Calibration Test
Test 6	Sleeve Integrity Test
Test 7	Treat Time Test

Standards

The CircuFlow™ 5150 conforms to the following standards:

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IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2 Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard:
AAMI ES 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 14971 Medical devices - Application of risk management to medical devices

Statement of Substantial Equivalence

The CircuFlow™ 5150 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.

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 CircuFlow™ 5150 is substantially equivalent to the predicate devices as described herein.

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

February 28, 2013

Devon Medical Inc.
c/o Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, MN 55313

Re: K123959
Trade/Device Name: CircuFlow 5150 Sequential Compression Device
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: February 15, 2013
Received: February 19, 2013

Dear Mr. Job:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Matthew G Hillebrenner

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

Enclosure

SECTION 4

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K123959

Device Name: CircuFlow™ 5150 Sequential Compression Device

Indications for Use:

The CircuFlow™ 5150 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.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Matthew G. Hillebrenner