K100446

SECTION 5

MAR - 5 2010

510(K) SUMMARY

Submitter:

Devon Medical, Inc.

Contact Person:

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1100 First Avenue, Suit 100
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Common Classification & Proprietary Names:

Common Names: Sequential Compression Device
Proprietary Name: CircuFlow 5100

Date Prepared:

December 31st 2009

Classification

The classification name, 21 CFR Part and Paragraph number, product code and classification of the CircuFlow 5100.

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

Predicate Devices:

The CircuFlow 5100 Sequential Compression Device is substantially equivalent to the following.

Predicate Device	Manufacturer	510(k)#
SC-3008 Sequential Circulator	Bio Compression Systems Inc.	K043423
GS-128 Sequential Compression System	MedMark Technologies	K050584

Device Description

The CircuFlow 5100 is a sequential pneumatic compression device designed to apply compression to a limb. The device is composed of two components:

- Pneumatic manual pump
- Limb sleeve or garment composes of 4 chambers

The CircuFlow 5100 enables different treatment pressures (0-120mmHg) and treatment times (30 minutes to continue) that should be used according to physician prescription. When activated, air flows into chamber, 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 prevent reverse gradient flow. Once all chambers are inflated, they are then all released simultaneously, and the cycle repeats. Pressure within chambers are adjustable –pressure to chamber 1 is controlled by user-adjusted regulator on the pump. Pressure in chambers 2, 3 & 4 are individually lowered according to the default factory settings.

A calibrated dial gauge displays pressure in the range of 0-200 mmHg.

Garments are available in 8 sizes, and custom garments are available in variations from standard sizes.

Intended Use:

The CircuFlow 5100 is a sequential gradient compression pneumatic device, intended for the primary or adjunctive treatment of primary or secondary lymphedema. The device is also intended for the additional or alternate treatment of venous insufficiency, and chronic venous static ulcers associated with venous insufficiency, as well as general treatment of swelling of the extremities. The device is intended for home or hospital use.

Technological Characteristics:

The manufacturer believes that the technological characteristic of the CircuFlow 5100 are substantially similar to those of the predicate devices.

The CircuFlow 5100 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 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 5100 are substantially similar to those of the predicate devices. The performance testing includes the following tests:

Electrical Safety Tests
Dielectric Strength Test
Leakage Current Test
Gradient Performance Test
Garment Tests
Pressure Performance Test
Tensile Strength Test
Material Biocompatibility Tests
Cytotoxicity Test
Sensitization Test
Irritation and Intracutaneous Reactivity Test

SECTION 5

Standards

The CircuFlow 5100 conforms to the following standards:

IEC 60601-1-1

IEC 60601-1-2

UL 60601-1

ISO 10993

ISO 14971

Statement of Substantial Equivalence

The CircuFlow 5100 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 Inc, believes that the CircuFlow 5100, is safe and effective and 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 Room W-O66-0609
Silver Spring, MD 20993-0002

MAR - 5 2010

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

Re: K100446
Circuflow 5100 Sequential Compression Device
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: February 16, 2010
Received: February 17, 2010

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,

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): K100446

Device Name: the Devon CircuFlow 5100 Sequential Compression Device

Indications for Use:

The CircuFlow 5100 Sequential Compression Device is a manual, sequential, pneumatic compression device, intended for the primary or adjunctive treatment of primary or secondary lymphedema. The device is also intended for the additional or alternate treatment of venous insufficiency, and chronic venous stasis ulcers associated with venous insufficiency, as well as general treatment of swelling of the extremities.
The device is intended for home or 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)

(Division Sign-Off)
Division of Cardiovascular Devices

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