

510(K) SUMMARY

JUL 0 1 2013

Submitter:

Devon Medical, Inc.

Contact Person:

Ruth Wu, COO
 1100 First Avenue, Suite 202
 King of Prussia, PA 19406
 Phone: 610.757.4103
 Fax: 610.930.4035

Common Classification & Proprietary Names:

Common Names: Intermittent Pneumatic Compression Device
 Proprietary Name: Cirona™ DVT Foot Garment

Date Prepared:May 20th, 2013**Classification**

The classification name, 21 CFR Part and Paragraph number, product code and classification of the Cirona™ DVT Foot Garment.

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

Predicate Devices:

The Cirona Deep Vein Thrombosis Prevention Therapy Foot Garment is substantially equivalent to the following.

Predicate Device	Manufacturer	510(k)#
HEALTHCARE SERVICE AND SUPPLY PVA/ALP FOOT GARMENT	Healthcare Service and Supply	K964188
Devon Cirona 6100 DVT Prevention System	Devon Medical, Inc	K130571

Device Description

The Cirona™ deep vein thrombosis prevention therapy foot garment is intended to be used with Devon Cirona™ 6100 deep vein thrombosis prevention system (K130571). The Cirona™ deep vein thrombosis prevention foot garment is a pair of single patient reusable soft compression garment(s) (sleeves), that consists of a brushed nylon outer material bonded to a foam inner liner. An inflatable polyvinylchloride (PVC) pressure bladder is encapsulated in an additional foam material. The patient

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contact material is polyurethane foam and the extension tubing set connects to the garment on one end through quick connectors and to the pump on the other end. It is intended to be used noninvasively helps reduce the incidence of deep vein thrombosis, a potentially life threatening condition.

The FDA cleared Cirona™ 6100 system (K130571) consists of a pump, a pair of single patient reusable soft compression garment(s) (sleeves), and the extension tubing set for calf and calf-thigh. This submission is for the new Cirona DVT Foot Garment which will be used in conjunction with the Cirona 6100 system. The device will alternatively inflate the two garments and mimic the natural walking pace in order to enhance circulation. The device supplied compression provides a 60-second automatically timed cycle consisting of an approximately 12-second inflation period followed by a 48-second period of relaxation. A pressure of 40mm Hg is used for all applications. This pressurization enhances venous flow and fibrinolytic activity in order to ultimately prevent early blood clotting.

Intended Use:

The Cirona™ DVT Prevention Therapy Foot Garment is a prescription device intended to be used preventatively to increase venous blood flow in patients at risk of deep vein thrombosis due to the associated risk factors for thrombus formation during: trauma, critical care, general medicine, general surgery, as well as neurological, orthopedic, urologic, obstetric conditions and treatments.

Contraindications:

The Cirona™ DVT Prevention Therapy Foot Garment should NOT be used in the following conditions:

- Severe atherosclerosis or other ischemic vascular diseases
- Suspected or known acute deep vein thrombosis
- Severe congestive cardiac failure
- Existing pulmonary edema
- Existing pulmonary embolism
- Extreme deformity of the limbs
- Any local skin or tissue condition in which the garments would interfere:
 - Gangrene
 - Untreated or infected wounds
 - Recent skin graft
 - Dermatitis
- Known presence of malignancy in the legs
- Limb infections, including cellulitis, that have not received antibiotic coverage
- Presence of lymphangiosarcoma

Technological Characteristics:

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The manufacturer believes that the technological characteristics of the Cirona™ DVT Prevention Therapy Foot Garment are substantially equivalent to those of the predicate devices.

The Cirona™ DVT Foot Prevention Therapy Garment has the same components to its predicate devices and has very similar principles of operation. The material used in the foot garment is identical to previously FDA cleared Devon Cirona garments (K130571). The device consists of an electrically generated source of compressed air; tubing to convey the pressurized air to the sleeve and, like the predicates, pressure is applied cyclically for 12 seconds inflated and 48 seconds deflated. The pressure delivered is 40mmHg.

Performance Testing

Various bench and laboratory testing were performed and they assure that the product meets its specifications. The sleeve bladder burst test was performed to ensure sleeves are structurally sound during treatment and all sleeves tested maintained structural integrity at the highest pressure setting for anticipated maximum treatment time. The device passed all the tests listed below. The manufacturer believes that the technological characteristics of the Cirona™ DVT Prevention Therapy Foot Garment are substantially equivalent to those of the predicate devices. The performance testing includes the following tests:

List of Performance Tests	
Test 1	Pressure Accuracy
Test 2	Cycle Time Test
Test 3	Alarm Function Test
Test 5	Sleeve Bladder Burst Test

Test Conclusion: Based on the specification for the Cirona DVT Prevention Therapy Foot Garment, for which substantially equivalency is claimed, there is no significant difference in the inflation, deflation and pressure hold time when used in conjunction with previously FDA cleared Devon Cirona 6100 DVT Prevention Therapy System (K130571). At the end of the sleeve bladder burst test, all samples continued to function in the original and intended manner and structure integrity was well maintained. This indicates that the Foot Garment is safe to use.

Standards

The Cirona™ DVT Prevention Therapy Foot Garment conforms to the following standards:

ISO 14971:2007 Medical devices - Application of risk management to medical devices

ISO 10993-5:2009 Biological evaluation of medical devices, Part 5: Tests for in vitro cytotoxicity

ISO 10993-10: 2012 Biological evaluation of medical devices, Part 10: Tests for irritation and skin

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sensitization

ISO 10993-12: 2007 Biological evaluation of medical devices, Part 12: Biological evaluation of medical devices, Part 12: Sample preparation and reference materials

ANSI/ASQ Z1.9-2008 American National Standard: Sampling procedures and Tables for inspection by variables for percent nonconforming

Statement of Substantial Equivalence

The Cirona™ DVT Prevention Therapy Foot Garment 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 Cirona™ DVT Prevention Therapy Foot Garment, is substantially equivalent to the predicate devices as described herein.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 1, 2013

Devon Medical Inc.
c/o Mr. Mark Job
1394 25th Street NW
Buffalo MN 55313

Re: K131743

Trade/Device Name: Cirona 6100 Deep Vein Thrombosis Prevention Therapy Foot Garment
Regulation Number: 21 CFR 870.5800
Regulation Name: Compression Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: June 17, 2013
Received: June 18, 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

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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 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>. 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,



for

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

Enclosure

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INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K131743

Device Name: Cirona™ 6100 Deep Vein Thrombosis Prevention Therapy Foot Garment

Indications for Use:

The Cirona™ DVT Prevention Therapy Foot Garment is a prescription device intended to be used preventatively to increase venous blood flow in patients at risk of deep vein thrombosis due to the associated risk factors for thrombus formation during: trauma, critical care, general medicine, general surgery, as well as neurological, orthopedic, urologic, obstetric conditions and treatments.

Prescription Use X AND/OR
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use
(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)

