510(K) SUMMARY

JUN 27 2014

Submitter:

Devon Medical Products

Contact Person:

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King of Prussia, PA 19406
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Common Classification & Proprietary Names:

Common Names: Intermittent Pneumatic Compression Device
Proprietary Name: Cirona™ 6200

Date Prepared:

Apr 16th, 2014

Classification

The classification name, 21 CFR Part and Paragraph number, product code and classification of the Cirona™ 6200.

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

Predicate Devices:

The Cirona 6200 Deep Vein Thrombosis Prevention Therapy System is substantially equivalent to the following.

Predicate Device	Manufacturer	510(k)#
Cirona 6100	Devon Medical Products	K130571
RESTEP DVT SYSTEM, MODEL RSP-101	STORTFORD MEDICAL LLC	K090308
Flowtron Universal AC600	HNE HEALTHCARE, INC	K010744

Device Description

The Cirona™ 6200 Series deep vein thrombosis prevention system is a pneumatic compression device that noninvasively helps reduce the incidence of deep vein thrombosis, a potentially life threatening condition.

The Cirona™ 6200 Series system consists of a device and a pair of soft compression garment(s) (sleeves) and the extension tubing set for the calf, calf-thigh, and foot. 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 40mmHg is used for the calf and calf-thigh treatments, where a pressure of 120mmHg is used for the foot treatment.

This pressurization enhances venous flow and fibrinolytic activity in order to ultimately prevent early blood clotting.

Intended Use:

The Cirona™ 6200 Series system 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™6200 system** 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 embolisms
- 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:

The manufacturer believes that the technological characteristics of the Cirona™ 6200 are substantially equivalent to those of the predicate devices.

The Cirona™ 6200 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 and, like the predicates, pressure is applied cyclically for 12 seconds inflated and 48 seconds deflated. A pressure of 40mmHg is used for the calf and calf-thigh treatments, where a pressure of 120mmHg is used for the foot treatment.

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 Cirona™ 6200 are substantially equivalent to those of the predicate devices. The performance tests are included in section 18 Bench Test.

List of Performance Tests	
Test 1	Cirona 6200 System Level Software Test
Test 2	Cirona 6200 Pressure Accuracy
Test 3	Cirona 6200 Cycle Time Test
Test 4	Cirona 6200 Alarm Function Test
Test 5	Cirona 6200 Foot Bladder Burst
Test 6	Cirona 6200 Battery Depreciation Test

Standards

The Cirona™ 6200 conforms to the following standards:
IEC 60601-1:2005 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2007 Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard:
AAMI ES 60601-1: 2005 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN ISO 14971:2012 Medical devices - Application of risk management to medical devices

Statement of Substantial Equivalence

The Cirona™ 6200 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 6200, 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

June 27, 2014

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

Re: K141578
Trade/Device Name: Cirona 6200 Deep Vein Thrombosis Prevention System
Regulation Number: 21 CFR 870.5800
Regulation Name: Compression Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: June 11, 2014
Received: June 13, 2014

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 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" (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 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 yours,

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)*

K141578

Device Name

Cirona 6200 Deep Vein Thrombosis Prevention Therapy System

Indications for Use *(Describe)*

The Cirona 6200 Series system 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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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