



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

Devon Medical Products  
Steve Xu  
Regulatory Affairs Specialist  
1100 First Avenue, Suite 202  
King Of Prussia, Pennsylvania 19406

Re: K151189  
Trade/Device Name: Cirona 6300 Disposable Deep Vein Thrombosis (DVT) Prevention System  
Regulation Number: 21 CFR 870.5800  
Regulation Name: Compressible Limb Sleeve  
Regulatory Class: Class II  
Product Code: JOW  
Dated: August 7, 2015  
Received: August 10, 2015

Dear Steve Xu,

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" (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.

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,

A handwritten signature in black ink, appearing to read "M. D. Zuckerman". The signature is written in a cursive style and is positioned above the printed name.

for

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K151189

Device Name  
Cirona 6300 Disposable Deep Vein Thrombosis Prevention System

### Indications for Use (Describe)

The Cirona 6300 disposable deep vein thrombosis prevention system is intended to be an easy to use portable system, prescribed by a physician, to help prevent the onset of DVT in patients by stimulating blood flow in the extremities (simulating muscle contractions).

This device can be used in the home or clinical settings to:

- Aid in the prevention of DVT
- Enhance blood circulation
- Diminish post-operative pain and swelling
- Reduce wound healing time
- Aid in the treatment of: stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency and reduction of edema in the lower limbs
- As a prophylaxis for DVT by persons expecting to be stationary for long periods of time

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.

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**510K Summary****Submitter:**

Devon Medical Products

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King of Prussia, PA 19406

Phone: 610.757.4127

Fax: 610.930.4035

Contact Person: John Siegel, COO

Date Prepared: September 18, 2015

**Device:**

Common Names: Intermittent Pneumatic Compression Device

Proprietary Name: Cirona™ 6300 Disposable Deep Vein Thrombosis Prevention System

Regulatory Class II

Product Code: JOW

**Predicate Devices:**

The Cirona 6300 Deep Vein Thrombosis Prevention System is equivalent to the following:

Predicate Device	Manufacturer	510(k)#
Vena Pro	Innovamed Health LLC	K133274

**Device Description**

Premarket notification device:

Cirona 6300 Disposable Deep Vein Thrombosis Prevention System

The Cirona™ 6300 disposable deep vein thrombosis prevention system (refer as Cirona 6300 below) is an easy to use portable pneumatic compression system that noninvasively helps prevent the onset of DVT in patients by simulating blood flow in the extremities (simulating muscle contractions). The Cirona 6300 system consists of a pair of pump and sleeve assemblies.

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The device will alternatively inflate and deflate the garment (sleeve) to stimulate blood flow in the extremities (muscle contraction). The device provides a 50mmHg pressure and followed by 50 seconds of deflation period once it reaches the desired pressure.

### **Intended Use:**

The Cirona 6300 disposable deep vein thrombosis prevention system is intended to be an easy to use portable system, prescribed by a physician, to help prevent the onset of DVT in patients by stimulating blood flow in the extremities (simulating muscle contractions).

This device can be used in the home or clinical settings to:

- Aid in the prevention of DVT
- Enhance blood circulation
- Diminish post-operative pain and swelling
- Reduce wound healing time
- Aid in the treatment of: stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency and reduction of edema in the lower limbs
- As a prophylaxis for DVT by persons expecting to be stationary for long periods of time

### **Technological Characteristics:**

Below is a table of comparison for the technological characteristics against the predicate device:

<b>Predicate</b>	<b>Innovamed Vena Pro</b>
Indication for Use	S
Components	S
Material	SE
Biocompatibility	SE
Principle of Operation	SE
Pressure	S
User Interface	S

\*SE – Substantial Equivalent

\*S - Same

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The manufacturer believes that the technological characteristics of the Cirona 6300 Disposable Deep Vein Thrombosis Prevention System are substantially similar to those of the predicate device. Cirona 6300 has very similar components to its predicate devices and very similar principles of operation.

### **Performance Tests**

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

The following tests were conducted:

Function Performance Tests	
TR36.0001	Pressure Accuracy Test Report
TR36.0002	Pressure Switch Test Report
TR36.0003	Cirona 6300 Cycle Time Test Report
TR36.0004	Alarm Function Test Report
TR36.0005	Battery Life Test Report
TR36.0010	Cirona 6300 Garment Burst Testing Report

The conclusions drawn from the performance tests demonstrate that the device is performing as intended, and is substantially equivalent to the predicate.

### **Biocompatibility**

Biocompatibility test evaluation for Cirona 6300 is done in according to the FDA Good Laboratory Practice. The following tests were done:

- Cytotoxicity
- Sensitization
- Irritation

### **Sterilization and Shelf Life**

Sterilization and shelf life is not applicable to Cirona 6300.

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### **Electrical Safety and Electromagnetic Compatibility (EMC)**

EMC tests were conducted according to the following standards:

- IEC 60601-1: 2005+C1:2006+C2:2007 Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2007 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: 2010 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

### **Software Verification and Validation**

Software verification and validation was conducted and documentation is provided. The software was considered as a “moderate” level of concern, since a failure or latent flaw in the software could directly result in serious injury to the patient or operator.

### **Animal Study and Clinical Study**

No animal study or clinical study was conducted.

### **Statement of Substantial Equivalence**

The Cirona 6300 Disposable Deep Vein Thrombosis Prevention System 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.