Section 8: 510(k) Summary

Aircast® VenaFlow® Elite System

JUL - 9 2009

510(k) Number K091700

Applicant's Name:

DJO, LLC
1430 Decision Street
Vista, CA 92081

Contact Person:

Christine Otis
Senior Regulatory Affairs Specialist
Phone: 760-734-3504
Fax: 760-734-5544
E-mail: christine.otis@djoglobal.com

Trade Name:

Aircast VenaFlow Elite System

Classification Name:

Compressible Limb Sleeve

Classification:

Compressible Limb Sleeves have been classified as Class II, 74J--OW. Regulation number 21 CFR 870.5800, Cardiovascular Devices.

Device Description:

The Aircast VenaFlow Elite System is a prescription only, intermittent pneumatic compression device design to apply rapid inflation with graduated sequential compression to a patient's calf, thigh or foot for the purpose of assisting blood flow in the veins. This rapid inflation and graduated, sequential compression device accelerates venous velocity and enhances fibrinolysis. The Aircast VenaFlow Elite System provides the user with an option of battery operation in addition to operation from the mains power. The Aircast VenaFlow Elite System is easy to use and provided the user with several cuff type options: calf, thigh and foot as well as combined compression of any combination of two cuffs.

Indications for Use:

The Aircast VenaFlow Elite System is indicated as a prophylaxis for deep vein thrombosis (DVT).

Intended Use:

The Aircast VenaFlow Elite System is an intermittent pneumatic compression device that is intended to apply intermittent application of pressure to a patient's calf, thigh or foot for the purpose of assisting blood flow in the veins.

Contraindications:

The VenaFlow Elite System should not be used by persons with known or suspected deep vein thrombosis, severe congestive heart failure, pulmonary edema, thrombophlebitis, severe arteriosclerosis or active infection. Do not use on extremities which are not sensitive to pain, where cuff will interfere with gangrene, on patients with vein ligation or recent skin grafts, or extreme deformity of the leg. Do no use the VenaFlow Elite System where increased venous or lymphatic return is undesirable.

Substantial Equivalence:

The modified Aircast VenaFlow System (e.g., Elite) is substantially equivalent in all aspects (technological characteristics, modes of operation, performance characteristics, intended use, etc. to the previously cleared Aircast VenaFlow System. The modified system provides an optional battery operation configuration.

The pressure profile of the new Aircast VenaFlow Elite System is similar to the previously cleared Aircast VenaFlow System. Additionally, the energy type and design and software modifications were verified through bench testing and validated through clinical analysis that was performed on healthy volunteers.

Test results demonstrate that the new Aircast VenaFlow Elite System performs according to its predetermined specifications in a safe and effective manner.

Performance Data:

Safety and performance testing including bench testing and clinical comparison between the previously cleared Aircast VenaFlow System and the modified device (e.g., Aircast VenaFlow Elite System) demonstrates that the modified system is substantially equivalent to the previously cleared device (predicate) and does not raise any new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 9 2009

DJO, LLC
c/o Ms. Christine Otis
Senior Regulatory Affairs Specialist
1430 Decision Street
Vista, CA 92081

Re: K091700
Aircast VenaFlow Elite System
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: June 5, 2009
Received: June 10, 2009

Dear Ms. Otis:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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): K091700

Device Name: Aircast VenaFlow Elite System

Indications for Use: Prophylaxis for Deep Vein Thrombosis (DVT)

Prescription Use X AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochniak

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K091700