510(k) SUMMARY

510(k) Notification: K103113

FEB - 2 2011

GENERAL INFORMATION

Applicant:
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3270 Alpine Road
Portola Valley, CA 94028
U.S.A.
Phone: 650-646-3327
Fax: 650-854-4772

Contact Person:
Albert Boniske
Regulatory Affairs Project Manager
Experien Group, LLC
155-A Moffett Park Drive, Suite 210
Sunnyvale, CA 94089
U.S.A.
Phone: 408-400-0856
Fax: 408-400-0865

Date Prepared: October 18, 2010

DEVICE INFORMATION

The Vasculaire Compression System is an ambulatory, intermittent pneumatic compression system intended to provide sequential compression therapy to a patient's lower limbs. The Vasculaire Compression System includes three components: the Patient Sleeve, the Controller, and the Charger.

Classification:

Compressible Limb Sleeve, 21 CFR§870.5800

Product Code:

JOW

Trade Name:

Vasculaire Compression System

Generic/Common Name:

Compressible Limb Sleeve

PREDICATE DEVICE

Medical Compression Systems, ActiveCare®++ System (K060146)

510(k) SUMMARY

INDICATIONS FOR USE

The Vasculaire Compression System is indicated for use in:

- Preventing deep vein thrombosis (DVT)
- Enhancing blood circulation
- Diminishing post-operative pain and swelling
- Reducing wound healing time
- Treatment and assistance in healing: stasis dermatitis; venous stasis ulcers; arterial and diabetic leg ulcers
- Treatment of chronic venous insufficiency
- Reducing edema

PRODUCT DESCRIPTION

The Vasculaire Compression System is an ambulatory, intermittent pneumatic compression system intended to provide sequential compression therapy to a patient's lower limbs. The Vasculaire Compression System includes three components: the Patient Sleeve, the Controller, and the Charger.

The Patient Sleeve is a multiple-cell bladder intended to be attached directly to the patient's lower limb. It is intended to provide compression action to the tissue surrounding the venous vasculature in the foot and calf of a patient. The Controller is connected to the Patient Sleeve using two independent Flange Ports and can be mounted directly onto the Patient Sleeve for a completely ambulatory system. The Flange Ports allow the air from the Controller to control the compression action on the Calf and Foot Zones independently. The Controller is a lightweight (less than 1 lb), battery-powered, electromechanical control unit intended to provide and monitor the inflation cycle for enhanced circulation therapy.

SUBSTANTIAL EQUIVALENCE

The indications for use for the Vasculaire Compression System are substantially equivalent to the proposed indications for use for the predicate device. Any differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness. Thus, the Vasculaire System is substantially equivalent to the predicate device.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

There are no FDA performance standards established and required for the proposed device. All necessary bench and clinical testing was conducted on the Vasculaire System to support a determination of substantial equivalence to the predicate device. The pre-clinical testing performed included:

- Reliability testing of component interactions
- Physical bench testing including specification verification and transit testing
- Software verification and validation
- Electrical safety and electromagnetic compatibility testing
- Cytotoxicicity testing

SUMMARY

The Vasculaire Compression System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

FEB - 2 2011

Venous Health Systems, Inc.
c/o Mr. Albert Boniske
Regulatory Affairs Project Manager
Experien Group, LLC
155-A Moffett Park Drive, Suite 210
Sunnyvale, CA 94089

Re: K103113
Vasculaire Compression System
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: January 7, 2011
Received: January 10, 2011

Dear Mr. Boniske:

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): K103113

Device Name: Vasculaire Compression System

Indications For Use:

The Vasculaire Compression System is indicated for use in:

- Preventing deep vein thrombosis (DVT)
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- Treatment of chronic venous insufficiency
- Reducing edema

Prescription Use _X_ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use _____ (21 CFR Part 801 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
510(k) Number K103113