



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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December 09, 2015

Currie Medical Specialties, Inc.
Owen Bry
Director Of Quality Assurance
8758 Hellman Ave
Rancho Cucamonga, California 91730

Re: K151158
Trade/Device Name: ALP® VasQcare™ System
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: November 30, 2015
Received: December 1, 2015

Dear Owen Bry:

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 "Bram D. Zuckerman". The signature is written in a cursive style and is positioned above the typed 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)
K151158

Device Name
ALP® VasQcare™ System

Indications for Use (Describe)

The Alternating Leg Pressure® (ALP®) VasQcare™ System is a non-invasive system for reducing the incidence of deep vein thrombosis. The application of external intermittent pneumatic compression has six effects:

1. Increases blood flow velocity
2. Reduces the risk of deep vein thrombosis
3. Enhances blood circulation
4. Reduces pain and swelling
5. Reduces wound healing time
6. Aids in the treatment and healing of stasis dermatitis, venous stasis, arterial and diabetic leg ulcers, chronic vein insufficiency and reduction of edema in the lower limbs

The ALP® VasQcare™ System consists of a pump and a pair of single use calf sleeves. The pump provides intermittent cycles of compressed air, which alternately inflate the calf sleeves. The compression, when applied properly to the patient, increases blood velocity back to the heart and helps to prevent deep vein thrombosis.

The pump operates on timed cycles consisting of approximately 12 seconds of inflation where the calf sleeve compresses the limb followed by approximately 48 seconds of deflation where there is no pressure applied to the limb. Each limb compresses once per minute.

The ALP® VasQcare™ System may be used on patients at risk for developing deep vein thrombosis and in conjunction with medical therapy for high-risk patients.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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Section 11: 510(k) Summary

Submitters Name and Address:	Currie Medical Specialties, Inc. 8758 Hellman Avenue Rancho Cucamonga, CA 91730 Phone: (909) 912-0900 Fax: (909) 944-3030
FDA Registration Number:	2023637
Contact Person:	Craig Lynch, Director of Quality
Date Summary Prepared:	12/10/2015
Trade or Proprietary Name(s):	ALP® VasQcare™ System
Common Name:	Compression sleeve limb
Product Code:	JOW
Panel:	Cardiovascular
Regulation Number:	870.5800
Classification:	Class II
Predicate Device(s):	K112311 – Currie Medical Specialties, ALP 501RB System K133274 – Innovamed Health LLC, Vena Pro K061125 – Doctors Order, DVTcare CA5

Device Description:

Currie Medical Specialties (CMS) ALP® VasQcare™ System provides intermittent pneumatic pressure to a patient's leg for the prevention of deep vein thrombosis (DVT). When the compression sleeve is inflated, the veins collapse, which forces blood to move upward toward the heart. After compression is complete, the sleeves deflate which allows the veins to reopen and bring oxygenated blood to the calf. The VasQcare™ pump controller predicates the inflation and deflation sequence.

Intended Use:

The intended use of this device, as well as the predicate device, is to provide external limb compression in order to artificially imitate the pumping action of the leg muscles. This provides muscle contraction required by the venous return system, thereby helping to prevent venous stasis and subsequent thrombosis and embolism. The cyclic and alternating inflation and deflation of the garments closely simulates the normal healthy pumping action of the limb muscles to stimulate deep venous blood flow and the reactivation or increase in the body's fibrinolytic system.

This submission is intended for use of the pump at pressure levels of 45 mm Hg.

Indications for Use:

The Alternating Leg Pressure® (ALP®) VasQcare™ System is a non-invasive system for reducing the incidence of deep vein thrombosis. The application of external intermittent pneumatic compression has six effects:

1. Increases blood flow velocity
2. Reduces the risk of deep vein thrombosis
3. Enhances blood circulation
4. Reduces pain and swelling
5. Reduces wound healing time
6. Aids in the treatment and healing of stasis dermatitis, venous stasis, arterial and diabetic leg ulcers, chronic vein insufficiency and reduction of edema in the lower limbs

The ALP® VasQcare™ System consists of a pump and a pair of single use calf sleeves. The pump provides intermittent cycles of compressed air, which alternately inflate the calf sleeves. The compression, when applied properly to the patient, increases blood velocity back to the heart and helps to prevent deep vein thrombosis.

The pump operates on timed cycles consisting of approximately 12 seconds of inflation where the calf sleeve compresses the limb followed by approximately 48 seconds of deflation where there is no pressure applied to the limb. Each limb compresses once per minute.

The ALP® VasQcare™ System may be used on patients at risk for developing deep vein thrombosis and in conjunction with medical therapy for high-risk patients.

Technological characteristics of the ALP® VasQcare System:

The ALP® VasQcare™ System indications for use, fundamental scientific technology, overall design, materials, energy source, mode of operation, performance characteristics are similar and no different than the predicate devices.

Summary of Comparison Tests (Non-Clinical Tests):

Bench testing was conducted to ensure that the new design did not compromise the performance or safety and efficacy of the device in a manner that is substantially equivalent to that of the predicate devices.

Bench testing was conducted to demonstrate a electrical safety, EMC, mechanical integrity and environmental and life cycle testing has shown that the ALP® VasQcare™ has performance characteristics that are substantially equivalent to the predicate devices. The ALP®

VasQcare™ System and its accessories have been evaluated based on the requirements of IEC 60601-1-1, 60601-1-6 and 606061-1-11 (Appendix 8), which were confirmed by an accredited third-party.

Biocompatibility

Due to the materials used in the predicate device (K112311) and ALP® VasQcare™ System being identical to each other, biocompatibility of the ALP® VasQcare™ System is not affected.

Summary

Per the requirements of 21 CFR 807, clinical data, non-clinical bench testing and the information provided within this 510(k) pre-market submission, Currie Medical Specialties, Inc., concludes that the ALP® VasQcare™ System performs in a manner that is substantially equivalent to the predicate devices listed above.