



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

July 31, 2015

Advanced Vascular Dynamics  
Matthew Semler  
President  
4252 SE International Way, Suite F  
Milwaukie, Oregon 97222

Re: K151363

Trade/Device Name: Zephyr Vascular Compression Device  
Regulation Number: 21 CFR 870.4450  
Regulation Name: Vascular Clamp  
Regulatory Class: Class II  
Product Code: DXC  
Dated: May 15, 2015  
Received: May 21, 2015

Dear Mr. Semler:

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 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)

K151363

Device Name

Zephyr™ Vascular Compression Devices

Indications for Use (Describe)

The Zephyr™ Vascular Compression Devices are indicated for use by medical professionals to promote hemostasis following a catheterization or other puncture into a blood vessel in a patient's arm or leg, including: radial, brachial, dorsalis pedis, or tibial blood vessels, arterial or venous line or sheath removal, hemodialysis, and in anticoagulation therapy.

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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## 510(k) Summary

Submitter's name: Advanced Vascular Dynamics  
4252 SE International Way, Ste. F  
Milwaukie, OR 97222

Contact name and address: Matthew Semler, President  
4252 SE International Way, Ste. F  
Milwaukie, OR 97222  
(503-223-2333 ext. 382)

Date summary prepared: 23 July 2015

Device name:

Proprietary name: Zephyr™ Vascular Compression Devices  
Common or usual name: Vascular compression device  
Classification name: Vascular clamp (870.4450), Vascular clamp (DXC)

Legally marketed device for substantial equivalence comparison:

The predicate devices for this submission are the TR Band from Terumo International Systems (K070423), Vasc Band from Lepu Medical Technologies (K111831), and RadAR Vascular Compression Devices from Advanced Vascular Dynamics (K142122).

Description of the device:

The Zephyr™ Vascular Compression Devices are external compression devices deployed on a patient's arm or leg to promote hemostasis at a puncture site in a blood vessel. The Zephyr™ devices are single-use, sterile, individually pouched inflatable devices, deployed onto a skin surface by clinicians to help achieve hemostasis for vascular puncture sites in post-procedure patients. Zephyr is available in different lengths, with and without a separate cuff balloon. The strap measures approximately 1.5" x 8.25" (small) or 9.5" (large) and is composed of biocompatible multiple-layer PVC film and PVC tube, and a syringe and valve made of biocompatible thermoplastics. Hook and loop material is used to secure the strap in position. Only the PVC film comes into contact with broken skin.

Intended use of the device:

The Zephyr™ Vascular Compression Devices are indicated for use by medical professionals to promote hemostasis following a catheterization or other puncture into a blood vessel in a patient's arm or leg, including: radial, brachial, dorsalis pedis, or tibial blood vessels, arterial or venous line or sheath removal, hemodialysis, and in anticoagulation therapy.

Technological characteristics:

The device features of the Zephyr™ Vascular Compression Devices and the predicate TR Band Device and the Vasc Band are similar, in that all three are straps applied around a limb and use inflated balloons to apply compression to a limb, applying pressure to underlying vasculature. The RadAR predicate device also applies compression to a limb, using a mechanical means.

Testing conducted:

Zephyr Vascular Compression devices were subjected to inspections and tests to determine that the product met specifications.

Performance Testing:

Inflation of the Zephyr strap and cuff assemblies was verified and application of compression was verified.

Preclinical Testing:

Preclinical testing, including compression testing, deployment testing, inflation and deflation testing, syringe plunger force, syringe airflow testing, and syringe air volume testing was conducted to confirm the device would function as intended. All testing passed acceptance criteria and demonstrated that the performance of the Zephyr™ Vascular Compression Devices is equivalent to the predicate devices. Biocompatibility included cytotoxicity, sensitization, and irritation testing and was conducted in accordance with ISO 10993. All tests demonstrated the materials and processes used in the design and manufacture of the devices are non-cytotoxic, non-sensitizing and non-irritants.

Conclusion:

The Zephyr™ Vascular Compression Devices passed all testing and are substantially equivalent to the indicated predicate devices, base upon the preclinical testing.

The Zephyr™ Vascular Compression Devices are deemed suitable for the stated intended use.