K050146

MAY 27 2005

510(K) SUMMARY

Common/Usual Name:	Topical Hemostat/Vascular Clamp Accessory
Product Trade Name:	D-Stat Clamp Accessory
Classification Name:	Vascular Clamp, 21CFR 870.4450, product code DXC
Manufacturer:	Vascular Solutions, Inc. 6464 Sycamore Court Minneapolis, Minnesota 55369
Establishment Registration:	2134812
Contact:	Linda Busklein Sr. Regulatory Affairs Associate (763) 656-4217 phone (763) 656-4250 fax
Performance Standards:	No performance standards have been developed under section 514 for this device.
Device Description:	The D-Stat Clamp Accessory consists of a lyophilized pad containing thrombin, sodium carboxymethylcellulose, and calcium chloride secured to a compressible translucent pad and plastic base. The device is designed for attachment to several commercially available femoral access compression devices or as a standalone device. After hemostasis has been achieved, the lyophilized pad may be removed from the Clamp Accessory base, covered with a provided adhesive bandage, and left in place for up to 24 hours.
Intended Use:	The D-Stat Clamp Accessory is indicated for use with the Compressar Universal System (Advanced Vascular Dynamics) and the Femoral Artery Vascular Clamp (Pressure Products) compression devices or as a stand alone device to assist in the control of bleeding following catheterization or cannulation procedures. Following achieving hemostasis the D-Stat Dry Bandage may be detached from the D-Stat Clamp Accessory and left in place for up to 24 hours and is indicated for the control of surface bleeding from vascular access sites and percutaneous catheters or tubes.
Summary of Non-Clinical Testing:	Tests conducted included assessment of the ability to separate the lyophilized pad from the Clamp Accessory Base and a biocompatibility assessment of new materials.
Predicate Devices:	Vascular Solutions D-Stat Clamp Accessory (K040730) Vascular Solutions D-Stat Dry Hemostatic Bandage (K030836)
Conclusions:	The D-Stat Clamp Accessory is substantially equivalent to the currently marketed D-Stat Clamp Accessory and the D-Stat Dry Hemostatic Bandage based on a comparison of the indications for use and the technological characteristics of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 2005

Vascular Solutions, Inc.
c/o Ms. Linda Busklein
Sr. Regulatory Affairs Associate
6464 Sycamore Court
Minneapolis, MN 55369

Re: K050146
D-Stat Clamp™ Accessory
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II (Two)
Product Code: DXC
Dated: April 13, 2005
Received: April 14, 2005

Dear Ms. Busklein:

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 (301) 443-6597 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 Statement

510(k) Number: K050146

Device Name: **Vascular Solutions D-Stat Clamp Accessory**

Indications for Use:

The D-Stat Clamp Accessory is indicated for use with the Compressar Universal System (Advanced Vascular Dynamics) and the Femoral Artery Vascular Clamp (Pressure Products) compression devices or as a stand alone device to assist in the control of bleeding following catheterization or cannulation procedures. Following achieving hemostasis the D-Stat Dry Bandage may be detached from the D-Stat Clamp Accessory and left in place for up to 24 hours and is indicated for the control of surface bleeding from vascular access sites and percutaneous catheters or tubes."

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vedrine

(Division Sign-Off)
Division of Cardiovascular Devices

Number K050146