

JUN 18 2004

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS
K040730

Common/Usual Name: Topical Hemostat/Vascular Clamp

Product Trade Name: D-Stat Clamp™ Accessory

Classification Name: Vascular Clamp (21 CFR 870.4450)

Manufacturer: Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, Minnesota 55369

Establishment Registration: 2134812

Contact: Deborah L. Neymark
Vice President, Regulatory Affairs

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 foam pad and plastic base. The device is designed for attachment to several commercially available femoral access compression devices or as a standalone device.

D-Stat Clamp achieves its principal intended action (hemostasis) by creating a physical barrier to blood flow and facilitating wound compression. The thrombin contained in the lyophilized pad further facilitates hemostasis through enzymatic cleavage and conversion of fibrinogen to fibrin.

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 standalone device to assist in the control of bleeding following catheterization or cannulation procedures.

Summary of Non-Clinical Testing:

No additional non-clinical testing of this product for this use was conducted as it represents a slight modification of an existing product.

Summary of Clinical Testing:

No clinical evaluations of this product for this use have been conducted.

510(k) Summary of Safety and Effectiveness

K040730

Page 2

Predicate Devices:

D-Stat Dry Hemostatic Bandage (K030836)

CompressAR (K002767)

Femoral Artery Vascular Clamp (K964662 and K973216)

Femostop Compression System (K024107)

Conclusions:

The D-Stat Clamp is similar in design and function to the currently marketed D-Stat Dry Hemostatic Bandage, performs the same function as the disposable clamp components used with the CompressAR and Femoral Artery Vascular Clamp devices, and incorporates a hemostatic material like the Femostop Compression System. It may therefore be considered as substantially equivalent to the identified predicate devices.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Vascular Solutions, Inc.
c/o Ms. Deborah L. Neymark
V.P. Regulatory Affairs, Clinical Research and Quality Systems
6464 Sycamore Court
Minneapolis, MN 55369

Re: K040730
D-Stat Clamp™ Accessory
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II (two)
Product Code: DXC
Dated: May 4, 2004
Received: May 5, 2004

Dear Ms. Neymark:

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.

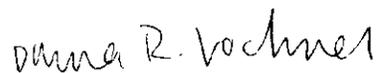
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 – Ms. Deborah L. Neymark

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 (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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/dsma/dsmamain.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 (if known): K040730

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 standalone device to assist in the control of bleeding following catheterization or cannulation procedures.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Lochner
(Division 510(k))
Division of Vascular Devices

510(k) number: K040730