K061219
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D-Stat Dry Hemostatic Bandage 510(k) Summary

OCT - 6 2006

Common/Usual Name: Topical Hemostat
Product Trade Name: D-Stat Dry™ Hemostatic Bandage
Classification Name: Unclassified
Product Code: DXC

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

Establishment Registration: 2134812

Contact: Linda Busklein
Regulatory Affairs Manager
(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 Dry Hemostatic Bandage consists of the following components:

- Lyophilized pad consisting of thrombin, sodium carboxymethylcellulose (CMC) and calcium chloride
- Adhesive bandage

The D-Stat Dry Hemostatic Bandage achieves its principal intended action (hemostasis) by creating a physical barrier to blood flow with compression supplied by the bandage. The lyophilized components (thrombin, CMC, and calcium chloride) establish an environment in which a natural blood clot can build and form a physical barrier to bleeding. The thrombin facilitates hemostasis by enhancing the surface-activated clotting cascade through enzymatic cleavage and conversion of fibrinogen to fibrin.

Intended Use:
The D-Stat Dry is applied topically as an adjunct to manual compression and is indicated for the control of surface bleeding from vascular access sites and percutaneous catheters or tubes and reducing the time-to-hemostasis in patients undergoing diagnostic endovascular procedures utilizing 4-6 Fr. introducer sheaths.

Summary of Non-Clinical Testing:
No non-clinical testing was conducted.

Summary of Clinical Testing:
A prospective, randomized, non-significant risk clinical investigation was conducted and provided clinical evidence that use of the D-Stat Dry Hemostatic Bandage in the intended study population was safe and reduced the time-to-hemostasis following diagnostic catheterization procedures.

Predicate Devices:
D-Stat Dry™ Dry Hemostatic - K030836
Syvek $_{excel}$ Vascular Access Hemostasis System – K053300

Conclusions:
The D-Stat Dry™ Hemostatic Bandage is substantially equivalent to the D-Stat Dry™ Hemostatic Bandage, based on comparisons between the intended use, construction materials, and device dimensions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 6 2006

Vascular Solutions, Inc.
c/o Ms. Julie Tapper
Regulatory Affairs Associate
6464 Sycamore Court
Minneapolis, Minnesota 55369

Re: K061219
Trade Name: D-Stat Dry Hemostatic Bandage accessory
Regulation Number: 21 CFR 870.4450 and unclassified
Regulation Name: Vascular Clamp, Topical Hemostat
Regulatory Class: Class II
Product Code: DXC, FRO
Dated: September 28, 2006
Received: October 3, 2006

Dear Ms. Tapper:

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—D-Stat Dry™ Hemostatic Bandage

510(k) Number: K061219

Device Name: Vascular Solutions D-Stat Dry™ Hemostatic Bandage

Indications for Use:
The D-Stat Dry is applied topically as an adjunct to manual compression and is indicated for the control of surface bleeding from vascular access sites and percutaneous catheters or tubes and reducing the time-to-hemostasis in patients undergoing diagnostic endovascular procedures utilizing 4-6 Fr. introducer sheaths.

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)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K061219