February 10, 2023

Vascular Solutions, Inc.
Gregory W. Sachs
Director of Regulatory Affairs
2495 Xenium Lane North
Minneapolis, Minnesota 55441-3625

Re: K033709
Trade/Device Name: Vascular Solutions D-Stat 2 Dry™ Hemostatic Bandage
Regulatory Class: Unclassified
Product Code: QSX

Dear Gregory W. Sachs:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated December 18, 2003. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code QSX.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Julie Morabito, OHT4: Office of Surgical and Infection Control Devices, 240-402-3839, Julie.Morabito@fda.hhs.gov.

Sincerely,

Julie A. Morabito -S

Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 8 2003

Mr. Gregory W. Sachs
Director of Regulatory Affairs
Vascular Solutions, Inc.
2495 Xenium Lane North
Minneapolis, Minnesota 55441

Re: K033709
Trade/Device Name: Vascular Solutions D-Stat 2 Dry™ Hemostatic Bandage
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 25, 2003
Received: November 28, 2003

Dear Mr. Sachs:

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 (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033709

Device Name: Vascular Solutions D-Stat 2 Dry™ Hemostatic Bandage

Indications For Use:

The Vascular Solutions D-Stat 2 Dry Hemostatic Bandage is intended for use under the direction of a healthcare professional for the local management and control of bleeding from vascular access sites and percutaneous catheters and 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)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K033709

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K033709

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Common/Usual Name:	Topical Hemostat
Product Trade Name:	D-Stat 2 Dry™ Hemostatic Bandage
Classification Name:	Unclassified Product Code FRO
Manufacturer:	Vascular Solutions, Inc. 2495 Xenium Lane North Minneapolis, Minnesota 55441
Establishment Registration:	2134812
Contact:	Gregory W. Sachs Director of Regulatory Affairs
Performance Standards:	No performance standards have been developed under section 514 for this device.

Device Description:
The D-Stat 2 Dry hemostatic bandage consists of the following components:

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

The D-Stat 2 Dry hemostatic bandage achieves their principal intended action (hemostasis) by creating a physical barrier to blood flow with compression supplied by the adhesive 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 Vascular Solutions D-Stat 2 Dry Hemostatic Bandage is intended for use under the direction of a healthcare professional for the local management and control of bleeding from vascular access sites and percutaneous catheters and tubes.

Summary of Non-Clinical Testing:
No additional non-clinical testing of this product for this use was conducted.

Summary of Clinical Testing:
No clinical evaluations of this product for this use have been conducted.

Predicate Devices:
The intended use of the D-Stat 2 Dry Hemostatic Bandage is a subset of the intended use of the:

- Vascular Solutions Inc., D-Stat Dry Hemostatic Bandage

Conclusions:
The D-Stat Dry 2 Hemostatic Bandage is substantially equivalent to Vascular Solutions Inc. D-Stat Dry Hemostatic Bandage.