February 10, 2023

Vascular Solutions, Inc.
Linda Busklein
Senior Regulatory Affairs Associate
6464 Sycamore Court
Minneapolis, Minnesota 55369

Re: K050133
Trade/Device Name: D-Stat Dry Radial Hemostatic Band
Regulatory Class: Unclassified
Product Code: QSX

Dear Linda Busklein:

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 February 18, 2005. 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

FEB 18 2005

Ms. Linda Busklein
Senior Regulatory Affairs Associate
Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, Minnesota 55369

Re: K050133
Trade/Device Name: D-Stat Dry Radial Hemostatic Band
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 20, 2005
Received: January 21, 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) 276-0115. 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,

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 Statement

510(k) Number: K050133

Device Name: **Vascular Solutions D-Stat Dry Radial Hemostatic Band**

Indications for Use:

The D-Stat Radial Hemostatic Band is applied topically and is indicated for the control of surface bleeding from vascular access sites and percutaneous catheters or tubes.

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 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 K050133

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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Common/Usual Name:	Topical Hemostatic
Product Trade Name:	D-Stat® Radial Hemostatic Band
Classification Name:	Unclassified, Product Code FRO
Manufacturer:	Vascular Solutions, Inc. 6464 Sycamore Court Minneapolis, Minnesota 55369
Establishment Registration:	2134812
Contact:	Linda Busklein Sr. Regulatory Affairs Associate (763) 656-4349 phone (763) 656-4250 fax
Performance Standards:	No performance standards have been developed under section 514 for this device.
Device Description:	The D-Stat Radial Hemostatic Band consists of a lyophilized pad containing thrombin, sodium carboxymethylcellulose, and calcium chloride secured to a application device consisting of an adjustable retention strap, retainer, and attached pads. After hemostasis has been achieved, the lyophilized pad may be removed from the application device, covered with a provided adhesive bandage, and left in place for up to 24 hours.
Intended Use:	The D-Stat Radial Hemostatic Band is applied topically 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 retainer and a biocompatibility assessment of new materials.
Predicate Devices:	Vascular Solutions D-Stat Radial Hemostatic Band (K030836) Vascular Solutions D-Stat Dry Hemostatic Bandage (K030836)
Conclusions:	The D-Stat Radial Hemostatic Band is substantially equivalent to the currently marketed D-Stat Radial Hemostatic Band and the D-Stat Dry Hemostatic Bandage, based on a comparison of the indications for use and the technological characteristics of the device.