February 10, 2023

Vascular Solutions, Inc.
c/o Lisa Gallatin
Senior Regulatory Affairs Associate
6464 Sycamore Court
Minneapolis, Minnesota 55369

Re: K092612
Trade/Device Name: D-Stat® Rad-band
Regulatory Class: Unclassified
Product Code: QSX

Dear Lisa Gallatin:

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 September 11, 2009. 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

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 11 2009

Vascular Solutions, Inc.
% Ms. Lisa Gallatin
Senior Regulatory Affairs Associate
6464 Sycamore Court
Minneapolis, Minnesota 55369

Re: K092612
Trade Name: D-Stat® Rad-Band
Product Code: FRO
Dated: August 25, 2009
Received: August 26, 2009

Dear Ms. Gallatin:

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.

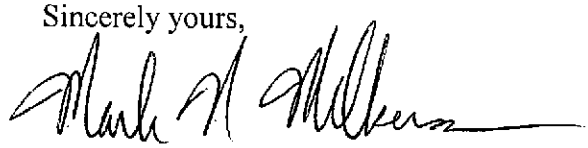
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092612

Device Name: D-Stat® Rad-Band

Indications for Use:

D-Stat® Rad-Band: The D-Stat Rad-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 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

David Krause for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092612

3 510(k) Summary

Date Prepared: September 9, 2009

Submitter's Name / Contact Person

Manufacturer
Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, MN 55369 USA
Establishment Registration # 2134812

Contact Person
Lisa Gallatin, RAC
Senior Regulatory Affairs Associate
Tel: 763.656.4399 (direct); Fax: 763.656.4253
Email: lgallatin@vascularsolutions.com

General Information

Trade Name	D-Stat® Rad-Band
Common Name	Topical Hemostat
Classification Name	Unclassified
Predicate Device	K050133, D-Stat® Radial Hemostatic Band (Vascular Solutions, Inc.) K073264, D-Stat® Dry Clear Hemostatic Bandage (Vascular Solutions, Inc.)

Device Description

The D-Stat Rad-Band consists of a gauze pad secured to a release tab and retainer pad on a polycarbonate retainer at the end of an adjustable copolymer retention strap. Two foam pads included on the strap can be adjusted (or removed) for patient comfort. The D-Stat Rad-Band has a lyophilized non-woven gauze pad containing thrombin, sodium carboxymethylcellulose, and calcium chloride to facilitate hemostasis. By pulling the release tab between the gauze pad and the retainer after hemostasis is achieved, the retention strap/retainer can be removed from the patient, leaving the gauze pad behind on the access site. The D-Stat Rad-Band includes an adhesive bandage.

Intended Use / Indications

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

Substantial Equivalence and Summary of Studies

The D-Stat Rad-Band is substantially equivalent in intended use and indications to the predicate device. Technological differences in design and materials have been qualified through biomaterial assessments and other design verification testing, the results of which did not raise any new safety or performance questions.