February 10, 2023

Vascular Solutions LLC
Melissa Sommerfeld
Principal Regulatory Product Specialist
6401 Sycamore Court North
Maple Grove, Minnesota 55369

Re: K200720
Trade/Device Name: D-Stat Radial Topical Hemostat
Regulatory Class: Unclassified
Product Code: QSX

Dear Melissa Sommerfeld:

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 June 26, 2020. 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

June 26, 2020

Vascular Solutions LLC
Melissa Sommerfeld
Principal Regulatory Product Specialist
6401 Sycamore Ct N
Maple Grove, Minnesota 55369

Re: K200720
Trade/Device Name: D-Stat Radial Topical Hemostat
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 28, 2020
Received: May 29, 2020

Dear Melissa Sommerfeld:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Anjana Jain -S

Anjana Jain, Ph.D.
Acting 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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200720

Device Name:

D-Stat Radial Topical Hemostat

Indications for Use *(Describe)*

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

Type of Use *(Select one or both, as applicable)*

[X] Prescription Use (Part 21 CFR 801 Subpart D) [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

[As required by 21 CFR 807.92]

Date Prepared: June 26, 2020

510(k) Number: K200720

Submitter's Name / Contact Person

Manufacturer
Vascular Solutions LLC
6464 Sycamore Court North
Minneapolis, MN 55369 USA
Establishment Registration # 2134812

Contact Person
Melissa Sommerfeld
Principal Regulatory Product Specialist
Tel: 763-656-4300

General Information

Trade Name	D-Stat Radial Topical Hemostat
Common / Usual Name	D-Stat Radial
Classification Name	Unclassified
Regulatory Class:	Unclassified
Product Code:	FRO
Predicate Device	K050133, D-Stat Radial Hemostatic Band (Vascular Solutions, Inc.)
Reference Device	K092612, D-Stat Radial Rad-Band (Vascular Solutions, Inc.)

Device Description

D-Stat Radial topical hemostat (D-Stat Radial) is a hemostatic band consisting of an application device containing a lyophilized pad consisting of thrombin, sodium carboxylmethylcellulose and calcium chloride in a nonwoven gauze, and an adjustable retention strap and attached foam pads. Hemostasis is achieved by the physiological coagulation-inducing properties of the lyophilized pad combined with the compression delivered by the application device.

The D-Stat Radial has been sterilized with irradiation.

Indications for Use

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

Technological Characteristics Comparison

The key technological difference between the D-Stat Radial and the predicate device is a change to the retention strap material.

Substantial Equivalence and Summary of Studies

The technological difference between the subject and predicate device has been evaluated through performance and biocompatibility tests to provide evidence of substantial equivalence for D-Stat Radial.

The device performance was verified through the following test:

- Securement Force

Device samples passed the following biocompatibility tests performed in accordance with ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The D-Stat Radial is considered a surface device that contacts the skin for a limited duration (under 24 hours). The battery of tests included the following:

- Cytotoxicity
- Sensitization
- Irritation

Conclusions

The D-Stat Radial Hemostatic Band is substantially equivalent in both the indications for use and technological characteristics to the predicate device and do not raise new questions of safety or effectiveness.