February 10, 2023

Vascular Solutions, Inc.
c/o James Chapman
Regulatory Affairs Associate
6464 Sycamore Court
Minneapolis, Minnesota 55369

Re: K063860
Trade/Device Name: ThrombiGel® Thrombin/Gelatin Foam Hemostat
Regulatory Class: Unclassified
Product Code: QSX

Dear James Chapman:

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 13, 2007. 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

Vascular Solutions, Inc.
% Mr. James Chapman
Regulatory Affairs Associate
6464 Sycamore Court
Minneapolis, Minnesota 55369

FEB 13 2007

Re: K063860
Trade/Device Name: ThrombiGel® thrombin/gelatin foam hemostat
Regulatory Class: Unclassified
Product Code: FRO
Dated: December 26, 2006
Received: December 28, 2006

Dear Mr. Chapman:

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 (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 General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K063860

Device Name: **ThrombiGel® thrombin/gelatin foam hemostat**

Indications for Use:

The ThrombiGel® thrombin/gelatin foam hemostat is applied topically and is indicated as a trauma dressing for temporary control of moderate to severely bleeding wounds and 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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K063860

510(k) Summary

FEB 13 2007

(As required by 21 CFR 807.92(c))

510(k) Number: K063860

Date Prepared: **December 26, 2006**

Submitter Information

Submitter's Name: Vascular Solutions, Inc.
Address: 6464 Sycamore Court
Minneapolis, MN 55369

Establishment Registration 2134812

Contact Person: James Chapman
Regulatory Affairs Associate
Phone: (763) 656-4380
Fax: (763) 656-4253

Device Information

Trade Name: ThrombiGel® thrombin/gelatin foam hemostat.
Common Name: Topical hemostat
Classification Name: Unclassified
Product Code: FRO
Regulation: Not Applicable

Predicate Device(s)

The predicate device is the currently marketed ThrombiGel® thrombin/gelatin foam hemostat (K053644, K050511).

Device Description

The ThrombiGel® thrombin/gelatin foam hemostat consists of a lyophilized absorbable gelatin sponge, USP containing thrombin, sodium carboxymethylcellulose (CMC), and calcium chloride.

The ThrombiGel® thrombin/gelatin foam hemostat is applied directly over the source of bleeding, creating a physical barrier to blood flow through the application of adjunctive manual compression. 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.

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The thrombin facilitates hemostasis by enhancing the surface-activated clotting cascade through enzymatic cleavage and conversion of fibrinogen to fibrin. Vascular Solutions, Inc.

The ThrombiGel® thrombin/gelatin foam hemostat is wetted before use with sterile water for injection or saline (not provided.) There are three versions of the pad which differ in their dimensions. The ThrombiGel® 10 thrombin/gelatin foam hemostat is approximately 10 cm^2, the ThrombiGel® 40 thrombin/gelatin foam hemostat is approximately 40 cm^2 and the ThrombiGel® 100 thrombin/gelatin foam hemostat is approximately 100 cm^2. A desiccant is added to the package to maintain the moisture content.

Intended Use/Indications for Use

The ThrombiGel® thrombin/gelatin foam hemostat is applied topically and is indicated as a trauma dressing for temporary control of moderate to severely bleeding wounds and for the control of surface bleeding from vascular access sites and percutaneous catheters or tubes.

Summary of Non-Clinical Testing

Testing included assessment of the physical properties of the ThrombiGel® thrombin/gelatin foam hemostat utilizing the Vascular Solutions Inc. manufactured absorbable gelatin sponge, USP and its ability to achieve its intended use. Bench testing of the physical properties of the ThrombiGel® thrombin/gelatin foam hemostat confirmed the suitability of the device for its intended use. The following physical tests were performed;

Moisture Content Testing
Thrombin Activity Testing
Thrombin Activity Testing post 4 hours pot-life
Wetting Time
pH

A biocompatibility assessment was also performed. The purpose of the biocompatibility testing was to demonstrate that samples of ThrombiGel® thrombin/gelatin foam hemostat utilizing Vascular Solutions, Inc. manufactured absorbable gelatin sponge, USP and Vascular Solutions, Inc. absorbable gelatin sponge, USP alone were biocompatible on the basis of the following testing;

MEM Elution
Intracutaneous Injection Test
Systemic Injection Test
Rabbit Pyrogen Test
Kligman Skin Sensitization

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The results of the tests confirmed the suitability of the device for its intended use.

Summary of Clinical Testing

No human clinical testing was required for this device.

Statement of Equivalence

The ThrombiGel® thrombin/gelatin foam hemostat is substantially equivalent to the currently marketed ThrombiGel® thrombin/gelatin foam hemostat based on a comparison of the indications for use and the technological characteristics of the device.

Conclusion

The ThrombiGel® thrombin/gelatin foam hemostat utilizing an absorbable gelatin sponge, USP manufactured by Vascular Solutions, Inc. is substantially equivalent to the currently marketed ThrombiGel® thrombin/gelatin foam hemostat based on the technological characteristics, and sterilization methods. Bench tests confirmed the suitability of the device for its intended use.