510(k) Summary
(As required by 21 CFR 807.92(c))

DEC 09 2008

510(k) Number: K080022

Date of Original Submission: December 28, 2007

Submitter Information

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

Establishment Registration 2134812

Contact Person: Lisa Gallatin, RAC
Senior Regulatory Affairs Associate
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Device Information

Trade Name: Gel-Sponge ENT, Absorbable Gelatin Sponge, USP
Common Name: Gelatin Sponge
Classification Name: Ear, Nose and Throat Synthetic Polymer Material
Product Code: KHJ, LYA
Regulation: 21 CFR 874.3620

Predicate Device(s)
The predicate device is the currently marketed Gelita-Spon Absorbable Gelatin Sponge, USP (K060878) and ThrombiGel® thrombin/gelatin foam hemostat (K063860).

Device Description
The Gel-Sponge ENT is a sterile, absorbable gelatin sponge, USP available in sizes ranging from a 1.5 cm^2 disk to a 100 cm^2 rectangular size. It is able to absorb and hold within its interstices, many times its weight of blood and other fluids.

The Gel-Sponge ENT, Absorbable Gelatin Sponge, USP is applied directly over the source of bleeding, creating a physical barrier to blood flow through the application of adjunctive manual compression. Hemostasis is achieved by the physiological coagulation-inducing properties of the absorbable gelatin sponge, USP.

The Gel-Sponge ENT, Absorbable Gelatin Sponge, USP is applied dry or is wetted before use with sterile water for injection or saline (not provided).

Intended Use/Indications for Use
The Gel-Sponge ENT, Absorbable Gelatin Sponge, USP is intended for use during and after ENT surgeries for the control of minimal to moderate bleeding by tamponande effect, blood absorption and platelet aggregation.

Summary of Non-Clinical Testing
Testing included assessment of the physical properties of the Gel-Sponge ENT, Absorbable Gelatin Sponge, USP and its ability to achieve its intended use. Bench testing of the physical properties of the Gel-Sponge ENT, Absorbable gelatin sponge, USP confirmed the suitability of the device for its intended use. The following physical tests were performed;

Pepsin Digestion	Absorption
Residue on Ignition	pH Testing
Formaldehyde Residual	

A biocompatibility assessment was also performed. The purpose of the biocompatibility assessment was to demonstrate that samples of the Gel-Sponge ENT, Absorbable Gelatin Sponge, USP were biocompatible on the basis of the following testing;

MEM Elution	Intracutaneous Injection Test
Systemic Injection Test	Rabbit Pyrogen Test
Kligman Skin Sensitization	Ames Reverse Mutation Assay
Short Term Subcutaneous Implantation Testing	

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 Gel-Sponge ENT, Absorbable Gelatin Sponge, USP is substantially equivalent to the currently marketed Gelita-Spon Absorbable Gelatin Sponge, USP based on a comparison of the indications for use and the technological characteristics of the devices.

Conclusion
The Gel-Sponge ENT, Absorbable Gelatin Sponge, USP is substantially equivalent to the currently marketed Gelita-Spon Absorbable Gelatin Sponge, USP based on a comparison of the indications for use and the technological characteristics of the devices based on the technological characteristics, and sterilization methods. Bench tests confirmed the suitability of the device for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 9 2008

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

Re: K080022
Trade/Device Name: Gel-Sponge ENT, Absorbable Gelatin Sponge, USP
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, nose, and throat synthetic polymer material
Regulatory Class: Class II
Product Code: KHJ
Dated: December 2, 2008
Received: December 3, 2008

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 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

M. B. Eydelman, MD

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K080022

Indications for Use Statement

510(k) Number: K080022

Device Name: **Gel-Sponge ENT, Absorbable Gelatin Sponge, USP**

Indications for Use:

The Gel-Sponge ENT, Absorbable Gelatin Sponge, USP is intended for use during and after ENT surgeries for the control of minimal bleeding by tamponade effect, blood absorption and platelet aggregation.

Prescription Use X		Over-The-Counter Use
(Part 21 CFR 801 Subpart D)	AND/OR	(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)

Daniel C Coleman

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devices
510(k) Number K080022