APR 2 5 2014

510(k) Summary

[As required by 21 CFR 807.92]

Date Prepared: April 25, 2014

510(k) Number: K133237

Submitter's Name / Contact Person

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

Contact Person
Ellie Gillespie
Sr. Regulatory Product Specialist
Tel: 763-656-4300
Fax: 763-656-4253

General Information

Trade Name	Gel-Bead embolization spheres
Common / Usual Name	embolization spheres
Classification Name	870.3300, KRD – Device, vascular, for promoting embolization, Class II
Predicate Device(s)	K021397 – Embosphere Microspheres (Biosphere Medical, Inc./Merit Medical Systems, Inc.) K113266 – Gel-Block Embolization Pledgets (Vascular Solutions, Inc.)

Device Description

The Gel-Bead embolization spheres (Gel-Bead) consists of biodegradable gelatin spheres pre-filled in a 20 ml syringe. The syringe contains 1 ml of spheres suspended in 5 ml of saline. Gel-Bead is offered in four size ranges: 100-300 µm, 300-500 µm, 500-700 µm and 700-1000 µm. The spheres are intended to be used with a delivery catheter with an inner diameter that is adequate for sphere delivery (not included). The finished product is sterilized by Gamma irradiation and is intended for single use only.

Intended Use / Indications

Gel-Bead embolization spheres is intended for use in embolization of hypervascular tumors.

Technological Characteristics

Gel-Bead has the same intended use as both predicate devices but Embosphere and Gel-Block are also intended for use in arteriovenous malformations and Embosphere is also intended for use in symptomatic uterine fibroids. Gel-Bead is similar in design to the predicate devices as they are gelatin-containing embolization devices delivered through a catheter with the same principle of operation (create a mechanical obstruction to blood flow in the target vessel, as evidenced by disruption in the contrast flow rate). Gel-Bead size ranges are within the range of Embosphere Microspheres (Embosphere). Gel-Bead is biodegradable like Gel-Block embolization pledgets (Gel-Block). The only technological difference between the subject device and the predicate devices is the materials of construction.

Substantial Equivalence and Summary of Studies

The subject device design was evaluated through biocompatibility and animal tests to provide evidence of safe and effective use of Gel-Bead. Gel-Bead is substantially equivalent to the specified predicate devices based on comparisons of device functionality, technological characteristics, and indications for use. The subject device design has been verified through an animal study and the following biocompatibility tests performed as recommended by ISO 10993-1:

- Cytotoxicity
  - L929 MEM Elution
  - Agar Diffusion
- Sensitization
  - Kligman Maximization Sensitization Test (Direct)
- Irritation/Intracutaneous Reactivity
  - Intracutaneous Injection (Direct)
- Acute Systemic Toxicity
  - Acute Systemic Injection Test
  - Material Mediated Rabbit Pyrogen (Direct Exposure)
- Hematology
  - Hemolysis (Direct)
  - Hemolysis (Indirect)
  - Complement Activation (Direct)
- Genotoxicity
  - Bacterial Mutagenicity Test – Ames Assay
  - Mouse Lymphoma Forward Mutation Assay
  - Rodent Bone Marrow Micronucleus Assay

A GLP animal study was conducted on twelve mature miniature swine, with animals survived up to 12 weeks following implantation. Eight animals were implanted with Gel-Bead and four animals implanted with a control (Embosphere). Gel-Bead spheres were consistently and reliably implanted in the selected target arteries of appropriate size and not in additional non-target tissues or regions. All instances of Gel-Bead delivery resulted in successful arterial occlusion at the time of implant, as confirmed by angiography. There were similar well-demarcated foci of infarction, indicative of successful embolization, observed in the target organs of both test article and control article animals. There were no clinically significant abnormalities identified in the clinical pathology blood results that negatively reflected on either the test or control devices. Examination of the tissues distant to the implantation sites did not identify any systemic abnormalities.

Verification, animal study, and biocompatibility test results met the specified acceptance criteria and did not raise new safety or performance issues. Therefore, Gel-Bead is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 25, 2014

Vascular Solutions, Inc.
Ellie Gillespie
Senior Regulatory Product Specialist
6464 Sycamore Court North
Minneapolis, MN 55369

Re: K133237
Trade/Device Name: Gel-Bead™ Embolization Spheres
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: March 18, 2014
Received: March 20, 2014

Dear Ms. Gillespie:

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. 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); 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 contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm 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 Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133237

Device Name: Gel-Bead embolization spheres

Indications for Use:

Gel-Bead embolization spheres is intended for use in embolization of hypervascular tumors.

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)

Kenneth J. Cavanaugh -S