October 25, 2017

Vascular Solutions, Inc.
Lisa Gallatin
Director of Regulatory
6464 Sycamore Court North
Minneapolis, Minnesota 55369

Re: K171946
Trade/Device Name: Gel-Bead
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: October 2, 2017
Received: October 3, 2017

Dear Lisa 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. 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 (DICE) 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 (DICE) 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,

Nicole G. Ibrahim -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*
K171946

Device Name
Gel-Bead

Indications for Use *(Describe)*
Gel-bead embolization spheres are intended for use in embolization of hypervascular tumors.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

[As required by 21 CFR 807.92]

Date Prepared: June 27, 2017

510(k) Number: K171946

Submitter's Name / Contact Person

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

Contact Person
Lisa Gallatin
Director of Regulatory
Tel: 763-656-4300
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General Information

Trade Name	Gel-Bead
Common / Usual Name	Embolization spheres
Classification Name	Class II – 21 CFR 870.3300; KRD – Device, vascular, for promoting embolization
Predicate Device	K133237 – Gel-Bead embolization spheres, Vascular Solutions, Inc.
Reference Device	K150870 - HydroPearl microspheres, MicroVention, 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 2 ml of spheres suspended in 4 ml of saline. Gel-Bead is offered in four nominal 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

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

Technological Characteristics Comparison

The table below compares the technological characteristics of the Gel-Bead embolization spheres.

Characteristic	Subject Device Gel-Bead (2 ml fill)	Predicate Device Gel- Bead (K133237)	Reference Device HydroPearl (K150870)
Indications for use	Gel-Bead embolization spheres are intended for use in embolization of hypervascular tumors.	Same	Similar
Sphere volume	2 ml spheres	1 ml spheres	2 ml spheres

Characteristic	Subject Device Gel-Bead (2 ml fill)	Predicate Device Gel- Bead (K133237)	Reference Device HydroPearl (K150870)
Sphere sizes	100-300μm; 300-500 μm; 500-700 μm; 700-1000 μm	Same	Similar 75-1000 μm
Compatible delivery catheters (inner diameter)	100 – 300 μm: 0.020” 300 – 500 μm: 0.020” 500 – 700 μm: 0.023” 700 – 1000 μm: 0.038”	Same	Similar Microspheres can be delivered through a catheter of 0.017” – 0.041’ ID
Material	Porcine-derived gelatin	Same	Polyethylene glycol diacrylamide
Sterility	Gamma irradiation	Same	Steam

Substantial Equivalence and Summary of Studies

The technological differences between the subject and predicate devices have been evaluated through bench tests to provide evidence supporting Gel-Bead embolization spheres (2 ml fill) substantial equivalence. The Gel-Bead embolization spheres (2 ml fill) product is substantially equivalent to the specified predicate device based on comparisons of the device functionality, technological characteristics, and indications for use. The device design has been verified through the following tests:

- Sphere suspension in contrast
- Pepsin digestion
- Supplied volume
- Deliverability
- Glutaraldehyde residuals

The results of the verification tests met the specified acceptance criteria and did not raise new safety or performance issues. Therefore, the Gel-Bead embolization spheres (2 ml fill) product is substantially equivalent to the predicate device.