January 19, 2018

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

Re: K173891
Trade/Device Name: Gel-Bead Embolization Spheres (600-800μm - 1 ml and 2 ml sphere volumes)
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: December 20, 2017
Received: December 21, 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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
Indications for Use

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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)

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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PRASStaff@fda.hhs.gov

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K173891
510(k) Summary

[As required by 21 CFR 807.92]

Date Prepared: January 16, 2018

510(k) Number: ___K173891____________________

Submitter’s Name / Contact Person

Manufacturer: Vascular Solutions

Contact Person: Lisa Gallatin

6464 Sycamore Court North

Director of Regulatory

Minneapolis, MN  55369 USA

Tel: 763-656-4300

Establishment Registration # 2134812

Fax: 763-656-4253

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: Gel-Bead embolization spheres, Vascular Solutions

(K133237 cleared April 25, 2014; K171946 cleared October 25, 2017)

Device Description

The Gel-Bead embolization spheres product consists of biodegradable gelatin spheres pre-filled in a 20 ml syringe. The syringe contains either 1 ml or 2 ml of spheres suspended in 5 ml or 4 ml of saline, respectively. Offered in five nominal size ranges (100-300 µm, 300-500 µm, 500-700 µm, 600-800 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 subject and predicate device.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Subject Device</th>
<th>Predicate Device</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>600-800 µm embolization spheres</td>
<td>Gel-Bead (2 ml fill) (K171946)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Gel-Bead (original) (K133237)</td>
</tr>
<tr>
<td>Indications for use</td>
<td>Gel-Bead embolization spheres are intended for use in embolization of hypervascular tumors.</td>
<td>Same</td>
</tr>
<tr>
<td>Sphere volume</td>
<td>1ml and 2 ml sphere fill volumes</td>
<td>Same - 2 ml spheres</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Same -1 ml spheres</td>
</tr>
<tr>
<td>Characteristic</td>
<td>Subject Device</td>
<td>Predicate Device</td>
</tr>
<tr>
<td>--------------------------------</td>
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<tr>
<td>Sphere sizes</td>
<td>600-800 µm</td>
<td>Current sizes bracket the new 600-800 µm size</td>
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<tr>
<td></td>
<td></td>
<td>100 – 300 µm</td>
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<td>300 – 500 µm</td>
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<td>700 – 1000 µm</td>
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<td>Current compatibility sizes bracket the new 600-800 µm size</td>
<td>Current sizes bracket the new 600-800 µm size</td>
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<td>100 – 300 µm</td>
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<td>700 – 1000 µm</td>
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<tr>
<td>Compatible delivery catheters (inner diameter)</td>
<td>600-800 µm: 0.027”</td>
<td>Current compatibility sizes bracket the new 600-800 µm size</td>
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<td>100 – 300 µm: 0.020”</td>
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<td>300 – 500 µm: 0.020”</td>
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<td>500 – 700 µm: 0.023”</td>
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<td>700 – 1000 µm: 0.038”</td>
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<td>Current compatibility sizes bracket the new 600-800 µm size</td>
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<tr>
<td>Material</td>
<td>Porcine-derived gelatin</td>
<td>Same</td>
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<tr>
<td>Sterility</td>
<td>Gamma irradiation</td>
<td>Same</td>
</tr>
</tbody>
</table>

**Substantial Equivalence and Summary of Studies**

The technological differences between the subject and predicate device have been evaluated through bench tests to provide evidence supporting the substantial equivalence of the 600-800 µm size embolization spheres. The 600-800 µm size 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:

- Deliverability
- Sphere Diameter
- Sphericity

The verification test results demonstrate that the Gel-Bead embolization spheres (600-800 µm) met the specified acceptance criteria and did not raise new safety or performance issues. Therefore, the 600-800 µm embolization spheres product is substantially equivalent to the predicate devices.