



Food and Drug Administration
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March 7, 2016

Biocompatibles UK Ltd
% Simon Leppard
Director of Regulatory Affairs
BTG International, Inc.
Lakeview, Riverside Way, Watchmoor Park
Camberley, Surrey, GU15 3YL, GB

Re: K150876
Trade/Device Name: Bead Block™
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: NAJ
Dated: February 2, 2016
Received: February 4, 2016

Dear Simon Leppard,

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,


Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K150876

Device Name

Bead Block™

Indications for Use (Describe)

Bead Block™ microspheres are intended to be used for the embolization of hypervascular tumors, including uterine fibroids and arteriovenous malformations (AVMs).

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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

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**510(k) Summary
for the Biocompatibles UK Ltd.
Bead Block™ (per
21CFR 807.92)**

1. SUBMITTER/510(K) HOLDER

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Date Prepared: March 4, 2016

2. DEVICE NAME

Proprietary Name: Bead Block™
Common/Usual Name: Embolic Agents
Regulation: 870.3300, vascular embolization device
Regulatory Class: II
Product Code: NAJ, uterine artery embolization

3. PREDICATE DEVICES

The primary predicate device has been identified as listed below:

- Predicate Device: Embosphere Microspheres, Biosphere Medical, Inc. (K021397)

4. DEVICE DESCRIPTION

Bead Block™ is made up of preformed soft, deformable microspheres that occlude arteries for the purpose of blocking the blood flow to a target tissue, such as a fibroid or a cancerous tumor. Bead Block™ compressible microspheres consist of a macromer derived from polyvinyl alcohol (PVA). The fully polymerized microsphere is approximately 90-95% water and is compressible to approximately 30% by diameter. Bead Block™ microspheres are dyed blue to aid in the visualization of the microspheres in the delivery syringe. The microspheres can be delivered through typical microcatheters in the 1.5-5Fr range.

Bead Block™ is available in the configurations shown in the table below.

Bead Block™ Product Configurations				
Product Code	Size Range	Quantity Bead Block	Quantity Saline	Intended for *UFE
EB1S103	100-300µm	1 ml	6 ml	No
EB1S305	300-500µm	1 ml	6 ml	No
EB1S507	500-700µm	1 ml	6 ml	No
EB1S709	700-900µm	1 ml	6 ml	Yes
EB1S912	900-1200µm	1 ml	6 ml	Yes
EB2S103	100-300µm	2 ml	5 ml	No
EB2S305	300-500µm	2 ml	5 ml	No
EB2S507	500-700µm	2 ml	5 ml	No
EB2S709	700-900µm	2 ml	5 ml	Yes
EB2S912	900-1200µm	2 ml	5 ml	Yes

*Uterine Fibroid Embolization

5. INDICATION FOR USE/INTENDED USE

Bead Block™ microspheres are intended to be used for the embolization of hypervascular tumors, including uterine fibroids and arteriovenous malformations (AVMs).

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICE/S

Bead Block™ and the proposed predicate device are size calibrated spherical particles delivered by microcatheters to occlude a target blood vessel. Bead Block™ and the predicate device (K021397) have the same intended use and similar technological characteristics including the following:

- Intended for the embolization of hypervascular tumors and arteriovenous malformations
- Size calibrated microspheres for embolization
- Delivery via microcatheter to the site of desired embolization
- Visualization of the embolization process using radiographic imaging
- A range of sizes permits selection of the most appropriate size for target vessels

The indications for use of Bead Block™ are comparable to the predicate device. However, Bead Block™ and the predicate device have different technological characteristics, as the subject device is made of polyvinyl alcohol and the predicate device is made of acrylic polymer and porcine derived gelatin. However, the difference in technological characteristics between the subject and predicate device do not raise different questions of safety and effectiveness.

7. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

The device is subject to Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices issued on 29 December 2004.

The safety and effectiveness of Bead Block™ has been confirmed by non-clinical testing including:

- Residual starting material specifications
- Residual solvent material
- Visual inspection (visual defects, color, solution clarity)
- Catheter delivery, including catheter clogging, formation of aggregates, ease of injection, and shape of embolization particle after injection
- Confirmation of particle size range
- Particle fiber shedding
- pH
- Packaging integrity
- Shelf life
- Sterilization validation
- Endotoxin (<0.06 EU/ml)
- Biocompatibility

No additional testing was conducted since the predicate and subject devices have equivalent technical characteristics, manufacturing, processing, and sterilization.

8. SUMMARY OF ANIMAL PERFORMANCE TESTING AS A BASIS FOR SUBSTANTIAL EQUIVALENCE

The animal studies used to assess uterine artery embolization included a sheep penetration model to evaluate the short term performance of Bead Block™ when compared to the predicate device; specifically local effects of the embolization and the distribution of microspheres in the vasculature. The second study assessed the possible side effects of embolization in sheep uteri (e.g., tissue necrosis and inflammation) when using Bead Block™. The results of the first study demonstrate that the performance of Bead Block™ is similar to the predicate device, with both showing normal, thrombosis and some rupture of the internal elastic lamina. The results of the second study demonstrate that Bead Block™ is associated with minimal tissue necrosis and a common foreign body reaction; however, the intensity of inflammatory reaction is moderate, without humoral response or cytotoxicity.

9. SUMMARY OF CLINICAL TESTING AS A BASIS FOR SUBSTANTIAL EQUIVALENCE

The clinical information submitted included a review of Bead Block™ published and unpublished data on the use of Bead Block™ for the treatment of leiomyoma uteri (uterine fibroids) [outside the United States] over the last ten years. Review of the published and unpublished data regarding adverse events associated with Bead Block™ has not identified any unique safety concerns.

10. CONCLUSION

The results of the testing described above provide reasonable assurance that Bead Block™ is as safe and effective as the predicate device and supports a determination of substantial equivalence.