September 7, 2022

ABK Biomedical Inc
Brandi Woods
Director, Regulatory Affairs
155 Chain Lake Drive
Unit 32
Halifax, NS B3S 1B3
Canada

Re: K220567
Trade/Device Name: Easi-Vue embolic microspheres System
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: August 18, 2022
Received: August 19, 2022

Dear Brandi Woods:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Misti Malone
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220567

Device Name
Easi-Vue™ embolic microspheres System

Indications for Use *(Describe)*
Easi-Vue™ embolic microspheres System is intended for embolization of arteriovenous malformations and 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.

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

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1 510(k) Summary

The following information is provided as required by 21 CFR § 807.92 and the Safe Medical Devices Act 1990.

1.1 General Information

Company: ABK Biomedical
155 Chain Lake Drive
Unit 32
Halifax Nova Scotia B3S 1B3
Canada

Contact: Brandi Woods
Director, Regulatory Affairs
919-619-6417
b.woods@abkbiomedical.com

Date of Summary: 6 September 2022

1.2 Device Name and Classification

Proprietary Name: Easi-Vue™ embolic microspheres System
Common Name: Device, Vascular, For Promoting Embolization
Classification Name: Vascular Embolization Device
Regulatory Class: 2
Regulation: 870.3300
Product Codes: KRD

1.3 Predicate Device

Proprietary Name: Embosphere® Microspheres
Common Name: Device, Vascular, For Promoting Embolization
510(k) Number: K021397
Regulatory Class: 2
Regulation: 870.3300
Product Codes: KRD
Predicate device has not been subject to a design-related recall.

1.4 Indication for Use

Easi-Vue™ embolic microspheres System is intended for embolization of arteriovenous malformations and hypervascular tumors.

1.5 Device Description

Easi-Vue embolic microspheres are biocompatible, radiopaque, non-compressible, non-resorbable glass microspheres. The Easi-Vue embolic microspheres are included with the Easi-Vue embolic microspheres System which is comprised of Easi-Vue embolic microspheres Administration Kit and the Easi-Vue embolic microspheres Refill Syringe. The device utilizes the Administration Kit for controlled and targeted delivery of imageable radiopaque microspheres. The Easi-Vue™ embolic microspheres System is offered in three sizes: 50 µm, 100 µm, and 150 µm to occlude various size arteries for the purpose of blocking blood flow to a target tissue (as summarized in Table 1).

The Easi-Vue™ embolic microsphere System is sterile, single use, and available only for prescription use. The device is compatible with a catheter with minimum inner diameter of 0.021" and a length between 110-150 cm (as appropriate for the diameter of the intended treatment vessel).

Table 1: Product Availability

	Easi-Vue™ embolic microspheres Administration Kit	Easi-Vue™ embolic microspheres Refill Syringe
50 µm size	EVA50	EVR50
100 µm size	EVA100	EVR100
150 µm size	EVA150	EVR150

1.6 Technological Comparison

Easi-Vue™ Embolic Microspheres System is substantially equivalent, for the purpose of this 510(k), to Embosphere® Microspheres (K021397), the predicate device. The subject device and predicate devices are similar in intended use, design, and principle of operation. This is based upon the comparison of the operational characteristics, product technical characteristics, performance and safety characteristics, sterility, and product handling. Easi-Vue™ embolic microspheres are made from radiopaque glass, which is a different material compared to the predicate, acrylic polymer sphere impregnated with porcine gelatin. The differences in material composition has shown no new questions of safety based upon bench, biocompatibility and animal testing.

Unlike the predicate Easi-Vue™ embolic microspheres are non-compressible, meaning they are non-deformable during delivery. In animals, Easi-Vue™ embolic microspheres has demonstrated equivalent effectiveness at occluding the target vessel, with no migration observed.

While differences in the technology characteristics exist between the Easi-Vue™ embolic microspheres System and the predicate device, these differences, which are detailed in Table 2, do not raise different questions of safety or effectiveness.

Table 2: Comparison to Predicate

	Easi-Vue™ Embolic Microspheres System	**Embosphere® Microspheres**	**Comparison**
Company	ABK Biomedical, Inc	Biosphere Medical, S.A.	
	Subject Device	Predicate Device	
510(k) Number	K220567	K021397	
Product Code	KRD	KRD (also NAJ, NOY, & HCG)	Same
Intended use	Vascular Embolization Device	Vascular Embolization Device	Same
Indications for Use	Easi-Vue™ Embolic Microspheres System is intended for use in embolization of hypervascular tumors and arteriovenous malformations	Embosphere Microspheres are indicated for use in embolization of arteriovenous malformations, hypervascular tumors, and symptomatic uterine fibroids	Equivalent Subject device has more restrictive indication.
Mechanism of Action	Mechanical occlusion	Mechanical occlusion	Same
Principle of Operation	The microspheres are administered into the patient's artery via a catheter under radiographic imaging	The microspheres are administered with contrast medium into the patient's artery via a catheter under radiographic imaging	Equivalent Subject device does not require contrast medium for imaging.
Material Composition of spheres	tantalum-barium-boron-sodium-silicon oxide glass Saline	Acrylic polymer sphere impregnated with Porcine gelatin Saline	No new safety concern
Size Range	50 ±20 microns 100 ±35 microns 150 ±50 microns	40- 120 microns 100-300 microns 300-500 microns 500-700 microns 700-900 microns 900- 1200 microns	Equivalent
Physical Characteristics	Biocompatible, radiopaque, non-compressible, non-resorbable	Biocompatible, hydrophilic, compressible, non-resorbable	No new safety concern
Performance	Controlled, targeted embolization at the desired level of vessel occlusion	Controlled, targeted embolization at the desired level of vessel occlusion	Same
Pyrogenicity	Non-pyrogenic	Non-pyrogenic	Same
MR Safe	MR Safe	MR Safe	Same
Sterility (method)	Sterile (gamma) to SAL 10^{-6}	Sterile (steam) to SAL 10^{-6}	Equivalent
Quantity of microspheres per package	Each 1 mL syringe contains approximately 1.25 g of microspheres in saline.	Each 20 mL syringe or 8 mL glass vial contains approximately 1.0 mL or 2.0 mL of microspheres in saline.	Equivalent
Packaging	Tyvek pouch	A peel-away tray	Equivalent

1.7 Non-Clinical Performance Summary

Bench testing, biocompatibility, and non-clinical studies were conducted to support substantial equivalence of Easi-Vue embolic microspheres System to the predicated device. Easi-Vue embolic microspheres System was demonstrated to be biocompatible according to ISO 10993. Bench testing, including simulated use, MR compatibility and performance verification confirmed that Easi-Vue embolic microspheres System met all the acceptance criteria and performed as intended. A GLP animal study confirmed the ease of delivery, effectiveness of arterial occlusion and there were no clinically significant pathological abnormalities or systemic abnormalities. No new safety or effectiveness concerns were raised during testing.

1.8 Conclusion

Based on the intended use, technological characteristics, performance characteristics and data included in this application, the Easi-Vue embolic microspheres System is substantially equivalent to the predicate device.