February 13, 2024

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

Re: K234123
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: December 28, 2023
Received: December 28, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Misti L. Malone -S

Misti Malone, PhD
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K234123

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

Registration number: 3013505221

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

Date of Summary: 9-Feb-2024

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: Easi-Vue™ embolic microspheres System
Common Name: Device, Vascular, For Promoting Embolization
510(k) Number: K220567
Regulatory Class: 2
Regulation: 870.3300
Product Codes: KRD
Predicate device has not been subject to a design-related recall.

1.4 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 Delivery Device and the Easi-Vue embolic microspheres Refill Syringe. The Delivery Device provides for controlled

and targeted delivery of imageable radiopaque microspheres contained in the Refill Syringe. The Easi-Vue® embolic microspheres System is offered in three sizes: 50µm, 100µm, and 150µm 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

Size and Color Code	Easi-Vue embolic microspheres Delivery Device	Easi-Vue embolic microspheres Refill Syringe
50 µm size, Red	EVD50	EVR50
100 µm size, Yellow	EVD100	EVR100
150 µm size, Blue	EVD150	EVR150

1.5 Indication for Use

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

1.6 Indications for Use Comparison

The intended use and indication for use of Easi-Vue Embolic Microspheres System and the predicate device are equivalent. The intended use is for the embolization of hypervascular tumors and arteriovenous malformations.

1.7 Technological Comparison

Easi-Vue Embolic Microspheres System is substantially equivalent to the predicate device, which is the previously approved Easi-Vue Embolic Microspheres System (K220567). The subject device and predicate devices are the same in regard to 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 no different than the predicate. Easi-Vue embolic microspheres Delivery Device has different materials of construction and design than the previously approved Administration Device. The current Administration Device is composed of a tubing assembly, cartridge, rack, and control handle. The new Easi-Vue Delivery Device will consist only of a tubing assembly on a backing plate. The differences in material composition has shown no new questions of safety based upon bench and biocompatibility testing.

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

Table 2: Comparison to Predicate

	Easi-Vue® Embolic Microspheres System	**Easi-Vue™ Embolic Microspheres System**	**Comparison**
Company	ABK Biomedical, Inc	ABK Biomedical, Inc	
	Subject Device	Predicate Device	
510(k) Number	K234123	K220567	
Product Code	KRD	KRD	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	Easi-Vue Embolic Microspheres System is intended for use in embolization of hypervascular tumors and arteriovenous malformations	Same
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 into the patient's artery via a catheter under radiographic imaging	Same
Material Composition of spheres	tantalum-barium-boron-sodium-silicon oxide glass Saline	tantalum-barium-boron-sodium-silicon oxide glass Saline	Same
Material Composition of the Delivery Device	Delivery Device composed of TPU tubing, PC connectors and UV adhesive, attached to a color-coded backing plate corresponding to the size range of microspheres.	Single Administration Kit consisting of Cartridge Assembly, which includes PVC tubing, polycarbonate fluid connectors and a 30 mL syringe, and a Control Handle (composed of custom plastic components and springs).	Material differences raise no new safety concerns.
Size Range	50 ±20 microns 100 ±35 microns 150 ±50 microns	50 ±20 microns 100 ±35 microns 150 ±50 microns	Same
Physical Characteristics	Biocompatible, radiopaque, non-compressible, non-resorbable	Biocompatible, radiopaque, non-compressible, non-resorbable	Same
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 (gamma) to SAL 10^{-6}	Same
Quantity of microspheres per package	Each 1 mL syringe contains approximately 1.25 g of microspheres in saline.	Each 1 mL syringe contains approximately 1.25 g of microspheres in saline.	Same
Packaging	Tyvek pouch	Tyvek pouch	Same

1.8 Non-Clinical Performance Summary

Bench testing and biocompatibility 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 and performance verification confirmed that Easi-Vue embolic microspheres System met all the acceptance criteria and performed as intended. No new safety or effectiveness concerns were raised during testing.

1.9 Conclusion

Based on the intended use, technological characteristics, and nonclinical data included in this application, the Easi-Vue embolic microspheres System meets the requirements that are essential for its intended use and is substantially equivalent to the predicate device.