May 16, 2025

Biosphere Medical, S.A.
Regina Gatse
Regulatory Affairs Specialist
Parc des Nations Paris Nord 2
383 rue de la Belle Etolle
Roissy-en-France, 95700
France

Re: K250971
Trade/Device Name: Embosphere Microspheres
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD, NAJ, HCG, NOY
Dated: March 31, 2025
Received: March 31, 2025

Dear Regina Gatse:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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
Acting 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)*
K250971

Device Name
Embosphere Microspheres

Indications for Use *(Describe)*
Embosphere Microspheres are indicated for use in the embolization of:
-Hypervascular tumors, including symptomatic uterine fibroids
-Prostatic arteries for symptomatic Benign Prostatic Hyperplasia (BPH)
-Arteriovenous malformations
-Blood vessels to occlude blood flow to control bleeding/hemorrhaging in the peripheral vasculature

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.

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:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

General Provisions	Submitter Name:	Biosphere Medical, S.A.
	Address	Parc des Nations – Paris Nord 2 383, rue de la Belle Etoile 95700 Roissy-en-France, France
	Telephone Number	+33 (0)1 48 17 25 44
	Contact Person	Ms. Rosène Amossé
	Date of Preparation	31-MAR-2025
	Registration number	9615728
	Correspondent Name:	Biosphere Medical, S.A.
	Address	Parc des Nations – Paris Nord 2 383, rue de la Belle Etoile 95700 Roissy-en-France, France
	Telephone Number	+33 (0)1 48 17 25 49
	Contact Person	Ms. Regina Gatse
	Date of Preparation	31-MAR-2025
	Registration number	9615728
Subject Device	Trade Name	Embosphere® Microspheres
	Common/Usual Name	Embolization Microspheres
	Classification Name	Vascular Embolization Device Neurovascular embolization device Prostatic artery embolization device
Predicate Device	Trade Name	Embosphere® Microspheres
	Classification Name	Vascular Embolization Device
	Premarket Notification	K181300
	Manufacturer	Biosphere Medical, S.A.
Classification	Class	II
	Regulation Number	21 CFR 870.3300 21 CFR 882.5950 21 CFR 876.5550
	FDA Product Code	KRD HCG NAJ NOY

Intended Use / Indications for Use	Embosphere Microspheres are indicated for use in the embolization of: - Hypervascular tumors, including symptomatic uterine fibroids - Prostatic arteries for symptomatic Benign Prostatic Hyperplasia (BPH) - Arteriovenous malformations - Blood vessels to occlude blood flow to control bleeding/hemorrhaging in the peripheral vasculature
Device Description	Embosphere Microspheres are small, compressible, hydrophilic, biocompatible spheres made of acrylic polymer and porcine-derived gelatin. The microspheres are packaged in 0.9% saline and are provided sterile and non-pyrogenic in a vial or in a syringe. The product is provided in seven size ranges to allow physicians to choose the appropriate size necessary for the vessel being embolized. The size ranges available are : • 50-100 microns • 40-120 microns • 100-300 microns • 300-500 microns • 500-700 microns • 700-900 microns • 900-1200 microns The principles of operation for the subject device Embosphere Microspheres are the same as the predicate device Embosphere Microspheres (K181300). Embosphere Microspheres are permanent implantable devices and are designed for controlled, targeted embolization. All indications for Embosphere Microspheres; uterine arteries, arteriovenous malformations, hypervascular tumors and prostate arteries all involve arterial embolization. The procedure of arterial embolization is similar for all arteries. Appropriately sized microspheres for target vessel occlusion are chosen by the trained interventional radiologist. The delivery procedure involves arterial access through an artery, using a guidewire and microcatheter under fluoroscopic guidance. Once the catheter tip is placed in the artery(ies) supplying the targeted tissue, Embosphere Microspheres mixed with a non-ionic contrast agent are delivered in a controlled manner under visualization to occlude the feeding vessel(s) to interrupt artery blood flow to the targeted area. The device is intended for single use.
Indication for Use Comparison	The subject device Embosphere Microspheres of this 510(k) has the same indications for use as the predicate device Embosphere Microspheres, previously cleared by FDA (K181300).
Technological Comparison to predicate	The technological characteristics of the subject device, Embosphere Microspheres are identical to those of the predicate Embosphere Microspheres (K181300). The only difference between the subject device and the legally marketed predicate device Embosphere Microspheres (K181300) is an addition to the "Contraindications” section of the Instructions for Use to contraindicate for use in pulmonary arteries. Biosphere Medical believes that differences between the subject Embosphere Microspheres and cited predicate device do not raise new issues of safety and effectiveness.
Non-Clinical and/or Clinical Tests Summary	The subject device is identical to the predicate device, the legally marketed Embosphere Microspheres (K181300). No new testing was performed since the subject and predicate Embosphere Microspheres (K181300) have identical technological characteristics, manufacturing, processing and sterilization.

Summary of Substantial Equivalence	Based on the identical indications for use, design, safety and performance, the subject Embosphere Microspheres is substantially equivalent to the predicate device, the legally marketed Embosphere Microspheres, manufactured by BioSphere Medical (K181300).