DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 6, 2017

Biosphere Medical, S.A.
Lionel Ngando
Regulatory Affairs Specialist
Parc des nations – Paris Nord 2
383 Rue de la Belle Etoile
95700 Roissy en France, France

Re: K172372
Trade/Device Name: QuadraSphere Microspheres
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD, HCG
Dated: August 2, 2017
Received: August 7, 2017

Dear Lionel Ngando:

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 (DICE) 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 (DICE) 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,

Joyce M. Whang -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

Section 4
Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K172372

Device Name

QuadraSphere Microspheres

Indications for Use *(Describe)*

QuadraSphere Microspheres are indicated for embolization of hypervascularized tumors including hepatoma, and peripheral arteriovenous malformations.

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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FORM FDA 3881 (8/14) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

Section 5
510(k) Summary

August 02, 2017

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 29 Fax Number: +33 (0)1 49 38 02 68 Contact Person: Alix Fonlladosa 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 21 Fax Number: +33 (0)1 49 38 02 68 Contact Person: Lionel Ekedi Ngando Registration Number: 9615728
Subject Device	Trade Name: QuadraSphere® Microspheres Common/Usual Name: Embolization Device Classification Name: 21 CFR 870.3300 Vascular Embolization Device 21 CFR 882.5950 Neurovascular Embolization Device
Predicate Device	Trade Name: QuadraSphere® Microspheres Common/Usual Name: Embolization Device Classification Name: 21 CFR 870.3300 Vascular Embolization Device 21 CFR 882.5950 Neurovascular Embolization Device Manufacturer: Biosphere Medical, S.A. Premarket Notification: K153102, cleared November 23, 2015
Classification	Class II 21 CFR 870.3300 21 CFR 882.5950 FDA Product Code: KRD and HCG Review Panel: Division of Cardiovascular Devices

Intended Use

QuadraSphere Microspheres are indicated for embolization of hypervascularized tumors including hepatoma, and peripheral arteriovenous malformations.

Device Description

QuadraSphere Microspheres are sterile, biocompatible, hydrophilic, non-resorbable, expandable, acrylic copolymer microspheres. QuadraSphere Microspheres are packaged in a vial containing 25 mg of dry microspheres. The expansion rate is dependent on ionic concentration. When in contact with blood, non-ionic contrast media, or normal saline (NaCl 0.9%), QuadraSphere Microspheres expand to approximately 4 times their dry state diameter; equal to 64x volume.

They are available in a range of sizes.

Reference	Size range (µm)
V125QS	20-40
V225QS	30-60
V325QS	50-100
V525QS	100-150
V725QS	150-200

QuadraSphere Microspheres have the following properties:

- Spherical shape with consistent cross sectional diameter after reconstitution with aqueous-based solutions such as contrast media and 0.9% saline solution for predictable flow directed level of occlusion in the vasculature.
- Rapidly absorb contrast media and 0.9% saline solution.
- Conform to vessel lumen, providing more surface contact with vessel intima.
- Expand up to four times the stated dry diameter when hydrated with non-ionic aqueous solutions, resulting in an increase in surface area contact for a more complete vessel occlusion.

The principles of operation for the QuadraSphere Microspheres are the same as the predicate device K153102. QuadraSphere Microspheres are permanent implantable devices and are designed for controlled, targeted embolization. The device is provided dry (in a vial) and must be rehydrated before use. The microspheres are injected into the target vessel with an intravascular catheter(s) to selectively occlude blood vessels. Contrast enhancement using commercially available ionic or non-ionic contrast media allows the embolization procedure to be monitored using fluoroscopy. The embolization agents are intended for single use and are provided sterile.

Comparison to Predicate

The technological characteristics of the subject of this Special 510(k) are substantially equivalent to the predicate QuadraSphere Microspheres, K153102 cleared on November 23, 2015. Both devices use the same components and materials. The device indications remain unchanged.

Technological Characteristics Comparison Table			
Bold type indicates differences between subject and predicate device, K1513102.			
Attribute	**Predicate Device QuadraSphere Microspheres K153102**	**Subject Device QuadraSphere Microspheres 20-40µm**	**Comment**
Microspheres Size	30 to 60µm, 50 to 100µm, 100 to 150µm, 150 to 200µm	**20 to 40 µm** 30 to 60µm, 50 to 100µm, 100 to 150µm, 150 to 200µm	**Will be extended to 20-40µm**
Catheter compatibility	. **20 to 40µm - ≥ 0.020”** 30 to 60µm - ≥ 0.021” 50 to 100µm - ≥0.021” 100 to 150µm - ≥ 0.024” 150 to 200µm - ≥ 0.027”		**Injectable in 0.020” and wider ID microcatheters.**
Shelf Life (Single use)	Three years (36 months)	Three years (36months)	Same
Material (spheres)	PVA Acrylic Copolymer (vinyl alcohol-sodium acrylate)	PVA Acrylic Copolymer (vinyl alcohol-sodium acrylate)	Sa me
Physical Characteristics	Biocompatible, hydrophilic, non-resorbable, expandable, conformable and swell upon exposure to aqueous solutions	Biocompatible, hydrophilic, non-resorbable, expandable, conformable and swell upon exposure to aqueous solutions	Same
Principle of Operation	The microspheres are administered with radiopaque contrast medium into the patient’s artery via a microcatheter.	The microspheres are administered with radiopaque contrast medium into the patient’s artery via a microcatheter.	Same principle of operation

Sterilization	Radiation Sterilized	Radiation Sterilized	Same
Performance	Designed for controlled, targeted embolization when vessel conformity is desired	Designed for controlled, targeted embolization when vessel conformity is desired	Same
Volume of Microspheres in Vial (dry)	25 mg per vial	25 mg per vial	Same

Safety & Performance Tests

BioSphere Medical, S.A. bases its claim of the substantial equivalence of the QuadraSphere Microspheres with the cited predicate device based on intended use, indic ntal scientific technological characteristics, and fundamental operational characteristics. In all cases, the embolization agent is delivered to selected sites through catheters with a diameter that is appropriate for the vascular target and the size of the embolization agent. Accurate placement is assured through visualization of the injection process using fluoroscopic imaging. Embolization agents are mixed with the contrast media before injection to optimize visualization of the embolization procedure. The subject device, QuadraSphere® Microspheres, is available in a 20 to 40 µm size microspheres to permit selection of the appropriate size for target vessels. All cited embolization agents are intended for single use and are provided sterile.

No performance standards applicable to this device have been adopted under Section 514 of the Act. However, vascular embolization devices are subject to the special controls specified in "Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices," issued on December 29, 2004.

Biocompatibility assessment was performed in accordance with ISO 10993-1 for permanent implants in contact with blood for the predicate device and are being adopted for this subject device based upon the fact that both devices are made from the same materials using the same processes with now the inclusion of an additional size offering.

In-vitro and in-vivo (animal study) design verification and validation testing demonstrates that the BioSphere Medical QuadraSphere Microspheres 20 to 40µm fulfill design and performance specifications. Performance testing of the subject device was conducted based on the requirements of design input and output requirements as below:

- Macroscopic appearance of the powder
- Microscopic examination of the microspheres
- Swelling in Hexabrix of the microspheres
- Humidity of the microspheres

	• Bacterial endotoxins • Catheter compatibility • Animal testing The results of the testing demonstrated that the subject BioSphere Medical QuadraSphere Microspheres 20 to 40 µm met the pre-determined acceptance criteria applicable to the size requirements and performance of the device.
Summary of Substantial Equivalence	Based on the same intended use, design, fundamental scientific technological characteristics, fundamental operational characteristics and safety and performance testing, the BioSphere Medical subject QuadraSphere Microspheres 20 to 40 µm device meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, QuadraSphere Microspheres K153102.