DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 27, 2015

BioSphere Medical S.A.
Alix Fonlladosa
Regulatory Affairs Manager
Parc des Nations - Paris Nord 2
383 rue de la Belle Étoile
95700 Roissy-en-France
France

Re: K151187
Trade/Device Name: QuadraSphere Microspheres
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: II
Product Code: KRD, HCG
Dated: April 30, 2015
Received: May 4, 2015

Dear Alix Fonlladosa,

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 at (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" (21CFR 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,

Benjamin R. Fisher -S

Benjamin R. Fisher, PhD
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K151187

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.

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Section 5

510(k) Summary

General Provisions

Submitter Name: BioSphere Medical S.A.
Address: 383 Rue de la Belle Étoile
95700 Roissy-en-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: 383 Rue de la Belle Étoile
95700 Roissy-en-France
Telephone Number: +33 (0)1 48 17 25 30
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: Vascular Embolization Device

Predicate Device

Premarket Notification Predicate Device # 1:
Trade Name: QuadraSphere Microspheres (Size:50-100µm, 100-150µm, 150-200 µm)
Common/Usual Name: Embolization Device
Classification Name: Vascular Embolization Device
Manufacturer: BioSphere Medical S.A.
Premarket Notification: K052742, cleared Nov 7, 2006

Premarket Notification Predicate Device # 2:
Trade Name: QuadraSphere Microspheres (Size: 30-60µm)
Common/Usual Name: Embolization Device
Classification Name: Neurovascular Embolization Device
Manufacturer: BioSphere Medical S.A.
Premarket Notification: K113822, cleared Feb 6, 2012

BioSphere Medical S.A
QuadraSphere® Microspheres
Traditional Premarket Notification 510(k):
Change in Indication for use

Classification	Class II 21 CFR § 870.3300, 21 CFR § 882.5950 Product code: KRD, HCG 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 in vials 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)
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 devices K052742 (50-100µm, 100-150µm and 150-200µm) and K113822 (30-60µm). 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 Traditional 510(k) are identical to the predicate QuadraSphere Microspheres, K052742 (50-100µm, 100-150µm and 150-200µm) cleared on November 7, 2006 and K113822 (30-60µm) cleared on February 6, 2012. Only the indications for use change between the subject device and the legally marketed QuadraSphere Microspheres, K052742 and K113822. The indications for use statement of the subject QuadraSphere Microspheres includes a specific indication by identifying "hepatoma" as being a subset of hypervascularized tumors treated with vascular embolization devices, as established by 21 CFR § 870.3300.

Technological Characteristics Comparison Table				
Attribute	**Predicate Device QuadraSphere Microspheres 50-100µm 100-150µm 150-200 µm**	**Predicate Device QuadraSphere Microspheres 30-60µm**	**Subject Device QuadraSphere Microspheres 30-60µm 50-100µm 100-150µm 150-200 µm**	**Comment**
Shelf Life (single use)	Three years (36 months)	Three years (36 months)	Three years (36 months)	Same
Material	PVA Acrylic Copolymer (vinyl alcohol-sodium acrylate)	PVA Acrylic Copolymer (vinyl alcohol-sodium acrylate)	PVA Acrylic Copolymer (vinyl alcohol-sodium acrylate)	Same
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	Biocompatible, hydrophilic, non-resorbable, expandable, conformable and swell upon exposure to aqueous solutions	Same
Sterilization	Radiation Sterilized	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	Designed for controlled, targeted embolization when vessel conformity is desired	Same
Volume of Microspheres in Vial (dry)	25 mgs per vial	25 mgs per vial	25 mgs per vial	Same

Safety & Performance Tests	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. Non-clinical performance testing conducted on the predicate device includes: • Chemical analysis • Size range • Catheter compatibility • Density • Packaging performance • Shelf Life • Sterility • Biocompatibility Biocompatibility evaluation was performed in accordance with ISO 10993-1:2009 for permanent implants in contact with blood for the predicate devices K052742 (50-100µm, 100-150µm and150-200µm) and K113822 (30-60µm), and is being adopted for this subject device based upon the fact that all devices are made from the same materials using the same manufacturing and sterilization processes. No new testing was performed since both predicate devices, K052742 (50-100µm, 100-150µm and150-200µm) and K113822 (30-60µm), and the subject QuadraSphere Microspheres have identical technological characteristics, manufacturing, processing and sterilization.
Summary of Substantial Equivalence	Based on the same intended use (other than the requested change that is the objective of this submission), design, fundamental scientific technological characteristics, fundamental operational characteristics and safety and performance testing, the BioSphere Medical subject QuadraSphere Microspheres device meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate devices, QuadraSphere Microspheres K052742 (50-100µm, 100-150µm and 150-200µm) and K113822 (30-60µm).