K113822

MAR - 8 2012

510(K) SUMMARY

General Provisions	Submitter Name:	BioSphere Medical, Inc.
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	Telephone Number:	(781) 681-7900
	Fax Number:	(781) 871-2325
	Contact Person:	Linda J. Varroso
	Date of Preparation:	December 23, 2011
	Registration Number:	1226551
Subject Device	Trade Name:	QuadraSphere Microspheres
	Common/Usual Name:	Neurovascular Embolization Device
	Classification Name:	Neurovascular Embolization Device
Predicate Device	Trade Name:	QuadraSphere Microspheres
	Classification Name:	Neurovascular embolization device
	Premarket Notification:	K052742
	Manufacturer:	BioSphere Medical, S.A.
Classification	Class II 21 CFR § 882.5950 Neurovascular Embolization Device	
Intended Use	QuadraSphere Microspheres are indicated for embolization of hypervascularized tumors and peripheral arteriovenous malformations.	

Device Description

The QuadraSphere Microspheres are sterile, biocompatible, hydrophilic, non-resorbable, expandable, acrylic copolymer microspheres. QuadraSphere Microspheres size is: 30 to 60µm in containers (*vials*) containing 25 mg of dry microspheres, which can absorb aqueous media up to 64 times their dry state volume. 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.

The QuadraSphere Microspheres have the following properties:

- Retains 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 absorbs contrast media and 0.9% saline solution. The spheres are positively charged, which allows them to bond ionically with negatively charged aqueous based solutions.
- Compresses in the vessel lumen, providing more surface contact with vessel intima.
- Expands 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. 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 technological characteristics of the subject of this Special 510(k) are substantially equivalent to the predicate device, QuadraSphere Microspheres, 510(k) K052742, cleared on November 7, 2006.

The only difference between the new subject device and the predicate device is the additional size offering (30 to 60µm) of the QuadraSphere Microsphere. **The indications for use remain the same.** All of the QuadraSphere Microspheres react the same and expand approximately 4 times their dry size when properly reconstituted in saline.

Technological Characteristics

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

BioSphere Medical, Inc. bases its claim of the substantial equivalence of the QuadraSphere Microspheres with the cited predicate device based on intended use, indications for use, fundamental 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 30 to 60µm size microsphere to permit selection of the appropriate size for target vessels. All cited embolization agents are intended for single use and are provided sterile. The following testing successfully met requirements, which evaluated fundamental characteristics: Bioburden; Endotoxin; Granulometry (size distribution) Swelling in Contrast Agent; Optical Inspection; and Water Content (Microsphere).

Safety & Performance Tests

The parameter evaluated (animal study) concerning fundamental operational characteristics for the subject device were met. An animal study to evaluate safety and product performance of QuadraSphere Microspheres 30-60um was conducted using healthy minipigs. The objective was to evaluate location of occlusion, in vitro granulometry, histopathology, and safety. Evaluation of location of occlusion was determined by the diameter of blood vessels occluded by the microspheres in histopathology specimens. Safety was assessed from animal behavior, blood tests, and histopathologic examination. In vitro granulometry demonstrated that microspheres were within the expected size range. Embolization was successful for all animals, and there were no significant adverse events post procedure. The mean diameter of the occluded vessels was 146± 46µm (median 136µm), and the mean number of microspheres in the occluded vessel section was 1.4±0.8 µm (median 1.0 µm). Macrophages were present in most of the occluded vessels, while neutrophils, lymphocytes and eosinophils were rare. These findings are consistent with similar studies of histological response to several types of embolic particles. The results of the study demonstrated that hepatic artery embolization in the pig liver with QuadraSphere 30-60µm was feasible and tolerated well both clinically and biologically by the animals.

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 testing 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 30 to 60µm fulfill design and performance specifications. Performance testing of the subject device was conducted based on the requirements of design input and output requirements. The results of the testing demonstrated that the subject BioSphere Medical QuadraSphere Microspheres 30 to 60µm met the pre-determined acceptance criteria applicable to the size requirements and performance of the device.

Summary of Substantial Equivalence	Based on the same indications for use, design, scientific technology and safety and performance testing, the BioSphere Medical QuadraSphere Microspheres 30 to 60µm device meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

BioSphere Medical, Inc.
c/o Ms. Linda J. Varroso, RAC
Quality Assurance and regulatory Affairs Director
1050 Hingham Street
Rockland, MA 02370

MAR - 8 2012

Re: K113822
Trade/Device Name: QuadraSphere® Microspheres
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG
Dated: February 6, 2012
Received: February 7, 2012

Dear Ms. Varroso:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113822

Device Name: QuadraSphere® Microspheres

Indications for Use:

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

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jeffrey Toy

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K113822