

K05 2742

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**510(k) Summary
for the BioSphere Medical, Inc.
QuadraSphere™ Microspheres**

1. SUBMITTER/510(K) HOLDER

BioSphere Medical, Inc.
1050 Hingham Street
Rockland, MA 02370 USA

NOV - 7 2006

Contact Person: Irina Kulinets
Telephone: 781-681-7900

Date Prepared: September 29, 2005

2. DEVICE NAME

Proprietary Name: QuadraSphere™ Microspheres
Common/Usual Name: Embolization device
Classification Name: Vascular embolization device

3. PREDICATE DEVICES

- Biocompatibles UK Ltd., GelSpheres, BeadBlock Compressible Microspheres (K042231)
- Boston Scientific Corporation, Contour SE (K022427, K032542)
- Interventional Therapeutics Corporation, Contour Emboli (K944354)
- BioSphere Medical, Inc., Embospheres (K991549)

4. DEVICE DESCRIPTION

BioSphere Medical, Inc., QuadraSphere™ Microspheres are sterile, biocompatible, hydrophilic (*absorbent*), non-resorbable, acrylic copolymer microspheres. They are provided in three (nominal) microsphere sizes: 50 to 100 µm, 100 to 150 µm, and 150 to 200 µm in containers (*vials*) containing 50 mg of the dry spheres.

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5. INTENDED USE

The BioSphere QuadraSphere™ Microspheres are intended for embolization of hypervascularized tumors and peripheral vascular arteriovenous malformations (AVMs).

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

BioSphere Medical, Inc. bases its claim of the substantial equivalence of the QuadraSphere™ Microspheres with the cited predicate devices based on intended use, indications for use, fundamental 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. Like predicate devices the QuadraSphere™ Microspheres are available in a range of sizes to permit selection of the most appropriate size for target vessels. All cited embolization agents are intended for single use and are provided sterile.

7. PERFORMANCE TESTING

In-vitro and in-vivo design verification and validation testing demonstrates that the BioSphere Medical, Inc. QuadraSphere™ Microspheres fulfill design and performance specifications.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Biosphere Medical, Inc.
% Medical Device Consultants, Inc.
Rosina Robinson, RN, Med, RAC
Principal Consultant
49 Plain Street
North Attleboro, Massachusetts 02760

NOV - 7 2006

Re: K052742
Trade/Device Name: QuadraSphere™ Microspheres
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular embolization device
Regulatory Class: II
Product Code: KRD, HCG
Dated: August 15, 2006
Received: August 16, 2006

Dear Ms. Robinson:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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.

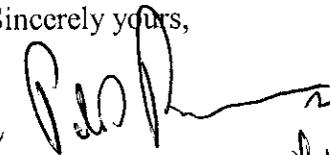
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

For  *from*
Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health
DEB
AAS

Enclosure

K052742

Indications for Use

510(k) Number (if known): K052742

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)

(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K052742