APR 2 6 2000

K991549

510(k) Summary
for
Biosphere Medical, Inc.
EMBOSPHERE® Microspheres

1. SPONSOR

Biosphere Medical, Inc.
1050 Hingham Street
Rockland, MA 02370
Telephone: (781) 681-7900
Fax: (781) 681-5093

Contact Individual: Jon McGrath

2. DEVICE NAME

Proprietary Name:	EMBOSPHERE® Microspheres
Common/Usual Name:	Artificial embolization device
Classification Name:	Artificial embolization device

3. PREDICATE DEVICES

- ITC Contour Emboli (K944354)
- ITC Radiopaque Spherical Emboli (RSE) (K871047)
- Target Therapeutics Berenstein Coil (K961923, K964112)

4. DEVICE DESCRIPTION

EMBOSPHERE® Microspheres are spherical microbeads for arterial embolization, made of acrylic polymer impregnated with gelatin. They are delivered with the help of a microcatheter in an amount appropriate to the area to be embolized. Six ranges of EMBOSPHERE® Microspheres are available in order to allow the physician to choose the calibration necessary for the vessel being embolized:

- 40-120 microns
- 100-300 microns
- 300-500 microns
- 500-700 microns
- 700-900 microns
- 900-1200 microns

5. INTENDED USE

EMBOSPHERE® Microspheres are indicated for embolization of hypervascular tumors and arteriovenous malformations.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The method of application for EMBOSPHERE® Microspheres and all of the predicate devices is the same. All are intended to be delivered to selected sites through catheters with a diameter appropriate for the vascular target and the size of the emboli. Accurate placement of all of the embolization devices is assured through visualization of the embolization process using radiographic imaging. The RSE silicone elastomer microspheres and the Berenstein Coils are both radiopaque, while the PVA particles and EMBOSPHERE® Microspheres are mixed with a radiopacity agent prior to injection to permit visualization. The EMBOSPHERE® Microspheres, like the predicate devices, are available in a range of sizes to permit selection of the most appropriate size for target vessels. EMBOSPHERE® Microspheres and all of the substantially equivalent embolization devices are intended for single use. The ITC RSE silicone microspheres are supplied non-sterile, while the EMBOSPHERE® Microspheres, and all of the other predicate devices, are supplied sterile.

7. PERFORMANCE TESTING

The substantial equivalence of EMBOSPHERE® Microspheres was supported by both in-vitro and in-vivo performance testing, which included the following:

- biocompatibility testing conducted in accordance with ISO 10993
- bench testing conducted during the development of the product[1]
- animal testing to examine ease of injection, depth of penetration, and tissue reaction[2]
- clinical data describing the European experience with using EMBOSPHERE® Microspheres to treat a variety of hypervascular tumors and arteriovenous malformations[3]
- the results of a clinical study comparing EMBOSPHERE® Microspheres to PVA for preoperative embolization of meningiomas.[4]

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[1] Laurent A, Beaujeux R, Wassef M, et al.: Trisacryl gelatin microspheres for the therapeutic embolization, I: Development and in vitro evaluation. AJNR, 17:533-40, Mar 1996.
[2] Derdeyn CP, Graves VB, Salamat MS, et al.: Collagen-coated acrylic microspheres for embolotherapy: In vivo and in vitro characteristics. AJNR, 18:647-53, Apr 1997.
[3] Beaujeux R, Laurent A, Wassef M, et al.: Trisacryl gelatin microspheres for therapeutic embolization, II: Preliminary clinical evaluation in tumors and arteriovenous malformations. AJNR, 17:541-48, Mar 1996.
[4] Bendszus M, Klein R, Burger R, et al.: Efficacy of trisacryl gelatin microspheres versus polyvinyl alcohol particles in the preoperative embolization of meningiomas. AJNR, 21(2):255-61, Feb 2000.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Biosphere Medical, Inc.
c/o Ms. Sheila Hemeon-Heyer, J.D., R.A.C.
Senior Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

APR 26 2000

Re: K991549
Trade Name: EMBOSPHERE® Microspheres
Regulatory Class: III
Product Code: HCG
Dated: January 26, 2000
Received: January 27, 2000

Dear Ms.Hemeon-Heyer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K991549

510(k) Number (if known): K991549

Device Name: BioSepra EMBOSPHERE® Microspheres

Indications For Use:

EMBOSPHERE® Microspheres are indicated for embolization of hypervascular tumors and arteriovenous malformations.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of [illegible] Devices

510(k) Number K991549

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____