510(k) Summary

DEC 16 2002

September 13, 2002

Submitter: BioCure, Inc
2975 Gateway Drive
Suite 100
Norcross, GA
(678) 966-3422

Contact: Dennis Goupil, PhD

510(k) Numbers and Product Codes of equivalent devices.

Biosphere Medical, Inc,
Embospheres® Microspheres
510K Number: #K991549
Product Code: HCG
CFR Section: 882.5950

Biosphere Medical, Inc,
EmboGold™ Microspheres
510K Number: #K010026
Product Code: HCG
CFR Section: 882.5950

Indications for Use and Intended Population

GelSpheres™ Embolic Agent are indicated for Embolization of hypervascular tumors and arteriovenous malformations (AVM's)

Device Description

GelSpheres™ Embolic Agent are preformed soft, deformable microspheres that occlude arteries for the purpose of blocking the blood flow to a target tissue, such as a hypervascualr tumor or arteriovenous malformations (AVM's). GelSpheres™ Embolic Agent consists of a macromer derived from polyvinyl alcohol (PVA). The fully polymerized microsphere is approximately 90% water and is compressible to approximately 20-30% by diameter. GelSpheres™ Embolic Agent is dyed blue to aid in the visualization of the microspheres in the delivery syringe. The microspheres can be delivered through typical microcatheters in the 1.8-5Fr range.

The product is supplied sterile and packaged in sealed glass bottles for V-Series Model numbers, and in pre-filled syringes for S- Series model numbers. Two quantities will be available in a vial: (1) 1.0 mL GelSpheres™ Embolic Agent in sterile physiologic buffered saline (PBS) to a volume of 8 mL, and (2) 2.0mL GelSpheres™ Embolic Agent in sterile PBS to a volume of 8 mL. Two quantities will be available in a pre-filled syringe: (1) 1.0mL GelSpheres™ Embolic Agent in sterile PBS to a volume of 5 mL, and (2) 2.0mL GelSpheres™ Embolic Agent in sterile PBS to a volume of 5 mL.

GelSpheres™ Embolic Agent is supplied in several units covering the range from 100μm to 1200μm diameter. The product size ranges are listed below:

Size Range	1 ML Vial (7-11)	2 ML Vial (7-11)	1 ML Syringe (7-1)	2 ML Syringe (7-1)
100-300μm	V210GS	V220GS	S210GS	S220GS
300-500μm	V410GS	V420GS	S410GS	S420GS
500-700μm	V610GS	V620GS	S610GS	S620GS
700-900μm	V810GS	V820GS	S810GS	S820GS
900-1200μm	V1010GS	V1020GS	S1010GS	S1020GS

At the time of use, GelSpheres™ Embolic Agent is mixed with a nonionic contrast agent, e.g. Omnipaque, to make a 30-50% by weight solution. The bolus of contrast agent elutes from the vascular bed to leave a radiolucent, embolized vessel.

Similarities and Differences to Predicates

The Intended Use of GelSpheres™ Embolic Agent and the predicate devices is the same. All devices 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. All of the devices are mixed with a radiopacity agent prior to injection to permit visualization. GelSpheres™ Embolic Agent, like the predicate devices are available in a range of sizes to permit selection of the most appropriate size for target vessels. GelSpheres™ Embolic Agent are made from polyvinyl alcohol, whereas Embospheres® Microspheres and EmboGold™ Microspheres are comprised of acrylic polymer impregnated with gelatin. GelSpheres™ Embolic Agent and Embospheres® Microspheres are deformable microspheres. GelSpheres™ Embolic Agent and EmboGold™ microspheres are colored to make the device more visible to the physician when preparing and injecting the embolic agents in a syringe. GelSpheres™ Embolic Agent and the substantially equivalent

devices are intended for single use and are supplied sterile and non pyrogenic. GelSpheres™ Embolic Agent , Embospheres™ Microspheres and EmboGold™ are all supplied in both bottles and syringes.

There are more similarities than differences when comparing BioCure, GelSpheres™ to the predicate devices.

Performance Standards

The BioCure GelSpheres™ Embolic Agent meets the following Performance Standards:

- Guidance For Industry; 2000: FDA Guidance for Neurological Embolization Products
- ISO/EN 10993-1; 1997 Biological Evaluation of Medical Devices, Part I: Evaluation and Testing
- ISO/EN 10993-3; 1993 Biological Evaluation of Medical Devices, Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.
- ISO/EN 10993-4; 1993 Biological Evaluation of Medical Devices, Part 4: Selection of tests for interaction with blood.
- ISO/EN 10993-6; 1995 Biological Evaluation of Medical Devices, Part 6: Test for local effects after implantation.
- ISO/EN 10993-10; 1995 Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Sensitization.
- ISO/EN 10993-11; 1993 Biological Evaluation of Medical Devices, Part 11: Tests for Systemic Toxicity.
- ISO/EN 10993-13; 1995 Biological Evaluation of Medical Devices, Part 13: Identification and Quantification of potential degradation products from polymers.
- ISO/EN 11607; 1997 – Packaging for terminally sterilized products.
- AAMI TIR 22;1998 – Guidance for application of EN 11607, Packaging for terminally sterilized products
- AAMI 11134; 1993 – Sterilization of Health Care Products – Requirements for validation and routine control – Industrial moist heat sterilization 2nd edition.
- ANSI/AAMI/ISO 14937; 2000 – Sterilization of Health Care Products – Characterization of a Sterilizing Agent and the Development, Validation and Routine Control of a Sterilization Process for Medical Devices.

- EN 554: Sterilization of Medical Devices – validation and Routine Control of Sterilization by Moist Heat

Conclusion

There are more similarities than differences between the predicate devices and the BioCure, Inc. GelSpheres™ Embolic Agent. Both the predicate devices and GelSpheres™ have the same intended use, warnings and contraindications. Both the predicate devices and GelSpheres are similar in design. When used in accordance with the instructions for use, by qualified personnel, the BioCure, Inc. GelSpheres™ are safe and effective, as indicated, for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 2002

BioCure, Inc.
c/o Mr. John Greenbaum
Generic Devices Consulting, Inc.
20310 SW 48th Street
Fort Lauderdale, Florida 33332

Re: K023089
Trade/Device Name: GelSpheres Embolic Agent
Regulation Number: 21 CFR 882.5950; 21 CFR 870.3300
Regulation Name: Artificial embolization device; Arterial Embolization Device
Regulatory Class: III
Product Code: HCG; KRD
Dated: September 13, 2002
Received: September 17, 2002

Dear Mr. Greenbaum:

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 (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for 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

K023089

510(k) Number(if known):_____

Device Name: GelSpheres™ Embolic Agent

Indications For Use:

"GelSpheres™ Embolic Agent is intended for embolization of hypervascular tumors and arteriovenous malformations."

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_X_ OR Over-The-Counter Use___
(Per 21 CRF 801.109)

(Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023089