NOV 1 2 2004

510(k) Summary

Submitter: Biocompatibles UK Ltd.
Weydon Lane
Chapman House
Weydon Lane, Farnham, Surrey
+44 1252732732

Contact: Dr. Alistair Taylor

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

Biocure, Inc,
GelSpheres™ Microspheres
510K Number: #K023089
Product Code: HCG
CFR Section: 882.5950

Biocompatibles UK Ltd.
GelSpheres™ Microspheres
Bead Block™ Compressible Microspheres
510K Number: #K033761
Product Code: HCG
CFR Section: 882.5950

Indications for Use and Intended Population

"GelSpheres™/Bead Block™ Compressible Microspheres are indicated for Embolization of hypervascular tumors and arteriovenous malformations (AVM's).

Device Description

GelSpheres™ and Bead Block™ Compressible Microspheres are preformed soft, deformable microspheres that occlude arteries for the purpose of blocking the blood flow to a target tissue, such as a hypervascular tumor or arteriovenous malformations (AVM's). GelSpheres™ and Bead Block ™ Compressible Microspheres consist 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. Bead Block™ Compressible Microspheres is dyed blue (GelSpheres™ are

K042231
2/3

available in natural color) 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.

GelSpheres™ Microspheres is supplied sterile and packaged in sealed glass vials. Bead Block™ Compressible Microspheres is supplied sterile and packaged in a polycarbonate syringe. Two quantities will be available in a vial: (1) 1.0 mL GelSpheres™ /Bead Block™ Compressible Microspheres in sterile physiologic buffered saline (PBS) to a volume of 8 mL, and (2) 2.0mL GelSpheres™/Bead Block™ Compressible Microspheres in sterile PBS to a volume of 8 mL.

GelSpheres™ and Bead Block Compressible Microspheres are supplied in several unit sizes covering the range from 100μm to 1200μm diameter. At the time of use, GelSpheres™/Bead Block™ Compressible Microspheres 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™ /Bead Block™ Compressible Microspheres and the predicate device are the same and unchanged other than product names. This pre-market notification addresses the change of the final packager from BioCure, inc to Biocompatibles UK LTD.

There are more similarities than differences when comparing Biocompatibles, GelSpheres™/Bead Block™ to the predicate devices.

Performance Standards

GelSpheres™/BeadBlock Compressible Microspheres meet the following Performance Standards:

- Guidance For Industry; 2004: 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 device and the Biocompatibles GelSpheres™/Bead Block™ Compressible Microspheres. The product, manufacturing and primary packaging are unchanged from K023089/K033761. The predicate device and GelSpheres™/Bead Block™ Compressible Microspheres have the same intended use, warnings and contraindications. The predicate device and GelSpheres™/Bead Block™ Compressible Microspheres are identical in design, and unchanged from K023089. When used in accordance with the instructions for use, by qualified personnel, the Biocompatibles GelSpheres™/Bead Block™ Compressible Microspheres 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

NOV 12 2004

Biocompatibles U.K. Ltd.
C/o John Greenbaum
Generic Devices Consulting, Inc.
20310 SW 48th Street
Ft. Lauderdale, Florida 33332

Re: K042231
Trade/Device Name: GelSpheres™ Microspheres
Bead Block™ Compressible Microspheres
Regulation Number: 21 CFR 882.5950
Regulation Name: Artificial embolization device
Regulatory Class: III
Product Code: HCG
Dated: August 14, 2004
Received: August 17, 2004

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 (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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

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

K042231

007

510(k) Number(if known):_____

Device Name: GelSpheres™ Microspheres
Bead Block™ Compressible Microspheres

Indications For Use:

"GelSpheres™ Microspheres & Bead Block™ Compressible Microspheres is intended for embolization of hypervascular tumors and arteriovenous malformations."

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042231

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 1-2-96)