

4 510K Summary

Submitter:

DEC 24 2008

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/KRD
CFR Section: 882.5950

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

Biocompatibles UK Ltd.
GelSpheres Microspheres
Bead Block™ Compressible Microspheres
510K Number: #K042231
Product Code: HCG
CFR Section: 870.3300

4.1 Indications for Use and Intended Population

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

4.1.1 Device Description

LC Bead 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). LC Bead 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 (LC Bead are 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.

LC Bead 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 LC Bead /Bead Block™ Compressible Microspheres in sterile physiologic buffered saline (PBS) to a volume of 8 mL, and (2) 2.0mL LC Bead/Bead Block™ Compressible Microspheres in sterile PBS to a volume of 8 mL.

LC Bead and Bead Block Compressible Microspheres are supplied in several unit sizes covering the range from 100µm to 1200µm diameter.

At the time of use, LC Bead/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.

4.2 Similarities and Differences to Predicates

The Intended Use of LC Bead /Bead Block™ Compressible Microspheres and the predicate device are the same and unchanged other than product names. This pre-

market notification addresses Biocompatibles UK Ltd. intent to market LC Bead with the Vascular (KRD) Code and to update its registration and listing with this code.

Other than trade name there are no differences when comparing Biocompatibles, LC Bead/Bead Block™ to the predicate devices.

4.3 Performance Standards

LC Bead/Bead Block 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 1: 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 11607; 1997 – 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



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 24 2008

Generic Devices Consulting, Inc.
c/o Mr. John Greenbaum
20310 SW 48th Street
Ft. Lauderdale, FL 33332

Re: K083091

LC Bead Microspheres, Bead Block Compressible Microspheres
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: October 11, 2008
Received: October 17, 2008

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.

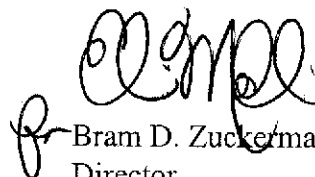
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,



Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number(if known): K083091

Device Name:

LC Bead Microspheres
Bead Block™ Compressible Microspheres

Indications For Use:

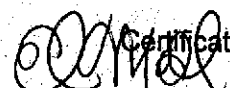
"LC Bead Microspheres & Bead Block™ Compressible Microspheres is intended for embolization of hypervascular tumors and arteriovenous malformations."

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 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)



Certification Statement

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K083091