K073417

DEC 15 2008

510(k) Summary

Contact Information: CeloNova BioSciences, Inc.
49 Spring Street
Newnan, GA 30263
Telephone: (770) 502-0304
Facsimile: (770) 502-0773

Trade Name: Embozene™ Microspheres
Embozene™ Color Advanced Microspheres

Common Name: Vascular Embolization Particles

Classification Name: Artificial Embolization Device

Device Product Codes: KRD

Regulation Numbers: 21 CFR 870.3300

Substantial Equivalence: The CeloNova BioSciences, Inc. Embozene™ Microspheres and Embozene™ Color Advanced Microspheres are substantially equivalent in basic design, construction, indication for use, and performance characteristics to other commercially available vascular embolization particles.

Device Description: Celonova BioSciences, Inc. Embozene™ Microspheres are spherical embolic hydrogels. They are artificial embolization devices used to obstruct or reduce blood flow to hypervascularized tumors or arteriovenous malformations via selective microcatheter delivery.

The embolization particles are available in seven (7) size ranges of 40, 100, 250, 400, 500, 700 and 900 µm diameters to enable appropriate size selection for the tumor or malformation to be treated. Embozene™ Microspheres are designed for use under fluoroscopic guidance through compatible delivery catheters. The product is provided as a sterile, non pyrogenic, single use device. It is an uncolored or color-coded particle that is opaque under fluoroscopy. The product and its delivery container are steam sterilized.

Indications for Use: Embozene™ Microspheres are indicated for the embolization of hypervascular tumors and arteriovenous malformations. Embozene™ Microspheres may be used for vascular occlusion of blood vessels within the neurovascular system.

Predicate Devices: Embozene™ Microspheres are substantially equivalent to these predicate devices:

Biocompatibles Gelspheres™ Microspheres (Vial) (colored) - K033761
Biocompatibles Bead Block™ Microspheres (Syringe) (colored) - K033761
Boston Scientific Contour SE™ Microspheres K032707
Boston Scientific Contour SE™ Microspheres K034068
Boston Scientific Contour SE™ Microspheres K071634

Clinical Data: None required.

Adverse Safety & Effectiveness Information: None.

Signature _____ **Date** 28 April 2008
Ralph E. Gaskins, Jr, MD, JD
Vice President, Legal and Intellectual Property

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 2008

CeloNova BioSciences, Inc.
c/o Mr. Thomas A. Gordy
President and Chief Executive Officer
49 Spring Street
Newnan, GA 30263

Re: K073417
Enbozene™ Microspheres
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: October 8, 2008
Received: October 9, 2008

Dear Mr. Gordy:

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 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,

Donna R. Vichmes

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073417 Device

Name: **Embozene™ Microspheres** Indications

For Use:

Embozene™ Microspheres are indicated for the embolization of hypervascular tumors and arteriovenous malformations.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____ (Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vollmer
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K073417