

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.

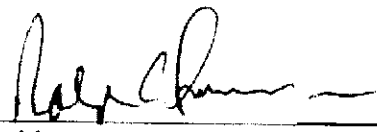
**Indications for Use:** Embozene™ Microspheres are indicated for the embolization of hypervascular tumors and arteriovenous malformations. Embozene™ Microspheres may be used for vascular occlusion of blood vessels within the neurovascular system.

**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**   
Ralph E. Gaskins, Jr, MD, JD  
Vice President, Legal and Intellectual Property

**Date** 28 April 2008



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.

Page 2 - Mr. Thomas A. Gordy


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" (21 CFR 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*

 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  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)

*Diana B. Williams*  
(Division Sign-Off)  
Division of Cardiovascular Devices  
510(k) number K073417