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# 510(k) Summary

Per 21 CFR §807.92

APR 16 2010

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|---|---|
| **Submitter's Name and Address** | Boston Scientific Corporation<br>One Scimed Place<br>Maple Grove, MN 55311 |
| **Contact Name and Information** | Debbie McIntire<br>Senior Regulatory Affairs Specialist<br>Phone: (408) 935-4679<br>Fax: (763) 494 2981 |
| **Date Prepared** | March 5, 2010 |
| **Proprietary Name(s)** | Contour™ Embolization Particles |
| **Common Name** | Contour Embolization Particles |
| **Product Code** | NAJ |
| **Classification of Device** | Class II, 21 CFR Part 870.3300 |
| **Predicate Device** | Contour™ Embolization Particles K030966 September 23, 2003 |
| **Device Description** | Contour Embolization Particles are artificial embolization devices. These devices are intended to provide vascular occlusion upon selective placement via an angiographic catheter. Contour Embolization Particles are packaged sterile by gamma irradiation. Each vial is intended for single patient use only.<br><br>The Contour™ Embolization particles are packaged in 1 cc dry volume per vial. The vials (glass with screw cap closure) are contained within a poly/Tyvek® pouch. The pouches are placed in boxes, in either a 2 vial/box or 5 vial/box configurations. All vials and boxes are appropriately labeled. The labels are color coded to differentiate between the different size ranges. The device is sterilized by gamma irradiation and labeled with a 26 month shelf life.<br><br>The Contour Embolization Particles are available in a range of sizes as tabulated below: |

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**Device Description (continued)**

| Size | Minimum Compatible Catheter ID |
|---|---|
| 45-150 µm<br>150-250 µm<br>250-355 µm<br>355-500 µm | 0.53 mm (0.021 in)<br>(e.g. Renegade™ 18, Renegade STC) |
| 500-710 µm | 0.69 mm (0.027 in)<br>(e.g. Renegade Hi-Flo) |
| 710-1000 µm<br>1000-1180 µm | 1.12 mm (0.044 in)<br>(e.g. Imager™ II Selective) |

The Contour Embolization Particles are made of polyvinyl alcohol, which has been used for embolization procedures since 1972.

**Intended Use of Device**

Boston Scientific's Contour Embolization Particles are used for the embolization of peripheral hypervascular tumors, including leiomyoma uteri and peripheral arteriovenous malformations (AVMs).

**Comparison of Technological Characteristics**

The materials and design of the Contour Embolization Particles are equivalent to the predicate Contour Embolization Particles.

**Support of Substantial Equivalence**

Boston Scientific Corporation considers the proposed Contour Embolization Particles to be substantially equivalent to the existing Contour Embolization Particles (K030966, cleared September 23, 2003). This assessment is based upon identical device materials and design characteristics. The only change being initiated is to the labeling. The 510(k) is being submitted to delete two contraindications from the Directions for Use and add two new contraindications.

**Conclusion**

Based on the indications for use and the technological characteristics, the Contour Embolization Particles has been shown to be equivalent in intended use and is considered to be substantially equivalent to the Contour Embolization Particles (K030966; cleared September 23, 2003).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Ms. Debbie McIntire
Senior Regulatory Affairs Specialist
Boston Scientific Corporation
One Scimed Place
MAPLE GROVE MN 55311

APR 16 2010

Re: K100663
Trade Name: Contour™ Embolization Particles
Regulation Number: 21 CFR § 870.3300
Regulation Name: Vascular embolization device
Regulatory Class: II
Product Code: NAJ
Dated: March 5, 2010
Received: March 8, 2010

Dear Ms. McIntire:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

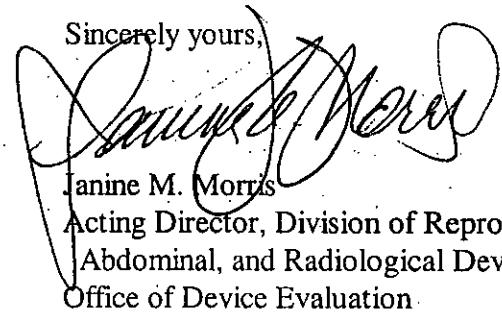
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use Statement

**510(k) Number:** K100663

**Device Name:** Contour™ Embolization Particles

**Indications for Use:**

The Contour Embolization Particles are used for the embolization of peripheral hypervascular tumors, including leiomyoma uteri and peripheral arteriovenous malformations (AVMs).

Do not use particles smaller than 355 microns for the treatment of leiomyoma uteri.

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K100663