Special 510(k)
Modified CSEM
Boston Scientific Corporation
June 14, 2007

Summary of Safety and Effectiveness

K071634

JUL 12 2007

General Information

Submitter: Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752
508-683-4234

Contact Person: Shilpa Prem

General Provisions

Trade Name: Contour SE™ Microspheres (Syringe)

Classification Name: Vascular Embolization Device

Name of Predicate Devices

Contour SE™ Microspheres

Classification

Class II

Performance Standards

Performance Standards have not been established by FDA under Section 514 of the Food, Drug and Cosmetic Act

Intended Use Device Description

Contour SE Microspheres (Syringe) is intended to be used for the embolization of hypervascular tumors, including leiomyoma uteri and arteriovenous malformations (AVMs).

Device Description

Contour SE Microspheres are spherical-shaped polyvinyl alcohol embolic devices to provide targeted vascular occlusion or reduction of blood flow within targeted vessels. The product is packaged sterile syringe containing a 1 mL of or 2 mL of Contour SE Microsphere and 5 mL of saline. Each syringe is packaged in a sterile, peel-away barrier.

Contour SE Microspheres are designated for smooth delivery through a variety of infusion catheters.

Summary of Substantial Equivalence

The Contour SE Microspheres (Syringe) have been tested and compared to the predicate devices. All data gathered demonstrate this device as substantially equivalent. No new issues of safety and efficacy have been raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Boston Scientific Corporation, Inc
% Ms. Shilpa Prem
Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, Massachusetts 01752-1234

JUL 12 2007

Re: K071634
Trade/Device Name: Contour SE™ Microspheres
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular embolization device
Regulatory Class: II
Product Code: HCG, KRD
Dated: June 14, 2007
Received: June 15, 2007

Dear Ms. Prem:

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K071634

Device Name: Contour SE™ Microspheres

Indications For Use: Contour SE Microspheres are indicated for the embolization of hypervascular tumors, including leiomyoma uteri and arteriovenous malformations (AVMs).

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K071634