Section 15

Summary of Safety and Effectiveness

General Provisions	**Trade Name**: Contour SE™ Microspheres **Classification Name:** Artificial Embolization Device
Name of Predicate Devices	Contour SE™ Microspheres (K022427, K032707 & K032542) Contour™ Emboli PVA (K030966)
Classification	Class III
Performance Standards	Performance Standards have not been established by FDA under Section 514 of the Food, Drug and Cosmetic Act
Intended Use and Device Description	Contour SE™ Microspheres may be used for the embolization of hypervascular tumors, **including leiomyoma uteri,** and arteriovenous malformations (AVMs).
Biocompatibility	No new materials have been introduced during this modification to the indications for use statement as compared to the predicate devices. The predicate devices have been tested for biocompatibility per ISO 10993. All data demonstrate this device is biocompatible for its intended use.
Summary of Substantial Equivalence	The Contour SE™ Microspheres have been tested and compared to the predicate device. All data gathered demonstrate this device as substantially equivalent. No new issues of safety or efficacy have been raised. Clinical data were collected in a prospective clinical study to support the safety and effectiveness of these devices for treatment of uterine fibroids.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 26 2004

Ms. Jennifer Bolton, RAC
Senior Regulatory Affairs Specialist
Boston Scientific Corporation
One Boston Scientific Place
NATICK MA 01760-1537

Re: K034068
Trade/Device Name: UAE Contour SE™ Microspheres
Regulation Number: 21 CFR 870.3300
Regulation Name: Arterial embolization device
Regulatory Class: III
Product Code: 74 KRD and 85 NAJ
Dated: December 30, 2003
Received: December 31, 2003

Dear Ms. Bolton:

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 one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K034068

Device Name: **Contour® SE™ Microspheres**

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

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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K034068