SEP 2 3 2003

510(k) Summary K032707

General Provisions	**Trade Name**: Contour SE™ Microspheres **Classification Name:** Artificial Embolization Device
Device Description/ Indications for Use	The Contour SE ™ Microspheres are spherical embolic particles and are available in a variety of particle sizes and are indicated for use for the embolization of hypervascular tumors and arteriovenous malformations. These particles are provided in a sterilized syringe.
Data Summary Prepared	September 16, 2003
Contact Name/ Number	Jodi Lynn Greenizen Regulatory Affairs Project Manager Boston Scientific Corporation 10 Glens Falls Technical Park Glens Falls, NY 12801
Name of Predicate Devices	Contour® Emboli PVA Embosphere Microspheres EmboGold Microspehers
Classification	Class III, 21 CFR 882.5950 Submitted Per 21 CFR 807
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 are indicated for use for the embolization of hypervascular tumors and arteriovenous malformations.

Biocompatibility

The Contour SE™ Microspheres 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 3 2003

Ms. Jodi Lynn Greenizen
Regulatory Affairs Project Manager
Boston Scientific Corporation
Miami Technology Center
8600 N.W. 41 Street
Miami, Florida 33166

Re: K032707
Trade/Device Name: Contour SE™ Microspheres (Syringe)
Regulation Number: 21 CFR 882.5950
Regulation Name: Artificial Embolization Device
Regulatory Class: III
Product Code: HCG
Dated: August 29, 2003
Received: September 2, 2003

Dear: Ms. Greenizen:

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 (301) 594-4659. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

K032707

510(k) Number (if known)	Unknown
Device Name:	Contour SE™ Microspheres
Indications for Use	Contour SE™ Microspheres are indicated for use for the embolization of hypervascular tumors and arteriovenous malformations.

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

510(k) Number K032707

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over-The Counter Use_____ (Optional Format 1-2-96)