K030966

SEP 2 3 2003



# Section 8

## Summary of Safety and Effectiveness

| | |
|---|---|
| **General Provisions** | **Trade Name**: Contour® Emboli PVA and FasTracker®-325 Infusion Catheter<br><br>**Classification Name:** Artificial Embolization Device and Intravascular Infusion Catheter |
| **Name of Predicate Devices** | Contour® Emboli PVA (K871047, K914866, K944354)<br>Fas-Tracker®-325 Infusion Catheter (K926243)<br>Embosphere Microspheres(K991549, K021397)<br>EmboGold Microspheres (K010026) |
| **Classification** | Class III, Contour® Emboli PVA<br>Class II, FasTracker®-325 Infusion Catheter |
| **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** | The Contour® Emboli PVA are used for the embolization of hypervascular tumors, **leiomyoma uteri**, and arteriovenous malformations.<br><br>The FasTracker-325® Infusion Catheters are designed to assist in the delivery of diagnostic agents, such as contrast, and therapeutic agents, to the peripheral and coronary vasculature. **This includes the delivery of the Contour® Emboli PVA to the uterine arteries for the purpose of occluding blood flow to leiomyoma uteri.** |
| **Biocompatibility** | The Contour® Emboli PVA and FasTracker®-325 Infusion Catheter have been tested for biocompatibility per ISO 10993. All data demonstrate this device is biocompatible for its intended use. |

*Continued on next page*

# Summary of Safety and Effectiveness, Continued

**Summary of Substantial Equivalence**

The Contour® Emboli PVA and FasTracker®-325 Infusion Catheter 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

SEP 23 2003

Ms. Jodi Lynn Greenizen
Regulatory Affairs Project Manager
Boston Scientific Corporation
Oncology Division
10 Glen Falls Technical Park
Dix Avenue
GLEN FALLS NY 12801

Re: K030966
Trade/Device Name: Contour® Emboli PVA and FasTracker®-325 Infusion Catheter
Regulation Number: 21 CFR §882.5950
Regulation Name: Artificial embolization device
Regulatory Class: III
Product Code: 85 NAJ
Dated: June 20, 2003
Received: June 23, 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 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)** ~~Unknown~~ K030966

**Device Name:** Contour® Emboli PVA
Fas-Tracker®-325 Infusion Catheters

**Indications for Use**

The Contour® Emboli PVA are used for the embolization of hypervascular tumors, **leiomyoma uteri**, and arteriovenous malformations.

The FasTracker-325® Infusion Catheters are designed to assist in the delivery of diagnostic agents, such as contrast, and therapeutic agents, to the peripheral and coronary vasculature. **This includes the delivery of the Contour® Emboli PVA to the uterine arteries for the purpose of occluding blood flow to leiomyoma uteri.**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David B. Lynn

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K030966

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