This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date prepared: March 7, 2005
Contact Person:
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Boston Scientific
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Tel: (510) 440-7604

Device Name:
Tracker™ Excel™-14 Pre-Shaped Microcatheter, Class II

Common name: Microcatheters
Classification name: Percutaneous Catheters

Product Code: DQY

Device Description:
The Tracker™ Excel™-14 Pre-Shaped Microcatheter is a single lumen device designed to aid the physician in accessing the distal vasculature when used with a guiding catheter and steerable guidewire. Graded shaft stiffness ranging from a highly flexible tip to a semi-rigid proximal section aids the physician in tracking over selectively placed guidewires. A luer fitting located on the catheter hub is used for the attachment of accessories. A radiopaque tip facilitates fluoroscopic visualization. The outer diameter is coated with a hydrophilic surface that reduces friction during manipulation in the vessel. The catheter is packaged individually with a variety of pre-shaped tips.

Indications for Use:
Like the predicate devices, Boston Scientific's Tracker™ Excel™-14 Pre-Shaped Microcatheter is intended to assist in the delivery of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils into the peripheral, coronary, and neuro vasculature.

Predicate Device(s):
Tracker™ Excel™-14 Microcatheter (510(k) # K994155 cleared August 3, 2000)

Testing in Support of Substantial Equivalence Determination
The predicate device which was originally cleared for straight steam-shapeable tip was modified to include pre-shaped tips. The modification is made for ease of use to the physicians. The modification involves a new tip shaping process and the necessary packaging modifications to protect the new tip shapes.

The results of in-vitro testing (tip shape retention, appearance of the tip, tip dimensions, static rupture, tensile strength of tip, buckling test, and coil, guidewire and guide catheter compatibility) and biological safety testing support the claim of substantial equivalence.
Technological Characteristics and Product Feature Comparison

Tracker™ Excel™-14 Pre-Shaped Microcatheter is substantially equivalent to the predicate device in terms of functionality, materials, method of operation, intended use, indications for use, and biological safety.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Results</th>
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</thead>
<tbody>
<tr>
<td>Shaft Materials</td>
<td>Same as predicate* device</td>
</tr>
<tr>
<td>Shaft Design</td>
<td>Same as predicate* device</td>
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<tr>
<td>Distal Shaft Length</td>
<td>Same as predicate* device</td>
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<tr>
<td>Proximal ID / OD</td>
<td>Same as predicate* device</td>
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<tr>
<td>Distal ID / OD</td>
<td>Same as predicate* device</td>
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<tr>
<td>Tip Markers</td>
<td>Same as predicate* device</td>
</tr>
<tr>
<td>Coating</td>
<td>Same as predicate* device</td>
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<tr>
<td>Effective Length</td>
<td>Same as predicate* device</td>
</tr>
<tr>
<td><strong>GDC™ Compatibility</strong></td>
<td>Same as predicate* device</td>
</tr>
<tr>
<td>Tip Configuration</td>
<td>Offered with Pre-Shaped Tips with the option of secondary shaping for proper adjustment to the anatomy prior to use.</td>
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<td></td>
<td>As compared to the predicate which was cleared with straight tip, steam shapeable by physician prior to use.</td>
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</table>

* Tracker Excel -14 Microcatheter cleared under K994155 on August 3, 2000

**Boston Scientific's Guglielmi Detachable Coils, K962503 & K001083
510(K) Summary of Safety and Effectiveness

Results of the performance and biocompatibility testing, as presented in this Special 510(K), demonstrate that the Pre-Shaped devices are substantially equivalent to the respective predicate unmodified devices.

The subject catheters with Pre-Shaped tips are substantially equivalent to their respective predicate devices with respect to the following:

- functionality
- intended use
- indications for use
- materials
- method of operation
- biological safety

Based on the above information provided in this submission, Boston Scientific’s Tracker™ Excel™-14 Pre-Shaped Microcatheter is substantially equivalent to Boston Scientific’s Tracker™ Excel™-14 Microcatheter.
Dear Mr. Ham:

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) 276-0120. 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/industry/support/index.html.

Sincerely yours,

[Signature]

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
INDICATIONS FOR USE STATEMENT

510(k) Number: K050599

Device Name: 
Tracker™ Excel™-14 Pre-Shaped Microcatheter

Indications for Use:

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Prescription Use _X_ OR Over The Counter Use ________
(Per 21 CFR 801.109)

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K050599