K050599

510(K) Summary of Safety and Effectiveness

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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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.

Product Feature Comparison for the

Tracker™ Excel™-14 Pre-Shaped Microcatheter

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

* *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.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 - 2005

Boston Scientific
c/o Mr. Victor Ham
Regulatory Affairs Project Manager
47900 Bayside Parkway
Fremont, CA 94538

Re: K050599
Trade/Device Name: Tracker™ Excel™-14 Pre-Shaped Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: II
Product Code: DQY
Dated: May 3, 2005
Received: May 4, 2005

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,

Donna R. Lochner

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

Enclosure

K050599

INDICATIONS FOR USE STATEMENT

510(k) Number: K050599

Device Name:

Tracker™ Excel™ 14 Pre-Shaped Microcatheter

Indications for Use:

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.

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)

Donna R. Vochniak

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K050599