K971254

April 2, 1997

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ATTACHMENT K

SUMMARY OF SAFETY AND EFFECTIVENESS

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Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Boston Scientific Corporation is required to submit with this Premarket Notification either an "...adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Boston Scientific Corporation choose to submit a summary of information respecting safety and effectiveness. According to §513(i)(3)(B), "Any summary under subparagraph (A) respecting a device shall contain detailed information regarding data concerning adverse health effects..."

The summary regarding the adverse health effects of the proposed **Transend EX Platinum Guidewire** is as follows:

Trade Name: Transend EX Platinum Guidewire

Manufacturer: BSC/SciMed Life Systems, Inc.
2010 E. Center Circle
Maplegrove, MN 55441

Device Generic Name: Guidewire

Classification: According to Section 513 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II, Performance Standards (CFR 870.1330).

Predicate Devices: BSC Transend EX Steerable Guidewire
BSC Preceder Guidewire
Terumo Corporation's Glidewire Gold Guidewire

Product Desription:

The BSC Transend EX Platinum Guidewire with hydrophilic coating and accessories are intended for general intravascular use including the peripheral and neurovasculature. The devices will be provided sterile, and are intended for one procedure use only. Testing and evaluation included tip tensile, tip flexibility, torque strength, torque response, coating adherance, coating extraction, lubricity testing, biocompatibility and in vivo testing.

Conclusion:

Based on the Indication for Use, technological characteristics and safety and performance testing, the **Transend EX Platinum Guidewire** has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Mary P. LeGraw
Regulatory Affairs Specialist
Boston Scientific Corporation
One Boston Scientific Place
Natick, Massachusetts 01760-1537

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Re: K971254
Transend EX Platinum Guidewire
Regulatory Class: II (two)
Product Code: DQX
Dated: April 2, 1997
Received: April 3, 1997

Dear Ms. LeGraw:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): New Application

Device Name: Transend EX Platinum Guidewire

Indications for Use:

The Transend EX Platinum Guidewire is intended for general intravascular use, including the neuro and peripheral vasculature. The wire can be torqued to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries. A torque device (pin vise) is included with the wire to facilitate directional manipulation of the guidewire. A guidewire introducer is included with each wire to facilitate the introduction of the guidewire into catheter hubs or hemostatic valves.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K971254

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)