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SECTION 11
510(k) SUMMARY

FOI RELEASABLE

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Boston Scientific Corporation is required to submit with this Premarket Notification "...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 chooses to submit a summary of information respecting safety and effectiveness.

Date:	June 21, 2002
Common/Usual Names:	Instrument, Manual, General Surgical
Trade/Proprietary Name:	The tradename of the device has not been finalized
Classification Name & Device Classification:	Class I

Name	Product Code	21 CFR Ref.
Instrument, Manual, General Surgical	79MDM	878.4800

Device Panel/Branch:	General and Plastic Surgery (DGRND)
Owner/Operator:	Boston Scientific Corporation One Boston Scientific Place Natick, MA 01760
Contact Person:	James D. McMahon Regulatory Affairs Specialist Boston Scientific Corporation One Boston Scientific Place Natick, MA 01760-1537

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DESCRIPTION OF DEVICE

The Pulmonary Guidewire is constructed of a core wire, outer jacket and a tip. The guidewire is designed to provide access to the tracheobronchial tree.

INDICATIONS FOR USE

The Pulmonary Guidewire is indicated for use to provide access to the tracheobronchial tree.

DESCRIPTIVE AND TECHNOLOGICAL CHARACTERISTICS OF PROPOSED AND PREDICATE DEVICES

The major components of the predicate and proposed devices are identical. A thorough comparison of the descriptive characteristics between the proposed Pulmonary Guidewires and the predicate devices show equivalence.

PERFORMANCE CHARACTERISTICS

A biocompatibility assessment was performed on the patient- and fluid-contact materials of the device with satisfactory results.

CONCLUSION

Boston Scientific Corporation has demonstrated that the Pulmonary Guidewire is substantially equivalent to the Boston Scientific Corporation currently marketed Microvasive® Guidewires.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 2002

Boston Scientific Corporation
James D. McMahon
Regulatory Affairs Specialist
One Boston Scientific Place
Natick, Massachusetts 01760-1537

Re: K022059
Trade/Device Name: Microvasive Pulmonary Guidewire
Regulation Number: 878.4800
Regulation Name: Instrument, manual, general surgical
Regulatory Class: Class I
Product Code: MDM
Dated: September 17, 2002
Received: September 20, 2002

Dear Mr. McMahon:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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 Part 807.97). 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,

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

SECTION 3
INDICATION FOR USE

510(k) Number: K022059

Device Name: Pulmonary Guidewire

Indication for Use:

The Pulmonary Guidewire is indicated for use to provide access to the tracheobronchial tree.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.1091) (Optional Format 1-2-96)

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

510(k) Number K022059