Appendix A. 510(k) Summary of Safety and Effectiveness

JUN 20 1997

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.

The assigned 510(k) number is: _____

Applicant Information:

Date Prepared:	January 2, 1997
Name:	Boston Scientific Corporation, BSC Sunnyvale
Address:	1327 Orleans Drive Sunnyvale, CA 94089
Contact Person:	Steve Jwanouskos
Phone Number:	(408) 328-7542

Device Information:

Classification:	Class II
Trade Name:	Sonicath Ultra™ Imaging Catheter
Common Names:	Ultrasound Diagnostic Imaging Catheter Diagnostic Ultrasonic Transducer (90ITX) Diagnostic Intravascular Catheter (74DQO)
Classification:	21 CFR 892.1570, Diagnostic Ultrasonic Transducer (90ITX) and 21 CFR 870.1200, Diagnostic Intravascular Catheter (74DQO)

Equivalent Devices:

The BSC Sonicath Ultra Imaging Catheter is substantially equivalent in intended use, design and/or method of operation to a combination of the following predicate devices:

1. BSC, Sunnyvale - MicroView 2.9 F Coronary Imaging Catheter

2. BSC, Sunnyvale - MicroRail 3.2F Coronary Imaging Catheter

3. BSC, Natick (Medi-tech) - Sonicath 3.5 F Interventional Ultrasound Imaging Catheter

510(k) Summary of Safety and Effectiveness (continued)

Intended Use:
The Sonicath Ultra Imaging Catheter is intended for the ultrasound examination of peripheral and coronary intravascular pathology. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal interventional procedures.

Comparison To Predicate Devices:
The BSC Sonicath Ultra Imaging Catheter is a sterile, single-use disposable device used for the ultrasound examination of intravascular pathology in both the coronary and peripheral vasculatures. The Sonicath Ultra 2.9 F and 3.2 F Imaging Catheters and predicate devices consist of two main components: (1) the catheter body and (2) the imaging core. The imaging core of both the Sonicath Ultra and the predicate device imaging catheters is comprised of a hi-torque, flexible, rotating drive cable with an outward looking ultrasonic transducer at the distal tip.

The Sonicath Ultra Imaging Catheter is equivalent in intended use, design and operational characteristics to the following devices: (1) BSC, Sunnyvale - MicroView 2.9 F Coronary Imaging Catheter, (2) BSC, Sunnyvale - MicroRail 3.2 F Coronary Imaging Catheter, and (3) BSC, Natick (Medi-tech)- Sonicath 3.5 F Interventional Ultrasound Imaging Catheter. All predicate devices are used for the ultrasound imaging of intravascular pathology in either the coronary or peripheral vasculature. The Sonicath Ultra Imaging combines various features of the predicate devices to allow for imaging in both the peripheral and coronary vasculature.

510(k) Summary of Safety and Effectiveness (continued)

Non-Clinical Test Results:
Bench, acoustic output, animal and biocompatibility testing demonstrate that the BSC, Sonicath Ultra Imaging Catheter is safe and effective, while meeting the anticipated clinical requirements for its intended use.

Bench Testing:
Bench testing was included to evaluate the physical integrity of the catheter shaft by testing the tensile strength of the catheter joints and shaft tubing. The catheter joint and shaft tubing strengths were determined to be acceptable and consistent with the intended use of the device. In addition, the physical integrity of the imaging core was examined by evaluating the tensile strengths of the weld joints. The imaging core weld joint strengths were also determined to be acceptable and consistent with the intended use of the device.

Acoustic Output Testing:
The Sonicath Ultra Imaging Catheter was tested for acoustic output as described in the FDA Guidance, The Revised 510(k) Diagnostic Ultrasound Guidance for 1993, Food and Drug Administration, and the 510(k) Guide for Measuring and Reporting Acoustic Output of Diagnostic Ultrasound Medical Devices, December, 1985, Food and Drug Administration. Acoustic output test results for the Sonicath Ultra 2.9 F and 3.2 F Imaging Catheters are below the FDA Track 1 limits.

Animal Testing:
Animal testing was performed to assess the in-vivo functional and imaging characteristics of the catheter. In conclusion, the performance of the Sonicath Ultra Imaging Catheters was consistent with the intended clinical use of the device.

Biocompatibility
The materials used to fabricate the BSC, Sonicath Ultra Imaging Catheter are similar to the predicate devices. The Sonicath Ultra Imaging Catheter was subjected to biocompatibility testing and meets the requirements for biocompatibility testing outlined in ISO 10993-1 Part 1 "Biological Evaluation of Medical Devices".

Summary:
Based on the intended use, design, performance and biocompatibility data provided in this Notification, BSC, Sonicath Ultra Imaging Catheters have been shown to be substantially equivalent to currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 20 1997

Dennis L. Wong
Manager, Regulatory Affairs
Boston Scientific Corporation
2710 Orchard Parkway
San Jose, CA 95134-2012

Re: K970049
BSC Sonicath Ultra™ Imaging Catheters
Dated: April 25, 1997
Received: April 28, 1997
Regulatory Class: II
21 CFR 892.1570/Procode: 90 ITX
21 CFR 870.1200/Procode: 74 DQO

Dear Mr. Wong:

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. You may, therefore, market the device, subject to the general controls provisions Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the BSC Sonicath Ultra™ Imaging Catheters, as described in your premarket notification:

Transducer Model Number

2.9F and 3.2F/20 MHZ

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's February 17, 1993 "Revised 510(k) Diagnostic Ultrasound Guidance for 1993." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your 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 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) 594-4591. 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 at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html."

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for David A. Lyerly

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

Ultrasound Device Indications Statement Page 1 of 2

510(k) Number (if known): K970049
Device Name: BSC Soricath Ultra Imaging Catheter 3.2F/20MHz

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-operative (Specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Luminal		✓								
Peripheral Vascular										
Laparoscopic										
Musculo-Skeletal										
Other (Specify)										

Additional Comments: _____

(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 Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K970049

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page 2 of 2

510(k) Number (if known): K970049
Device Name: BSC Soircath Ultra Imaging Catheter 2.9F/20MHz

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-operative (Specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Luminal		✓								
Peripheral Vascular										
Laparoscopic										
Musculo-Skeletal										
Other (Specify)										

Additional Comments: _____

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Edward A. Segmon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K970049

Prescription Use (Per 21 CFR 801.109)