

NOV 9 1998

*Intravascular Ultrasound Imaging Wire**510(k) Notification***BSC Intravascular Ultrasound Imaging Wire
510(k) Premarket Notification****510(k) SUMMARY****Submitter's Name, Address, Telephone Number, and Contact Person**

Boston Scientific Corporation
2710 Orchard Parkway
San Jose, CA 95134-2012
Phone: (408) 895-3607
Facsimile: (408) 895-2202
Contact Person: Donna K. Templeman
Manager, Regulatory Affairs

Date Prepared: August 10, 1998**Name of Device and Name/Address of Sponsor**

Trade name: BSC Sonicath Ultra Intravascular Ultrasound Imaging Wire

Boston Scientific Corporation
2710 Orchard Parkway
San Jose, CA 95134-2012

Classification Names:

Diagnostic Intravascular Catheter (21 C.F.R. § 870.1200);
Ultrasonic Pulsed Echo Imaging System (21 C.F.R. § 892.1560)
Diagnostic Ultrasonic Transducer (21 C.F.R. § 892.1570)

Predicate Devices

1. BSC Sonicath Ultra Intravascular Ultrasound Imaging Catheter (K970049)
2. BSC WiseWire Intravascular Ultrasound Imaging Core Wire (K942927)

Intended Use/Indications

The BSC Imaging Wire is intended to be used for the ultrasound examination of peripheral intravascular pathology only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal interventional procedures. The Imaging Wire is specifically indicated for use with diagnostic or interventional devices which are compatible with 0.035" guidewires.

Device Description

The Intravascular Ultrasound Imaging Wire consists of an imaging wire and a detachable or fixed adapter. The Imaging Wire is a 0.035" inch diameter, 180 cm long imaging wire that functions in a manner similar to a 0.035 inch exchange wire and includes ultrasonic imaging capabilities. The Imaging Wire consists of an outer sheath and an imaging core with a 20 MHz ultrasonic transducer. The distal tip coil and the transducer are radiopaque. Both the fixed and detachable adapters have electro-mechanical connectors that interface between the Imaging Wire and the BSC Motor Drive Unit/BSC Ultrasound Instrument System. The Imaging Wire allows up to 15 cm of linear movement of the imaging core for visualization through the outer sheath without moving the distal tip. The Imaging Wire is intended for use with the BSC ClearView Ultra™ and BSC Galaxy™ Ultrasound Instrument Systems.

Principle of Operation

Using sterile technique, the user removes the Imaging Wire from its sterile package. The user ensures that the movable imaging core is completely in the distal position via the telescoping shaft. For Imaging Wires with detachable adapters, the proximal end of the Imaging Wire is then inserted into the adapter. Both caps of either the fixed or detachable adapter are then closed to seal the flushport. The 1cc and 10cc syringes are connected to the 3-way stopcock. The assembly is then connected to the extension tube and both syringes are filled with heparinized saline. The user ensures that all air is expelled from the system. The extension tube is then connected to the luer on the flushport. The 10 cc syringe is used as a reservoir for refilling the 1 cc flushing syringe. The Imaging Wire is flushed twice with 1cc's of saline. The saline solution should be seen exiting the distal tip. The 10 cc syringe is refilled as needed and reattached to the stopcock without introducing air into the line.

The adapter which is attached to the Imaging Wire is then connected to the Motor Drive Unit by aligning the orientation marks between the proximal hub and the Motor Drive Unit. To ensure that the adapter is fully seated in the Motor Drive Unit, the user gently tugs on the hub. The user then activates the Motor Drive Unit to confirm proper operation. Proper operation is indicated by partial bright concentric rings on the instrument monitor. The user prepares the entry site with a sheath introducer according to standard practice. A guidewire and catheter are used to access the area of interest. The guidewire is removed. The distal end of the Imaging Wire is inserted into the wire lumen of the catheter. The Imaging Wire is advanced with direct, fluoroscopic visualization to the area of interest. The user continues advancing the Imaging Wire until the distal tip crosses a minimum of 4 cm beyond the region of interest. Keeping the outer sheath of the Imaging Wire fixed, the user activates the Imaging Wire and then retracts the imaging core slowly along its 15 cm travel, imaging any region of interest. When imaging is complete, the user fully advances the imaging core and stops the Motor Drive Unit.

Exchanges Using the Imaging Wire with Detachable Adapter

The imaging core is fully advanced and the Motor Drive Unit is stopped. The adapter is detached by gently pushing the proximal end of the Imaging Wire into the adapter. While the user maintains the distal position of the Imaging Wire, the imaging core can be retracted to the desired length in order to facilitate removal of the catheter. The catheter is removed by withdrawing it over the proximal end of the Imaging Wire. With the Imaging Wire held in place, the user introduces and tracks a 0.035" guidewire compatible diagnostic or interventional device over the proximal end of the Imaging Wire. The imaging core is advanced as the 0.035" guidewire compatible device is advanced. When imaging is desired, the user reconnects the detachable adapter by inserting the proximal end of the Imaging Wire into the adapter.

Data Demonstrating Substantial Equivalence

Performance testing on the Intravascular Ultrasound Imaging Wire demonstrated that the device meets or exceeds the performance requirements for the intended clinical use of the device. Laboratory/Bench Testing was conducted and the results demonstrated that the Intravascular Ultrasound Imaging Wire satisfies all of its performance specifications, which are designed to ensure that the device is safe and effective for its intended use.

Biocompatibility testing was conducted in accordance with International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing (1995). The results of these tests demonstrate that the BSC Imaging Wire is biocompatible.

Conclusion

Laboratory/Bench and biocompatibility testing demonstrate that the BSC Intravascular Ultrasound Imaging Wire is safe and effective for its intended use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Donna K. Templeman
Manager, Regulatory Affairs
Boston Scientific Corporation
2710 Orchard Parkway
San Jose, CA 95134-2012

Re: K982840
Trade Name: BSC Intravascular Ultrasound Imaging Wire
Regulatory Class: II
Product Code: IYO
Dated: August 10, 1998
Received: August 12, 1998

Dear Ms. Templeman:

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 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). 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 requirements, 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) 594-4586. 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" (21CFR 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/dsma/dsmamain.html>".

Sincerely yours,



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): K982840

Device Name: BSC Intravascular Ultrasound Imaging Wire

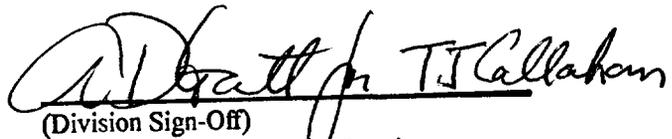
Indications For Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number K982840

Prescription Use

OR
(Per 21 CFR 801.109)

Over-The-Counter Use

(Optional Format 1-2-96)