K032183

AUG - 1 2003

510(k) Summary
per 21 CFR §807.92

Submitter's Name and Address	Boston Scientific Corporation (BSC) One Scimed Place Maple Grove, MN 55311
Contact Name and Information	Anne V. Rossi Specialist, Regulatory Affairs Phone: 763-494-2827 Fax: 763-494-2222 e-mail: Anne.Rossi@bsci.com
Date Prepared	July 16, 2003
Proprietary Name(s)	IQ™ Hydrophilic Guide Wire
Common Name	Catheter Guide Wire
Product Code	74DQX
Classification of Device	Class II, 21 CFR Part 870.1330

Predicate Devices

PT2™ Guide Wire	K030617	May 21, 2003
Luge™ Guide Wire	K973945	January 12, 1998

Device Description

The IQ™ Hydrophilic Guide Wires with ICE® hydrophilic coating are steerable, spring-tipped guide wires. The IQ™ Hydrophilic is available in a nominal diameter of 0.014 inches, Moderate Support, and nominal lengths of 185 and 300 centimeters with Brachial and Femoral marks at 90cm and 100cm respectively. The distal three centimeters of all models are radiopaque spring coils and available in either a straight shapeable or a pre-formed J-Tip.

The IQ™ Hydrophilic corewire consists of a PTFE coated SS corewire segment joined via a nickel-chromium alloy coupler to a tapered Nitinol corewire segment. The distal segment of this corewire is coated with an adhesive pre-coat that is jacketed with a Tungsten loaded polyurethane sleeve. This polymer sleeve is coated with ICE® Hydrophilic coating. A SS centering sleeve attaches a SS ribbon to the distal end of the corewire. The distal most portion of the corewire, the centering sleeve and the SS ribbon reside within the hollow center of the 3-cm spring-coil.

The 185-centimeter version of the IQ™ Hydrophilic is designed with a proximal extension section that allows connection to the AddWire™ Extension Wire.

Intended Use of Device

The IQ™ Hydrophilic Guide Wires are intended to facilitate the placement and exchange of balloon dilatation catheters or other therapeutic devices during PTCA or PTA or other intravascular interventional procedures. The IQ™ Hydrophilic Guide Wires are not intended for use in the cerebral vasculature. The devices are provided non-pyrogenic, sterile, and intended for one procedure only.

Technological Characteristics

The IQ™ Hydrophilic Guide Wires utilize similar materials and methods of construction as the currently marketed PT2^{TM} Guide Wire family of guide wires. The differences in construction are the addition of a spring-coil to the distal most tip and a SS ring at the ribbon/corewire joint.

Non-Clinical Test Summary

Testing and evaluation of the IQ™ Hydrophilic Guide Wires included torque response, tip prolapse, tip shapeability, marker location, coating adherence/presence, tensile, combined load, visual inspection, polymer peel, device compatibility, biocompatibility, and product shelf-life.
Test results verified that the IQ™ Hydrophilic Guide Wires met all of the minimum requirements and are adequate for their intended use.
The IQ™ Hydrophilic Guide Wires are considered to be substantially equivalent to guide wires currently marketed by Boston Scientific based on a comparison of intended use, design and the results of *in vitro* testing and evaluation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Boston Scientific Corporation
c/o Anne V. Rossi
Specialist, Regulatory Affairs
One Scimed Place
Maple Grove, MN 55311

Re: K032183
IQ™ Hydrophilic Guide Wire
Regulation Number: 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Product Code: DQX
Dated: July 16, 2003
Received: July 21, 2003

Dear Ms. Rossi:

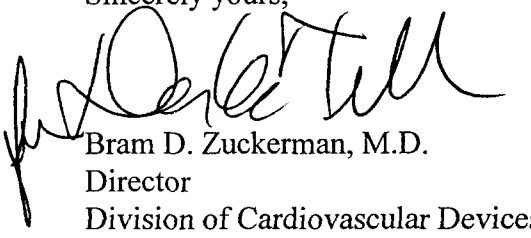
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (301) 594-4646. 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 Part 807.97) you may obtain. 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,



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

Indications for Use Statement

510(k) Number (if known)	**K032183**
Device Name	IQ™ Hydrophilic Guide Wire
Indications For Use	The IQ™ Hydrophilic Guide Wires are intended to facilitate the placement of balloon dilatation catheters or other therapeutic devices during PTCA, PTA, or other intravascular interventional procedures. The IQ™ Hydrophilic Guide Wires are not intended for use in the cerebral vasculature.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR §801.109)

OR Over-The-Counter Use_____

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K032183