K030617

MAY 21 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: 763-494-2323 e-mail: Anne.Rossi@bsci.com
Date Prepared	February 25, 2003
Proprietary Name(s)	PT2™ Guide Wire AddWire™ Extension Wire
Common Name	Catheter Guide Wire
Product Code	74DQX
Classification of Device	Class II, 21 CFR Part 870.1330

Predicate Devices

BSC Scimed		*(Clearance Date)*
PT Graphix™	**K962572**	December 17, 1996
Advanced Cardiovascular Systems, Inc. (ACS)		
Balance MiddleWeight™	**K021228**	May 15, 2002
(BMW)	**K983033**	November 10, 1998
	K973494	December 12, 1997
	K971815	July 9, 1997
Lake Region Manufacturing, Inc. (LRM)		
Extension Wire[1]	**K970376**	June 6, 1997
Steerable PTCA GW[2]	**K011968**	July 25, 2001
	K970376	June 6, 1997

[1] The LRM Extension Wire is currently marketed by Boston Scientific under the trade name Trooper™/Patriot™ Extension Wire.

[2] The LRM Steerable PTCA Guide Wire is currently marketed by Boston Scientific under the trade name Forté™ Guide Wire.

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Abbreviated 510(k)
BSC PT2^{TM} Guide Wire
BSC AddWire™ Extension Wire
February 25, 2003

Device Description – Guide Wire

The PT2^{TM} Guide Wires with ICE® hydrophilic coating are steerable, polymer-tipped guide wires. The PT2^{TM} is available in a nominal diameter of 0.014 inches, two rail support models, Light Support and Moderate Support, and nominal lengths of 185 and 300 centimeters with Brachial and Femoral marks at 90cm and 100cm respectively. The distal two centimeters of all models are radiopaque and available in either a straight shapeable or a pre-formed J-Tip.

The 185-centimeter version of the PT2^{TM} is designed with a proximal extension section. This proximal extension section allows connection to the AddWire™ Extension Wire or the similarly designed Trooper™/Patriot™ Extension Wire.

The PT2^{TM} corewire consists of a PTFE coated SS corewire segment coupled to a tapered Nitinol corewire segment. The PT2^{TM} coupler is a stainless steel material. The distal most end of the PT2^{TM} corewire is a SS ribbon.

The distal tapered Nitinol corewire segment of the PT2^{TM} is coated with an adhesive pre-coat. The pre-coated corewire is then jacketed with a Tungsten loaded polyurethane sleeve. The entire polymer sleeve of the PT2^{TM} Guide Wire is coated with ICE® Hydrophilic coating.

Intended Use of Device – Guide Wire

The PT2^{TM} 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 PT2^{TM} 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 – Guide Wire

The PT2^{TM} Guide Wires utilize similar materials and methods of construction as the currently marketed PT Graphix™ family of guide wires. The differences in construction are a minor change to the polymer sleeve formulation and the addition of a 2-part core wire. The 185-cm models also incorporate an extendable proximal section similar in construction to the BSC Forté™ extendable guide wires.

Non-Clinical Test Summary – Guide Wire

Testing and evaluation of the PT2^{TM} Guide Wires included tensile, combined load, coupler fatigue, torque response, tip prolapse, coating adherence, visual inspection, polymer peel, PTCA catheter compatibility, and biocompatibility.

Test results verified that the PT2^{TM} Guide Wires met all of the minimum requirements and are adequate for their intended use.

The PT2^{TM} Guide Wires are considered to be substantially equivalent to guide wires currently marketed by Boston Scientific and ACS based on a comparison of intended use, design and the results of *in vitro* testing and evaluation.

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Device Description – Extension Wire

The AddWire™ Extension Wire is a PTFE coated SS wire with a connector at the distal end that connects to the proximal end of BSC extendable guide wires. The nominal length is 145 cm and the nominal diameter is 0.014 inches. The AddWire™ Extension Wire is similar in design and materials to the LRM Extension Wire that is currently marketed by BSC as the Trooper™/Patriot™ Extension Wire.

Intended Use of Device – Extension Wire

The AddWire™ Extension Wire creates an extended guide wire that can be used to exchange out a therapeutic device without removing the original guide wire from the anatomy. When the exchange is complete, the Extension Wire can be detached and the original guide wire can be used in a conventional manner.

Technological Characteristics – Extension Wire

The AddWire™ Extension Wires utilize similar materials and methods of construction as the LRM Extension Wire that is currently marketed by BSC as the Trooper™/Patriot™ Extension Wire.

Non-Clinical Test Summary – Extension Wire

Testing and evaluation of the AddWire™ Extension Wires included tensile, coating adherence, visual inspection, PTCA catheter compatibility, exchange system connectability, and biocompatibility. Test results verified that the AddWire™ Extension Wire met all of the minimum requirements and are adequate for their intended use. The AddWire™ Extension Wire is considered to be substantially equivalent to the currently marketed BSC Trooper™/Patriot™ Extension wire 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

MAY 21 2003

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

Re: K030617
Trade/Device Name: PT^{2}™ Guide Wire and AddWire™ Extension Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire.
Regulatory Class: II
Product Code: DQX
Dated: February 25, 2003
Received: February 26, 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.

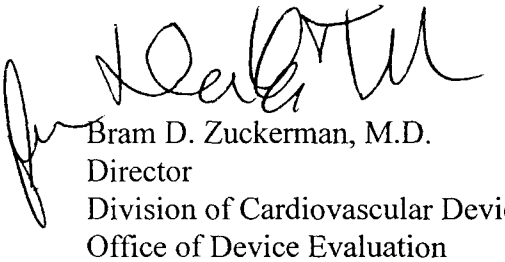
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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

Enclosure

K030617

Indications for Use Statement

510(k) Number (if known)	**Unknown**
Device Name(s)	PT^{2TM} Guide Wire AddWire™ Extension Wire
Indications For Use	The PT^{2TM} 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 PT^{2TM} Guide Wires are not intended for use in the cerebral vasculature. The AddWire™ Extension Wire creates an extended guide wire that can be used to exchange out a therapeutic device without removing the original guide wire from the anatomy. When the exchange is complete, the Extension Wire can be detached and the original guide wire can be used in a conventional manner.

(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 §801.109)

(Division Sign-Off)
Division of Cardiovascular Devices

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