



Food and Drug Administration
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December 16, 2015

Boston Scientific Corporation
Nikki M. Wahlberg
Senior Regulatory Affairs Specialist
One Scimed Place
Maple Grove, MN 55311-1566

Re: K151840

Trade/Device Name: Fighter™ Guidewire, Marvel™ Guidewire, Samurai™ Guidewire,
Samurai™ RC Guidewire, Stretch™ Extension Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: II
Product Code: DQX
Dated: November 13, 2015
Received: November 16, 2015

Dear Nikki Wahlberg:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K151840

Device Name

Fighter™ Guidewire, Marvel™ Guidewire, Samurai™ Guidewire, and Samurai™ RC Guidewire
Stretch Extension Wire

Indications for Use (Describe)

Fighter™, Marvel™, Samurai™, and Samurai™ RC Guidewires:

Boston Scientific Fighter™, Marvel™, Samurai™, and Samurai™ RC Guidewires are intended to facilitate the placement of balloon dilatation catheters or other interventional therapeutic devices during percutaneous transluminal coronary angioplasty (PTCA) or other intravascular interventional procedures. These guidewires are not intended for use in the cerebral vasculature.

Stretch Extension Wire:

Attachment of the Stretch Extension Wire to a Boston Scientific extendable guidewire creates an extended guide wire that can be used to exchange out a percutaneous transluminal coronary angioplasty (PTCA) or percutaneous transluminal angioplasty (PTA) catheter without removing the original guide wire from the artery. When the exchange is complete, the Stretch Extension Wire can be detached and the original guide wire can be used in a conventional manner.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

per 21 CFR §807.92

Sponsor:	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, Massachusetts 01752 USA		
Contact Name and Information	Nikki M Wahlberg One Scimed Place Maple Grove, MN 55311-1566 Phone: 763-494-2381 Fax: 763-494-2981 e-mail: Nikki.Wahlberg@bsci.com		
Prepared	01 July 2015		
Proprietary Name	Fighter™ Guidewire Marvel™ Guidewire Samurai™ Guidewire Samurai™ RC Guidewire Stretch Extension Wire		
Common Name	Catheter Guide Wire		
Product Code	DQX		
Classification	Class II, 21 CFR Part 870.1330		
Primary Predicate Device	ChoICE™ Guidewire	K143587	15 Jan 2015
	AddWire™ Extension Wire	K030617	21 May 2003
Reference Device(s)	ASAHI SION blue Guide Wire	K122468	08 Mar 2013
	ASAHI X-TREME Guide Wire	K072431	26 Sep 2007

Device Description

The Fighter™, Marvel™, Samurai™, and Samurai™ RC Guidewires are designed to facilitate the placement of interventional coronary devices such as dilating balloon catheters, stent delivery systems and other coronary artery diagnostic or therapeutic devices. The guide wires are available in a nominal diameter of 0.014 inches and nominal lengths of 190 cm and 300 cm. The 190 cm guide wires are compatible exclusively with the Stretch Extension Wire which can extend the guide wire length allowing for exchange of Over-The-Wire systems. The guide wires are composed of a stainless steel core wire which tapers at the distal end. The tapered distal end of the guide wire is covered with a proximal stainless steel coil and a distal platinum/nickel radiopaque coil that allows for visualization while using fluoroscopy. The proximal end of the guide wire contains a polytetrafluoroethylene (PTFE) coating and the distal portion of the wire is coated with a hydrophilic coating. All wires are available in a straight tip configuration. The Marvel and Samurai wires are available in an additional J-tip configuration.

The Stretch Extension Wire is composed of a stainless steel core wire coated with PTFE and contains a hypotube that is compatible with the 190 cm Fighter, Marvel, Samurai, and Samurai RC Guidewires.

Indications for Use / Intended Use Guide Wire

Boston Scientific Fighter™, Marvel™, Samurai™, and Samurai™ RC Guidewires are intended to facilitate the placement of balloon dilatation catheters or other interventional therapeutic devices during percutaneous transluminal coronary angioplasty (PTCA) or other intravascular interventional procedures. These guidewires are not intended for use in the cerebral vasculature.

Indications for Use / Intended Use Extension Wire

Attachment of the Stretch Extension Wire to a Boston Scientific extendable guidewire creates an extended guide wire that can be used to exchange out a percutaneous transluminal coronary angioplasty (PTCA) or percutaneous transluminal angioplasty (PTA) catheter without removing the original guide wire from the artery. When the exchange is complete, the Stretch Extension Wire can be detached and the original guide wire can be used in a conventional manner

Comparison of Technological Characteristics

The Fighter™, Marvel™, Samurai™, and Samurai™ RC Guidewires incorporate substantially equivalent device materials and design, packaging materials and design, fundamental technology, manufacturing processes, sterilization process and intended use as the ChoICE™ Guidewire (K143587).

The Stretch Extension Wire incorporates substantially equivalent device materials and design, packaging materials and design, fundamental technology, manufacturing processes, sterilization process and intended use as the AddWire™ Extension Wire (K030617).

Performance Data

Design verification testing was performed to support a determination of substantial equivalence according to *Coronary & Cerebrovascular Guide Wire Guidance January 1995* and EN ISO 11070. The result of the test provides reasonable assurance that the proposed devices have been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the testing.

The following performance tests were completed:

Dimensional Evaluation	Coating Durability	Radiodetectability
Tip Flexibility	Wire Flex	Particulate Evaluation
Tensile	Combined Load	Corrosion Testing
Device Compatibility	Torque Response	Exchange Connect
Coating Lubricity	Wire Fracture	Exchange Tensile
Master Shipping Carton/Condition	Pouch Seal Strength	Carrier Tube Assembly
Label Adhesion and Print Quality	Shelf Carton Condition	Withdrawal from Carrier Tube
Sterile Barrier Integrity	Visual Sterile Barrier Integrity	

The following biocompatibility tests were completed:

Cytotoxicity	Ames Mutagenicity	In vitro Hemocompatibility
Sensitization	Mouse Lymphoma	Materials Mediated Pyrogen
Intracutaneous Reactivity	Hemolysis Direct Contact	In Vivo Thrombogenicity
Acute Systemic Injection	Hemolysis Extract Method	USP Physicochemical
Natural Rubber Latex	Partial Thromboplastin Time	Complement Activation C3a and SC5b-9

Clinical Testing

Clinical evaluation was not required for this device.

Conclusion

Based on the indications for use, technological characteristics, safety and performance testing, the Fighter, Marvel, Samurai, and Samurai RC Guide Wires are appropriate for the stated intended uses and are considered to be substantially equivalent to the CHOICE Guide Wire (K143587) and the Stretch Extension Wire is considered to be substantially equivalent to the AddWire Extension Wire (K030617).
