April 12, 2018

Boston Scientific
Nikki Ibis
Principal Regulatory Affairs Specialist
Three Scimed Place
Maple Grove, Minnesota 55311-1566

Re: K180795
Trade/Device Name: JUDO 1 Guidewire, JUDO 3 Guidewire, JUDO 6 Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: March 23, 2018
Received: March 27, 2018

Dear Nikki Ibis:

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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Kenneth J. Cavanaugh -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K180795

Device Name
JUDO™ 1 Guidewire
JUDO™ 3 Guidewire
JUDO™ 6 Guidewire

Indications for Use *(Describe)*

Boston Scientific JUDO 1, JUDO 3, and JUDO 6 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.

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 Ibis Three Scimed Place Maple Grove, MN 55311-1566 Phone: 763-494-2381 Fax: 763-494-2981 e-mail: Nikki.Ibis@bsci.com		
Prepared	23 March 2018		
Proprietary Name	JUDO™ 1 Guidewire JUDO™ 3 Guidewire JUDO™ 6 Guidewire		
Common Name	Catheter Guide Wire		
Product Code	DQX		
Classification	Class II, 21 CFR Part 870.1330		
Predicate Device	Hornet™ Guidewire	K152231	12 February 2016
Reference Device(s)	Hornet™ 10 Guidewire Hornet™ 14 Guidewire	K152231	12 February 2016

Device Description

The Boston Scientific JUDO 1, JUDO 3, and JUDO 6 Guidewires are available with a nominal diameter of 0.014 inches (0.37 mm) and in nominal lengths of 190 cm or 300 cm. The guidewires are composed of a stainless steel core wire which tapers at the distal end. The tapered distal end of the guidewire 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 guidewire contains a polytetrafluoroethylene (PTFE) coating and the distal portion of the wire is coated with a hydrophilic coating. The guidewires are available in a straight tip shape only.

The 190 cm guidewires are designed with a 2.1 cm friction fit extension section for exchange of Over-the-Wire systems by using the Stretch Extension Wire (K151840). The 300 cm guidewire allows exchange of therapeutic devices without the use of an extension wire or exchange system.

Indications for Use / Intended Use

Boston Scientific JUDO 1, JUDO 3, and JUDO 6 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.

Comparison of Technological Characteristics

The JUDO 1, JUDO 3, and JUDO 6 Guidewires incorporate substantially equivalent design, packaging, fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the predicate, Hornet™ Guidewire, K152231.

Non-Clinical Test Summary

Bench testing was performed to support a determination of substantial equivalence. The result of the test provides reasonable assurance that the proposed devices with the modified distal core wire diameter have been designed and tested to assure conformance to the requirements for their intended use. No new safety or performance issues were raised during the testing.

The following device performance test was completed:

Tip Flexibility

Conclusion

Based on the indications for use, technological characteristics, safety and performance testing, the JUDO™ 1 Guidewire, JUDO™ 3 Guidewire, and JUDO™ 6 Guidewires are appropriate for the stated intended use and are considered to be substantially equivalent to the predicate device (K152231).