APR 16 2014

510(k) Summary

per 21 CFR §807.92

Submitter's Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311
Contact Name and Information	Lisa Mee Senior Regulatory Affairs Specialist Phone: 763-494-1185 Fax: 763-494-2222 e-mail: lisa.mee@bsci.com
Date Prepared	14 Mar 2014
Proprietary Name	Insertion Tool
Common Name	Insertion Tool/Needle
Product Code	DQX - wire, guide, catheter
Classification	Class II, 21 CFR Part 870.1330 – Cardiovascular
Predicate Device(s)	SCIMED AVENUE ™ Coronary Guidewire — K922410 — Jul 23, 1992 Encore™ 26 Advantage Kit — K123214 — Nov 13, 2012
Device Description	The Insertion Tool is a sterile accessory device indicated to facilitate the introduction of a guidewire into the lumen of a guiding catheter, without damage to the guidewire's distal tip. It is designed to accommodate guidewires with diameters from 0.010" to 0.018" and is composed of a rigid funnel known as the hub which is attached to a stainless steel hypotube. The interior of the hub is designed to allow a guidewire with multiple bends at the distal tip to be directed easily into the smaller diameter stainless steel hypotube.
Intended Use	The Insertion Tool is used to facilitate the introduction of 0.010" through 0.018" guidewires into the lumen of a catheter without damage to the guidewire distal tip. It may also be used to introduce the guidewire through the manifold of an over-the-wire type balloon dilation catheter. This is accomplished by passing the metal tube portion of the Insertion Tool through the hemostatic seal of the Y-Adapter or catheter manifold and then using this channel to introduce the guidewire.
Indications for Use	The Insertion Tool is used to facilitate the introduction of a guidewire during general intravascular procedures.
Comparison of Technological Characteristics	The Insertion Tool incorporates substantially equivalent device materials, device configuration, packaging, fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the Boston Scientific (previously known as SCIMED Life Systems, Inc.) predicate devices.

Comparison to Predicate Devices:

Characteristic	Proposed compared to Predicate
Mechanism of Action	Same Mechanism of Action
Components	Same components, configuration, design and function.
Materials	Same device materials with exception of the hub colorant.
Packaging	Same packaging materials with the exception of the change to the protective sheath material. Same packaging configuration.
Sterilization Method/SAL	Same method and level of sterility assurance.
Device Compatibility	Same compatibility.
Device Dimensions	Minor changes to dimensions.
Biocompatibility	Same biocompatibility.

Performance Data

Design Verification and Design Validation Testing was performed to support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed modified device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the device testing.
Therefore, these devices may be considered substantially equivalent to the predicate device.
The following Design Verification bench tests were completed:
ID Guidewire Compatibility (Hub to Shaft ID)
Hub Tensile Strength Test

The following Design Validation tests were completed:
Guidewire Insertion 0.018" Straight Tip Guidewire Insertion
Guidewire Insertion 0.014" J-Tip Guidewire Insertion
Y-Adaptor Compatibility

Conclusion

Based on the indications for use, technological characteristics, safety and performance testing, the Insertion Tool has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the AVENUE™ Coronary Guidewire as submitted in K922410 and the Encore™ 26 Advantage Kit as submitted in K123214.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 16, 2014

Boston Scientific Corporation
c/o Lisa Mee
Senior Regulatory Affairs Specialist
One Scimed Place
Maple Grove, MN 55311

Re: K140673
Trade/Device Name: Insertion Tool
Regulation Number: 21 CFR 870.1330
Regulation Name: Insertion Tool
Regulatory Class: Class II
Product Code: DQX
Dated: March 14, 2014
Received: March 18, 2014

Dear Ms. Mee:

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 Small Manufacturers, International and Consumer Assistance 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,

Bram D. Zuckerman -S

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): K140673

Device Name: Insertion Tool

Indications for Use:

The Insertion Tool is used to facilitate the introduction of a guidewire during general intravascular procedures.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
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