September 26, 2018

Boston Scientific Corporation
Andrea Dance
Regulatory Affairs Specialist
3 Scimed Place
Maple Grove, Minnesota 55311

Re: K182315
Trade/Device Name: Magic Torque DLVR Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: August 23, 2018
Received: August 27, 2018

Dear Ms. Dance:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

Michael John -S
2018.09.26 16:39:04 -04'00'

for 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)*

K182315

Device Name
Magic Torque™ DLVR Guidewire

Indications for Use *(Describe)*
The Magic Torque™ Guidewires facilitate placement of a catheter during diagnostic or interventional procedures. The wire can be torqued to facilitate navigation through tortuous arteries and/or avoid unwanted side branches. Not intended for use in coronary arteries.

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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SECTION 3. 510(K) SUMMARY PER CFR 807.92

Submitter's Name and Address	Boston Scientific Corporation Three Scimed Place Maple Grove, MN 55311 USA
Contact Name and Information	Andrea Dance Regulatory Affairs Specialist Phone: 763-494-1743 Fax: 763-494-2222 Email: andrea.dance@bsci.com
Date Prepared	August 23, 2018
Trade Name	Magic Torque™ DLVR Guidewires
Common Name	Wire, Guide, Catheter
Product Code	DQX
Classification Name	Class 2 according to 21 CFR 870.1330
Predicate Device	Magic Torque™ Guidewires (K933334) 26 Jan 1994
Description of Device	The 315 cm Magic Torque™ DLVR Guidewire facilitates placement of a catheter during diagnostic or interventional procedures. The guidewire contains a stainless steel (SS) core wire. A SS coil is wound over the distal 50 cm of the core wire. The most distal 10 cm of the SS coil is coated with a proprietary hydrophilic coating from Boston Scientific that provides a slippery surface to facilitate negotiation of difficult anatomy and tight lesions. The proximal 40 cm of the coil is coated with polytetrafluoroethylene (PTFE) for lubricity. A PTFE polymer sleeve jackets the proximal end of the core wire. The guidewire is clearly visible under fluoroscopy.
Intended Use	The Magic Torque™ Guidewires facilitate placement of devices during peripheral intravascular diagnostic or interventional procedures.
Indications for Use	The Magic Torque™ Guidewires facilitate placement of a catheter during diagnostic or interventional procedures. The wire can be torqued to facilitate navigation through tortuous arteries and/or avoid unwanted side branches. Not intended for use in coronary arteries.
Device Technology Characteristics and Comparison to Predicate Device	Magic Torque DLVR Guidewire incorporates substantially equivalent design, materials, packaging, fundamental technology, manufacturing processes, sterilization method, and intended use as those featured in the predicate Magic Torque Guidewire.

Non-Clinical Performance Data	Determination of substantial equivalence is based on an assessment of non-clinical performance data. **Biological Safety Testing:** A biocompatibility assessment in accordance with ISO 10993-1, microbial assessments including bioburden, endotoxin, and pyrogenicity, and sterility assurance testing were conducted. The assessments show the device to be biocompatible for its intended use. **Bench Testing:** The following tests were performed to demonstrate substantial equivalence to the predicate device. • Overall Length Measurement • Guidewire Withdrawal from the Carrier Tube The Magic Torque DLVR Guidewire met the predetermined acceptance criteria, thereby demonstrating substantial equivalence to the predicate device. No new safety or performance issues were raised during testing.
Clinical Performance Data	Not applicable; determination of substantial equivalence is based on an assessment of non-clinical performance data.
Conclusion	Based on the indications for use, technological characteristics and non-clinical testing, the proposed Magic Torque DLVR Guidewire is substantially equivalent to the predicate Magic Torque Guidewire (K933334) and it is at least as safe and effective for its intended use.