June 18, 2018

Boston Scientific Inc.
Jake Baldauf
Regulatory Affairs Specialist
Three Scimed Place
Maple Grove, Minnesota 55311

Re: K180726
Trade/Device Name: Savion DLVR Guidewire, Savion FLX Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: March 16, 2018
Received: March 20, 2018

Dear Jake Baldauf:

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 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,

Lydia S. Glaw -S
2018.06.18 15:37:11 -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)*

K180726

Device Name
Savion DLVR Guidewire
Savion FLX Guidewire

Indications for Use *(Describe)*

The Savion DLVR and Savion FLX Guidewires are intended to facilitate the placement of balloon dilatation catheters or other interventional therapeutic devices during PTCA, PTA, or other intravascular interventional procedures. They 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

per 21 CFR §807.92

Date Prepared	March 16, 2018
Submitter's Name and Address	Boston Scientific Corporation Three Scimed Place Maple Grove, MN 55311
Contact Name and Information	Jake Baldauf Regulatory Affairs Specialist II Phone: 763-494-2591 Fax: 763-494-2222 Email: jake.baldauf@bsci.com
Trade Name(s)	Savion DLVR™ Guidewires and Savion FLX™ Guidewires
Common or Usual Name	Catheter Guide Wire
Product Code	DQX
Classification of Device	Class 2 according to 21 870.1330

Predicate Device(s)			
	PT2 Guidewire	K030617	21 May 2003
	Mailman Guidewire	K143587	15 Jan 2015

Device Description

The Boston Scientific Savion DLVR and Savion FLX Guidewires with ICE® Hydrophilic Coating are available with a nominal diameter of 0.014 in (0.37 mm) and in nominal lengths of 182 cm, 185 cm, or 300 cm. These guidewires contain a metal core wire. Varying tapers along the core wire and differing tip materials (spring coil or polymer) provide combinations of rail support and tip flexibility to address user requirements. The proximal core wire section of all models is coated with polytetrafluoroethylene (PTFE) for lubricity.

The 182 cm and 185 cm guidewires are designed with an extension section for exchange of Over-the-Wire systems by using the AddWire™ Extension Wire (K030617). The 300 cm guidewires allow exchange of therapeutic devices without the use of an exchange system.

Intended Use/ Indications for Use

The Savion DLVR and Savion FLX Guidewires are intended to facilitate the placement and exchange of balloon dilatation catheters or other interventional therapeutic devices during PTCA, PTA, or other intravascular interventional procedures. They are not intended for use in the cerebral vasculature.

Comparison of Required Technological Characteristics

The Savion FLX Guidewire and Savion DLVR Guidewire incorporate substantially equivalent design, fundamental technology, packaging, sterilization method and intended use as the predicates PT2 Guidewire (K030617), Mailman Guidewire (K143587), respectively.

Summary of Nonclinical Tests

Nonclinical testing per FDA Guidance for Coronary and Cerebrovascular Guide Wires (1995) supports a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed devices 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 device testing.

Biocompatibility tests included:

Cytotoxicity	Acute Systemic Toxicity	Partial Thromboplastin Time
Sensitization	Direct Contact Hemolysis	Intracutaneous Reactivity
Materials Mediated Rabbit Pyrogenicity	In Vitro Hemocompatibility	Complement Activation

Performance tests included:

Tensile Strength	J-Tip Retention
Torque Strength	Surface
Torqueability	Polymer Sleeve Shear
Tip Flexibility	Adhesive/Potting Adherence
Coating Adherence/Integrity	Bends
Catheter Compatibility	Exchange System Coupling Strength
Pushability	Exchange System Connectability
Radiopacity	

Animal Studies

Not required.

Clinical Studies

Not required.

Conclusion

Based on the indications for use, technological characteristics, safety and performance testing, the Savion DLVR and Savion FLX are appropriate for the intended use and are considered to be substantially equivalent to the Mailman Guidewire (K143587) and PT2 Guidewire (K030617), respectively.