June 22, 2018

Boston Scientific Corporation
Toni Guidarelli
Sr. Regulatory Affairs Specialist
Three Scimed Place
Maple Grove, Minnesota 55446

Re: K180785
Trade/Device Name: iSLEEVE™ Introducer Set
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: March 23, 2018
Received: March 26, 2018

Dear Ms. Guidarelli:

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,

Jaime Raben -S

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)*
K180785

Device Name
iSLEEVE Introducer Set

Indications for Use *(Describe)*

14F iSLEEVE Introducer Set:
The 14F iSLEEVE Introducer Set is intended to facilitate femoral access to the vascular system for introduction and removal of the ACURATE TF Valve System and ancillary devices. The iSLEEVE Introducer Set is suitable for use in vessels ≥ 5.5 mm.

15F iSLEEVE Introducer Set:
The 15F iSLEEVE Introducer Set is intended to facilitate femoral access to the vascular system for introduction and removal of the LOTUS Edge Valve System and ancillary devices. The iSLEEVE Introducer Set is suitable for use in vessels ≥ 5.9 mm.

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	Toni Guidarelli Three Scimed Place Maple Grove, MN 55311-1566 Phone: 763-494-2870 Fax: 763-494-2222 e-mail: Toni.Guidarelli@bsci.com		
Prepared	March 23, 2018		
Proprietary Name	iSLEEVE™ Introducer Set		
Common Name	Catheter introducer		
Product Code	DYB		
Classification	Class II, 21 CFR Part 870.1340		
Primary Predicate Device	Creganna-Tactx Lotus™ Introducer Set	K140338	27 August 2014
Reference Device(s)	Edwards eSheath Introducer Set	K152225	24 November 2015

Device Description

The iSLEEVE™ Introducer Set is a sterile, single-use introducer catheter that provides percutaneous access to the femoral artery for introduction and removal of compatible valve systems and ancillary devices into the vascular system. The iSLEEVE Introducer Set is composed of a dilator and an introducer sheath with a three-way stopcock. The distal end of the introducer sheath is expandable which allows for transient sheath expansion when the compatible valve system is introduced through it. This reduces the time the access vessel is expanded. There is a hydrophilic coating on the introducer sheath which increases the lubricity of the surface to aid in delivery when activated.

The iSLEEVE Introducer Set is available in two sizes; 14F and 15F. The 14F iSLEEVE Introducer Set is for use with the ACURATE TF Valve System only and the 15F iSLEEVE Introducer Set is for use with the LOTUS Edge™ Valve System only. A product mandrel and flushing tube are also supplied with the iSLEEVE Introducer Set.

Indications for Use / Intended Use Guide Wire

14F iSLEEVE Introducer Set:

INTENDED USE:
The iSLEEVE Introducer Set is intended to facilitate femoral access to the vascular system.

INDICATIONS FOR USE:
The 14F iSLEEVE Introducer Set is intended to facilitate femoral access to the vascular system for introduction and removal of the ACURATE TF Valve System and ancillary devices. The iSLEEVE Introducer Set is suitable for use in vessels ≥ 5.5 mm diameter.

15F iSLEEVE Introducer Set:

INTENDED USE:
The iSLEEVE Introducer Set is intended to facilitate femoral access to the vascular system.

INDICATIONS FOR USE:
The 15F iSLEEVE Introducer Set is intended to facilitate femoral access to the vascular system for introduction and removal of the LOTUS Edge™ Valve System and ancillary devices. The iSLEEVE Introducer Set is suitable for use in vessels ≥ 5.9 mm.

Comparison of Technological Characteristics

The iSLEEVE™ Introducer Set incorporates substantially equivalent design, packaging, fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the predicate, Creganna-Tactx Lotus™ Introducer Set K140338.

Performance Data

The iSLEEVE Introducer Set was subjected to testing to support a determination of substantial equivalence according to *Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters,* September 8, 2010. The iSLEEVE Introducer Set also conforms to relevant sections of *EN ISO 10555-1: 2013, Sterile, single-use intravascular catheters; Part 1: General Requirements* and *EN ISO 11070:2014 Sterile single-use intravascular introducers, dilators and guidewires*. In addition biocompatibility testing was performed in accordance with *EN ISO 10993-1 Biological evaluation of medical devices.* A summary of testing completed is provided below;

- Dimensional Verification
- Device Deployment and Retraction
- Catheter Bond Strength
- Flexibility and Kink Test
- Torque Strength
- Radiopacity
- Coating Integrity
- Particulate Evaluation
- Catheter Body Burst Pressure
- System Insertion Force
- Valve Leakage
- Visual Appearance
- Package Integrity
- Sterility and EO Residuals
- Biocompatibility
- Endotoxin

In addition to the aforementioned testing, a preclinical study was executed to support a determination of substantial equivalence. The study evaluated the performance of the iSLEEVE device through an acute animal assessment in a simulated use environment and bench testing under simulated use conditions. As part of the acute animal assessment Tip and Dilator radiopacity performance was assessed.

The results of the tests provide reasonable assurance that the proposed 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 testing; therefore this device may be considered substantially equivalent to the predicate device.

Clinical Testing

Performance testing from clinical studies is not required to demonstrate substantial equivalence of the iSLEEVE Introducer Set.

Conclusion

Based on the indications for use, technological characteristics, and performance testing the iSLEEVE™ Introducer Set has been shown to be appropriate for its' intended use and is considered to be substantially equivalent to the Creganna-Tactx Lotus™ Introducer Set K140338.