October 6, 2020

Boston Scientific Corporation
Kripa Pandya
Regulatory Affairs Specialist
Three Scimed Place
Maple Grove, Minnesota 55311

Re: K202584
Trade/Device Name: iSleeve Introducer Set
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: September 4, 2020
Received: September 8, 2020

Dear Kripa Pandya:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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 Jaime Raben
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*
K202584

Device Name
iSLEEVE™ Introducer Set

Indications for Use *(Describe)*

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.

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

Sponsor	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, Massachusetts 01752 USA		
Contact Name and Information	Kripa Pandya Three Scimed Place Maple Grove, MN 55311-1566 Phone: 763-494-1654 Fax: 763-494-2222 e-mail: Kripa.Pandya@bsci.com		
Prepared by	Kripa Pandya 04 September 2020		
Proprietary Name	iSLEEVE™ Introducer Set		
Common Name	Catheter Introducer		
Product Code	DYB		
Classification	Class II, 21 CFR Part 870.1340		
Predicate Device	iSLEEVE™ Introducer Set	K191871	07 August 2019

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 transcatheter heart 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 passively expandable which allows for transient sheath expansion when the compatible valve system is introduced through it. Once expanded, this region of the introducer sheath is radially compliant, which allows it to expand and collapse as needed during device delivery and removal. This reduces the time the access vessel is expanded. A hydrophilic coating is applied to the entire iSLEEVE introducer sheath which increases the lubricity to aid in delivery when activated.

Indications for Use / Intended Use

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, iSLEEVE Introducer Set, K191871.

Device Modifications:

The 15F iSLEEVE Introducer Set has a modified distal tip designed to enhance advancement and withdrawal of the LOTUS Edge Valve System compared to the predicate (K191871).

Non-clinical Performance Data

Determination of substantial equivalence is based on an assessment of non-clinical performance bench testing data.

Bench Testing:

Bench testing was performed to evaluate physical integrity, functionality, and performance of the iSLEEVE Introducer Sheath Set. Performance criteria includes dimensional requirements, visibility under fluoroscopy, and interface with compatible devices.

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 identified predicate.