February 3, 2023

Boston Scientific Corporation
Kendall Lindenman
Regulatory Affairs Specialist
One Scimed Place
Maple Grove, Minnesota 55311

Re: K230051
Trade/Device Name: 14F iSLEEVE Introducer Set
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB
Dated: January 5, 2023
Received: January 6, 2023

Dear Kendall Lindenman:

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,

Jennifer Bastijanic -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230051

Device Name
iSLEEVE Introducer Set

Indications for Use *(Describe)*
The 14F iSLEEVE Introducer Set is intended to facilitate femoral access to the vascular system for introduction and removal of cardiovascular devices. The iSLEEVE Introducer Set is suitable for use in vessels ≥ 5.5 mm diameter.

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.

510(k) Summary (K230051)
per 21 CFR §807.92

Sponsor	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, Massachusetts 01752 USA		
Contact Name and Information	Kendall Lindenman One Scimed Place Maple Grove, MN 55311-1566 Phone: 763-494-1284 e-mail: Kendall.Lindenman@bsci.com		
Date Prepared by	January 5th, 2023		
Proprietary Name	14F iSLEEVE™ Introducer Set		
Common Name	Catheter Introducer		
Product Code	DYB		
Classification	Class II, 21 CFR Part 870.1340		
Predicate Device	iSLEEVE™ Introducer Set	K191871	August 07, 2019

Device Description

The 14F iSLEEVE Introducer Set is a sterile, single-use introducer catheter that provides percutaneous access to the femoral artery for introduction and removal of cardiovascular devices into the vascular system. The 14F 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 working end of the iSLEEVE introducer sheath which increases the lubricity to aid in delivery when activated.

A product mandrel and flushing tube are also supplied with the iSLEEVE Introducer Set.

Indications for Use / Intended Use

The 14F iSLEEVE™ Introducer Set is intended to facilitate femoral access to the vascular system for introduction and removal of cardiovascular devices. The iSLEEVE Introducer Set is suitable for use in vessels ≥ 5.5 mm diameter.

Comparison of Technological Characteristics

The modified device includes an alternative hydrophilic coating, there are no other design changes associated with this 510(k).

Comparison of the new coating and the currently marketed predicate device show that the technological characteristics such as performance, materials, design, sterilization, and packaging are equivalent. The subject 14F iSLEEVE Introducer Set intended purpose and principles of operation also remain unchanged.

Non-clinical Performance Data

Modifications to the predicate device were assessed according to risk-based failure mode effects analysis and with consideration of FDA Guidance, *Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters, September 8, 2010.* The following non-clinical testing was successfully completed on the modified device.

- Coating Material and Length
- Coating Lubricity and Durability (L&D)
- Introducer System Advancement Force
- Maximum Junction OD
- Particulate Evaluation
- Coating Integrity
- Visual Appearance

Testing demonstrated that the modified 14F iSLEEVE Introducer Set met all previously established acceptance criteria. No new safety or effectiveness issues were raised during verification activities, thereby supporting a determination of substantial equivalence.

Biocompatibility testing was also assessed with consideration of evaluation recommendations per ISO 10993-1, Biological Evaluation of Medical Devices – Part 1: 10993-1 (issued September 2020) for devices categorized as externally communicating with limited (<24 hours) direct circulating blood contact. The following is a list of the biocompatibility tests conducted on the modified 14F iSLEEVE Introducer Set.

- Cytotoxicity
- Irritation
- Sensitization
- Material Mediated Pyrogenicity
- Acute Systemic Toxicity
- Hemocompatibility
- Genotoxicity

Results confirm that the modified device remains biocompatible for its intended use.

Animal Study

A double-blinded animal study was conducted in the porcine model to further support a determination that the modified device with alternative hydrophilic coating is substantially equivalent to that of the predicate. Physicians were asked to separately evaluate the performance of the insertion and removal of the predicate and alternative hydrophilic coated device.

The animal study and simulated use evaluation further supports that the modified iSLEEVE Introducer Set, when coated with the alternate coating, demonstrates functionally equivalent performance as compared to the current coating.

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.