March 20, 2025

Boston Scientific
Elizabeth Ladriere
Regulatory Affairs Specialist II
One Scimed Pl
Maple Grove, Minnesota 55311

Re: K250468
Trade/Device Name: iSLEEVE Introducer Set
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: February 18, 2025
Received: February 18, 2025

Dear Elizabeth Ladriere:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

KAYLA M. SCOTT -S

Digitally signed by KAYLA M. SCOTT -S
Date: 2025.03.20 15:02:24 -04'00'

For
Finn Donaldson
Acting Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250468

Device Name
iSLEEVE Introducer Set

Indications for Use *(Describe)*
The 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) SUMMARY (K250468)

per 21 CFR §807.92

Sponsor	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, Massachusetts 01752 USA		
Contact Name and Information	Elizabeth LaDriere One Scimed Place Maple Grove, MN 55311-1566 Phone: 314-724-0036 e-mail: Elizabeth.LaDriere@bsci.com		
Date Prepared	February 18th, 2025		
Proprietary Name	iSLEEVE™ Introducer Set		
Common Name	Catheter Introducer		
Product Code	DYB		
Classification	Class II, 21 CFR Part 870.1340		
Predicate Device	14F iSLEEVE™ Introducer Set	K233503	30NOV2023

Device Description

The iSLEEVE Expandable Introducer Set (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 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 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 additional component for the iSLEEVE Introducer Set, which will be referred to as the Expansion Tool. There is no other design changes associated with this 510(k).

Comparison of the new component and the currently marketed predicate device show that the technological characteristics such as performance, materials, design, sterilization, biocompatibility, and packaging are equivalent. The subject 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. A summary of the testing which was successfully completed on the expansion tool consists of:

- Luer Connections
- Simulated Use Testing
- Dimensional Requirements
- Tensile Testing
- Packaging Testing
- Radiopacity
- Sterilization
- Usability

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

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.