



November 30, 2023

Boston Scientific Corporation
Alyssa Manno
Regulatory Affairs Specialist III
Two Scimed Place
Maple Grove, Minnesota 55311

Re: K233503

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: October 31, 2023
Received: October 31, 2023

Dear Alyssa Manno:

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.

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,


Julie B. Mackel -S

For

Jennifer Bastijanac
Acting 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

Indications for Use

510(k) Number (if known)

K233503

Device Name

14F 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.

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

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510(k) SUMMARY (K233503)

Sponsor	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, Massachusetts 01752 USA		
Contact Name and Information	Alyssa Manno One Scimed Place Maple Grove, MN 55311-1566 Phone: 763-494-2602 e-mail: Alyssa.Manno@bsci.com		
Date Prepared by	October 31 st , 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	K230051	February 3 rd , 2023

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 enhanced transition point between the sheath and hub components. There are no other design changes associated with this 510(k).

Comparison of the new design and the currently marketed predicate device show that the technological characteristics such as performance, materials, design, sterilization, biocompatibility, 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. The following non-clinical testing was successfully completed on the modified device.

- Sheath to Hub Tensile

Testing demonstrated that the modified 14F 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.
