February 1, 2024

Boston Scientific Corporation
Alexa Keenan
Senior Regulatory Affairs Specialist
300 Boston Scientific Way
Marlborough, Massachusetts 01752-1234

Re: K240018
Trade/Device Name: WATCHMAN TruSteer Access System (M635TU90050)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: January 2, 2024
Received: January 2, 2024

Dear Alexa Keenan:

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,

Katherine N. Trivedi -S

for Rachel Neubrander
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

Enclosure

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)*
K240018

Device Name
WATCHMAN TruSteer Access System (M635TU90050)

Indications for Use *(Describe)*
The WATCHMAN TruSteer Access System is intended to provide vascular and transseptal access for the family of WATCHMAN FLX LAAC Devices with Delivery Systems.

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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K240018
510(k) Summary
Per 21 CFR §807.92

Sponsor:	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, Massachusetts 01752 USA
Contact Name and Information	Alexa M Keenan One Scimed Place Maple Grove MN, 55311-1566 Phone: 763-494-1731 Fax: 763-494-2222 e-mail: Alexa.Keenan@bsci.com
Date Prepared:	02 January, 2024
Proprietary Name	WATCHMAN TruSteer™ Access System
Common Name	Catheter, Percutaneous
Product Code	DQY
Classification	Class II, 21 CFR Part 870.1250
Predicate Device	WATCHMAN FXD Curve™ Access System, K212228, cleared 13 August 2021
Device Description	The Boston Scientific WATCHMAN TruSteer™ Access System is composed of an Access Sheath and Dilator. The WATCHMAN TruSteer Access System is a steerable Access System intended to provide vascular and transseptal access specifically for the family of WATCHMAN™ FLX™ Left Atrial Appendage Closure Devices with Delivery Systems. The WATCHMAN TruSteer Access System will be used by interventional cardiologists and/or electrophysiologists who are trained in percutaneous and transseptal procedures.
Indications for Use / Intended Use	The WATCHMAN TruSteer Access System is intended to provide vascular and transseptal access for the family of WATCHMAN FLX LAAC Devices with Delivery Systems.

Device Technology Characteristics and Comparison to Predicate Device	WATCHMAN TruSteer Access System incorporates a substantially equivalent design, packaging, fundamental technology, manufacturing processes, sterilization process, and indications for use / intended use as those featured in WATCHMAN FXD Curve Access System, K212228.
Non-Clinical Performance Data	Design verification testing was performed to support a determination of substantial equivalence to WATCHMAN FXD Curve Access System per *Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters,* September 2010. The WATCHMAN TruSteer Access System also conforms to relevant sections of *EN ISO 10555-1, Sterile, Single-Use Intravascular Catheters; Part 1: General Requirements*. Based on the indications for use / intended use, design, and safety and performance testing, the WATCHMAN TruSteer Access System meets the requirements for its intended use and is substantially equivalent to the predicate device.
The following device performance tests were completed: • Dimensional Characterization • Curve Shape • Proximal and Distal Marker Location • Sheath Force Transmission • Kink Resistance • Atraumatic Tip • Torque Transmission • Radiopacity • Tensile • Surface • Leak-Free Conduits • Pressure Retention • Particulates • Hemostasis Valve Cap Detach Force • Access System Smooth Transition • Flowrate	
The following biocompatibility tests were completed: • Cytotoxicity • Sensitization • Intracutaneous Reactivity • Acute Systemic Toxicity • Complement Activation • Materials Mediated Pyrogenicity • Hemolysis Direct Contact • Hemolysis Extract Method • In Vitro Platelet and Leukocyte Count • Partial Thromboplastin Time	
Clinical Testing	Clinical evaluation was not required for this device.
Conclusion	The results of all testing demonstrate that the WATCHMAN TruSteer Access System is substantially equivalent to the WATCHMAN FXD Curve Access System, K212228.