August 13, 2021

Boston Scientific Corporation
Alexa Keenan
Regulatory Affairs Specialist II
Three Scimed Place
Maple Grove, Minnesota 55311-1566

Re: K212228
Trade/Device Name: WATCHMAN FXD Curve™ Access System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: July 15, 2021
Received: July 16, 2021

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 (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,

Rachel E. Neubrander -S

Rachel Neubrander
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular 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)*
K212228

Device Name
WATCHMAN FXD Curve™ Access System

Indications for Use *(Describe)*
The WATCHMAN FXD Curve Access System is intended to provide vascular and transseptal access for the WATCHMAN FLX Left Atrial Appendage Closure Device with Delivery System.

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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K212228

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
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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	Alexa M Keenan Three Scimed Place Maple Grove MN, 55311-1566 Phone: 763-494-1731 Fax: 763-494-2222 e-mail: Alexa.Keenan@bsci.com
Date Prepared:	July 15, 2021
Proprietary Name	WATCHMAN FXD Curve™ Access System
Common Name	Catheter, Percutaneous
Product Code	DQY
Classification	Class II, 21 CFR Part 870.1250
Predicate Device	WATCHMAN™ TruSeal™ Access System, K180864, cleared 20 July 2018
Device Description	The Boston Scientific WATCHMAN FXD Curve™ Access System is composed of an Access Sheath and Dilator. The WATCHMAN FXD Curve Access System is used to provide vascular and transseptal access for WATCHMAN™ FLX™ Left Atrial Appendage Closure Device with Delivery System. The WATCHMAN FXD Curve 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 FXD Curve™ Access System is intended to provide vascular and transseptal access for the WATCHMAN™ FLX™ Left Atrial Appendage Closure Device with Delivery System.

<table>
<tr><td>Device Technology Characteristics and Comparison to Predicate Device</td><td>WATCHMAN FXD Curve Access System incorporates substantially equivalent design, packaging, fundamental technology, manufacturing processes, sterilization process, and indications for use / intended use as those featured in WATCHMAN TruSeal Access System, K180864.</td></tr>
<tr><td>Non-Clinical Performance Data</td><td>Design verification testing was performed to support a determination of substantial equivalence to WATCHMAN TruSeal Access System per Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters, September 2010. The WATCHMAN FXD Curve 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 FXD Curve Access System meets the requirements for its intended use and is substantially equivalent to the predicate device.</td></tr>
<tr><td colspan="2">The following device performance tests were completed:
Dimensional Characterization
Curve Shape
Proximal and Distal Marker Location
Sheath Force Transmission
Kink Resistance
Tip Deflection
Torqueability
Radiopacity
Tensile
Surface
Leak-Free Conduits
Pressure Retention
Particulates
Access Sheath Cap Detachment Force
Access System Smooth Transition</td></tr>
<tr><td colspan="2">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</td></tr>
<tr><td>Clinical Testing</td><td>Clinical evaluation was not required for this device.</td></tr>
<tr><td>Conclusion</td><td>The results of all testing demonstrate that the WATCHMAN FXD Curve Access System is substantially equivalent to the WATCHMAN TruSeal Access System, K180864.</td></tr>
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