July 20, 2018

Boston Scientific
Nikki Ibis
Principal Regulatory Affairs Specialist
Three Scimed Place
Maple Grove, Minnesota 55311-1566

Re: K180864
Trade/Device Name: WATCHMAN TruSeal Access System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: June 27, 2018
Received: June 28, 2018

Dear Ms. Ibis:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180864

Device Name
WATCHMAN™ TruSeal™ Access System

Indications for Use *(Describe)*
The WATCHMAN™ TruSeal™ Access System is intended to provide vascular and transseptal access for all WATCHMAN Left Atrial Appendage Closure 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.

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
per 21 CFR §807.92

Sponsor:	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, Massachusetts 01752 USA		
Contact Name and Information	Nikki M Ibis Three Scimed Place Maple Grove, MN 55311-1566 Phone: 763-494-2381 Fax: 763-494-2981 e-mail: Nikki.Ibis@bsci.com		
Prepared	30 March 2018		
Proprietary Name	WATCHMAN™ TruSeal™ Access System		
Common Name	Catheter, Percutaneous		
Product Code	DQY		
Classification	Class II, 21 CFR Part 870.1250		
Primary Predicate Device	Amplatzer® TorqVue® 45°x45° Delivery Sheath	K083214	12 May 2009
Reference Device(s)	WATCHMAN® Access System	P130013	13 March 2015

Device Description

The Boston Scientific WATCHMAN™ TruSeal™ Access System is composed of an Access Sheath and Dilator. The TruSeal Access System is used to provide vascular and transseptal access for all WATCHMAN Left Atrial Appendage Closure Devices with Delivery Systems. The TruSeal 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™ TruSeal™ Access System is intended to provide vascular and transseptal access for all WATCHMAN Left Atrial Appendage Closure Devices with Delivery Systems.

Comparison of Technological Characteristics

The WATCHMAN™ TruSeal™ Access System incorporates substantially equivalent design, packaging, fundamental technology, and intended use as those featured in the predicate, Amplatzer® TorqVue® 45°x45° Delivery Sheath, K083214.

Performance Data

Design verification testing was performed to support a determination of substantial equivalence according to *Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters,* September 2010. The WATCHMAN™ TruSeal™ Access System also conforms to relevant sections of *EN ISO 10555-1: 2013, Sterile, single-use intravascular catheters; Part 1: General Requirements*. The results of the tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the testing.

The following device performance tests were completed:

- Dimensional Characterization
- Distal and Proximal Marker Location
- Curve Shape
- TruSeal Access System Guidance / Crossing
- Contrast Flow Rate
- Leak-Free Conduits
- Pressure Retention
- Corrosion Resistance
- Sheath Force Transmission
- Kink Resistance
- Tip Deflection
- Torqueability
- Snap Fit Attachment Force
- Access Sheath Compression Force
- Dilator Stiffness
- Tensile
- Radiopacity
- Luer Lock Testing
- Particulates
- Surface

The following package performance tests were completed:

- Master Shipper Carton Integrity
- Shelf Carton Condition
- Sterile Barrier Integrity
- Sterile Barrier Seal Strength
- Ease of Opening Pouch
- TruSeal Access System Containment
- Tray Condition
- Removal From Packaging
- DFU and eDFU Card Print Quality
- Label Adhesion and Print Quality

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

Based on the intended use use, technological characteristics, safety and performance testing, the WATCHMAN™ TruSeal™ Access System is appropriate for the stated intended use and is considered to be substantially equivalent to the Amplatzer® TorqVue® 45°x45° Delivery Sheath, K083214.