November 9, 2017

Boston Scientific Corporation
Lori Berends
Senior Regulatory Affairs Specialist
Three Scimed Place
Maple Grove, Minnesota 55311-1566

Re: K172453
Trade/Device Name: WATCHDOG Hemostasis Valve Kit
Regulation Number: 21 CFR 870.1330
Regulation Name: wire, guide, catheter
Regulatory Class: Class II
Product Code: DQX, DTL, PTL
Dated: August 10, 2017
Received: August 14, 2017

Dear Lori Berends:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Nicole G. Ibrahim -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K172453

Device Name
WATCHDOG™ Hemostasis Valve Kit

Indications for Use *(Describe)*
The WATCHDOG™ Hemostasis Valve is intended to maintain hemostasis during diagnostic/ interventional procedures. The WATCHDOG™ Hemostasis Valve is indicated for maintaining a seal around diagnostic/ interventional devices with combined outer diameters of up to 8F [0.105 in (2.67 mm)] during diagnostic/ interventional procedures.

The Insertion Tool is used to facilitate the introduction of a guidewire during general intravascular procedures.

The Torque Device is used for guidewire manipulation during general intravascular procedures.

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.

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510(k) Summary – K172453

Per 21 CFR §807.92

Common or Usual Name	Hemostasis Valve
Trade Name(s)	WATCHDOG™ Hemostasis Valve Kit
Product Code	Insertion Tool: DQX – wire, guide, catheter
Subsequent Product Codes	Hemostasis Valve: DTL – adaptor, stopcock, manifold, fitting, cardiopulmonary bypass Torque Device: PTL – wire, guide, catheter
Classification of Device	Hemostasis Valves are Class II devices according to 21 CFR 870.4290, and are 510(k) Exempt. Insertion Tools are Class II devices according to 21 CFR 870.1330. Torque Devices are Class II devices according to 21 CFR 870.1330, and are 510(k) Exempt.
Submitter's Name and Address	Boston Scientific Corporation Three Scimed Place Maple Grove, MN 55311-1566
Contact Name and Information	Lori Berends Sr. Regulatory Affairs Specialist Phone: 763-494-1528 Fax: 763-494-2222 Email: Lori.Berends@bsci.com
Date Prepared	10 Aug 2017
Section 514 of the Act Performance Standards	No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for percutaneous catheters.
Establishment Registration Numbers	**Owner /Operator:** Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA 01752 USA ERN: 9912058
	Manufacturing Facility: Boston Scientific Limited Business and Technology Park Model Farm Road Cork, IRELAND ERN: 9616684

	Sterilization Facility:	Synergy Health Ireland, LTD IDA Business and Technology Park Sragh, Tullamore Co. Offaly Ireland ERN: 3002807314
Predicate Device(s)	*WATCHDOG™ Hemostasis Valve Kit:* Guardian® II Hemostasis Valve K122301 (cleared September 7, 2012) *Insertion Tool:* Insertion Tool K140673 (cleared April 16, 2014)	
Reference Device(s)	*WATCHDOG™ Hemostasis Valve Kit:* GateWay™ PLUS Y-Adapter K951089 (cleared May 31, 1995) COPILOT™ Bleedback Control Valve K991102 (cleared June 9, 1999) *No Reference Devices are identified for the Insertion Tool.*	
Device Description	The WATCHDOG™ Hemostasis Valve kit includes the WATCHDOG™ Hemostasis Valve, an Insertion Tool and a Torque Device. The WATCHDOG™ Hemostasis Valve is designed to reduce blood loss and to facilitate pressure injections during interventional procedures. This device is intended to maintain hemostasis during the use of diagnostic or interventional devices by maintaining a seal around these devices. The WATCHDOG™ Hemostasis Valve has two seals; the low-pressure (Proximal) seal and the high-pressure (Distal) seal. The body of the device has two luer fittings, one on the main body and one on the side port. The side port has a female luer fitting and is used for connecting pressure monitoring and manual infusion equipment. The main body has a rotating male luer for connecting to guide or diagnostic catheters. The insertion tool is intended for use at the proximal end of the WATCHDOG™ Hemostasis Valve, which is attached to a guiding catheter hub. The insertion tool is used to facilitate the introduction of a guidewire through the WATCHDOG™ device, into the lumen of a guiding catheter, without damaging the guidewire distal tip. It may also be used to introduce a guidewire into an over-the-wire type balloon dilatation catheter. The Torque Device is a non-patient contacting accessory device used to apply torsional and/or axial force to the guidewire to manipulate its distal end in the vasculature. It is designed to accommodate guidewire with diameters from 0.010 to 0.018 inches.	
Intended Use/ Indications for Use	The WATCHDOG™ Hemostasis Valve is intended to maintain hemostasis during diagnostic/ interventional procedures. The WATCHDOG™ Hemostasis Valve is indicated for maintaining a seal around diagnostic/ interventional devices with combined outer diameters of up to 8F [0.105 in (2.67 mm)] during diagnostic/ interventional procedures. The Insertion Tool is used to facilitate the introduction of a guidewire during general intravascular procedures. The Torque Device is used for guidewire manipulation during general intravascular procedures.	

Comparison of Technological Characteristics

The WATCHDOG™ Hemostasis Valve Kit incorporates substantially equivalent design, packaging (all have sterile barriers), fundamental technology, manufacturing processes, sterilization process (specifically, the GateWay™ PLUS Y-Adapter) and intended use as those featured in the predicate, Guardian® II Hemostasis Valve K122301, and reference devices GateWay™ PLUS Y-Adapter K951089 and COPILOT™ Bleedback Control Valve K991102.

The Insertion Tool incorporates substantially equivalent design, packaging, fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the predicate, Insertion Tool K140673.

The Torque Device is a cleared device under K123024.

Summary of Non-Clinical Test Summary

Bench and biocompatibility testing for the WATCHDOG™ Hemostasis Valve Kit, including the Insertion Tool, was performed to support a determination of substantial equivalence. The results of these 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 device testing.

The following performance tests were completed on the WATCHDOG™ Hemostasis Valve Kit:

- Sterile Barrier Strength
- Sterile Barrier Seal Width
- Sterile Barrier Integrity
- Sterile Barrier Integrity, Visual
- Shelf Carton Condition, Visual
- Label Adhesion and Print Quality
- Ease of Opening – Tyvek
- Design Validation

The following performance tests were completed on the Insertion Tool:

- Corrosion Resistance
- Insertion Tool Length
- Insertion Tool ID Measurement (Guidewire Compatibility)
- Insertion Tool Hub to Hypotube Tensile Test
- Particulate Testing
- Design Validation

The following biocompatibility and chemical characterization tests were completed on the WATCHDOG™ Hemostasis Valve Kit, including the Insertion Tool:

- Minimum Essential Medium (MEM) Elution (Cytotoxicity)
- Guinea Pig Sensitization (Maximization Method)
- Intracutaneous Reactivity
- Systemic Toxicity (Acute)
- Material Mediated Pyrogenicity (Rabbit Pyrogen Test)
- Hemolysis Test – Extraction Method
- Chemical Characterization – Analytical Testing

Conclusion	Based on the indications for use, technological characteristics, safety and performance testing, the WATCHDOG™ Hemostasis Valve Kit is appropriate for the stated intended uses and is considered to be substantially equivalent to the Guardian® II Hemostasis Valve K122301. Based on the indications for use, technological characteristics, safety and performance testing, the Insertion Tool is appropriate for the stated intended uses and is considered to be substantially equivalent to the Insertion Tool K140673.