September 26, 2023

Boston Scientific Corporation
Kevin Catalano
Principal Regulatory Affairs Specialists
Two Scimed Place
Maple Grove, Minnesota 55311

Re: K230884
Trade/Device Name: AVVIGO+ Multi-Modality Guidance System
Regulation Number: 21 CFR 870.1110
Regulation Name: Blood Pressure Computer
Regulatory Class: Class II
Product Code: DSK, IYO, DSK, ITX
Dated: August 23, 2023
Received: August 24, 2023

Dear Kevin Catalano:

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,

Stephen C. Browning -S

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
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)*
K230884

Device Name
AVVIGO+ Multi-Modality Guidance System

Indications for Use *(Describe)*
The IVUS modality of the System is intended for ultrasound examinations of intravascular pathology. Intravascular ultrasound is indicated in patients who are candidates for transluminal interventional procedures such as angioplasty and atherectomy.

FFR and DFR™ are intended for use in catheterization and related cardiovascular specialty laboratories to compute, and display various physiological parameters based on the output from one or more electrodes, transducers, or measuring devices. FFR and DFR are indicated to provide hemodynamic information for use in the diagnosis and treatment of patients that undergo measurement of physiological parameters.

Refer to the Catheter Instructions for Use provided with all Boston Scientific Ultrasound Imaging Catheters to determine compatibility with the System. All Ultrasound Imaging Catheters will be referred to as Imaging Catheters throughout the remainder of this User Guide.

The Imaging Catheters generate ultrasound images and are intended for ultrasound examination of vascular and cardiac pathology. Boston Scientific manufactures a wide variety of catheters for different applications. The recommended use of each of these catheters may vary depending on the size and type of the catheter. Please refer to the Imaging Catheter Instructions for Use, packaged with each catheter.

Indications for Auto Pullback Use (IVUS Only)
Automatic Pullback is indicated when the following occurs:

- The physician/operator wants to standardize the method in which intravascular ultrasound images are obtained and documented: procedure-to-procedure, operator-to-operator.

- The physician/operator wants to make linear distance determinations post-procedurally, which requires the imaging core of a catheter to be pulled back at a known uniform speed.

- Two-dimensional, longitudinal reconstruction of the anatomy is desired.

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
per 21 CFR 807.92

Sponsor	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, Massachusetts 01752 USA
Contact Name and Information	Kevin Catalano Prin. Regulatory Affairs Specialist Phone: 612.817.2987 E-mail: Kevin.Catalano@bsci.com
Date Prepared	March 31, 2023
Proprietary Name	AVVIGO™+ Multi-Modality Guidance System
Common Name	Computer Diagnostic Programmable Blood Pressure Computer Ultrasonic Pulsed Echo Imaging System Diagnostic Ultrasonic Transducer
Classification Name	Primary: 21 CFR 870.1425 (Programmable Diagnostic Computer) Subsequent: 21 CFR 870.1110 (Blood Pressure Computer) 21 CFR 892.1560 (Ultrasonic Pulsed Echo Imaging System) 21 CFR 892.1570 (Diagnostic Ultrasonic Transducer)
Product Code	Primary: DQK (Computer, Diagnostic, Programmable) Subsequent: DSK (Computer, Blood-Pressure) IYO (System, Imaging, Pulsed Echo, Ultrasonic) ITX (Transducer, Ultrasonic, Diagnostic)
Classification	Class II, 21 CFR 870.1425
Predicate Device	AVVIGO™ Guidance System II K212490 cleared 02 OCT 2021

Device Description

The AVVIGO™+ Multi-Modality Guidance System is used by physicians to obtain physiologic, intravascular, and/or intracardiac anatomical information. The system utilizes an interactive display that displays information and allows the physician to:

- Perform intravascular physiology assessment by making measurements with a pressure wire that invasively obtains pressure readings from the vessels, and an FFR Link that retrieves the information from the pressure wire and transfers the information wirelessly to the interactive display,
  and/or
- Perform intravascular or intracardiac ultrasound imaging using a specially designed catheter with a miniaturized ultrasound probe attached to the distal end and a Motor Drive. A PC is used for data acquisition and processing to visualize ultrasound images of selected anatomical structures.

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The AVVIGO™+ Multi-Modality Guidance System hardware has been modified to include a V4 Acquisition PC for IVUS image processing, updates to the mobile pole, and a Table Side Controller user interface for user control access near the patient bedside.

The AVVIGO™+ Multi-Modality Guidance System software includes updated vessel and lumen border trace functionality to improve ease of use. Additionally, the AVVIGO+ Multi-Modality Guidance System GUI includes visual display of frame markers as well as graphical display of DFR with pullback support.

The AVVIGO™+ Multi-Modality Guidance System underlying fundamental principles and technology supporting IVUS and Physiology modalities are unmodified from that of the predicate. IVUS and FFR/DFR remain identical to that of the predicate device, AVVIGO Guidance System II.

AVVIGO™+ Multi-Modality Guidance System modifications do not raise any new issues of safety and effectiveness.

Intended Use/indications for Use

The IVUS modality of the System is intended for ultrasound examinations of intravascular pathology. Intravascular ultrasound is indicated in patients who are candidates for transluminal interventional procedures such as angioplasty and atherectomy.

FFR and DFR™ are intended for use in catheterization and related cardiovascular specialty laboratories to compute, and display various physiological parameters based on the output from one or more electrodes, transducers, or measuring devices.

FFR and DFR are indicated to provide hemodynamic information for use in the diagnosis and treatment of patients that undergo measurement of physiological parameters.

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- Two-dimensional, longitudinal reconstruction of the anatomy is desired.

Comparison of Technological Characteristics

The AVVIGO™+ Multi-Modality Guidance System has the same intended use, operational principles and technological characteristics supporting its intended use as the predicate device, AVVIGO™ Guidance System II. The AVVIGO™+ Multi-Modality Guidance System is substantially equivalent to the predicate device in intended use, IVUS and Physiology modalities, fundamental scientific technology and performance features supporting IVUS and Physiology modalities. Modifications within the AVVIGO™+ Multi-Modality Guidance System do not raise any new issues of safety and effectiveness as demonstrated via non-clinical performance data.

Non-Clinical Performance Data

Substantial equivalence of the AVVIGO™+ Multi-Modality Guidance System is determined through non-clinical performance evaluation including hardware, software, electrical safety, packaging verification and validation activities.

Non-clinical performance verification was performed on the complete AVVIGO™+ Multi-Modality Guidance System, including where applicable compatible equipment, according to recognized performance and safety standards including:

- ANSI AAMI ES 60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) FDA Recognition Number 19-4
- ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021] Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests [Including Amendment 1 (2021)] FDA Recognition Number 19-36
- IEC 60601-2-34 Edition 3.0 2011-05 Medical electrical equipment - Part 2-34: Particular requirements for the basic safety, including essential performance, of invasive blood pressure monitoring equipment FDA Recognition Number 3-115
- IEC 60601-2-37 Edition 2.1 2015 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment FDA Recognition Number 12-293
- IEC 62304 Medical Device Software – Software Lifecycle Processes, (edition 1.1 2015-06) FDA recognition: 13-79
- AAMI TIR69:2017/(R2020) Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems. FDA Recognition Number 19-22

To support a determination of substantial equivalence, non-clinical performance verification and validation was conducted in accordance with the following FDA guidance documents:

- Radio Frequency Wireless Technology in Medical Devices – Guidance for Industry and FDA Staff published August 14, 2013
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff published October 2, 2014
- Electromagnetic Compatibility (EMC) of Medical Devices Guidance for Industry and Food and Drug Administration Staff June 6, 2022

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Clinical Performance Data

Not applicable; determination of substantial equivalence is not based on clinical performance data. Substantial equivalence is based on an assessment of non-clinical performance data.

Conclusion

Based on a comparison of intended use, operating principles, and underlying fundamental design technology, including non-clinical performance verification and validation, the AVVIGO™+ Multi-Modality Guidance System is substantially equivalent to the predicate device, AVVIGO™ Guidance System II Multi-Modality Guidance System. A comparison of the modified device and predicate, including non-clinical performance verification tests performed, support a determination of substantial equivalence and raise no new issues of safety and effectiveness.