October 20, 2021

Boston Scientific Corporation
Margaret Batchelder
Principal Regulatory Affairs Specialist
Three Scimed Place
Maple Grove, Minnesota 55311

Re: K212490
Trade/Device Name: AVVIGO Guidance System II
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, DSK
Dated: September 20, 2021
Received: September 20, 2021

Dear Margaret Batchelder:

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,

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)*

K212490

Device Name
AVVIGO Guidance System II

Indications for Use *(Describe)*

Indications for System 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.

Refer to the Catheter Instructions for Use provided with all Boston Scientific Ultrasound Imaging Catheters to determine compatibility with the Polaris 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	Margaret Batchelder Principal Regulatory Affairs Specialist Three Scimed Place Maple Grove, MN 55311-1566 Phone: 763-494-1423 Fax: 763-257-6482 e-mail: Margaret.Batchelder@bsci.com
Date Prepared	October 20, 2021
Proprietary Name	AVVIGO™ Guidance System II
Common Name	Computer Diagnostic Programmable Blood Pressure Computer
Product Code	DQK DSK ITX IYO
Classification	Class II, 21 CFR 870.1425
Primary Predicate Device	iLab™ Polaris Multi -Modality Guidance System K210889, June 25, 2021
Other Predicate	AVVIGO™ Guidance System K201713, July 23, 2020

Device Description

The AVVIGO Guidance System II is a non-patient contacting medical device system that consists of hardware and software components which aid in supporting Intravascular Ultrasound (IVUS) Fractional Flow Reserve (FFR) and Diastolic hyperemia-Free Ratio™ (DFR™) functionalities.

The AVVIGO 2.0 software update maintains the current FFR/DFR functional modality of the AVVIGO Guidance System (K201713) and introduces the equivalent IVUS functional modality of the iLab Polaris Multi-Modality Guidance System (K210889).

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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Comparison of Technological Characteristics

The AVVIGO Guidance System II has the same fundamental design technology, functional modalities (IVUS and FFR/DFR), software functionality, power requirement, Windows 10 OS, DICOM, case archiving capability, and accessories, as the iLab Polaris Multi-Modality Guidance System (K210889) and AVVIGO Guidance System (K201713).

Non-clinical Performance

Determination of substantial equivalence is based on an assessment of non-clinical performance data which includes software, hardware, packaging and electrical safety verification and validation carried out on the AVVIGO Guidance System II. Testing was conducted according to applicable international standards, FDA recognized consensus standards, and the same well-established test methods and criteria applied to the predicate device. The following standards and guidance are applicable in demonstration of substantial equivalence related to software:

- IEC 62304 Medical Device Software – Software Lifecycle Processes, (edition 1.1 2015-06) FDA recognition: 13-79.
- ANSI AAMI ES 60601-1: 2005/(R)2012 and A1:2012- Medical Electrical Equipment-Part1: General requirements for Basic Safety and Essential Performance. FDA recognition number-19-4
- IEC 60601-1-2 Edition 3: 2007-03 – Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility – Requirements and Tests- FDA recognition number-19-1
- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices; May 11, 2005

- FDA Guidance for Radio Frequency Wireless Technology in Medical Devices; August 14, 2013

Clinical Performance Data

Not applicable. A determination of Substantial Equivalence for this modification is not based on clinical data. Substantial Equivalence is based on non-clinical performance data.

Conclusion

Based on a comparison of intended use, fundamental design technology, IVUS and FFR/DFR functional modalities, and performance features, the AVVIGO Guidance System II is substantially equivalent to the predicate devices. A comparison of the modified and predicate devices, along with verification and validation testing applicable to the modified device, supports a conclusion of substantial equivalence and raise no new issues of safety and effectiveness.