August 21, 2026

Boston Scientific
Kevin Catalano
Principal Regulatory Affairs Specialist
One Scimed Place
Maple Grove, Minnesota 55311

Re: K253692
Trade/Device Name: AVVIGO™+ Multi-Modality Guidance System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, DSK, IYO, ITX
Dated: July 22, 2026
Received: July 22, 2026

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jackson Hair -S

for

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253692

Please provide the device trade name(s).

AVVIGO™+ Multi-Modality Guidance System

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use (21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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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	November 21, 2025
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+™ Multi-Modality Guidance System K230884 cleared Sept 26, 2023

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.

The AVVIGO™+ Multi-Modality Guidance System hardware has been modified to include Frame Grabber Hardware.

The AVVIGO™+ Multi-Modality Guidance System software includes new advanced IVUS imaging features: Automated Stent Assessment, Side Branch Display, and IVUSConnect™.

The modified 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™+ Multi-Modality Guidance System.

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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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.

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+™ Multi-Modality Guidance System. The modified 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:

- IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION Medical electrical equipment - Part 1: General requirements for basic safety and essential performance FDA Recognition Number 19-49
- 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

Nonclinical Performance Data

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The proposed modification introducing the Automated Stent Assessment (ASA) algorithm, Side Branch Display and IVUSConnect™ for AVVIGO™+ IVUS Software was tested in accordance with Boston Scientific internal verification and validation procedures. Prior to user adjustment, automated relative stent expansion measurements demonstrated a mean absolute error of 13.1% (95% CI: 10.7–15.4%), and minimum lumen area measurements demonstrated a mean absolute error of 0.74 mm² (95% CI: 0.61–0.86 mm²) relative to the reference standard during verification testing. Testing was conducted to confirm the continued safe and effective performance of the software in compliance with the following standards:

- IEC 62304: Medical device software – Software life cycle processes, 2006/A1:2016
- IEC 62366-1: Medical devices – Part 1: Application of usability engineering to medical devices, 2015 + AMD1:2020
- ISO 14971: Medical devices – Application of risk management to medical devices, 2019

Non-clinical verification and validation testing were performed to evaluate the Stent Edge Identification Algorithm and Side Branch Identification Algorithm performance, reliability, and integration with the AVVIGO+ imaging system. Activities included:

- Requirements Review
- Risk Analysis and Management Review
- Product Specification Review
- Design Reviews

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
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, Guidance for Industry and Food and Drug Administration Staff February 3, 2026
- Electromagnetic Compatibility (EMC) of Medical Devices Guidance for Industry and Food and Drug Administration Staff June 6, 2022
- Content of Premarket Submissions for Device Software Functions June 14, 2023
- Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations – Draft Guidance for Industry and Food and Drug Administration Staff January 7, 2025

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 modified AVVIGO™+ Multi-Modality Guidance System is substantially equivalent to the predicate device, AVVIGO+™ 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.