July 23, 2020

Boston Scientific Corporation
Kevin Catalano
Senior Regulatory Affairs Specialist
Three Scimed Place
Maple Grove, Minnesota 55311

Re: K201713
Trade/Device Name: AVVIGO™ Guidance System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: June 22, 2020
Received: June 23, 2020

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,

LT Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology, Diagnostics, & 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: 0MB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201713

Device Name
AVVIGO™ Guidance System

Indications for Use *(Describe)*
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.

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.

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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 Senior Regulatory Affairs Specialist Three Scimed Place Maple Grove, MN 55311-1566 Phone: 763-494-2413 Fax: 763-257-6482 e-mail: Kevin.Catalano@bsci.com
Date Prepared	June 22, 2020
Proprietary Name	AVVIGO™ Guidance System
Common Name	Computer Diagnostic Programmable Blood Pressure Computer
Product Code	DQK DSK
Classification	Class II, 21 CFR 870.1425
Predicate Device	iLab™ Polaris Multi -Modality Guidance System K201178, May 29, 2020

Device Description

The AVVIGO Guidance System is a medical device system that consists of a touchscreen tablet with battery, a digital pen, a power supply and cable which can be mounted to a mobile pole via the pole docking station or set on tabletop via the desktop docking station. The tablet is a non-sterile, non-implantable tablet computer controlled by a graphic user interface (GUI) displayed on a touchscreen. The tablet is powered by either AC line power or a lithium polymer battery.

The system software displays patient's blood pressure measurements that are received from the coronary pressure guidewire and transducer that is connected to a FFR Link. The FFR Link digitizes and wirelessly streams the data which is displayed on the tablet.

Intended Use/Indications for Use

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.

Comparison of Technological Characteristics

The AVVIGO Guidance System is substantially equivalent to the predicate device, Polaris 2.12 (iLab 3.12) K201178, in intended use, fundamental design technology and FFR/DFR modalities, including DFR Equalization, and performance features.

Characteristic	Predicate Device (K201178) - iLab Polaris Multi-Modality Guidance System	Proposed Device - AVVIGO Guidance System	Comment
Indication for Use/Intended Use	The IVUS modality of the iLab™ Polaris Multi-Modality Guidance 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. The Imaging Catheters generate ultrasound images and are intended for ultrasound examination of vascular and cardiac pathology. Boston Scientific manufactures a wide variety	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.	Substantially Equivalent AVVIGO is not intended for IVUS.

	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 Directions 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.		
Overall Design	Two PCs (Acquisition and Imaging Processors) One BCM (Bluetooth Communication Module) One Imaging Display One Control Panel One AC Power Isolation Transformer One Rolling Cart Assembly (includes necessary cabling internal to the cart) One Printer	Tablet (with AVVIGO Software, touchscreen, Battery, and onboard Bluetooth) Power Supply Digital Pen Power Cable Tablet Mobile Pole Docking Station Desktop Docking Station Tablet Mobile Pole (packaged separately)	Substantially Equivalent Both systems use the same inputs and provide the same outputs to the user. Tablet integrates Bluetooth capability.
Connectivity to FFR Link; acquisition of Pd and Pa data	Bluetooth connection	Bluetooth connection	Same
Standard Conformity	IEC 62304 Medical device software- Software lifecycle	IEC 62304 Medical device software- Software lifecycle	Same

	processes, Edition 1.1 2015-06). FDA/CDRH recognition number 13-79 ANSI AAMI BP-22:1994 (R) 2016- Blood Pressure Transducers. FDA recognition number 3-44 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	processes, Edition 1.1 2015-06). FDA/CDRH recognition number 13-79 ANSI AAMI BP-22:1994 (R) 2016- Blood Pressure Transducers. FDA recognition number 3-44 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 60601-1-2:2014 4th Ed. Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests FDA/CDRH recognition number 19-8	
Compatible Accessories	Motordrive Unit, MDU5 Plus Sterile Bag, Disposable and Permanent Pullback Sled, FFR Link, Bluetooth Communication Module (BCM) Pressure Sensitive Guidewires • Comet • Comet II Intravascular Imaging Catheters • OptiCross™ • OptiCross™ 6OptiCross™ 18 • OptiCross™ HD • OptiCross™ 6 HD • Ultra Ice Plus	FFR Link Pressure Sensitive Guidewires- Comet Comet II	Substantially Equivalent AVVIGO is not intended to support IVUS which requires the use of the MD5 plus motordrive and disposable or permanent sled components. Additionally, AVVIGO contains onboard Bluetooth eliminating need for BCM.
Patient Contact	Non-patient contacting	Non-patient contacting	Same
Ergonomics of the User Interface	The iLab User Interface consists of a console with a touch screen and Windows	The AVVIGO User Interface consists of a tablet with a touch screen and Windows	Substantially Equivalent AVVIGO utilizes a tablet PC to

	based software Graphical User Interface (GUI).	based software Graphical User Interface (GUI).	support the GUI.
Software Technology	The iLab System is a Windows 7 based device.	The AVVIGO System is a Windows 10 based device.	Substantially Equivalent Both Operating Systems are Windows based however, the Avvigo System OS has been updated to Windows 10.
DICOM	DICOM 3.0, Auto-save still frames & scalable file compression, Supports lossless and lossy JPEG compression. Supports US Multi-frame Greyscale, (Pixel Data), US Multi-Frame Greyscale (Screenshot), Sec Capture (Screenshot), True Color Multi Frame Secondary Capture (Screenshot)	DICOM 3.0, Auto-save still frames & scalable file compression, Supports lossless and lossy JPEG compression. Supports US Multi-frame Greyscale, (Pixel Data), US Multi-Frame Greyscale (Screenshot), Sec Capture (Screenshot), True Color Multi Frame Secondary Capture (Screenshot)	Same
Electromagnetic Compatibility and Electrical Safety	In compliance with ANSI/AAMI ES60601- 1:2005+A2 (R2012) A1 and other applicable electrical standards	In compliance with ANSI/AAMI ES60601- 1:2005+A2 (R2012) A1 and other applicable electrical standards	Same
Functional Modality	IVUS and Physiology (FFR/ DFR)	Physiology (FFR/ DFR)	Substantially Equivalent AVVIGO is not intended to support IVUS.
Software Requirements Related to Diagnostics	The system shall calculate and display the FFR value when the following are met: • Pd and Pa trend values are available • Pa trend value is not 0 • Recording has started • Display FFR Value in Record is enabled in System Profile • If disabled, value is calculated but not displayed.	The system shall calculate and display the FFR value when the following are met: • Pd and Pa trend values are available • Pa trend value is not 0 • Recording has started • Display FFR Value in Record is enabled in System Profile • If disabled, value is calculated but not displayed.	Same

	The system shall display the following during DFR run recording • Pa waveform • Pd waveform • Pa and Pd DFR windows • Recorded time	The system shall display the following during DFR run recording • Pa waveform • Pd waveform • Pa and Pd DFR windows • Recorded time	Same

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. 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.
- FDA Guidance for Industry, Issued May 11, 2005, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

The following standards and guidance are applicable in demonstration of substantial equivalence related to Hardware:

- FDA Guidance for Industry, Issued August 14, 2013, Radio Frequency Wireless Technology in Medical Devices.
- 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

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, FFR/DFR modalities, including DFR Equalization and performance features, the AVVIGO Guidance System is substantially equivalent to the predicate device. 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.