July 2, 2019

Boston Scientific Corporation
Mugdha Dongre
Sr. RA Specialist
150 Baytech Drive
San Jose, California 95134

Re: K191008
Trade/Device Name: iLab Polaris 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: April 15, 2019
Received: April 16, 2019

Dear Mugdha Dongre:

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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191008

Device Name
iLab™ Polaris Multi-Modality Guidance System

Indications for Use *(Describe)*
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 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.

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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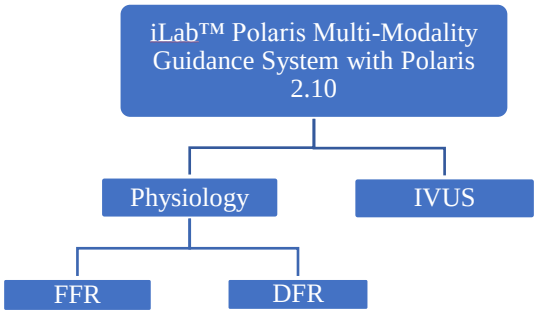
510(k) Summary per 21 CFR 807.92

Submitter's Name and Address	Boston Scientific Corporation 150 Baytech Drive, San Jose CA 945134 USA		
Contact Name and Information	Mugdha Dongre Sr. Regulatory Affairs Specialist Tel: 408.635.7239 Email: Mugdha.Dongre@bsci.com		
Trade Name	iLab™ Polaris Multi-Modality Guidance System		
Common Name	Computer Diagnostic Programmable Blood Pressure Computer Ultrasonic Pulsed Echo Imaging System Diagnostic Ultrasonic Transducer POLARIS Multi-Modality Guidance System		
Classification Name	21 CFR 870.1425 (Programmable Diagnostic Computer) 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	DQK (Computer, Diagnostic, Programmable) DSK (Computer, Blood-Pressure) IYO (System, Imaging, Pulsed Echo, Ultrasonic) ITX (Transducer, Ultrasonic, Diagnostic)		
Predicate Name	iLab™ Polaris Multi - Modality Guidance System	K151613	October 6, 2015
Reference Devices	Volcano IFR Modality	K133323	March 14, 2014
Device Description	iLab™ Polaris Multi-Modality Guidance System consists of hardware and software components which aid in supporting Intravascular Ultrasound (IVUS), Fractional Flow Reserve (FFR) and Diastolic hyperemia-Free Ratio™ (DFR™) functionalities.		



Polaris 2.10 is a software update for Boston Scientific's (BSC's), iLab™ Polaris Multi-Modality Guidance System. The Polaris 2.10 software update introduces two new features: Diastolic hyperemeia- Free Ratio (DFR™) and Smart Minimum. Smart Minimum is applicable only during calculation of Fractional Flow Reserve (FFR).

The IVUS modality allows the application of ultrasound technology to see inside the blood vessels out through the surrounding blood column, enabling the physician to visualize the coronary or peripheral vasculature. This software modification does not impact the IVUS modality.

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.

The FFR and DFR™ modality measures the pressure gradient across lesions to determine lesion severity and thus, in conjunction with other tools, help guide physicians in making treatment decisions. FFR is defined as the ratio of pressure distal of a lesion (Pd) to the pressure proximal of a lesion (Pa-aortic pressure) during maximum blood flow. Maximum blood flow is achieved by injection of a vasodilator to open the distal arteriole bed. DFR™ is defined as a resting index that measures multiple diastolic portions during the cardiac cycle. No hyperemic agent is required for DFR™ calculation.

Smart Minimum is a software feature that excludes technical artifacts from the calculation of FFR. A technical artifact refers to a disruption in the pressure waveform signal caused by external forces (not physiologic conditions presented by

	the patient). For example, technical artifacts include: removal of the pressure wire or opening the manifold to flush. Smart Minimum does not modify or exclude waveform data from being presented to the user. Overall physiological measurement performance remains unchanged.
Intended Use/Indications for 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 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.
Device Technology Characteristics and Comparison to Predicate Device	The Polaris 2.10 software upgrade introduces two new features; Diastolic hyperemeia- Free Ratio (DFR™) and Smart Minimum. Smart Minimum feature is applicable only during the calculation of Fractional Flow Reserve (FFR).

BSC's Diastolic hyperemia-Free Ratio (DFR™), introduced by the Polaris 2.10 software update, is designed to offer users an index that is subatantially equivalent to Volcano's iFR Modality (reference device K133323) in assessing the hemodynamic severity of a coronary lesion without administration of a hyperemic agent.

The algorithms used to calculate iFR® and DFR™ have similar measuring points:

Parameters	**iFR®**	**DFR™**
Clinical Application	Resting Flow Assessment without Hyperemia	Resting Flow Assessment without Hyperemia
Measure Output	Mean Pd over Mean Pa	Mean Pd over Mean Pa
Algorithm Performance	Fully Automatic Real-time Measurement	Fully Automatic Real-time Measurement
Measure Frequency	Every Beat	Every Beat
Cardiac Phase	>50% Diastolic Period	>50% Diastolic Period
Averaging Method	Five Beats Average	Five Beats Average
Measure Precondition	Pd Normalized to Pa	Pd Equalized to Pa

BSC compared the diagnostic performance of the Diastolic hyperemia-Free Ratio (DFR) to the Instantaneous Wave-Free Ratio (iFR) by comparing respective indices (DFR and iFR) to Fractional Flow Reserve (FFR) for the purposes of supporting a determination of substantial equivalence between DFR and iFR. There was no statistically significant difference between iFR and DFR when compared to FFR as a reference standard. All parameters passed the pre-defined test criteria with highly overlapping 95% confidence intervals; supporting a determination of substantial equivalence between DFR and iFR diagnostic performance.

The statistical comparison conducted between the two methods demonstrated that BSC DFR™ and Volcano iFR® have high equivalence output with the same raw waveform. Using the same cutoff value as that of iFR® of 0.89 in assessment of the hemodynamic severity of coronary lesions,

	DFR™ measurements were in agreement with iFR® with 97.6% Accuracy (99.2 % Specificity and 95.8% Sensitivity). Polaris 2.10 utilizes the same fundamental technology with the same intended use and indication of use as that of the predicate (K151613) and reference device (K133323). The Polaris 2.10 software update does not impact the intended use, indication of use, performance, manufacturing process or any other system hardware components of the iLab™ Polaris Multi-Modality Guidance System and its associated accessories i.e, Comet Pressure guidewire and compatible ultrasound catheters. No new risks or issues of safety and effectiveness are raised by this change. In addition, verification and validation addresses the modifications between the predicate and the subject device, further supporting a determination that the subject device is substantially equivalent to that of the predicate device.
Non-Clinical Performance Data	Non-clinical data includes Software Verification and Validation testing and non-clinical bench test methods performed on Polaris 2.10 algorithm. Smart Minimum and DFR were validated with non-clinical test methods, in which the non-clinical data were sourced from pre-recorded patient level data acquired from VERIFY2 and CONTRAST clinical trials. iFR data from the CONTRAST dataset was re-generated using a bench iFR setup with a commercially available Volcano FFR system. The accuracy of regenerated iFR data from this bench method was validated by demonstrating the equivalency of the bench iFR measurements to the original iFR values in the complete VERIFY2 dataset. BSC also demonstrated the waveform performance equivalency of the Comet pressure wire to the Volcano pressure wires used in VERIFY2 and St Jude pressure wires used in CONTRAST. A validation study was performed in a bench setup consisting of a pressurized chamber to regenerate patient pressure signals. The accuracy of this bench method was validated by demonstrating the equivalency of the bench FFR, iFR and DFR measurements to their original values in the complete VERIFY2 dataset. The agreement between the two measurements was evaluated in accordance with the FDA statistical analysis guidance including linear regression with lower and upper confidence intervals, Bland-Altman plot analysis and T-test for the paired difference. The two

	measurements were determined equivalent with no statistical difference found using the above analytical methods. Software Verification and Validation testing demonstrated compliance with following international and FDA- recognized consensus standards and FDA guidance documents: - IEC 62304 *Medical device software- Software life cycle* processes, (Edition 1.1 2015-06). FDA/CDRH recognition number 13-79 - FDA Guidance issued on May 11, 2005, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - FDA Guidance issued on March 13, 2007, Statistical Guidance on Reporting Results from Studies Evaluating Diagnostic Tests
Clinical Performance Data	Not applicable; determination of substantial equivalence is based on an assessment of non-clinical performance data.
Conclusion	iLab™ Polaris Multi- Modality Guidance System (subject device with Polaris 2.10 software) is substantially equivalent to the currently marketed predicate device, iLab™ Polaris Multi- Modality Guidance System (K151613) in terms of indications for use, technological characteristics and safety and effectiveness. The modifications to the predicate device are within predetermined specifications. Additionally, non-clinical performance tests provided in this 510(k) premarket notification demonstrate substantial equivalence to the predicate device and that conformance to IEC standards and guidance documents have been appropriately addressed. The tests performed support substantial equivalence of the modified device and demonstrate that the iLab™ Polaris Multi- Modality Guidance System, is as safe and effective as its predicate device without raising any new safety and/or effectiveness concerns.