May 29, 2020

Boston Scientific
Kevin Lam
Manager II, Regulatory Affairs
Three Scimed Place
Maple Grove, Minnesota 55311

Re: K201178
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 30, 2020
Received: May 1, 2020

Dear Kevin Lam:

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, 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)*
K201178

Device Name
iLab™ Polaris Multi-Modality 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

Sponsor	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, Massachusetts 01752 USA
Contact Name and Information	Kevin Lam Manager II, Regulatory Affairs Three Scimed Place Maple Grove, MN 55311-1566 Phone: 763-257-6482 Fax: 763-494-2222 e-mail: Kevin.Lam@bsci.com
Date Prepared	April 30, 2020
Proprietary Name	iLab™ Polaris Multi-Modality Guidance System
Common Name	Computer, Diagnostic, Programmable
Product Code	DQK, DSK, IYO, ITX
Classification	Class II, 21 CFR 870.1425
Predicate Device	iLab™ Polaris Multi -Modality Guidance System K191008, July 2, 2019

Device Description

The iLab™ Polaris Multi-Modality Guidance System is a non-patient contacting, diagnostic device designed to provide three (3) primary modalities: IVUS (Intravascular Ultrasound), FFR (Fractional Flow Reserve) and Diastolic hyperemia-Free Ratio (DFR).

The Polaris 2.12 (iLab 3.12) software update supports the iLab™ Polaris Multi-Modality Guidance System and supports existing device IVUS, FFR and DFRTM functionality as well as includes scaling updates to DFR™ equalization values, enhanced imaging modes and OS patches for additional security.

Diastolic hyperemia-Free Ratio™ (DFR) is a resting index that measures multiple diastolic portions during the cardiac cycle. DFR™ calculates the diastolic portion of the cardiac cycle averaged over five beats, using two criteria for the measurement windows: 1) Pa less than mean Pa and 2) down sloping Pa values. No hyperemic agent is required for DFR™ calculation. The Polaris 2.12 software update adds an automatic scaling feature for DFR™ equalization.

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.

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- 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 Polaris 2.12 (iLab 3.12) software update is substantially equivalent to the predicate Polaris 2.10 (iLab 3.10) K191008 in intended use, fundamental design technology, functional modalities and performance features. Additions of automatic DFR equalization, imaging modes and OS patches do not raise different questions of safety or effectiveness.

Non-clinical Performance

Determination of substantial equivalence is based on an assessment of non-clinical performance data which includes software verification and validation carried out on Polaris 2.12 (iLab 3.12) software. 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.

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, functional modalities and performance features the Polaris 2.12 (iLab 3.12) software 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.