



Food and Drug Administration  
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October 6, 2015

Boston Scientific Corporation  
Arlene Roche  
Sr. Regulatory Affairs Specialist  
One Scimed Place  
Maple Grove, Minnesota 55311

Re: K151613

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: September 3, 2015  
Received: September 4, 2015

Dear Ms. Roche:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

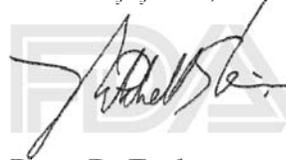
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a large, light gray watermark of the FDA logo.

for Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K151613

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.

Indications for Auto Pullback Use

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.

The FFR modality of the iLab Polaris Multi-Modality Guidance System is 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.

This modality is indicated to provide hemodynamic information for use in the diagnosis and treatment of patients that undergo measurement of physiological parameters, Fractional Flow Reserve (FFR).

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

### 510(k) Summary Complying with 21 CFR 807.92

## 510(k) Summary

### I. SUBMITTER

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Contact Person: Arlene Roche  
Date Prepared: June 12th, 2015

### II. DEVICE

**Name of Device:** iLab™ Polaris Multi-Modality Guidance System

**Common or Usual Name:**

Programmable Diagnostic Computer  
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)

**Regulatory Class:** Class II

**Product Code:**

DQK (Computer, Diagnostic, Programmable)  
DSK (Computer, Blood-Pressure)  
IYO (System, Imaging, Pulsed Echo, Ultrasonic)  
ITX (Transducer, Ultrasonic, Diagnostic)

### III. PREDICATE DEVICE

Medical RadiAnalyzer™ Xpress K092105  
iLab™ Ultrasound Imaging System K130243

## 510(k) Summary

### IV. DEVICE DESCRIPTION

The iLab Polaris Multi-Modality Guidance System is a diagnostic device designed to provide both intravascular ultrasound imaging (IVUS) and fractional flow reserve (FFR) modalities. Only one modality can be used at a time and are independent of one another.

The IVUS modality allows the application of ultrasound technology to see from inside blood vessels out through the surrounding blood column, enabling the physician to visualize the coronary or peripheral vasculature. The IVUS functionality consists of two non-sterile compact PC units (one for imaging processing and one for data acquisition) and two non-sterile display monitors (for the integrated system -one primary and an optional secondary). It also consists of a non-sterile Motordrive Unit (MDU), sterile bag which covers the MDU and a sterile disposable sled. The iLab Polaris Multi-Modality Guidance System interfaces with BSC imaging catheters at the Motordrive Unit (MDU), which provides the electro-mechanics for the rotating parts of the imaging catheter, and the interface between the catheter and the console and BSC proprietary software. The Motordrive Unit provides the rotation of the imaging catheter core required for cross-sectional imaging. An electro-mechanical connector interface at the proximal end of the imaging catheter makes the connection to the MDU. The MDU-catheter interface consists of an integrated mechanical drive hub and electrical connection. The MDU is the primary control for catheter positioning and movement through the vessel.

The FFR 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 ( $P_d$ ) to the pressure proximal of a lesion ( $P_a$ -aortic pressure) during maximum blood flow. Maximum blood flow is achieved by injection of a vasodilator to open up the distal arteriole bed.

The FFR modality will also utilize the two non-sterile compact PC units (one displays the physiological parameters and one for data acquisition) and two non-sterile display monitors (for the integrated system -one primary and an optional secondary). In addition the FFR modality consists of a Signal Processing Module (SPM- commercial name FFR Link), Bluetooth Communication Module (BCM) and Hemodynamic Cable Kit.

The iLab Polaris Multi-Modality Guidance System console interfaces with BSC's Pressure Guidewire through the optical cable connector of the pressure guidewire, the FFR Link and the Bluetooth Communication Module (BCM).

The Pressure Guidewire sensor is designed to output an optical signal that corresponds to the pressure distal ( $P_d$ ) of a lesion in a blood vessel. This optical signal is acquired and processed by the FFR Link. The FFR Link also acquires and processes the patient's aortic pressure signal ( $P_a$ ) obtained from a resistive bridge IBP transducer. The FFR Link processes, digitizes and wirelessly streams by Bluetooth the aortic pressure ( $P_a$ ) and distal pressure ( $P_d$ ). These wirelessly streamed pressure signals are received by the iLab Polaris Multi-Modality Guidance System console through the BCM. BSC's proprietary software processes the pressure signals received via the BCM for display of  $P_a$  and  $P_d$  waveforms,  $P_a$ ,  $P_d$  and  $P_d/P_a$  (FFR calculation) for physician interpretation. Additionally the FFR Link provides an analog, BP-22 compliant, signal which passes the IBP measurement, unchanged, to the catheterization lab's hemodynamic system.

## 510(k) Summary

### V. 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.

#### Indications for Auto Pullback Use

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.
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The FFR modality of the iLab Polaris Multi-Modality Guidance System is 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.

This modality is indicated to provide hemodynamic information for use in the diagnosis and treatment of patients that undergo measurement of physiological parameters, Fractional Flow Reserve (FFR).

The indication for use statements do not differ from those of the predicate devices.

### VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Ultrasound is the technological principle for the IVUS modality of the subject device and its predicate device. Therefore the technological characteristics are the same for the IVUS modality of the subject device and its predicate device.

The following technological differences do exist for the FFR modality of the subject device and its predicate device.

- The predicate device is an integrated single device whereas the subject device consists of separate components
- Pressure wire interface is wired for the predicate device whereas the subject device interfaces with the pressure wire wirelessly
- The predicate device is based on a piezoresistive effect to measure the distal pressure whereas the subject device is based on optical interferometry to measure distal pressure.
- Characteristics of pressure range, pressure accuracy and frequency response differ between the predicate device and the subject device

## 510(k) Summary

These technological differences do not raise any new questions of safety and effectiveness as the subject device meets the required FDA recognized consensus standards. In addition the data presented address the differences in technological characteristics between the predicate device and the subject device and provide sufficient evidence to demonstrate the predicate device and the subject device can be deemed substantially equivalent and the subject device is as safe and effective as the predicate device.

### VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:

#### **Software Verification and validation Testing**

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff 'Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices'. The software for this device was considered as a 'moderate' level of concern since a malfunction of, or a latent design flaw in, the software device could lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to minor injury.

#### **Electrical Safety and Electromagnetic Compatibility (EMC)**

Electrical safety and EMC testing was conducted for the iLab Polaris Multi-Modality Guidance System (mobile and integrated system). The system is in compliance with IEC 60601-1 and IEC 60601-2-37 standards for safety and IEC 60601-1-2 standard for EMC.

#### **Performance Testing-Bench**

The following bench testing was performed to support substantial equivalence

- ANSI/AAMI BP 22 - aortic pressure input and aortic pressure output
- IEC 60601-2-34 3rd Ed. Clause 201.12.1.101.1 Accuracy of Pressure Measurement
- IEC 60601-2-34 3rd Ed. Clause 201.12.1.101.2 Accuracy of Systolic and Diastolic Pressure
- IEC 60601-2-34 3rd Ed. Clause 201.12.1.101.3 Frequency Response
- Pressure Reading –Static Accuracy (System Level)
- Pressure Reading – System Dynamic Accuracy (System Level)
- Pressure Reading – System Frequency Response (System Level)
- Single Use Device Connection - Data Transfer – Calibration

#### **Animal Study**

The animal study evaluated acute pressure measurements (distal pressure) using the iLab Polaris Multi-Modality Guidance System and Comet™ Pressure Guide Wire compared to invasive blood pressure (aortic pressure) in the vasculature of the swine model. Two pigs were used for the study.

The animal study successfully evaluated acute pressure measurements (distal pressure) using the iLab Polaris Multi-Modality Guidance System and Comet Pressure Guide Wire compared to invasive blood pressure (aortic pressure) in the vasculature of the swine model and the system performed as intended.

## 510(k) Summary

### VIII. CONCLUSIONS

The non-clinical data supports the safety of the subject device and the hardware and software verification and validation demonstrate the iLab Polaris Multi-Modality Guidance System should perform as intended in the specified use conditions. Where technological differences exist between the subject device and predicate device no new questions of safety and effectiveness were raised, the methods used to evaluate the different characteristics were based on FDA recognized consensus standards and the data generated demonstrates substantial equivalence.