DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 24, 2017

Boston Scientific Corporation
Dan Krause
Regulatory Affairs Manager
47215 Lakeview Blvd.
Fremont, California 94538

Re: K170204
Trade/Device Name: FFR Link, FFR Signal Processing Module
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: Class II
Product Code: DRG
Dated: January 20, 2017
Received: January 23, 2017

Dear Dan Krause:

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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170204

Device Name
FFR Link, FFR Signal Processing Module

Indications for Use *(Describe)*
The FFR Link ™ is intended to condition physiological signals from measuring devices (BSC Pressure Guidewire or an external pressure transducer), transmit and receive via radiofrequency, and recondition the signals so they can be displayed on and/or recorded in a receiving device (iLab™ POLARIS Multi-Modality Guidance System or other monitoring device). The physiological signals can also be distributed by cable.

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.

510(k) Summary

510(k) Summary Complying with 21 CFR 807.92

510(k) Summary

I. SUBMITTER

Boston Scientific Corporation
47215 Lakeview Blvd
Fremont, CA. 94538
USA

Phone: 510-240-0048

Contact Person: Dan Krause
Date Prepared: January 20, 2017

II. DEVICE

Name of Device: FFR Link, FFR Signal Processing Module

Common or Usual Name:
Radiofrequency physiological signal transmitter and receiver.
FFR Link, FFR Signal Processing Module

Classification Name:
21 CFR 870.2910 - Radiofrequency physiological signal transmitter and receiver.

Regulatory Class: Class II

Product Code:
DRG - transmitters and receivers, physiological signal, radiofrequency

III. PREDICATE DEVICE

iLab Polaris Multi-Modality Guidance System - K151613

IV. REFERENCE DEVICE

AO USB Receiver, Wi-Box, Wi-Box PSU Kit, Wi-Box Xpress Cable, PW USB Receiver - K111854

V. DEVICE DESCRIPTION

During a fractional flow reserve procedure, the FFR Link receives, processes, and transmits aortic (Pa) and distal (Pd) blood pressure signals. On a continuous basis, the FFR Link receives the Pd input from a Boston Scientific pressure guidewire, and Pa input from an invasive blood pressure (IBP) transducer cable.

The FFR Link converts the Pd and Pa pressures to both a digital and an analog signal. The

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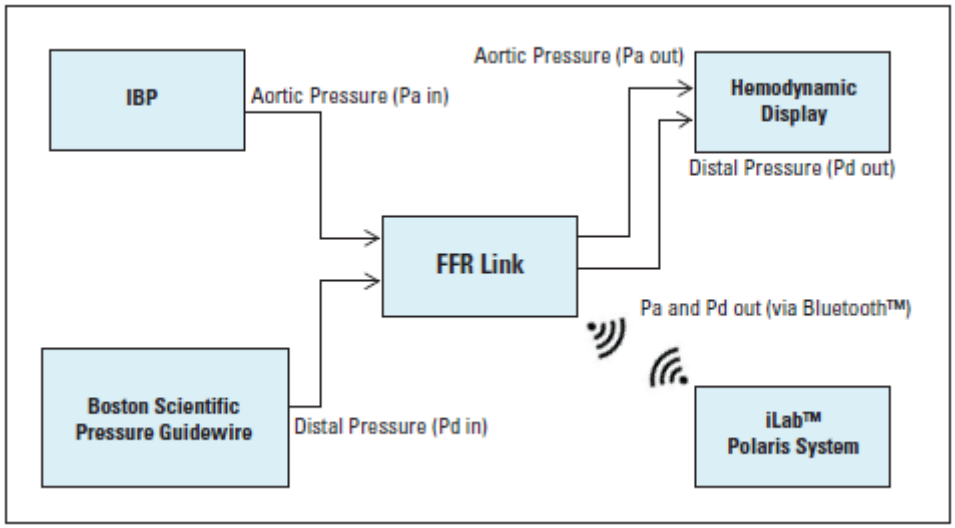
digital signal can be wirelessly transmitted to iLab Polaris Multi-Modality Guidance System. The analog signal for the Pa and Pd blood pressure can be connected by a cable for output to a hemodynamic display monitor.

The figure below depicts a typical cath lab set up including:

- Hospital owned invasive blood pressure monitor (provides Pa in to FFR Link)
- Boston Scientific Pressure Guidewire (i.e. Comet Pressure Guidewire K151610)
- FFR Link Signal Processing Module (subject of this Traditional 510(k))
- Hospital owned Hemodynamic Monitor
- BSC iLab Polaris Multi-Modality Guidance System



FFR Link Functional Block Diagram

VI. INDICATIONS FOR USE

The FFR Link is intended to condition physiological signals from measuring devices (BSC Pressure Guidewire or an external pressure transducer), transmit and receive via radiofrequency, and recondition the signals so they can be displayed on and/or recorded in a receiving device (iLab™ POLARIS Multi-Modality Guidance System or other monitoring device). The physiological signals can also be distributed by cable.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The FFR Link remains identical to the currently marketed FFR Link device. The primary purpose of this traditional 510(k) is to update the FFR Link indication for use statement and clarify Directions for Use (DFU) to more precisely align with the specific function of the FFR Link device. The design, fundamental technology and manufacturing of the currently cleared FFR Link device remain unchanged. The proposed indication for use statement is aligned with the FDA identification terminology for radiofrequency physiological signal transmitters and receivers under 870.2910 and with indication for use statements of comparable competitive systems (Reference Device, St. Jude Wi-Box - K111854).

This submission also introduces Pd Out cables to accommodate customers who wish to capture

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Pd out data on their hospital owned hemodynamic monitors in conjunction with or independent of iLab Polaris Multi-Modality Guidance System. No changes to FFR Link are required to support this capability as the analog Pd Out design was incorporated into the original FFR Link design.

VIII. PERFORMANCE DATA

As no design changes were made to the currently marketed FFR Link device, no additional performance testing in required to establish substantial equivalence. Bench, animal, electrical safety and EMC testing data submitted in K151613 remain valid and applicable to the proposed version of the FFR Link device.

IV. CONCLUSIONS

The design and technological characteristics of the proposed FFR Link device remain identical to the predicate FFR Link device cleared as a component of the iLab Polaris Multi-Modality Guidance System in K151613. This submission aims primarily to update the FFR Link Indications for Use to align more precisely with its specific function. In no way is this DFU update intended to expand the use of the FFR Link to applications other than fractional flow reserve diagnostic procedures. The target population and clinical use of the FFR signal (i.e., diagnostic procedures) between the predicate and proposed device remains identical. Thus, the proposed indication for use still falls within the broader system level intended use that was provided in the originally cleared FFR Link labeling.

Based on the fact that the design of the proposed FFR Link device remains unchanged and that the proposed indication for use falls within the originally cleared intended use of the iLab Polaris Multi-Modality Guidance System it is considered to be substantially equivalent to the FFR Link device cleared under K151613.