March 28, 2018

St. Jude Medical (now part of Abbott Medical)
Josh Johnson
Regulatory Affairs Specialist
One St. Jude Medical Drive
St. Paul, Minnesota 55117

Re: K180558
Trade/Device Name: PressureWire™ X
Regulation Number: 21 CFR 870.2870
Regulation Name: Catheter tip pressure transducer
Regulatory Class: Class II
Product Code: DXO, DQX, DRG
Dated: February 26, 2018
Received: March 1, 2018

Dear Josh Johnson:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180558

Device Name
PressureWire™ X

Indications for Use *(Describe)*
The PressureWire™ X guidewire is indicated to direct a catheter through a blood vessel and to measure physiological parameters in the heart and in the coronary and peripheral blood vessels. Physiological parameters include blood pressure. The PressureWire™ X guidewire can also measure blood temperature.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary K180558 Page 1 of 3	
510(k) Number:	K180558
Date Prepared:	March 27, 2018
Submitter Name & Address:	St. Jude Medical One St. Jude Medical Dr. St. Paul, MN 55117
Contact Person:	Josh Johnson Regulatory Affairs Specialist Phone (651) 756-3767 Fax (651) 756-3301 josh.johnson@abbott.com
Alternative Contact Person:	Marlene Peterson Regulatory Affairs Manager Phone (651) 756-3268 Fax (651) 756-3301 marlene.peterson@abbott.com
Proprietary Name:	PressureWire™ X
Common/Usual Name:	PressureWire
Product Classification Code:	Primary: DXO Secondary: DQX & DRG
Product Regulation Number and Name:	870.2870, Catheter tip pressure transducer 870.1330 – Wire, Guide, Catheter 870.2910 – Transmitters and Receivers, Physiological Signal, Radiofrequency
Device Class:	II
Predicate Device:	PressureWire™ X (K161171)
Device Description:	The PressureWire™ X guidewire has an integrated sensor element at the tip to enable measurements of physiological parameters. The wire is introduced into the patient's blood vessel. A torque device is used to steer the wire and sensor into the required position for pressure measurements according to standard clinical practice. PressureWire™ X guidewire is available in two different lengths. The guidewire is uniquely paired with a specific connection cable or with a specific transmitter. Both PressureWire™ X guidewire connection configurations connect to a diagnostic computer or a catheter laboratory hemodynamic recording system.
Intended Use:	The PressureWire™ guidewire is designed to fit inside a percutaneous catheter for the purpose of directing the catheter through a vessel. The signal output from the sensor is transmitted to associated equipment for analysis, calculations, and display of physiological parameters or indices based on pressure or temperature, e.g. Fractional Flow Reserve (FFR).
Indications for Use:	The PressureWire™ X guidewire is indicated to direct a catheter through a blood vessel and to measure physiological parameters in the heart and in the coronary and peripheral blood vessels. Physiological parameters include blood pressure. The PressureWire™ X guidewire can also measure blood temperature.
Comparison of Subject to Predicate Device:	A minor design modification was made to the pressure sensor jacket component of the PressureWire™ X guidewire. Specifically, the sensor jacket design changed from a one-window to a three-window jacket design, and the window length was extended. The sensor jacket is located near the distal tip of the PressureWire™ X, and functions to protect the pressure sensor. The openings in the sensor jacket, or windows, function to allow fluid flow to the sensor. There were no other changes to the device or IFU.

The intended use, indications for use, and technological characteristics of the PressureWire™ X device that is subject to this Special 510(K) submission are the same as the predicate, and are summarized in the following table:

	PressureWire™ X (Subject Device, K180558)	**PressureWire™ X (Predicate Device, K161171)**
Proprietary Name:	PressureWire™ X	PressureWire™ X
Common Name:	PressureWire	PressureWire
Product Classific-ation Code:	Primary: DXO Secondary: DQX & DRG	Primary: DXO Secondary: DQX & DRG
Product Regulation Number & Name:	Primary: 870.2870, Catheter tip pressure transducer Secondary: 870.1330, catheter guide wire and 870.2910 radiofrequency physiological signal transmitters and receivers	Primary: 870.2870, Catheter tip pressure transducer Secondary: 870.1330, catheter guide wire and 870.2910 radiofrequency physiological signal transmitters and receivers
Device Class:	II	II
Device Description:	The PressureWire™ X guidewire has an integrated sensor element at the tip to enable measurements of physiological parameters. The wire is introduced into the patient's blood vessel. A torque device is used to steer the wire and sensor into the required position for pressure measurements according to standard clinical practice. PressureWire™ X guidewire is available in two different lengths. The guidewire is uniquely paired with a specific connection cable or with a specific transmitter. Both PressureWire™ X guidewire connection configurations connect to a diagnostic computer or a catheter laboratory hemodynamic recording system.	The PressureWire™ X guidewire has an integrated sensor element at the tip to enable measurements of physiological parameters. The wire is introduced into the patient's blood vessel. A torque device is used to steer the wire and sensor into the required position for pressure measurements according to standard clinical practice. PressureWire™ X guidewire is available in two different lengths. The guidewire is uniquely paired with a specific connection cable or with a specific transmitter. Both PressureWire™ X guidewire connection configurations connect to a diagnostic computer or a catheter laboratory hemodynamic recording system.
Intended Use:	The PressureWire™ guidewire is designed to fit inside a percutaneous catheter for the purpose of directing the catheter through a vessel. The signal output from the sensor is transmitted to associated equipment for analysis, calculations, and display of physiological parameters or indices based on pressure or	The PressureWire™ guidewire is designed to fit inside a percutaneous catheter for the purpose of directing the catheter through a vessel. The signal output from the sensor is transmitted to associated equipment for analysis, calculations, and display of physiological parameters or indices based on pressure or

		temperature, e.g. Fractional Flow Reserve (FFR).	temperature, e.g. Fractional Flow Reserve (FFR).
	Indications for Use:	The PressureWire™ X guidewire is indicated to direct a catheter through a blood vessel and to measure physiological parameters in the heart and in the coronary and peripheral blood vessels. Physiological parameters include blood pressure. The PressureWire™ X guidewire can also measure blood temperature.	The PressureWire™ X guidewire is indicated to direct a catheter through a blood vessel and to measure physiological parameters in the heart and in the coronary and peripheral blood vessels. Physiological parameters include blood pressure. The PressureWire™ X guidewire can also measure blood temperature.
	Contra-indications:	This guidewire is contraindicated for use in the cerebral vasculature.	This guidewire is contraindicated for use in the cerebral vasculature.
	Technical Specifi-cations	Operating Pressure: -30 to +300 mmHg Temp. Performance Specification: 34 - 42ºC Radio Frequency Range: 2.4000 – 2.4835 GHz (ISM-band)	Operating Pressure: -30 to +300 mmHg Temp. Performance Specification: 34 - 42ºC Radio Frequency Range: 2.4000 – 2.4835 GHz (ISM-band)
Summary on Non-Clinical Testing	Performance bench testing was completed as part of design verification to demonstrate safety and effectiveness, and that the subject device performed as intended. Tests were conducted to evaluate the following: • Guidewire Tensile Strength • Torque Strength • Fatigue Resistance • Fracture Resistance • Signal Quality in Severe Bend • Signal Quality during Pullback Procedure Additionally, simulated-use testing was completed as part of design validation to demonstrate the subject device met user needs and the intended use. The following test was performed: • Signal Drift		
Summary of Clinical Testing:	No new clinical testing was completed, nor relied upon, in support of this Special 510(k) submission.		
Statement of Equivalence:	The PressureWire™ X device described in this Special 510(k) submission is substantially equivalent to the currently-marketed predicate device, K161171, based on comparisons of the device classifications, technological characteristics, intended use, and indications for use. The subject device met the pre-determined requirements, and raised no new safety or effectiveness concerns.		