



August 15, 2016

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

St. Jude Medical Inc.
Huda Yusuf
Regulatory Specialist II
5050 Nathan Lane North
Plymouth, Minnesota 55442

Re: K161171
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: April 25, 2016
Received: April 26, 2016

Dear Huda Yusuf:

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,



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)

K161171

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.

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**For the St. Jude Medical
PressureWire™ X
(per 21CFR 807.92)**

1. SUBMITTER/510(K) HOLDER

St. Jude Medical
5050 Nathan Lane North
Plymouth, MN 55442

Contact Person: Huda Yusuf
Telephone: 612-900-9527

Date Prepared: April 25, 2016

Alternative

Contact Person: Erdie De Peralta
Telephone: 978-577-3481

Date Prepared: April 25, 2016

2. DEVICE NAME

Proprietary Name: PressureWire™ X
Common/Usual Name: PressureWire™ X
Classification Name: Transducer, Pressure, Catheter Tip (870.2870)
Wire, Guide, Catheter (870.1330)
Transmitters and Receivers, physiological signal, radiofrequency
(870.2910)

3. PREDICATE DEVICE

- PressureWire™ Certus™ and Aeris™, cleared November 13, 2014 under K140466

4. 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.

5. 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.

6. PREDICATE DEVICE COMPARISON

PressureWire™ Certus™ and Aeris™ were cleared by FDA under 510(k) K140466 on November 13, 2014. The subject device is substantially equivalent to the predicate device in terms of intended uses, indication for use, operational characteristics, and fundamental design and technology characteristics.

The subject device, PressureWire™ X guidewire, is different from the last previous version of PressureWire™, PressureWire™ Certus™ and Aeris™ in the following ways:

- New Distal Tip Design
- New Shipping Box Design
- New Single IFU Booklet
- New Coating on Sensor Guidewire

7. TESTING SUMMARY

The PressureWire™ X guidewire has been tested and is in compliance with ISO 10993-1:2009 with C1:2010), Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, ISO TS 11135-2:2008, Sterilization of health care products – Ethylene Oxide – Part 2 Guidance on the application of ISO 11135-1, USP 33-NF 28 General chapter <788> Particulate matter in injections, and USP 36 <661> Containers – Plastics.

In addition to the Biocompatibility, Sterilization and Particulate testing performed, design verification and validation was performed on the PressureWire™ X guidewire in compliance with internal design control procedures which included bench testing. This bench testing

included physical, mechanical and coating integrity testing for fractures, friction force, and wire diameter and straightness.

The results of this testing concludes the PressureWire™ X guidewire is determined to be safe and effective and is substantially equivalent to the predicate device PressureWire™ Certus™ and PressureWire™ Aeris cleared in K140466.

8. Substantial Equivalence

The fundamental scientific technology for the subject device is the same for predicate device regarding signal transfer, mechanical properties and intended use. PressureWire™ X guidewire is substantially equivalent to the predicated device in intended use, indication for use, fundamental design and technology, and operating principles. Both devices connect to a diagnostic computer or a catheter laboratory hemodynamic recording system to enable measurements of physiological parameters with minor design changes incorporated into the PressureWire™ X guidewire from the predicate device:

- New Distal Tip Design
- New Shipping Box Design
- New Single IFU Booklet
- New Coating on Sensor Guidewire

The subject device, PressureWire™ X Guidewire, meets the design inputs and raises no new safety or efficacy concerns. PressureWire™ X Guidewire is determined to be substantially equivalent to the presently marketed predicated device, K140466.

9. Conclusion

The results of these activities demonstrate that the PressureWire™ X Guidewire is as safe, as effective, and performs as well as or better than the predicate device.