DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 13, 2014

St Jude Medical Systems AB
Mr. Jeffrey Roberts
Principal Regulatory Affairs Specialist
Palmbladsgatan 10, Box 6350
SE-751 35 Uppsala, Sweden

Re: K140466
Trade/Device Name: PressureWire Certus and Aeris
Regulation Number: 21 CFR 870.2870
Regulation Name: Catheter Tip Pressure Transducer
Regulatory Class: Class II
Product Code: DXO, DQX, DRG
Dated: September 25, 2014
Received: September 29, 2014

Dear Mr. Roberts:

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" (21CFR 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,

Melissa A. Torres -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140466

Device Name
PressureWire

Indications for Use *(Describe)*
PressureWire™ 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.

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.

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510(K) SUMMARY
510(K) NUMBER: K140466

for the St. Jude Medical Systems AB
PressureWire™
(per 21CFR 807.92)

1. SUBMITTER/510(K) HOLDER

St. Jude Medical Systems AB
Palmbladsgatan 10, Box 6350
SE-751 35 Uppsala, Sweden

Contact Person: Jeffrey Roberts
Telephone: 978-577-3451

Date Prepared: 11/5/14

2. DEVICE NAME

Proprietary Name:	PressureWire™
Common/Usual Name:	PressureWire™ Guidewire
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 PressureWire™ Aeris™, cleared September 5, 2013 under K131452.

4. DEVICE DESCRIPTION

The PressureWire 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 is available in two different lengths.

The guidewire is uniquely paired with a specific connection cable for PressureWire Certus or with a specific transmitter for PressureWire Aeris (subject device). Both PressureWire

connection configurations connect to a diagnostic computer or a catheter laboratory hemodynamic recording system.

5. INTENDED USE

PressureWire™ 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.

6. PREDICATE DEVICE COMPARISON

PressureWire was cleared by FDA under 510(k) K131452 on September 5, 2013. The subject device is substantially equivalent to the predicate device in terms of intended use, indication for use, operational characteristics, and fundamental design and technology characteristics.

The subject device, PressureWire™ (models Certus™ and Aeris™), has been modified with regards to the hydrophobic PTFE coating on the proximal part of the guidewire.

7. TESTING SUMMARY

The PressureWire 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 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 is determined to be safe and effective and is substantially equivalent to the predicate device PressureWire Certus and PressureWire Aeris.

8. SUBSTANTIAL EQUIVALENCE

The fundamental scientific technology for the subject device is the same as for predicate device regarding signal transfer, mechanical properties and intended use. Pressure Wire 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 a minor design change incorporated into the Pressure Wire guidewire from the predicate device:

- Modification of the hydrophobic PTFE coating on the proximal part of the guidewire.

The subject device, PressureWire™ (models Certus™ and Aeris™), meets the design inputs and raises no new safety or efficacy concerns. PressureWire™ is determined to be substantially equivalent to the presently marketed predicate device, K131452.

8. CONCLUSION

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