ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

St. Jude Medical Systems AB
Palmbladsgatan 10
Box 6350, SE-751 35 Uppsala
Sweden
Tel +46 (0)18 161000
Fax +46 (0)18 161099

Corporate ID no: 556335-9446

510(k) Summary

This 510(k) summary is submitted in accordance with the requirements in 21 CFR §807.92

Submitted by:	St. Jude Medical Systems AB Palmbladsgatan 10, Box 6350 SE-751 35 Uppsala, Sweden Phone:+46 18 161000 Fax: +46 18 161099
Contact Person:	Anna-Lisa Tiensuu
Date Prepared:	May 16, 2013
Proprietary Name:	PressureWire™
Common Name:	PressureWire™ Guidewire
Classification Name:	Transducer, Pressure, Catheter Tip (870.2870) Wire, Guide, Catheter (870.1330) Transmitters and Receivers, physiological signal, radiofrequency (870.2910)
Predicate Device:	(K113584) PressureWire™ cleared March 2, 2012.

SEP 05 2013

Device Description:

The modified PressureWire™ is essentially a modification of the previously cleared PressureWire™ (K113584). The subject device, The subject and predicate device, PressureWire is a 0.014" guidewire with an integrated sensor element at the tip to enable measurements of physiological parameters. The guidewire is uniquely paired with a specific connection cable for PressureWire Certus or with a specific transmitter for PressureWire Aeris. PressureWire is available in different lengths.

Indication for 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.

Predicate Device Comparison:

PressureWire was cleared by FDA under 510(k) K113584 on March 2, 2012. 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. Below list identifies the changes to the subject device.

- Adding an additional supplier of the hydrophilic coating used on the distal tube.
- Adding the coil material palladium to the radiopaque tip.

Testing summary:

A summary of PressureWire™ Design Control Activities with regards to risk analysis and verification and validation activities is provided in this 510k submission. The modifications applies to the corewire and do not change the operational principle. The successful completion of verification activities demonstrates that PressureWire™ meets the required product specifications. Based on passing verification specification criteria for mechanical and signal testing along with chemical characterization and biocompatibility, PressureWire™ performs substantially equivalent to predicate devices.

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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 minor changes incorporated into the Pressure Wire from the predicate device including:

- Adding an additional supplier of the hydrophilic coating used on the distal tube.
- Adding the option to use coil material palladium to the radiopaque tip.

The subject device, PressureWire™, 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, K113584.

Conclusion:

Based on the similarities in indication for use, design features and functional features, the modified PressureWire™ is substantially equivalent to the currently marketed predicate device PressureWire™, K113584.

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

September 5, 2013

St. Jude Medical
Ms. Anna-Lisa Tiensuu
Regulatory Affairs Manager
4 Robbins Rd.
Westford, MA 01886

Re: K131452
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, DRG, DQX
Dated: July 23, 2013
Received: July 24, 2013

Dear Ms. Anna-Lisa Tiensuu:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Owen P. Faris -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use Statement

510(k) Number: K131452

Device Name: PressureWire™

Indications for 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.

Prescription Use ____X_____ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Digitally signed by
Owen P. Faris -S
Date: 2013.09.05
10:12:09 -04'00'