K080813

JUL - 1 2008

5. 510(k) Summary

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements in the Safe Medical Device Act 1990 and 21 CFR §807.92

Submitted by:	Radi Medical Systems AB Palmbladsgatan 10 SE-754 50 Uppsala, Sweden Phone:(+46) 18161000
Contact Person:	Björn Palmgren
Date Prepared:	June 10, 2008
Proprietary Name:	PressureWire®
Common Name:	Pressure Guidewire
Classification Name:	Transducer, Pressure, Catheter Tip (870.2870) Wire, Guide, catheter (870.1330) Transmitters and receivers, physiological signal, radiofrequency (870.2910) Diagnostic intravascular catheter. (870.1200)
Predicate Devices:	PressureWire® (K062769) PressureWire® System (K972793) Wireless Physiologic Monitoring System (K053016) Mikro-Tip Catheter Pressure Transducer (K883651)

Description of the Device:
PressureWire® is a .014" guidewire with an integrated pressure and temperature sensor, together with a detachable cable or transmitter/receiver for connection to a diagnostic computer or a cathlab hemodynamic recording system.

Intended Use of the Device:
PressureWire® is designed to fit inside a percutaneous catheter for the purpose of directing the catheter through a vessel. The signal output from the senor is used for calculation and presentation of any physiological parameters, functions or indices based on temperature or pressure, e.g. Fractional Flow Reserve (FFR). The indication has been modified to address that the device is not only suitable for usage within peripheral and coronary vessels but also for intracardiac measurements within the actual heart.

Indication for Use of the Device:
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 vessel.

Technical Characteristics:
The guidewire part of subject device is identical to the predicate device (K062769).
The new version PressureWire® Aeris, transfer the signal using frequency hoping in the 2.4 GHz frequency radio band, instead of cable. The output from the PressureWire Receiver is compliant with the ANSI/AAMI BP22 standard.

Functional/Safety Testing:
Electrical safety, EMC, radio, sterilization and performance testing indicate that PressureWire® satisfies safety and performance requirements of the device specifications and do not raise additional safety issues.

Conclusion:
On the basis of the testing conducted, it may be concluded that PressureWire® satisfies specified safety and performance requirements. PressureWire® is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 1 2008

Radi Medical Systems AB
c/o Mr. Björn Palmgren
Regulatory Affairs Officer
Palmbladsgatan 10
SE-75450 Uppsala
SWEDEN

Re: K080813
Trade Name: PressureWire® Aeris and PressureWire® Receiver
Regulation Number: 21 CFR 870.2870
Regulation Name: Catheter Tip Pressure Transducer
Regulatory Class: Class II
Product Code: DXO and DQX
Dated: June 9, 2008
Received: June 11, 2008

Dear Mr. Palmgren:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for 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: K080813

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 vessel.

Prescription Use ____X_____ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801.Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ashley B. Boam for BDZ

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K080813