K092105
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5 510(k) Summary of Safety and Effectiveness

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.

Submitter's Information:

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Contact Person:	Mats Granlund

Date of Preparation: July 8, 2009

Device Name:

Trade Name:	RadiAnalyzer® Xpress
Common Name:	Diagnostic computer
Classification Name:	Programmable Diagnostic Computer §870.1425 Blood pressure computer § 870.1110

Predicate Device Names: RadiAnalyzer® Xpress (K042628)

RadiView® (K013943)

Device Description:
RadiAnalyzer® Xpress is a diagnostic computer designed to compute, record and display information from PressureWire® and other external transducers. The information is displayed as graphs as well as numerical values on the integrated screen and may also be transferred to a cardiac monitor, RadiAnalyzer® Printer and/or PC with external viewing software installed, such as RadiView® or PhysioMon™. Data includes: systolic, diastolic and mean blood pressure, heart rate, and Fractional Flow Reserve (FFR). RadiAnalyzer® Xpress can be upgraded with additional software, such as Thermo Option software to enable assessments of invasive temperature, Coronary Flow Reserve (CFR) or other physiological parameters such as first time derivative of pressure (dP/dt).

RadiAnalyzer® Xpress comes with one remote control, two monitor cables, one adapter cable, and one mains cable (standard configuration).

Intended Use:
RadiAnalyzer® Xpress is intended for use in catheterization and related cardiovascular specialty laboratories to compute, and display various physiological and blood flow parameters based on the output from one or more electrodes, transducers or measuring devices.

The indication has been modified to address that the device is not only suitable for usage for diagnosis and treatment of coronary or peripheral artery disease but for patients that undergo measurement of physiological parameters with PressureWire®.

Indication for Use:

RadiAnalyzer® Xpress is indicated to provide hemodynamic information for use in the diagnosis and treatment of patients that undergo measurement of physiological parameters with PressureWire®.

Technical Characteristic:
The mechanical, electrical and signal properties of RadiAnalyzer® Xpress are identical to the predicate device with the addition of the algorithm for calculation of the first time derivative of pressure and with the addition of the IMR (Index of Microcirculatory Resistance) calculation in the accessory RadiView®.

Functional/Safety testing:
The software verification/validation conducted indicate that RadiAnalyzer® Xpress and its accessories PhysioMon™ and RadiView® satisfy 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 RadiAnalyzer® Xpress and its accessories PhysioMon™ and RadiView® satify specified safety and performance requirements and are substantially equivalent to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Radi Medical Systems AB
Mr. Mats Granlund
Director, Quality & Regulatory Affairs
Palmbladsgatan 10,
SE-754 50 Uppsala
SWEDEN

OCT - 9 2009

Re: K092105
Trade/Device Name: RadiAnalyzer® Xpress
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Codes: DQK, DSK
Dated: July 8, 2009
Received: July 14, 2009

Dear Mr. Granlund:

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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,

M. S. Kellerman

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: K092105

Device Name: RadiAnalyzer® Xpress

Indications for Use: RadiAnalyzer® Xpress is indicated to provide hemodynamic information for use in the diagnosis and treatment of patients that undergo measurement of physiological parameters with PressureWire®.

RadiAnalyzer® Xpress is intended for use in catheterization and related cardiovascular specialty laboratories to compute, and display various physiological and blood flow parameters based on the output from one or more electrodes, transducers or measuring devices.

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)

M. A. Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092105