JAN 1 9 2005

K042628

Attachment 4

510(k) Summary

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

Submitted by:	RADI Medical Systems AB Palmbladsgatan 10 SE-754 50 Uppsala, Sweden Phone:(+46) 18161000
Contact Person:	Helene Ekstrand
Date Prepared:	September 23th, 2004
Proprietary Name:	RADIAnalyzer®
Common Name:	Programmable diagnostic computer
Classification Name:	§870.1425, Programmable diagnostic computer
Predicate Device:	RADIAnalyzer®System 510(k) # K022188

Description of the Device:
RADIAnalyzer® is a diagnostic computer designed to compute, record and display information, based on the input from PressureWire® Sensor and an Aortic Pressure Transducer (AO). 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® Software. Data includes: systolic, diastolic and mean blood pressure, heart rate, Fractional Flow Reserve (FFR), Coronary Flow Reserve (CFR) and temperature.

Intended Use of the Device:
RADIAnalyzer® is indicated to provide hemodynamic information for use in the diagnosis and treatment of coronary or peripheral artery disease.
RADIAnalyzer® is intended for use in catheterization and related cardiovascular specialty laboratories to compute, and display various physiological parameters based on the output from one or more electrodes, transducers or measuring devices.

Technical Characteristics:
The subject device, RADIAnalyzer®, version Xpress, is smaller and lighter version of the predicate device. Electrical and signal properties are equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 19 2005

Radi Medical Systems AB
c/o Ms. Helene Ekstrand
Regulatory Affairs Officer
Palmbladsgatan 10
SE-754 50 Uppsala
SWEDEN

Re: K042628
Trade Name: RadiAnalyzer®Xpress
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: 74 DQK
Dated: November 12, 2004
Received: November 15, 2004

Dear Ms. Ekstrand:

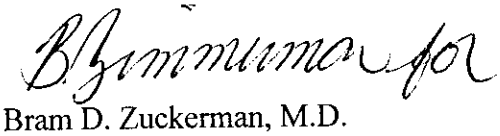
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 Office of Compliance at (240) 276-0295. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

Indication for Use

510(k) Number: K042628

Device Name: RadiAnalyzer®

Indications for Use: RadiAnalyzer® is indicated to provide hemodynamic information for use in the diagnosis and treatment of coronary or peripheral artery disease.

RadiAnalyzer® is intended for use in catheterization and related cardiovascular specialty laboratories to compute, and display various physiological 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)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K042628