K022188

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3 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter's Information:

Name:	RADI Medical Systems AB
Address:	Palmbladsgatan 10, SE-754 50 Uppsala, Sweden
Phone/Fax:	+46-18-161000 / +46-18-161099
Contact Person:	Mats Granlund
Date of Preparation:	July 1, 2002

Device Name:

Trade Names:	RADIAnalyzer™
Common Name:	Programmable Diagnostic Computer
Classification Name:	§870.1425

Predicate Device Names:

RADIAnalyzer (K013943 / K002067)
SmartFlow (K020127)
Thermometer Models ST8631 (K021048)

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

Intended 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 specially laboratories to compute, and display various physiological parameters based on the output from one or more electrodes, transducers or measuring devices.

Technical Characteristic:
The mechanical, electrical and signal properties of RADIAnalyzer™ are identical to the predicate device.

Performance Data:
The RADIAnalyzer™ complies with the voluntary standards as detailed in section 7 of this submission. The following quality assurance measures were applied to the development of the RADIAnalyzer™.

- Requirements specification review
- Code inspection
- Software and hardware testing
- Safety testing
- Environmental testing
- Final validation

Conclusions:
The results of these measures demonstrate that the RADIAnalyzer™ is as safe, as effective, and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 3 2002

RADI Medical Systems AB
c/o Mr. Mats Granlund
Quality and Regulatory Affairs Manager
Palmbladsgatan 10
SE-754 50 Uppsala, Sweden

Re: K022188
Trade Name: RADIAnalyzer™ Model 12710
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: July 1, 2002
Received: July 5, 2002

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.

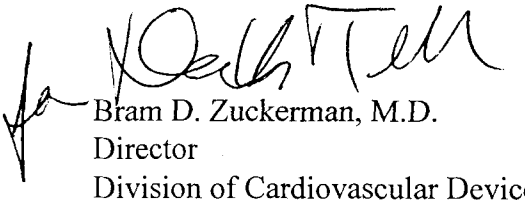
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,



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

Enclosure

2 Statement of Indications for Use

510(k) Number: K022188

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 specially laboratories to compute, and display various physiological parameters based on the output from one or more electrodes, transducers or measuring devices.

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

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1/2/96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K022188