DEC 1 8 2001

Attachment 4

K013943

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:	Mats Granlund
Date Prepared:	November 27, 2001
Proprietary Name:	RadiAnalyzer™ System
Common Name:	Blood Pressure Computer
Classification Name:	§870.1110 Blood Pressure Computer
Predicate Device:	RadiAnalyzer™ System 510(k) # K002067

Description of the Device: The RadiAnalyzer™ is a blood pressure computer, to be used as a diagnostic tool when the diagnosis is based on patient blood pressures.
The device comprises a graphic display that presents real-time pressure curves as well as numerical values, and is operated via a remote control.
The device has two entries for pressure signals, one for a PressureWire™ Sensor, and another for an External Pressure Transducer (EPT) and corresponding outlets for connection to a cardiac monitor. The RadiAnalyzer™ could also be connected to a RadiAnalyzer™-Printer or to a PC with the RadiView™ software installed.

Intended Use of the Device: The RadiAnalyzer is intended for use under the direction of a licensed physician to calculate, display and record vascular data. Data is acquired from a PressureWire Sensor and an External Pressure Transducer (EPT).
The information is displayed on the integrated screen and/or transferred to a cardiac monitor. Data includes: systolic, diastolic and mean blood pressure, heart rate, and Fractional Flow Reserve (FFR).
The RadiAnalyzer is intended for use in catheterization and related cardiovascular specially laboratories.

Technical Characteristics: The mechanical, electrical and signal properties of RadiAnalyzer™ are identical to the predicate devices. RadiView is a new PC-software for digital transfer of RadiAnalyzer™ physiological recordings.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 8 2001

Mr. Mats Granlund
Quality & Regulatory Affairs Manager
RADI Medical Systems AB
Palmbladsgatan 10
SE-754 52 Uppsala
SWEDEN

Re: K013943
Trade Name: RadiAnalyzer™ System
Regulation Number: 21 CFR 870.1110
Regulation Name: Blood Pressure Computer
Regulatory Class: Class II (two)
Product Code: DSK
Dated: November 27, 2001
Received: November 29, 2001

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) 594-4645. 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.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

Indication for Use Statement

510(k) Number: K013943

Device Name: RadiAnalyzer™ System

Indications for Use: The RadiAnalyzer is intended for use under the direction of a licensed physician to calculate, display and record vascular data. Data is acquired from a PressureWire Sensor and an External Pressure Transducer (EPT).
The information is displayed on the integrated screen and/or transferred to a cardiac monitor. Data includes: systolic, diastolic and mean blood pressure, heart rate, and Fractional Flow Reserve (FFR).
The RadiAnalyzer is intended for use in catheterization and related cardiovascular specially laboratories.

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

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013943

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