K031662
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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:	Mats Granlund
Date Prepared:	May 26, 2003
Proprietary Name:	PressureWire™ Sensor
Common Name:	Pressure Guide Wire
Classification Name:	Catheter Guide Wire (870.1330) Catheter Tip Pressure Transducer (870.2870)
Predicate Device:	PressureWire™ Sensor 510(k) # K022188

Description of the Device: The PressureWire™ Sensor is a 0.014" diameter, 183 or 300 cm long guidewire with a pressure sensor mounted three cm from the distal end and a detachable cable for connection to a programmable diagnostic computer manufactured by the submitter.

Intended Use of the Device: These devices have the same intended use as the predicate PressureWire™ Sensor.
The PressureWire Sensor is indicated to direct a catheter through a blood vessel and to measure physiological parameters in the coronary and peripheral blood vessels.

Technical Characteristics: With exception of the internal dimension modifications, the subject device has the same technological characteristics as the predicate PressureWire™ Sensor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2003

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

Re: K031662
Trade Name: Pressure Wire™ Sensor
Regulation Number: 21 CFR 870.2870
Regulation Name: Catheter tip pressure transducer
Regulatory Class: Class II (two)
Product Code: DXO
Dated: May 26, 2003
Received: May 28, 2003

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), please contact the Office of Compliance at (301) 594-4646. 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/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

K031662

Attachment 2

Indication for Use Statement

510(k) Number: K031662

Device Name: PressureWire™ Sensor

Indications for Use: The PressureWire Sensor is indicated to direct a catheter through a blood vessel and to measure physiological parameters in the coronary and peripheral blood vessels.

(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 K031662

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)