

2972793

APR 24 1998

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

A. Submitter's Information:

Name:	Radi Medical Systems AB
Address:	Palmbladsgatan 10, S-754 50 Uppsala, Sweden
Phone:	46-18-161000
Fax:	46-18-161099
Contact Person:	Mats Granlund
Date of Preparation:	January 21, 1998

B. Device Name:

Trade Name:	PressureWire™ System including PressureWire™ Sensor, PressureWire™ Interface and PressureWire™ Monitor Cables.
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Common Name:	Transducer, Pressure, Guidewire
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Classification Names:	Transducer, Pressure, Guidewire
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C. Predicate Device Names:	ACS Guidewires Millar Pressure Measurement System
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D. Device Description:

The RADI Medical Systems **PressureWire™** System consists of a guidewire with a near-end mounted pressure sensor and an interface to facilitate connection to an ordinary pressure-monitoring system.

E. Intended Use:

"The **PressureWire™** System is indicated for the measurement of blood pressure in the coronary vasculature and to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA).

F. Technical Characteristics:

The mechanical properties of the PressureWire™ Sensor are similar to ACS Guidewires. Most of the materials used the construction, which will be in contact with blood, are typical for similar devices. These include stainless steel and platinum alloy. The technical properties of PressureWire™ System are similar to the Millar Pressure Measurement System.

G. Performance Data:

Safety and performance testing was performed to demonstrate that the RADI Medical Systems PressureWire™ System is substantially equivalent to the predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 24 1998

Mr. Mats Granlund
Quality Manager
RADI Medical Systems AB
Palmladsgatan 10
S-754 50 UPPSALA,
Sweden

Re: K972793
Trade Name: Pressure Wire™ System with Pressure Wire™ Sensor,
Pressure Wire™ Interface and Pressure Wire™ Monitor Cables
Regulatory Class: II
Product Code: DQX
Dated: January 22, 1998
Received: January 26, 1998

Dear Mr. Granlund:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in

regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K972793

Device Name: PressureWire™ System with PressureWire™ Sensor,
PressureWire™ Interface and PressureWire™ Monitor Cables.

Indications for Use: "The PressureWire™ System is indicated for the measurement of blood pressure in the coronary vasculature and to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA).

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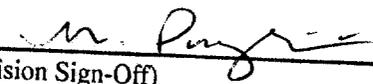
CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1/2/96)



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____