K970466

MAY 20 1997

510(K) SUMMARY

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Radius Medical Technologies, Inc. is required to submit with this Premarket Notification either an "...adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Radius Medical Technologies, Inc. chooses to submit a summary of information respecting safety and effectiveness.

A. GENERAL INFORMATION

Submitter's Name:	Radius Medical Technologies, Inc.
Address:	63 Great Road Maynard, MA 01754
Contact Person:	Maureen A. Finlayson
Date of Preparation:	February 5, 1997
Device Generic Name:	PTCA Guidewire
Device Trade Name:	Radius PTCA Guidewire
Classification Name:	Wire, Guide, Cardiovascular (74DQX)

B. INDICATIONS

The Radius PTCA Guidewire is intended to facilitate the placement of balloon dilitation catheters during PTCA and/or PTA. **Radius PTCA Guidewires** are compatible with all currently approved and marketed PTCA balloon catheters which are labeled for use with an .014 guidewire.

C. DESCRIPTIVE CHARACTERISTICS

The **Radius PTCA Guidewire** is constructed from a solid stainless steel core to which a coil is attached to the tapered distal section. Table 1 lists the key dimensional characteristics for the proposed device. The proximal section of the wire is coated with PTFE, and the distal coil portion of the wire is silicone coated. The device is packaged in a protective hoop sealed into a Tyvek/mylar pouch, and is sterilized using ETO gas.

Table 1

	Specification
G/W Outer Diameter	.014"
G/W Overall Length	180cm or 300cm
Overall Coil Length	15cm to 30cm
Radiopaque Length	3cm to 30cm
Floppy Tip Length	2.5cm to 3cm

D. COMPARATIVE INFORMATION

The **Radius PTCA Guidewires** are substantially equivalent to the currently marketed **ACS High Torque Guidewire** family. ACS High Torque Guidewires, marketed by:

Advanced Cardiovascular Systems, Inc.
26531 Ynez Road
Temecula, California 92390-1856

E. PERFORMANCE TESTING

The following in vitro performance tests were performed on the **Radius PTCA Guidewire**:

1. Tensile Strength
2. Torque Strength
3. Torqueability
4. Tip Flexibility
5. Coating Adherence/Integrity

In all cases, the performance of the **Radius PTCA Guidewires** was comparable to that of the predicate **ACS guidewires**.

F. BIOCOMPATIBILITY

Biocompatibility testing was conducted on the proposed line of **Radius PTCA Guidewires** according to General Program Memorandum - #G95-1 issued May 1, 1995 from the ODE. Following is a summary of the tests performed:

1. Cytotoxicity
2. Sensitization
3. Intracutaneous Toxicity
4. Acute systemic toxicity
5. Material Mediated Pyrogenicity
6. ASTM Hemolysis

All test results were acceptable.

CONCLUSION:
Based on the indications for use, technological characteristics, and safety and performance testing, the proposed **Radius PTCA Guidewire** meets the minimum requirements that are considered adequate for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 20 1997

Ms. Maureen A. Finlayson
President
Radius Medical Technologies, Inc.
63 Great Road
Maynard, Massachusetts 01754

Re: K970466
Radius PTCA Guidewire
Regulatory Class: II (two)
Product Code: LIT
Dated: April 23, 1997
Received: April 24, 1997

Dear Ms. Finlayson:

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 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 (Premarket 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4648. 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" (21 CFR 807.97). 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 at (301) 443-6597.

Sincerely yours,

Thomas J. Callahan

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

Enclosure

510(k) Number (if known): K970466

Device Name: Radius PTCA Guidewire

Indications for Use:

The Radius PTCA Guidewire is indicated to facilitate the placement of balloon dilatation catheters during PTCA and/or PTA.

(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, Respiratory,
and Neurological Devices
510(k) Number K970466

Prescription Use ✓ OR Over-the-counter Use ___
(Per 21 CFR 801.109)