K024327

MAR 25 2003

250 Chesapeake Drive
Redwood City
Cal· 94063
Tel. 0) 363.8000
Fax. +1 (650) 363.2400

510[k] Summary of Safety and Effectiveness

Submitter Information

Company:	Radiant Medical, Inc. 250 Chesapeake Drive Redwood City, CA 94063 (650) 363-8000
Contact Person:	Andrew Cleeland Sr. Vice President of Regulatory, Clinical and Quality Affairs
Summary Date:	_____

Name and Classification

Proprietary Name:	SetPoint® Endovascular Temperature Probe
Classification Name:	Percutaneous catheter (DQY) [21 CFR 870.1250]
Class:	II

Predicate Devices

a) SetPoint® Catheter and SetPoint General Purpose Temperature Probe, components of the SetPoint Endovascular Temperature Management System (K012512)

b) The Arrow International Inc. Multi-Lumen Central Venous Catheter (K904404).

Indication for Use

The SetPoint Endovascular Temperature Probe is indicated for use with the SetPoint Endovascular Temperature Management System to measure core body temperature.

Description of Device

The SetPoint Endovascular Temperature Probe consists of a sheath containing two 400-series equivalent thermistors on separate and independent circuits. This Probe

250 Chesapeake Drive
Redwood City
Cal: 94063
Tel. :0) 363.8000
Fax. +1 (650) 363.2400

is intended for endovascular placement similar to other venous catheters with temperature measurement capability, including the Arrow International Inc. Multi-Lumen Central Venous Catheter (K904404). The outer sheath is Pebax and has a soft, straight Pebax tip. The Endovascular Probe is heparin-coated for hemocompatibility. It is compatible with a 4 Fr. introducer with Touhy-Borst hemostasis valve. The intended use is to measure a patient's core body temperature via venous blood temperature.

The Endovascular Probe is for single use only. It is provided sterile and packaged in a polyethylene/Tyvek pouch. Sterilization is by gamma irradiation.

Summary of Technological Characteristics

The SetPoint Endovascular Temperature Probe measures venous blood temperature via endovascular access in the femoral vein. Patient temperature is measured by the SetPoint Controller via the 400 series-equivalent thermistors in the probe.

Performance Test

The SetPoint Endovascular Temperature Probe has been tested for functionality in accordance with BS EN ISO 10555 and for biocompatibility in accordance to ISO 10993. The SetPoint Controller has been tested for electrical safety in accordance to EN 60601, as previously reported in K012512.

Conclusion

Based upon the successful performance tests and the comparison to the predicate devices, the SetPoint Endovascular Temperature Probe performs with similar safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 5 2003

Radiant Medical, Inc.
c/o Mr. Andrew Cleeland
250 Chesapeake Drive
Redwood City, CA 94063

Re: K024327
SetPoint® Endovascular Temperature Probe
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: December 23, 2002
Received: December 26, 2002

Dear Mr. Cleeland:

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. 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) you may obtain. 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

Statement of Indications for Use

SetPoint Endovascular Temperature Probe
K024327

The SetPoint Endovascular Temperature Probe is indicated for use with the SetPoint Endovascular Temperature Management System to measure core body temperature.

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K024327

Prescription Use Only