

K042388



OCT 28 2004

250 Chesapeake Drive
Redwood City, CA 94063-4745
tel. 650.363.8000
toll. 888.867.5179
fax. 650.363.2400
www.radiantmedical.com

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
Senior Vice President of Regulatory & Clinical Affairs

Summary Date: August 31, 2004

Name and Classification

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

Predicate Device

a) Radiant Medical Endovascular Temperature Probe (K024327)

Indication for Use

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

Description of Device

The Endocatheter Temperature Probe consists of a sheath containing two thermistors on separate and independent circuits. This Probe is intended for



250 Chesapeake Drive
Redwood City, CA 94063-4745

tel. 650.363.8000
toll. 888.867.5179
fax. 650.363.2400

www.radiantmedical.com

placement into the inferior vena cava through the guidewire lumen of the catheter. The outer sheath is Pebax and has a soft, straight Pebax tip. The Endocatheter Probe is heparin-coated for hemocompatibility. The intended use is to measure a patient's core body temperature via venous blood temperature.

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

Summary of Technological Characteristics

The Endocatheter Temperature Probe measures blood temperature in the inferior vena cava. Patient temperature is measured by the SetPoint/Reprieve Controller via the thermistors in the probe.

Performance Test

The Endocatheter Temperature Probe has been tested for functionality in accordance with BS EN ISO 10555 and for biocompatibility in accordance to ISO 10993.

Conclusion

Based upon the successful completion of performance verification tests and the comparison to the predicate devices, the Radiant Medical Endovascular Temperature Probe performs with safety and effectiveness equivalent to the predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 28 2004

Mr. Andrew Cleeland
Senior Vice President of Regulatory & Clinical Affairs
Radiant Medical, Inc.
250 Chesapeake Drive
Redwood City, CA 94063

Re: K042388
Trade/Device Name: Endocatheter Temperature Probe
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: II
Product Code: DQY
Dated: August 31, 2004
Received: September 2, 2004

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.

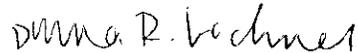
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

Page 2 – Mr. Andrew Cleeland

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 (240) 276-0120. 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

Indications for Use

510(k) Number (if known): K042388

Device Name: Radiant Medical Endocatheter Temperature Probe

Indications For Use: The Radiant Medical Endocatheter Temperature Probe is indicated for use with the SetPoint/Relieve Endovascular Temperature Management System to measure core body temperature.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Danah R. Johnson
Division Sign-Off
Division of Cardiovascular Devices

510(k) number K042388

Page 1 of 1