K063185 Page 1 of 2

SPECIAL 510(K) SUMMARY

NOV 17 2006

This summary of Special 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:

1. Submitter's Identification:

Radiant Innovation Inc.,
1F, No.3 Industrial E. 9th Rd., Science-Based
Industrial Park, HsinChu, Taiwan

Contact:

Mr. Frank Lin
QA Dept. Manager

Date Summary Prepared: Sep/27/2006

2. Name of the Modification Device:

Infrared Ear Thermometer TH5XY series (TH500/50Z, TH520 and TH560/56Z)

3. Current Clearance Device:

Radiant Innovation Infrared Ear Thermometer, Models TH00XY series (FDA#: K051269), THXXN series (FDA#: K040377), TH1 series (FDA#: K030324), TH88 series (FDA#: K020504) and TH8 series (FDA#: K011059).

4. Device Description:

The Radiant Innovation Inc., Infrared Ear Thermometer, Models TH5XY series are electronic thermometers using an infrared detector (thermopile detector) to detect body temperature from the auditory canal. Its operation is based on measuring the natural thermal radiation emanating from the tympanic membrane and the adjacent surfaces of the patient.

To measure ear temperature, the ear thermometer is inserted into a patient's outer ear canal. A start button is pressed to start the measurement through the radiation exchanges. The electrical signal read out from the detector is fed to the circuit for amplification and calculation. The measured temperature then appears on a LCD display. The total operation takes a few seconds.

300 新竹科學園區工業東九路 3 號 1 樓 http://www.radiantek.com.tw
1F, No.3, Industrial E. 9th Rd., Science-Based Industrial Park, HsinChu, Taiwan 300, R.O.C. TEL:+886 3 5644185 FAX: +886 3 5644170

5. Intended Use:

The device is an electronic clinical thermometer using an infrared sensor to detect body temperature from the auditory canal in the neonatal, pediatric and adult population used in the home setting.

6. Tests Performed for Determination of Substantial Equivalence are as follows:

Compliance to applicable voluntary standards includes ASTM E1965-98 and EN12470-5:2003, as well as IEC 60601 -1 and EN 60601-1-2 requirements.

Guidance Documents included the FDA "*Guidance On The Content of Premarket Notification (510(k)) Submissions for Clinical Electronic Thermometers*", " *How to Prepare A Special 510(k)* ", "*Deciding When to Submit a 510(k) for a Change to an Existing Device*"..

9. Conclusions:

The RII Infrared Ear Thermometer TH5XY series, have the same intended use and similar characteristics as the cleared device TH00XY series. Moreover, bench testing contained in this submission supplied demonstrate that the modification of TH5XY do not raise any new questions of safety or effectiveness. Thus, the RII Infrared Ear Thermometer, Models TH5XY series is substantially equivalent to the predicate device.

300 新竹科學園區工業東九路 3 號 1 樓
http://www.radiantek.com.tw
1F, No.3, Industrial E. 9th Rd., Science-Based Industrial Park, HsinChu, Taiwan 300, R.O.C.
TEL:+886 3 5644185
FAX: +886 3 5644170

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Frank Lin
Quality Assurance Department Manager
Radiant Innovation, Incorporated
1F, No. 3, Industrial East 9th Road
Science-Based Industrial Park
HsinChu, Taiwan 300
Republic of China

NOV 17 2006

Re: K063185
Trade/Device Name: Radiant Innovation Inc. Infrared Ear Thermometer
TH5XY Series
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: September 26, 2006
Received: October 20, 2006

Dear Mr. Lin:

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.

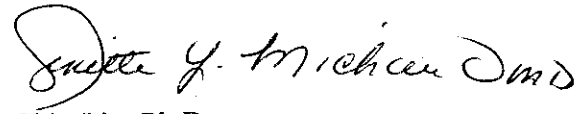
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. 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/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K063185

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Radiant Innovation Inc. Infrared Ear Thermometer TH5XY series

Indications For Use:

The device is an electronic clinical thermometer using an infrared sensor to detect body temperature from the auditory canal in the neonatal, pediatric and adult population used in the home setting.

Prescription Use _____ AND/OR Over-The-Counter Use ☒
(Part 21 CFR 801 Subpart D) (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)

Smith Y. Michaud M.D.
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

(Division Sign-Off) Number: K063185

300 新竹科學園區工業東九路 3 號 1 樓
http://www.radiantek.com.tw
1F, No.3, Industrial E. 9th Rd., Science-Based Industrial Park, HsinChu, Taiwan 300, R.O.C.
TEL:+886 3 5644185
FAX: +886 3 5644170