SEP 16 2004

EXHIBIT # 1

SPECIAL 510(K) SUMMARY

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: K040377 (0.1of2)

1. Submitter's Identification:

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

Contact:

Mr. Frank Lin
QA Dept. Manager

Date Summary Prepared: Jan/15/2004

2. Name of the Modification Device:

Infrared Ear Thermometer THxxN series (TH10N(E),TH80N(E),TH83N(E) and TH88N(E))

3. Current Clearance Device:

Radiant Innovation Infrared Ear Thermometer, Models TH1 series (FDA#: K030324) and TH8 series (FDA#: K011059).

4. Device Description:

The Radiant Innovation Inc., Infrared Ear Thermometer, Models THxxN 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.

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, 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 THxxN series, have the same intended use and similar characteristics as the cleared device TH1 and TH8 series. Moreover, bench testing contained in this submission supplied demonstrate that the modification of THxxN do not raise any new questions of safety or effectiveness. Thus, the RII Infrared Ear Thermometer, Models THxxN series is substantially equivalent to the predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 2004

Mr. Frank Lin
Quality Assurance Manager
Radiant Innovation, Incorporated
1F, No. 3, Industrial E. 9th Road
Science-Based Industrial Park, HsinChu,
TAIWAN, R.O.C.

Re: K040377
Trade/Device Name: RII Infrared Ear Thermometer, Model THXXN Series
Regulation Number: 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: September 6, 2004
Received: September 10, 2004

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 (301) 594-4618. 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,

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

EXHIBIT # B

Indications for Use

510(k) Number (if known): K040377

Device Name: Radiant Innovation Inc. Infrared Ear Thermometer THxxN 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)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K040377

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