EXHIBIT # 1

510(K) SUMMARY

JUL 17 2012

This 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: K121428

1. Submitter's Identification:

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

Contact:

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Date Summary Prepared: May/11/2012

2. Name of the Device:

Non-contact Clinical Thermometer, Model THB0F.
Classification Name: Thermometer, Electronic, Clinical
Regulatory Class: II
Product Code: FLL
Regulation Number: 21 CFR 880.2910

3. Predicate Device :

TECNIMED srl, Thermofocus 01500 series Thermometer.(510(k) #K072108)

4. Device Description:

The RII Non-contact Clinical Thermometer, Model THB0F is electronic thermometer using an infrared detector (thermopile detector) to detect body temperature from the Forehead. Its operation is based on measuring the natural thermal radiation emanating from the temples to hairline upper eyebrows.

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The thermometer consists mainly of the following parts: an IR sensor with a built-in ambient temperature sensor, a thermo-mass, and the associated circuit. The forehead skin, which is thin and beneath, which is the temporal artery, with blood very near to the core temperature. The forehead skin must cover the whole FOV(Field of View) of the sensor. When measuring, radiation fluxes transfer from the skin to the IR detector. The ambient sensor is mounted in the IR sensor package, and near the IR detector element to monitor the ambient temperature.

To measure core temperature, the probe of the thermometer are slide through the skin of the a patient's forehead. A activation 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 appear on a LCD display. The total operation takes a few seconds.

5. Intended Use:

The Non-contact Clinical Thermometer, Model THB0F is an infrared thermometer intended for the intermittent measurement of human body temperature in people of all ages.

6. Technological Characteristics and Substantial Equivalence:

The subject device is substantially equivalent to the predicate devices, Thermofocus 01500 series Thermometer (K072108) marketed by TECNIMED srl. The substantial equivalence chart is provided as follows:

Characteristics	Subject device(THB0F)	Predicate device (THP series)
510(k)#	K	K072108
Measurement Method	Infrared radiation detection	
Measuring Range	Forehead mode: 93.2~108°F(34~42.2℃) Surface mode: -7.6~176°F(-22~80℃)	Forehead mode: 93.2~108.5°F(34~42.5℃) Surface mode: 33.8~131°F (1~55℃)
Accuracy	Forehead mode: ±0.4°F(0.2℃) within 96.8~102°F (36~39℃), ±0.5°F(0.3℃) for other range Surface mode: ±4% of reading or ±4°F(2℃) whichever is greater	Forehead mode: ±0.4°F(0.2℃) within 96.8~102°F(36~39℃), ±0.5°F(0.3℃) for other range Surface mode: ±0.4°F(0.2℃) within 96.9~102°F(36~39℃), ± 0.5°F(0.3℃) within 68~96.7°F(20~35.9℃) and 102.3~108.5°F(39.1~42.5℃), ± 1.8°F(1℃) within 33.8~67.9°F(1~19.9℃) and 108.1~131°F(42.6~55℃)
Display Resolution	0.1°F(0.1℃)	
Measurement Distance	2~3cm	2.5cm
Scale Selection	°F/℃	
Display Type	LCD	
Key	4 button(Mode/ Memory, On/Off, Light/Set, Scan)	3 button(Face, Memory, Home)
Memory	60 sets	9 sets
Sensor Type	Thermopile	
Case	ABS	

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Weight	104.7g	90g
Dimension (LxWxH)	180.3x47.5x29.2mm	165x40x21.9 mm
Power Source	AAA(1.5V)*2	AAA(1.5V)*4
Operating Condition	50~104°F(10~40°C)	60.8~104°F(16~40°C)

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

- Compliance to applicable voluntary standard ASTM E1965-98.
- The recognized consensus standards for safety of medical electrical equipment: EN 60601-1 (IEC 60601-1) for safety and EN 60601-1-2 (IEC 60601-1-2) for electromagnetic compatibility are complied.
- Guidance Documents included the "*FDA Guidance On The Content of Premarket Notification 510(k) Submissions for Clinical Electronic Thermometers*".

8. **Discussion of Clinical Tests Performed:**

The clinical investigation report and data analysis is followed the requirements the ASTM E 1965-98. The test report shows the three group's temperature readings difference between digital thermometer and the subject device, THB0F are within acceptable range. It can conclude that the Non-contact Clinical Thermometer, Model THB0F is acceptable to measure human body's temperature.

9. **Conclusions:**

The RII Non-contact Clinical Thermometer, Model THB0F, has the same intended use and similar characteristics as the predicate device. Moreover, the subject device demonstrates product safety by successful completion of testing to the EN 60601-1(IEC 60601-1) standard and electromagnetic standard EN 60601-1-2(IEC 60601-1-2). The performance test demonstrates the THB0F meets the ASTM E1965-98 standard and concludes that any differences in their characteristics do not raise any safety and effectiveness issues. Thus, the RII Non-contact Clinical Thermometer, Model THB0F is substantially equivalent to the predicate devic.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

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JUL 17 2012

Re: K121428
Trade/Device Name: Non-Contact Clinical Thermometer, Model THB0F
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: May, 14, 2012
Received: May 14, 2012

Dear Mr. Huang:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

FOR

Anthony D. Watson, B.S., M.S., M.B.A.
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):_____

Device Name: Radiant Innovation Inc. Non-contact Clinical Thermometer, Model THB0F

Indications For Use:

The Non-contact Clinical Thermometer, Model THB0F is an infrared thermometer intended for the intermittent measurement of human body temperature in people of all ages.

Prescription Use _____ 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)

7/9/12

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

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