DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 9, 2017

Radiant Innovation Inc.
Monica Chung
Quality Assurance Engineer
1F, No. 3 Industrial E. 9th Rd.
Science-based, Industrial Park
Hsinchu, 30075
TAIWAN

Re: K162083
Trade/Device Name: RII Multi-function Infrared Thermometer, Model TH52Z
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: November 25, 2016
Received: November 28, 2016

Dear Monica Chung:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Tina Kiang -S

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162083

Device Name
RII Multi-function Infrared Thermometer, Model TH52Z

Indications for Use *(Describe)*

The RII Multi-function Infrared Thermometer, Model TH52Z is intended for the intermittent measurement of human body temperatures. The device is intended for the use at home by people of all ages including neonates and it can be selected Ear mode or Forehead mode.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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EXHIBIT # 1

510(K) SUMMARY

This summary of 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: **K162083**

1. Submitter's Identification:

Radiant Innovation Inc.,
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Contact:

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Date Summary Prepared: Jan/04/2017

2. Device:

Trade Name/Device Name: RII Multi-function Infrared Thermometer, Model **TH52Z**.
Common Name: Infrared Thermometer
Regulation Number: 21 CFR 880.2910
Classification Name: Thermometer, Electronic, Clinical
Regulatory Class: II
Product Code: FLL
Classification Panel: General Hospital

3. Predicate Device :

510(k) #K063185
Device Name: RII, Infrared Ear Thermometer, Model TH520
Common Name: Infrared Thermometer
Regulation Number: 21 CFR 880.2910
Classification Name: Thermometer, Electronic, Clinical
Regulatory Class: II
Product Code: FLL
Classification Panel: General Hospital

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510(k) #K121428
Device Name: RII, Non-Contact Clinical Thermometer, Model THB0F
Common Name: Infrared Thermometer
Regulation Number: 21 CFR 880.2910
Classification Name: Thermometer, Electronic, Clinical
Regulatory Class: II
Product Code: FLL
Classification Panel: General Hospital

4. Device Description:

The RII Multi-function Infrared Thermometer, Model TH52Z is an electronic thermometer using an infrared sensor (thermopile) to detect body temperature from the auditory canal or central forehead. Its operation is based on measuring the natural thermal radiation from the tympanic membrane or central forehead.

The end of ear canal is the tympanic membrane, which is thin and flooded with blood at the core temperature. The central forehead skin is thin & flat, and the temperature is uniform to cover the Whole FOV (Field of View) of the sensor.

The thermometer consists mainly of two parts - an IR sensor with a built-in ambient temperature sensor and the associated circuit. To measure body temperature, the probe of the thermometer is inserted into a patient's outer ear canal or put onto the skin of a patient's central forehead. Pressing the activation button (for ear or forehead) to start the measurement of target's infrared radiation. The electrical signal read out from the detector is fed to the circuit for amplification and calculation. The final measured temperature will be appeared on a LCD display. The total operation takes a few seconds.

5. Indications for Use:

The RII Multi-function Infrared Thermometer, Model **TH52Z** is intended for the intermittent measurement of human body temperatures. The device is intended for the use at home by people of all ages including neonates and it can be selected Ear mode or Forehead mode.

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6. Technological Characteristics and Substantial Equivalence:

The subject device TH52Z is substantially equivalent to the predicate devices, Infrared Ear Thermometer, Model TH520 (K063185) and Non-Contact Clinical Thermometer, Model THB0F (K121428). The substantial equivalence chart is provided as follows:

Characteristics	Subject device (TH52Z)	Predicate device (Ear:TH520)	Predicate device (Forehead:THB0F)	Comparison
510(k)#	K	K063185	K121428	Similar
Indications for Use	The RII Multi-function Infrared Thermometer, Model TH52Z is intended for the intermittent measurement of human body temperatures. The device is intended for the use at home by people of all ages and it can be selected Ear mode or Forehead mode.	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.	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.	Similar
Manufacturer	Radiant Innovation Inc.	Radiant Innovation Inc.	Radiant Innovation Inc.	Same
Measurement Method	Infrared radiation detection	Infrared radiation detection	Infrared radiation detection	Same
Measuring Range	Ear / Forehead mode: 93.2~108℉(34~42.2℃)	Ear mode: 93.2~108℉(34~42.2℃)	Forehead mode: 93.2~108℉(34~42.2℃)	Same
Accuracy for body temperature measurement	±0.4°F (0.2°C) within 95~107.6°F (35~42°C), ±0.5°F (0.3°C) for other range.	±0.4°F (0.2°C) within 95~107.6°F (35~42°C), ±0.5°F (0.3°C) for other range.	±0.4°F (0.2°C) within 95~107.6°F (35~42°C), ±0.5°F (0.3°C) for other range.	Same
Performance	Meet ASTM E1965-98 and EN ISO 80601-2-56	Meet ASTM E1965-98 and EN ISO 80601-2-56	Meet ASTM E1965-98 and EN ISO 80601-2-56	Same
Display Resolution	0.1℉(0.1℃)	0.1℉(0.1℃)	0.1℉(0.1℃)	Same
Measurement Distance	Within 1 cm	NA	2~3cm	Acceptable
Scale Selection	℉/℃	℉/℃	℉/℃	Same
Display Type	LCD	LCD	LCD	Same
Key	3 button(On ,Memory/Ear / Forehead)	2 button(On, Memory/Ear)	4 button(Mode/ Memory, On/Off, Light/Set, Scan)	Acceptable
Memory	9 sets	9 sets	60 sets	Acceptable
Sensor Type	Thermopile	Thermopile	Thermopile	Same
Case	ABS	ABS	ABS	Same
Weight	63.3g	56.9g	104.7g	Acceptable
Dimension (LxWxH)	146.4x38.3x54.8mm	146.4x38.3x54.8mm	180.3x47.5x29.2mm	Acceptable
Power Source	CR2032 *1	CR2032 *1	AAA(1.5V)*2	Acceptable

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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.
- Biocompatibility Evaluation for patient contacting components: ISO 10993-5 and ISO 10993-10 are complied.
- Guidance Documents included the "*FDA Guidance On The Content of Premarket Notification 510(k) Submissions for Clinical Electronic Thermometers*".

8. Summary of Clinical Investigation:

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, TH52Z are within acceptable range. It can conclude that the Multi-function Infrared Thermometer, Model **TH52Z** is acceptable to measure human body's temperature.

9. Conclusions:

The RII Multi-function Infrared Thermometer, Model TH52Z, 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 TH52Z 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 Multi-function Infrared Thermometer, Model TH52Z is substantially equivalent to the predicate device.

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