December 6, 2018

Radiant Innovation Inc.
Monica Chung
Product Certification Engineer
1F, No.3 Industrial E. 9th Road,
Science-Based, Industrial Park
HsinChu, 30075
Taiwan

Re: K163601
Trade/Device Name: RII Smart IR Thermometer, Model TMS-01A
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: October 29, 2018
Received: November 5, 2018

Dear Ms. 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Geeta K.
Pamidimukkala -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K163601

Device Name

RII Smart IR Thermometer, Model TMS-01A

Indications for Use *(Describe)*

The RII Smart IR Thermometer, Model TMS-01A is a non-contact infrared forehead thermometer and can only be used with an APP since the display only on a device with the APP. It is intended for the intermittent measurement of human body temperatures and is to be used at home for people of all ages.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

The assigned 510(k) number is: **K163601**

1. Submitter's Identification:

Radiant Innovation Inc.,
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Industrial Park, HsinChu, Taiwan

Contact:

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Date Summary Prepared: 11/10/2018

2. Device:

Trade Name/Device Name: RII, Smart IR Thermometer, Model **TMS-01A**.
Common Name: Infrared Thermometer
Regulation Number: 21 CFR 880.2910
Classification Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Classification Panel: General Hospital

3. Predicate Device :

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

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Reference device: 510(k) #K132514
Device Name: Kinsa Smart Thermometer
Common Name: Thermometer
Regulation Number: 21 CFR 880.2910
Classification Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Classification Panel: General Hospital

4. Device Description:

The RII Smart IR Thermometer, Model TMS-01A is an electronic thermometer using an infrared sensor (thermopile) to detect body temperature from center of forehead. The principle of operation is based on measuring the natural thermal radiation from the center of forehead.

The thermometer consists mainly of two parts - an IR sensor with a built-in ambient temperature sensor and an associated circuit. TMS-01A can only be used with an APP called “Radiant Forehead” which is available on APP store for iOS devices with version 7.0 or above. The APP is designed for use with TMS-01A to take forehead temperature by plugging the TMS-01A in the phone jack of the iOS devices.

To measure body temperature, simply aim the device within 1 cm from the center of forehead. Press the "MEASURE" button on the smart phone touch screen, the temperature sensor detects the infrared thermal energy emitted from the targeted area. The electrical signal is sent to the circuit for amplification and calculation. The final measured temperature can be display on smart phone. The time consuming for measurement might be 1 second.

5. Indications for Use:

The RII Smart IR Thermometer, Model TMS-01A is a non-contact infrared forehead thermometer and can only be used with an APP since the display only on a device with the APP. It is intended for the intermittent measurement of human body temperatures and is to be used at home for people of all ages.

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6. Technological Characteristics and Substantial Equivalence:

The subject device TMS-01A is substantially equivalent to the two predicate devices. The substantial equivalence chart is provided as follows:

Characteristics	Subject device (TMS-01A)	Primary Predicate device (THB0F)	Reference device (Kinsa)	Comparison
510(k)#	K163601	K121428	K132514	--
Indications for Use	The RII Smart IR Thermometer, Model TMS-01A is a non-contact infrared forehead thermometer and can only be used with an APP since the display only on a device with the APP. It is intended for the intermittent measurement of human body temperatures and is to be used at home for people of all ages.	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.	--	--
Measurement Method	Infrared radiation detection	Infrared radiation detection	--	Same
Measuring Range	Forehead mode: 93.2~108℉(34~42.2℃)	Forehead mode: 93.2~108℉(34~42.2℃)	--	Same
Accuracy for body temperature measurement	±0.4℉ (0.2℃) within 95~107.6℉ (35~42℃), ±0.5°℉ (0.3℃) for other range.	±0.4℉ (0.2℃) within 95~107.6°F (35~42°C), ±0.5℉ (0.3℃) for other range.	--	Same
Performance	Meets ASTM E1965-98 and EN ISO 80601-2-56	Meets ASTM E1965-98 and EN ISO 80601-2-56	--	Same
Display Resolution	0.1℉(0.1℃)	0.1℉(0.1℃)	--	Same
Measurement Distance	Non-contact within 1 cm	2~3cm	--	Different
Scale Selection	°F/°C	°F/°C	--	Same
Display Type	Smart phone display	LCD	Smart phone display	Different
Key	0	4 buttons	0	Different
Memory	Full temperature history available on mobile device	60 sets	Full temperature history available on mobile device	Similar
Sensor Type	Thermopile	Thermopile	--	Same
Materials	ABS	ABS	--	Same
Power Source	Smart Phone	AAA(1.5V)*2	Smart Phone	Different
Bio-compatibility	Meets ISO 10993-1, ISO 10993-5 and ISO 10993-10	Meets ISO 10993-1, ISO 10993-5 and ISO 10993-10	--	Same
Safety	Comply with IEC 60601-1	Comply with IEC 60601-1	Comply with IEC 60601-1	Same
EMC	Comply with IEC 60601-2	Comply with IEC 60601-2	Comply with IEC 60601-2	Same

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Discussion:
The differences exist between the subject and predicate devices are as follows:

- **Indications for Use** – The subject device measurement temperature displays on a device with an APP. It is different from the predicate which the measurement temperature displays on the device itself. It is same as reference device. The subject device complied with the standard ISO 80601-2-56, ASTM E1965-98, IEC 60601-1, IEC 60601-1-11 and IEC 60601-1-2, so this difference does not cause any new safety or performance issue.
- **Measurement Distance** – The measurement distance of subject device is shorter than predicate device, the subject device complied with the standards ISO 80601-2-56 and ASTM E1965-98. This difference does not cause any new performance issue.
- **Display Type** and **Key** – The subject device is inserted into smart phone's phone jack and measurement will be displayed through app on the smart phone which is same as reference device. In addition, the subject device complied with the standard ISO 80601-2-56, ASTM E1965-98, IEC 60601-1, IEC 60601-1-11 and IEC 60601-1-2, so this difference does not cause any new safety or performance issue.
- **Power Source** –The power supply of the subject device is from smart phone which is same as reference device. In addition, the subject device complied with the standard IEC 60601-1, IEC 60601-1-11 and IEC 60601-1-2, so this difference does not cause any new safety issue.

The differences described in the comparison table demonstrate that the Smart IR Thermometer, Model TMS-01A is substantially equivalent to predicate device and does not raise any new question.

7. <u>Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:</u>

Non- clinical test were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1:2005+A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- ISO 80601-2-56 Medical electrical equipment -- Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
- IEC 60601-1-11, Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- ASTM E1965-98, Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature
- ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10, Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
- The software verification and validation was provided in accordance with the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," dated May 11, 2005.

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8. Clinical Test Data:

The clinical tests evaluated 198 of subjects. Each model was evaluated in three groups: 1) infants—newborn to one year; 2) children—greater than one to five years; and 3) adults—greater than five years old. The clinical performance test protocol and data analysis is conducted as the requirement of ASTM E1965-98. The test report showed the clinical performance of the subject device complied with the requirement of ASTM E1965-98.

9. Conclusions:

Verification and validation tests were conducted on the subject device and all tests met specified criteria. Based on the information provided in this submission, the RII Smart IR Thermometer, Model TMS-01A is substantially equivalent to the predicate device.

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