January 10, 2019

HeTaiDa Technology Co., Ltd.
℅ Yijie You
Manager
Qimmiq Medical Consulting Service Co., Ltd.
RM.1711, Building K, NO.101 Science Ave International
Creative Valley Development Zone
Guangzhou, 510663
China

Re: K180387
Trade/Device Name: Infrared Ear Thermometer, Model HTD8208C
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: November 19, 2018
Received: November 23, 2018

Dear Yijie You:

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,

Sapana Patel -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)*
K180387

Device Name
Infrared Ear Thermometer, Model: HTD8208C

Indications for Use *(Describe)*
The Infrared Ear Thermometer, Model: HTD8208C, is an electronic clinical thermometer using an infrared sensor to detect body temperature from the auditory canal in people of all ages for home setting use.

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

K180387

1. Submitter's Information

Establishment Registration Information

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Date to prepare: January 9, 2019

2. Device Information

Type of 510(k) submission:	Traditional
Device Common Name:	Clinical electronic thermometer
Trade Name:	Infrared Ear Thermometer
Model:	HTD8208C
Regulation name:	Clinical electronic thermometer
Review Panel:	General Hospital
Product Code:	FLL
Regulation Class:	II
Regulation Number:	880.2910

3. Predicate Device Information

510(k) submitter/holder:	Radiant Innovation Inc.
510(K) Number:	K011059
Device:	INFARED EAR THERMOMETER, Model: TH839
Trade name:	TH839 Ear-Type Thermometer

4. Device description

Infrared Ear Thermometer, model: HTD8208C, is an electronic thermometer using an infrared sensor (thermopile) to detect body temperature from the auditory canal. The principle of operation is based on measuring the natural thermal radiation emanating from the tympanic membrane when the thermometer is inserted in the ear canal.

The Infrared Ear Thermometer measures temperature by reading infrared radiation emitting from the eardrum tissue when the thermometer is inserted into the ear canal. Pressing the measuring button 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 display on the device's LCD. The total operation takes less than 5 seconds.

5. Indications for Use

The Infrared Ear Thermometer, Model: HTD8208C, is an electronic clinical thermometer using an infrared sensor to detect body temperature from the auditory canal in people of all ages for home setting use.

6. Summary of technological characteristics of device compared to the predicate devices (K011059)

	Subject device K180387 (Infrared Ear Thermometer, model: HTD8208C)	Predicate device (K011059, INFARED EAR THERMOMETER, Model: TH839)	Discussion of difference
Indications for Use	The Infrared Ear Thermometer, Model: HTD8208C, is an electronic clinical thermometer using an infrared sensor to detect body temperature from the auditory canal in people of all ages for home setting 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.	Similar The device name is included in the subject device.
Principle of operation	Measure temperature by reading infrared radiation emitting from the eardrum tissue when the thermometer is inserted into the ear canal.	Measure temperature by reading infrared radiation emitting from the eardrum tissue when the thermometer is inserted into the ear canal.	Same

target population	people of all ages	Neonatal, pediatric, and adult	Same
Measurement site	auditory canal	auditory canal	Same
Material of Patient contact components	ABS	ABS	Same
Biocompatibility	Comply with ISO 10993-5, ISO 10993-10	Comply with ISO 10993-5, ISO 10993-10	Same
Environment	home	home	Same
Design	Handheld	Handheld	Same
Measurement method	Infrared radiation detection	Infrared radiation detection	Same
Display Type	LCD	LCD	Same
Measurement mode	Ear measure mode	Ear measure mode	Same
Key	2 button(scan, ON/Memory button)	2 button(scan, ON/Memory button)	Same
Scale selection	°C/°F	°C/°F	Same
Display unit	°C/°F	°C/°F	Same
High temperature warning	Yes	Yes	Same
Low battery indicator	Yes	Yes	Same
Case Material	ABS	ABS	Same
Sensor Type	Thermopile	Thermopile	Same
Performance	Meet ASTM E1965-98 and ISO 80601-2-56	Meet ASTM E1965-98	Similar The proposed device complies with standards ASTM E1965-98 and ISO 80601-2-56. The difference does not affect the determination of substantial equivalence.
Measuring range	34.0℃~42.9℃; (93.2~109.22°F)	34~42.2°C (93.2~108.0°F)	Similar The proposed device meets ASTM E1965-98, ISO 80601-2-56 and the difference does not affect the determination of substantial equivalence.

Display resolution	0.1°F (0.1℃)	0.1°F (0.1℃)	Same
Measuring accuracy	±0.2°C (0.4°F) within 35~42°C (95~107.6°F), ±0.3°C (0.5°F) for other range	±0.2°C (0.4°F) within 35~42°C (95~107.6°F), ±0.3°C (0.5°F) for other range	Same
Memory	10 set	9 set	Similar The memory capacity will not affect the determination of substantial equivalence
Measure time	≤5S	About 1 second	Similar The Measure time will not affect the determination of substantial equivalence
Power source	DC 3V (Alkaline AAA size battery x 2)	DC 3V, One lithium cell (CR2032 x 1).	Similar The proposed device was demonstrated electromagnetic compatibility and electrical safety by the testing. The difference does not affect the determination of substantial equivalence.
Operating condition	15℃~35℃(59~95°F)，Relative Humidity≤85%	10~40°C (50~104°F),15%~85% RH	Similar The operating condition of subject device has passed the safety test, and the Instructions for Use provides the operating condition, so the difference between the operating conditions of subject device and predicate device will not affect the determination of substantial equivalence.

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

Standards	Standards Name
IEC 60601-1: 2005+A1:2012	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
IEC 60601-1-2: 2014	Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests
IEC 60601-1-11: 2015	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: 2009	Medical Electrical Equipment - Part 2-56: Particular Requirements For Basic Safety And Essential Performance Of Clinical Thermometers For Body Temperature Measurement.
ASTM E1965-98	Standard Specification For Infrared Thermometers For Intermittent Determination Of Patient Temperature
ISO 10993-5:2009	Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
ISO 10993-10:2010	Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization
IEC 62304:2006+A1:2015	Medical device software - Software life cycle processes

The subject device is a non-sterile device. The validation testing result for cleaning and disinfection of the subject device is adequate.

Software validation and verification test:
The software contained in the subject device complies with the applicable requirements set forth in the referenced guidance document, “Guidance for the Content of Premarket Submissions for Software Contained, issued on May 11, 2005.

8. Discussion of Clinical Tests Performed:

The clinical investigation report and data analysis followed the requirements of the ASTM E 1965-98 and ISO 80601-2-56.

The clinical tests evaluated 140 of subjects. Each model was evaluated in each of the following age groups: 0 up to 3 months, 3 months up to one year, older than 1 year and younger than 5 years, and older than 5 years. The clinical performance test protocol and data analysis was conducted as the requirement of

ASTM E1965-98 (2009). The test report demonstrated the clinical performance of the subject device complied with the requirement of ASTM E1965-98 (2009).

9. Conclusions

Infrared Ear Thermometer, model HTD8208C, has the same intended use and similar characteristics as the predicate device. Based on performance testing and compliance with standards demonstrate the subject device Infrared Ear Thermometer, model HTD8208C is substantially equivalent to the predicate device.