May 11, 2018

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

Re: K180385
Trade/Device Name: Infrared Body Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: December 10, 2017
Received: February 15, 2018

Dear You Yijie:

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.

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.

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,

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)*
K180385

Device Name
Infrared Body Thermometer

Indications for Use *(Describe)*
The Infrared Body Thermometer, Model: HTD8216C, is an electronic clinical thermometer using an infrared sensor to detect body temperature from the forehead or 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

1. Submitter's Information

Establishment Registration Information

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Email: Jet.you@qimmiq-med.com
Date to prepare: May. 9, 2018

2. Device Information

Type of 510(k) submission:	Traditional
Device Common Name:	Clinical electronic thermometer
Trade Name:	Infrared Body Thermometer
Model:	HTD8216C
Classification name:	thermometer, electronic, clinical
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: K162083
Device: RII Multi-Function Infrared Thermometer, Model TH52Z
Trade name: TH52Z Multi-function Infrared Thermometer

4. Device description

Infrared Body Thermometer, model: HTD8216C, is an electronic thermometer using an infrared sensor (thermopile) to detect body temperature from the central forehead or auditory canal. Its operation is based on measuring the natural thermal radiation emanating from the central forehead or tympanic membrane.

The forehead mode of Infrared Body Thermometer measure temperature by reading infrared radiation emitting from the central forehead skin. The central forehead skin is thin & flat, and the temperature is uniform to cover the Whole FOV (Field of View) of the sensor.

The ear mode of Infrared Body Thermometer measure temperature by reading infrared radiation emitting from the eardrum tissue. The ear mode of Infrared Body Thermometer measure temperature by reading infrared radiation emitting from the eardrum tissue when the thermometer is inserted into the ear canal.

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. Intended Use

The Infrared Body Thermometer, Model: HTD8216C, is an electronic clinical thermometer using an infrared sensor to detect body temperature from the forehead or auditory canal in people of all ages for home setting use.

6. Summary of technological characteristics of device compared to the predicate devices (K162083)

SE Comparisons	Subject device Present application (Infrared Body Thermometer, model: HTD8216C)	Predicate device (K162083, RII Multi-Function Infrared Thermometer, Model: TH52Z)	Discussion of difference
Classification	21CFR 880.2910	21CFR 880.2910	Same
Product Code	FLL	FLL	Same
FDA Class	II	II	Same

Intended Use	The Infrared Body Thermometer, Model: HTD8216C, is an electronic clinical thermometer using an infrared sensor to detect body temperature from the forehead or auditory canal in people of all ages for home setting 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.	Same
target population	people of all ages who need to detect body temperature	people of all ages who need to detect body temperature	Same
anatomical site	central forehead auditory canal	central forehead auditory canal	Same
where used	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/ Forehead mode	Ear measure mode/ Forehead mode	Same
Key	2 button(ON / scan button, measurement unit switch button is behind the battery cover)	3 button(“ear button”, “forehead button” ON/Memory button)	Acceptable The Key number will not affect the safety and effectiveness of the proposed device
Scale selection	°C/°F	°C/°F	Same
Fever 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 and ISO 80601-2-56	Same
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 raise

			the issue of product's safety and effectiveness.
Display resolution	0.1℉(0.1℃)	0.1℉(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	1 set	9 set	Acceptable The memory capacity will not affect the safety and effectiveness of the proposed device
Measure time	≤5S (ear mode)	Ear: 1sec.	Acceptable The Measure time will not affect the safety and effectiveness of the proposed device
	≤2S (Forehead mode)	Forehead Mode: 5~30sec.	
Power source	1.5V (AAA) Alkaline batteryX2	DC 3V, One lithium cell (CR2032 x 1).	Acceptable The proposed device was demonstrated electromagnetic compatility and electrical safety by the testing. The difference does not raise the issue of product's safety and effectiveness.
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 performance 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 safety and effectiveness of subject device.

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

The recognized consensus standards for safety of medical electrical equipment: IEC 60601-1, IEC 60601-1-11 for safety, IEC 60601-1-2 for electromagnetic compatibility, ASTM E 1965-98 and ISO 80601-2-56 for performance, ISO 10993-5 and ISO

10993-10 for Biocompability 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 followed the requirements of the ASTM E 1965-98 and ISO 80601-2-56. The test report shows the three group's temperature readings difference between digital thermometer and the subject device, HTD8216C is within acceptable range. It is concluded that the Infrared Body Thermometer, model HTD8216C is acceptable to measure human body's temperature.

9. Conclusions

Infrared Body Thermometer, models HTD8216C, has the same intended use and similar characteristics as the predicate device. Moreover, the subject device demonstrates compliance with the IEC 60601 -1, IEC 60601-1-11standards and electromagnetic standard IEC 60601-1-2. The performance test demonstrates the HTD8216C meets the ASTM E 1965-98 and ISO 80601-2-56 standard and concludes that any differences in their characteristics do not raise different questions of safety and effectiveness. Thus, Infrared Body Thermometer, model new HTD8216C is substantially equivalent to the predicate device.