January 5, 2021

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

Re: K200159
Trade/Device Name: Infrared Body Thermometer, Model: HTD8823US
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: December 7, 2020
Received: December 7, 2020

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. 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

CAPT Alan Stevens
Acting Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K200159

Device Name
Infrared Body Thermometer, Model: HTD8823US

Indications for Use *(Describe)*
The Infrared Body Thermometer, Model: HTD8823US, is an electronic clinical thermometer using an infrared sensor to detect body temperature from the forehead 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.

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510(K) Summary

K200159

1. Submitter's Information

Establishment Registration Information

Name: HeTaiDa Technology Co., Ltd
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Contact Person of applicant

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Date prepared: Dec. 16, 2020

2. Device Information

Device Common Name:	Clinical electronic thermometer
Trade Name:	Infrared Body Thermometer
Model:	HTD8823US
Regulation name:	Clinical electronic thermometer
Review Panel:	General Hospital
Product Code:	FLL
Regulation Class:	II
Regulation Number:	880.2910

3. Predicate Device Information

Primary predicate device:

510(k) submitter/holder:	KAZ USA, Inc., A Helen of Troy Company
510(K) Number:	K163516
Model:	Braun No Touch + Forehead NTF3000 Thermometer
Trade name:	Infrared Thermometer
Review Panel:	General Hospital
Product Code:	FLL

Regulation Class: II
Regulation Number: 880.2910

Secondary predicate device:
510(k) submitter/holder: Exergen Corporation
510(K) Number: K011291
Trade name: TemporalScanner Thermometer, SensorTouch
Review Panel: General Hospital
Product Code: FLL
Regulation Class: II
Regulation Number: 880.2910

4. Device description

Infrared (IR) Body Thermometer, model: HTD8823US, is a hand-held, battery powered, infrared thermometer that measures human body temperature from forehead. The reference body site is oral.

The device can measure temperature with two modes, forehead mode and forehead scan mode, and both modes measure forehead temperature.

The forehead mode measures temperature from center of the forehead.

Forehead scan mode measures temperature by gently positioning the probe flush (flat) on the center of the forehead, midway between the eyebrow and the hairline, press and hold the On/Scan button. Lightly slide the thermometer across the forehead keeping the sensor flat and in contact with the skin until reaching the right hairline, release the On/Scan button and remove the thermometer from the forehead, then the temperature will display on the screen, the whole process takes 3~10 seconds.

Principle of operation:

Infrared Body Thermometer, model: HTD8823US, is an electronic thermometer uses IR sensor (thermopile) to detect infrared radiation emitting from forehead. The IR sensor outputs electrical signal which is fed to circuit for amplification and then inputted to the microcontroller unit (MCU). For forehead mode, the MCU captures the temperature measured from center of forehead. The measured temperature will finally appear on LCD display. For forehead scan mode, the MCU captures the highest temperature during scanning sampling process and calculation, finally the measured temperature will appear on LCD display.

5. Indications for Use

The Infrared Body Thermometer, Model: HTD8823US, is an electronic clinical thermometer using an infrared sensor to detect body temperature from the forehead in people of all ages for home setting use.

6. Summary of technological characteristics of device compared to the predicate devices (K163516 and K011291)

SE Comparisons	Subject device K200159 (Infrared Body	Primary predicate device (K163516, Infrared Thermometer, Model: Braun	Secondary predicate device (K011291,	Discussion of difference

	Thermometer, model: HTD8823US)	**No Touch + Forehead NTF3000 Thermometer) (**compared with Forehead mode of HTD8823US**)**	**TemporalScanner Thermometer, SensorTouch) (**compared with Forehead scan mode of HTD8823US**)**	
Classification	21CFR 880.2910	21CFR 880.2910	21CFR 880.2910	**Same**
Product Code	FLL	FLL	FLL	**Same**
FDA Class	II	II	II	**Same**
Intended Use	The Infrared Body Thermometer, Model: HTD8823US, is an electronic clinical thermometer using an infrared sensor to detect body temperature from the forehead in people of all ages for home setting use.	The Braun No Touch + Forehead NTF3000 Thermometer is a non-sterile, reusable clinical thermometer intended for the intermittent determination of human body temperature in a touch and no touch mode on the center of the forehead as the measurement site on people of all ages.	The TemporalScanner Thermometer is an infrared thermometer intended for the intermittent measurement of human body temperature of people of all ages	**Similar** (Discussion is indicated in D1)
Principle of operation	Forehead mode: Measure temperature by reading infrared radiation emitting from the forehead when the thermometer is placed within few centimeters of forehead.	Measure temperature by reading infrared radiation emitting from the forehead when the thermometer is placed within few centimeters of forehead.	NA	**Same**
	Forehead scan mode: Measure temperature by reading infrared radiation emitting from the forehead when the thermometer is placed on the forehead.	NA	Measure temperature by reading infrared radiation emitting from the forehead when the thermometer is placed on the forehead.	**Same**
target population	people of all ages	people of all ages	people of all ages	**Same**
Measurement site	forehead	forehead	forehead	**Same**
Material of Patient contact components	ABS (device housing/ handle and power button); PMMA(LCD screen)	ABS (device housing/ handle and power button); TPR (temperature button and nose / forehead touch bumper).	ABS	**Similar** (Discussion is indicated in D2)
Biocompability testing	Meets ISO 10993- 5 ISO 10993-10	Meets ISO 10993 and FDA Bluebook memo G95-1	Not public	**Similar** (Discussion is indicated in D3)
Environment	home	home	home	**Same**
Design	Handheld	Handheld	Handheld	**Same**
Measurement method	Infrared radiation detection	Infrared radiation detection	Infrared radiation detection	**Same**
Display Type	LCD	LCD	LCD	**Same**
Measurement Mode	Forehead mode	Forehead mode	NA	**Same**
	Forehead scan mode	NA	Forehead scan mode	**Same**
Key	One button(ON/Scan	Two button(Power button,	One button(SCAN	**Similar** (Discussion is

	button)	Temperature button)	Button)	indicated in D4)
Scale selection	°C/°F	°C/°F	°C/°F	**Same**
Display unit	°C/°F	°C/°F	°C/°F	**Same**
High temperature warning	Yes	Yes	Yes	**Same**
Low battery indicator	Yes	Yes	Yes	**Same**
Case Material	ABS	ABS	ABS	**Same**
Sensor Type	Thermopile	Thermopile	Thermopile	**Same**
Performance Testing	Meets ASTM E1965-98 and ISO 80601-2-56	Meets ASTM E1965-98 and ISO 80601-2-56	Meets ASTM E1965-98	**Similar** (Discussion is indicated in D5)
Electrical Safety	ANSI AAMI ES60601-1	ANSI AAMI ES60601-1	ANSI AAMI ES60601-1	**Same**
EMC Meets	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	**Same**
Measuring Range for Forehead mode	34.0°C ~ 43.0°C (93.2°F ~109.4°F)	34.4°C ~42.2°C (93.9°F to 108.0°F)	NA	**Similar** (Discussion is indicated in D6)
Measuring Range for Forehead scan mode	34.0°C ~ 43.0°C (93.2°F ~109.4°F)	NA	Forehead scan: 15.5°C to 42°C (60°F to 107.6°F)	**Similar** (Discussion is indicated in D7)
Display resolution	0.1°F (0.1℃)	0.1°F (0.1℃)	0.1°F (0.1℃)	**Same**
Measuring accuracy	±0.2°C (0.4°F) within 35°C ~ 42°C (95°F~107.6°F); ±0.3°C (0.5°F) for other range	±0.2°C (0.4°F) within 35°C ~42°C (95°F ~107.6°F); ±0.3°C (0.5°F) for other range	±0.2°C (0.4°F) within 35~42°C (95°F ~107.6°F); ±0.3°C (0.5°F) for other range	**Same**
Measure time	≤2S for Forehead mode; 3~10s for Forehead scan mode;	≤2S	Seconds	**Similar** (Discussion is indicated in D8)
Color Indication	Green: ≥ 35.8°C - 37.4 °C (96.4°F -99.3°F) Yellow: ≥ 37.5°C- 38.5°C (99.5°F -101.3°F) Orange: ≥ 38.6°C - 43.0°C (≥101.5°F -109.4°F)	Green: > 35.7 °C -37.4 °C (> 96.3°F - 99.3 °F) Yellow: > 37.4 °C - 38.5 °C (> 99.4°F - 101.3 °F) Red: > 38.5 °C - 42.2 °C (> 101.3°F - 108.0 °F)	NA	**Similar** (Discussion is indicated in D9)
Measuring Distance for forehead mode	1 CM -5CM	1 CM -5CM	NA	**Same**
Measuring Distance for forehead scan mode	0 cm	NA	0 cm	**Same**

Power source	3 V d.c. (2X AAA batteries)	Two (2) AA batteries	9 volt Alkaline	**Similar** (Discussion is indicated in D10)
Operating condition	Temperature: 5°C ~40°C (41°F ~104°F) Humidity: ≤ 95%(no condensing)	Temperature: 15°C ~40°C (59°F ~104°F) Humidity: Not public	Temperature:15.5°C ~40°C (60°F ~104°F) Humidity: ≤ 95%(no condensing)	**Different** (Discussion is indicated in D11)

The discussion of differences exist between the subject and predicate devices is listed in following:

D1: There is only difference in description, all three devices are infrared electronic clinical thermometer used to measure body temperature of all ages from forehead.
D2: The proposed device has been validated for cytotoxicity per ISO 10993- 5 and Irritation as well as Sensitization per ISO 10993-10. The difference will not affect the safety and effectiveness.
D3: The proposed device has been validated for the lasted version of ISO 10993-5: 2009 and ISO 10993-10:2010, the difference will not affect the safety and effectiveness.
D4: The different button number will not affect the safety and effectiveness.
D5: The proposed device conducted performance testing in accordance with ASTM E1965-98, ISO 80601-2-56 to demonstrate the difference does not affect the safety and effectiveness.
D6: The proposed device conducted performance testing in accordance with ASTM E1965-98, ISO 80601-2-56 to demonstrate the difference does not affect the safety and effectiveness.
D7: The proposed device conducted performance testing in accordance with ASTM E1965-98, ISO 80601-2-56 to demonstrate the difference does not affect the safety and effectiveness.
D8: The Measure time of proposed device was validated through performance testing in accordance with ASTM E1965-98, ISO 80601-2-56 to demonstrate the difference does not affect the safety and effectiveness.
D9: The Color Indication of proposed device in upper temperature range ≥ 38.6°C - 43.0°C is orange and the predicate is red in upper temperature range > 38.6°C - 42.2°C, it's only different in visual effect of color, this difference does not affect the safety and effectiveness.
D10: The proposed device was electromagnetic compatility and electrical safety in accordance with IEC 60601-1-2 and ANSI AAMI ES60601-1. The difference does not affect the safety and effectiveness.
D11: The operating condition of subject device has passed the safety test, and the subject device complies the standard IEC 60601-1-11, so the difference between the operating conditions of subject device and predicate device will not affect the safety and effectiveness.

7. Discussion of Non-Clinical Tests Performed for Safety and effectiveness are as follows:

The recognized consensus standards for safety of medical electrical equipment: ANSI AAMI ES60601-1, IEC 60601-1-11 for safety, IEC 60601-1-2 for electromagnetic compatibility, ASTM E 1965-98 and ISO 80601-2-56 for performance and IEC 62304 are complied, and see below table for details.

Standards	Standards Name
ANSI AAMI ES60601-1:2005/(R)2012 and 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: 2017	Medical Electrical Equipment - Part 2-56: Particular Requirements For Basic Safety And Essential Performance Of Clinical Thermometers For Body Temperature Measurement.
ASTM E1965-98:2016	Standard Specification For Infrared Thermometers For Intermittent Determination Of Patient Temperature
IEC 62304:2006+A1:2015	Medical device software - Software life cycle processes

Software verification and validation was performed for the subject device in accordance with Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff, May 2005.

8. Discussion of Clinical Accuracy Testing Performed:

The clinical accuracy test report and data analysis followed the requirements of the ASTM E 1965-98 (2016).

The clinical accuracy testing evaluated 140 of subjects. Each model was evaluated in 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 age groups. The test data showed the clinical accuracy of the subject device complied with the requirements of ASTM E1965-98 (2016).

9. Conclusions

Based on performance testing, comparison and analysis, the subject device Infrared Body Thermometer, model HTD8823US is substantially equivalent to the predicate devices.