December 9, 2020

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

Re: K200781
Trade/Device Name: Infrared Body Thermometer, Model: HTD8222US
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: November 9, 2020
Received: November 9, 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
Director (acting)
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200781

Device Name
Infrared Body Thermometer, Model: HTD8222US

Indications for Use *(Describe)*
The Infrared Body Thermometer, Model: HTD8222US, is an electronic clinical thermometer using an infrared sensor for the intermittent determination of body temperature from the forehead and 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.

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510(K) Summary

1. Submitter's Information

Establishment Registration Information

Name: HeTaiDa Technology Co., Ltd
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Date prepared: December 8, 2020

2. Device Information

Type of 510(k) submission:	Traditional
Device Common Name:	Clinical electronic thermometer
Trade Name:	Infrared Body Thermometer
Model:	HTD8222US
Regulation name:	thermometer, electronic, clinical
Review Panel:	General Hospital
Product Code:	FLL
Regulation Class:	II
Regulation Number:	880.2910
510(K) number:	K200781

3. Predicate Device Information

Predicate Device #1:

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

Predicate Device #2:
510(k) submitter/holder: Exergen Corporation
510(K) Number: K011291
Trade name: TemporalScannerThermometer
Review Panel: General Hospital
Product Code: FLL
Regulation Class: II
Regulation Number: 880.2910

Predicate Device #3:
510(k) submitter/holder: KAZ USA, Inc (a Subsidiary of Helen of Troy, Inc)
510(K) Number: K152748
Trade name: Braun Thermoscan® PRO 6000 Ear Thermometer
Review Panel: General Hospital
Product Code: FLL
Regulation Class: II
Regulation Number: 880.2910

4. Device description

Infrared Body Thermometer, model: HTD8222US, is a hand-held, battery powered, infrared thermometer that measures human body temperature through the opening of the auditory canal or on forehead, by measuring the infrared energy emitted in the area around the user's forehead or tympanic membrane and adjacent surfaces when placed within 1~5 centimeter of the subject's forehead or insert into auditory canal. The Infrared Body Thermometer uses a thermopile sensor with integrated thermistor for the target reading, a thermistor mounted in the head of the thermometer for ambient temperature readings, a parabolic mirror to help focus the infrared energy emitted from the forehead or tympanic membrane and the adjacent surfaces for detection of non-contact use and contact use and compensation of the temperature reading.

The Infrared Body Thermometers measure temperature by pressing the On/Scan 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 be appeared on a LCD display. The total operation takes a few seconds.

The device can measure temperature with three modes, forehead mode, forehead scan mode and ear mode.

Both forehead mode and forehead scan mode modes are non-contact with human body and measure forehead temperature. The forehead mode measures temperature from middle of the forehead, forehead scan mode measures temperature by scan the forehead from left to right or from right to left with position light spot following within approximately 3~10 seconds, then the maximum temperature will display on the screen.

The ear mode of Infrared Body Thermometer measure temperature by reading infrared radiation emitting from the eardrum tissue. After removing the probe covering cap, the small cone-shape end of the thermometer is inserted into the ear canal, where the eardrum (tympanic membrane) and surrounding tissues emit IR radiation.

Principle of operation:

Infrared Body Thermometer, model: HTD8222US, is a hand-held, battery powered, infrared thermometer that measures human body temperature through the opening of the auditory canal or on forehead, by measuring the infrared energy emitted in the area around the user's forehead or tympanic membrane and adjacent surfaces when placed within 1~5 centimeter of the subject's forehead or insert into auditory canal. 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.

5. Indications for Use

The Infrared Body Thermometer, Model: HTD8222US, is an electronic clinical thermometer using an infrared sensor for the intermittent determination of body temperature from the forehead and auditory canal in people of all ages for home setting use.

6. Comparison of technological characteristics with the predicate devices (K163516, K011291 and K152748)

SE Comparisons	**Subject device K200781 (Infrared Body Thermometer, model: HTD8222US)**	**Predicate device #1 (K163516, Infrared Thermometer, Model: Braun No Touch + Forehead NTF3000 Thermometer)** (compared with Forehead mode of HTD8222US)	**Predicate device #2 (K011291, TemporalScanner Thermometer)** (compared with Forehead scan mode of HTD8222US)	**Predicate device #3 (K152748, Braun Thermoscan® PRO 6000 Ear Thermometer)** (compared with ear mode of HTD8222US)	**Discussion of difference**
Classification	21CFR 880.2910	21CFR 880.2910	21CFR 880.2910	21CFR 880.2910	**Same**
Product Code	FLL	FLL	FLL	FLL	**Same**
FDA Class	II	II	II	II	**Same**
Indications for Use	The Infrared Body Thermometer, Model: HTD8222US, is an electronic clinical thermometer using an infrared sensor for the intermittent determination of body temperature from the forehead and auditory canal 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.	A non-sterile, re-useable clinical thermometer intended for the intermittent determination of the human's body temperature for people of all ages	**Same**
Principle of operation	Measure temperature by reading infrared	Measure temperature by reading infrared radiation	Measure temperature by reading infrared	Measure temperature by reading infrared	**Same**

	radiation emitting from the forehead tissue or tympanic membrane and adjacent surfaces when the thermometer is placed within few centimeters of forehead or inserted into auditory canal.	emitting from the forehead tissue when the thermometer is placed within few centimeters of forehead.	radiation emitting from the forehead tissue when the thermometer is placed within few centimeters of forehead.	radiation emitting from tympanic membrane and adjacent surfaces when the thermometer is inserted into auditory canal.	
target population	people of all ages	people of all ages	people of all ages	people of all ages	**Same**
Measurement site 1	Forehead	forehead	forehead	NA	**Same** Predicate 3 has no forehead mode, the subject device is compared with predicated devices 1 and 2 for this technical item, and shows same with predicated devices 1 and 2. Since modes work not at the same time, The difference will not affect the determination of substantial equivalence
Measurement site 2	ear	NA	NA	ear	**Same** Predicate 1 and 2 has no ear mode, the proposed device is compared with predicated device 3 for this technical item, and shows same with predicated device 3. Since modes work not at the same time, the difference will not affect the determination of substantial equivalence

Type of thermometer	intermittent	intermittent	intermittent	intermittent	**Same** All three predicate device declare they are intended for intermittent measurement of human body temperature which is indicated in the intended use/ Indications for Use of 510(K) summary.
Material of Patient contact components	ABS	NA, not contact with Patient body	ABS	Common Materials- including an impact resistant casing. Biocompatible metals and resins.	**Similar** 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 determination of substantial equivalence
Biocompability	Nature of body contact category: Surface Contact class: A (<24 h) **User and patient contacting material** Button:ABS757 (green) LCD screen: PMMA (transparent) Shell: ABS757 (white) Meets ISO 10993-5 and ISO 10993-10	Nature of body contact category: Surface Contact class: A (<24 h) **User contacting material** housing / handle and power button: ABS temperature button and nose/forehead touch bumper: TPR Meets ISO 10993	Nature of body contact category: Surface Contact class: A (<24 h) **User and patient contacting material** ABS Not public	Nature of body contact category: Surface Contact class: A (<24 h) **User and patient contacting material** Common Materials- including an impact resistant casing. Biocompatible metals and resins. Meets ISO 10993-5 and ISO 10993-10	**Similar** Since 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 determination of substantial equivalence
Environment	home	home	home	home	**Same**
Design	Handheld	Handheld	Handheld	Handheld	**Same**
Measurement method	Infrared radiation detection	Infrared radiation detection	Infrared radiation detection	Infrared radiation detection	**Same**

Display Type	LCD	LCD	LCD	LCD	**Same**
Measurement mode	Forehead mode/ Forehead scan mode/ ear mode	No touch way	Forehead scan	ear mode	**Same**
Key	One button(ON/Scan button)	Two buttons(Power button, Temperature button)	One button (SCAN Button)	Four buttons (Measure button C/F button Memory button Timer button)	**Similar** The different button number will not affect the determination of substantial equivalence
Scale selection	°C/°F	°C/°F	°C/°F	°C/°F	**Same**
Display unit	°C/°F	°C/°F	°C/°F	°C/°F	**Same**
High temperature warning	Yes	Yes	Yes	No	**Similar** The existed difference will not affect the determination of substantial equivalence
Low battery indicator	Yes	Yes	Yes	Yes	**Same**
User contacting material	Button:ABS757 (green) LCD screen: PMMA (transparent) Shell: ABS757 (white)	housing / handle and power button: ABS temperature button and nose/forehead touch bumper: TPR	ABS	Common Materials- including an impact resistant casing. Biocompatible metals and resins.	**Similar** Since 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 determination of substantial equivalence
Sensor Type	Thermopile	Thermopile	Thermopile	Thermopile	**Same**
Performance	Meets ASTM E1965	Meets ASTM E1965-98	Meets ASTM E1965-98	Meets ASTM E1965-98	**Same**
Electrical Safety	ANSI AAMI ES60601-1	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	IEC 60601-1-2	**Same**
Measuring Range (forehead mode)	34.0°C ~ 43.0°C	34.4~42.2°C	NA	NA	**Similar** The proposed device meets ASTM E1965-98, ISO

					80601-2-56 and the difference does not affect the determination of substantial equivalence.
Measuring Range (forehead scan mode)	34.0°C ~ 43.0°C	NA	15.5 to 42°C	NA	**Similar** The proposed device meets ASTM E1965-98, ISO 80601-2-56 and the difference does not affect the determination of substantial equivalence.
Measuring Range (ear mode)	34.0°C ~ 43.0°C	NA	NA	20.0 to 42.2°C (68 to 108°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℃)	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 34.0°C ~ 34.9°C and 42.1°C ~ 43.0°C	±0.2°C (0.4°F) within 35~42°C (95~107.6°F), ±0.3°C (0.5°F) for 34.4°C ~ 34.9°C and 42.1°C ~ 42.2°C	±0.2°C (0.4°F) within 35~42°C (95~107.6°F), ±0.3°C (0.5°F) for 34.0°C ~ 34.9°C and 42.1°C ~ 43.0°C	±0.2°C (0.4°F) within 35~42°C (95~107.6°F), ±0.3°C (0.5°F) for 20.0°C ~ 34.9°C and 42.1°C ~ 42.2°C	**Same**
Measure time	≤2S for Forehead mode; 3~10s for Forehead scan mode; ≤5s for ear mode.	≤2S	Seconds	2~3 Seconds	**Similar** The Measure time will not affect the determination of substantial equivalence
Color Indication	Green: ≥ 35.8°C - 37.4 °C (96.2°-99.4°F) Yellow: ≥ 37.5°C-38.5°C (99.5°F - 101.3°F)	Green: > 35.7°-37.4 °C (> 96.3° - 99.4 °F) Yellow: > 37.4° - 38.5 °C (> 99.4° - 101.3 °F)	NA	NA	**Similar** The Color Indication will not affect the determination of substantial equivalence

	Orange: ≥ 38.6 - 43.0°C (101.4 - 109.4°F)	Red: > 38.5° - 42.2 °C (> 101.3° - 108.0 °F)			
Measuring Distance	1 CM -5CM	1 CM -5CM	0 CM	0 CM	**Similar** The Measuring Distance of proposed device is validated and this existed difference will not affect the determination of substantial equivalence
Power source	DC3.0V X1 (CR2032)	Two (2) AA batteries	9 volt Alkaline	Two AA Alkaline Batteries	**Similar** The proposed device was demonstrated electromagnetic compatility and electrical safety by the testing. The difference does not affect the determination of substantial equivalence.
Expected battery life	More than 1000 measurements	at least 1000 measurements	Approximately 7,500 readings	1000 measurements	**Similar** The proposed device equipped with function of “Low battery warning”, when the battery is too low, there is a “MESSAGE” display on device screen, it prompts the user to change a new battery, therefore, the difference of battery capacity will not affect the determination of substantial equivalence.
Clinical accuracy (forehead mode)	Clinical bias: 0.14°C/0.15°C/0.15°C with Uncertainty: ±0.14/±0.15/±0.14 for group I/II/II Clinical repeatability:	Not public	NA	NA	**Different** The information of predicate device is not public, can be compared, however, according to ASTM E1965-98,the clinical biases, uncertainties and Repeatability of ear mode

	0.12 °C (Calculated per ASTM E:1965-98)				of proposed device are sufficiently small and acceptable which will not affect the determination of substantial equivalence even though any difference existed.
Clinical accuracy (forehead scan mode)	Clinical bias: 0.16°C/0.15°C/0.14°C with Uncertainty: ±0.10/ ±0. 09/ ±0.09 for group I/II/II Clinical repeatability: 0.12 °C (Calculated per ASTM E:1965-98)	NA	Meets ASTM E1965-98 and EN60601-1 standards for electronic and radiation thermometers to the extent applicable to thermometers which measure the surface of the skin over the temporal artery.	NA	**Similar** The clinical biases, uncertainties and Repeatability of ear mode of proposed device are sufficiently small and acceptable and meet the requirement of ASTM E1965-98. Therefore, the difference existed will not affect the determination of substantial equivalence.
Clinical accuracy (ear mode)	Clinical bias: 0.12 °C/0.10/0/10 with Uncertainty: ± 0.12 °C/ ± 0.14 °C/ ± 0.14 °C for group I/II/II Clinical repeatability: 0.12 °C (Calculated per ASTM E:1965-98)	NA	NA	Clinical bias: 0.09 °C Limits of agreement: 0.58 °C Clinical repeatability: 0.19 °C (Calculated per ASTM E:1965-98) (less than the standard < 0.3 °C (0.57 °F)	**Similar** These clinical biases, uncertainties and Repeatability of ear mode of proposed device are sufficiently small and acceptable. The difference existed will not affect the determination of substantial equivalence.
Dimensions of the auditory probe	Short radius: 3.6mm Length radius: 7mm High: 23.31mm	NA	NA	Not public	**Different** Since the performance and safety of ear mode of the proposed device are validated, the difference existed will not affect the determination of substantial

					equivalence.
Operating condition	10°C ~40°C (50~104°F)	15~40°C (59~104°F)	15.5~40°C (60~104°F)	10~40 °C (50~104 °F)	**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.
Storage conditions	Temp.: -20-55°C Relative Humidity: ≤ 95% Atmospheric pressure:70-106Kpa	Temperature range: -25 °C to 60 °C; Humidity range: 15- 95% Atmospheric pressure range: 700-1060hPA;	Temperature range: -20 °C to 50 °C; Humidity range: ≤ 95% Atmospheric pressure range: Not public	Temperature range: -25 °C to 55 °C; Humidity range: 15-95% Atmospheric pressure range: Not public	**Similar** The storage condition of subject device has passed the safety test, and the Instructions for Use provides the storage 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:

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, ISO 10993-5 and ISO 10993-10 for Biocompability 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
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 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 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

Guidance Documents included:
1. FDA Guidance On The Content of Premarket Notification 510(k) Submissions for Clinical Electronic Thermometers.

2. Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff, May 2005.

3. General Principles of Software Validation; Final Guidance for Industry and FDA Staff, January 2002.

8. Clinical Accuracy Testing:
The clinical investigation report and data analysis followed the requirements of the ASTM E

1965-98 (2016).

The clinical tests evaluated 140 of subjects. Each mode was evaluated in 0 up to one year, older than 1 year and younger than 5 years, and older than 5 years age groups. The clinical performance test protocol and data analysis is conducted as the requirement of ASTM E1965-98 (2016). The test report showed the clinical performance of the subject device complied with the requirement of ASTM E1965-98 (2016).

9. Conclusions

Infrared Body Thermometer, model HTD8222US, has the same intended use and similar characteristics with the predicate device. Based on performance testing and compliance with standards demonstrate that the subject device Infrared Body Thermometer, model HTD8222US performs comparably to the predicate device that is currently marketed for the same intended use.