May 4, 2021

HeTaiDa Technology Co., Ltd.
Karen Ren
Official Correspondent
4F, BaiShiDa High-Tech Park, XiangDong Industrial Area
DaLingShan Town
DongGuan City, Guangdong 523820
China

Re: K203332
Trade/Device Name: Non-contact Infrared Body Thermometer, Model HTD8808C, HTD8818A, HTD8816C
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical electronic thermometer
Regulatory Class: Class II
Product Code: FLL

Dear Karen Ren:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated February 25, 2021. Specifically, FDA is updating this SE Letter due to a typo in the applicant name as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Payal Patel, OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices, (240) 402-6029, payal.patel@fda.hhs.gov.

Sincerely,

James M. Simpson Jr -S7

for Payal Patel
Acting Assistant 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

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Re: K203332
Trade/Device Name: Non-contact Infrared Body Thermometer, Model HTD8808C, HTD8818A, HTD8816C
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: January 22, 2021
Received: January 26, 2021

Dear Karen Ren:

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.

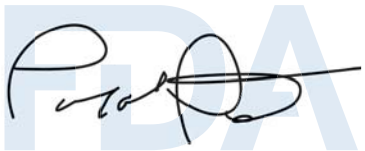
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

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,



Payal Patel
Acting Assistant Director
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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)*

K203332

Device Name

Non-Contact Infrared Body Thermometer HTD8818A, HTD8816C, and HTD8808C

Indications for Use *(Describe)*

The HeTaiDa electronic thermometers HTD8818A, HTD8816C, HTD8808C are infrared thermometers which use infrared sensor to detect human body temperature of patients of all ages. It is intended to be used on one's forehead to detect body temperature. The HTD8818A, HTD8816C, HTD8808C are intended for use in home and clinical environment.

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

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

1. Submitter's Information

1.1 Contact person of Applicant

Name:	HeTaiDa Technology Co., Ltd
Address:	4F, BaiShiDa High-Tech Park, XiangDong Industrial Area, DaLingShan Town, DongGuan City, Guangdong, China.
Phone No:	+86 769-82658050
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Contact Person:	Tom Chen
Email	tomchen@hetaida.com.cn

1.2 Contact person of the submission

Name:	HeTaiDa Technology Co., Ltd
Address:	4F, BaiShiDa High-Tech Park, XiangDong Industrial Area, DaLingShan Town, DongGuan City, Guangdong, China.
Phone No:	+86 769-82658050
Fax No:	+86 769-82658050
Contact Person:	Karen Ren
Email	Hetaida10@hetaida.com.cn
Date Summary Prepared:	July 31th, 2020

2. Device information

Type of 510(k) submission:	Special
Device Common Name:	Clinical electronic thermometer
Name:	Non-contact Infrared Body Thermometer
Model	HTD8808C, HTD8818A, HTD8816C
510(k) number	K203332
Classification name:	thermometer, electronic, clinical
Product Code:	FLL
Regulation Class:	II

Regulation Number:	880.2910

3. Predicate Device(s)

Manufacturer	Predicate Device	510(k) number
Hetaida Technology Co., Ltd.	Non-contact infrared Body thermometer	K171888

4. Device Description

The HeTaiDa infrared body thermometer, Models HTD8818A，HTD8816C，HTD8808C are hand-held device powered by batteries and designed to measure human body temperature without contacting patient's forehead. The thermometer can switch modes between "Body Mode" and "Surface Mode". The "Surface Mode" is DIRECT MODE and the "Body Mode" is ADJUSTED MODE. Forehead temperature of the ADJUSTED MODE is calculated by converting the measured temperature of the DIRECT MODE to an axillary equivalent temperature without contacting the patients' forehead.

This submission is to notify that a legally marketed device (predicate) are modified by extending output range of body mode to 34℃~43℃,operating mode to 15℃~40℃, deleting offset parameter settings, shelf-life change from 3 years to 5 years.

5. Indication for Use.

No changes to the indication for use are proposed by this submission. The indication for Use are as follows:

The HeTaiDa electronic thermometers HTD8818A, HTD8816C, HTD8808C are infrared thermometers which use Infrared sensor to detect human body temperature of patients of all ages, It is intended to be used on one's forehead to detect body temperature. The HTD8818A, HTD8816C, HTD8808C are intended for use in home and clinical environment.

6. Comparison of Technological Characteristics

The modified HeTaiDa HTD8818A, HTD8816C and HTD8808C thermometers expand the measurement range of body mode from 34℃~42.9℃ to 34℃~43.0℃, operating temperature from 15℃~35℃ to 15℃~40℃, deleting offset parameter settings compared with unmodified HTD8818A, HTD8816C and HTD8808C thermometers. No changes have been made to the device's indications for use, intended use, algorithm or fundamental scientific technology as a result of the modification that has prompted this submission.

Substantial Equivalence Comparison Table

Element of Comparison	Subject device(s)	Predicate device(s)	Comparison
Type of Thermometer	Non-Contact Infrared body thermometer	Non-Contact Infrared body thermometer	Identical
Model	HTD8818A，HTD8816C，HTD8808C	HTD8818A，HTD8816C，HTD8808C	/

510(K)	K203332	K171888	/
Principles of operation	Based on Infrared Sensor technology. The IR sensor can output different signal when measuring different object temperature or in different ambient temperature, and the ASIC can turn the signal from IR Sensor to a digital value and display it on the LCD.	Based on Infrared Sensor technology. The IR sensor can output different signal when measuring different object temperature or in different ambient temperature, and the ASIC can turn the signal from IR Sensor to a digital value and display it on the LCD.	Identical
Indication for Use	The HeTaiDa electronic thermometers HTD8818A, HTD8816C, HTD8808C are infrared thermometers which use Infrared sensor to detect human body temperature of patients of all ages, It is intended to be used on one's forehead to detect body temperature. The HTD8818A, HTD8816C, HTD8808C are intended for use in home and clinical environment.	The HeTaiDa electronic thermometers HTD8818A, HTD8816C, HTD8808C are infrared thermometers which use Infrared sensor to detect human body temperature of patients of all ages, It is intended to be used on one's forehead to detect body temperature. The HTD8818A, HTD8816C, HTD8808C are intended for use in home and clinical environment.	Identical
labeling	Instructions for use, package, and label	Instructions for use, package, and label	Identical
components	Power / temperature measurement button, Mode button, Memory button, Set button, sensor, microcontroller, & LCD	Power / temperature measurement button, Mode button, Memory button, Set button, sensor, microcontroller, & LCD	Identical
Sensor	The thermometer uses an infrared thermopile sensor with integrated thermistor mounted in the head of the thermometer for the target reading and ambient temperature reading	The thermometer uses an infrared thermopile sensor with integrated thermistor mounted in the head of the thermometer for the target reading and ambient temperature reading	Identical
Power Supply	Two (2), AAA batteries	Two (2), AAA batteries	Identical
Materials	User contacting materials include ABS (device housing / handle, power / temperature button, memory button, mode button). Patient contact materials: None as non-contact with patient	User contacting materials include ABS (device housing / handle, power / temperature button, memory button, mode button). Patient contact materials: None as non-contact with patient	Identical

Biocompatibility	1. Type of contact: direct contact for users, non-contact for patients. 2. Nature of body contact category: Surface Contact class: A (<24 h) 3. Meets ISO 10993-5 and ISO 10993-10	1. Type of contact: direct contact for users, non-contact for patients. 2. Nature of body contact category: Surface Contact class: A (<24 h) 3. Meets ISO 10993-5 and ISO 10993-10	Identical
Operating environment	Temperature: 15℃~40℃ R.H.: ≤85%for HTD8808C, HTD8816C, ≤95% for HTD8818A 700-1060 hPA	Temperature: 15℃~35℃ R.H.: ≤85% 700-1060 hPA	Similar The operating temperature environment of the subject and devices have pass ISO80601-2-56 and IEC60601-1-11 test, meet these performance standards. and the difference does not affect the determination of substantial equivalence.
Storage environment	-20°C -55°C / -4 °F - 131°F, ≤93% R.H. for HTD8808C, HTD8816C, -25°C -55°C / -13 °F - 131°F, ≤95% R.H. for HTD8818A 700-1060 hPA	-20°C -55°C / -4 °F - 131°F, ≤93% R.H.; 700-1060 hPA (0.7-1.06 atm)	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.
Display resolution	0.1℉/0.1℃	0.1℉/0.1℃	Identical
Measurement Range	34℃~43.0℃	34℃~42.9℃	Technological characteristics are similar

Accuracy	34.0℃~34.9℃:±0.3℃/ 93.2°F - 94.8°F:±0.5°F; 35.0 ℃~42.0 ℃:±0.2 ℃/95.0°F - 107.6°F:±0.4°F; 42.1℃~43.0℃:±0.3℃/107.8°F - 109.4°F: ±0.5°F;	34.0℃~34.9℃:±0.3℃/ 93.2°F - 94.8°F:±0.5°F; 35.0℃~42.0℃:±0.2℃/95.0°F - 107.6°F:±0.4°F; 42.1℃~42.9℃:±0.3℃/107.8°F -109.2°F: ±0.5°F;	Technological characteristics are similar
Response time	≤2 seconds	≤2 seconds	Identical
Feature	Memory capacity： 50 readings for HTD8808C, HTD8816C, 10 readings for HTD8818A	Memory capacity ： 50 readings	Similar, the difference does not affect the determination of substantial equivalence.
	Parameter setting： F1-Unit F2-Fever alert setting F3-Sound on/off setting for HTD8808C and HTD8816C, Unit setting/Prompt Sound on/off setting for HTD8818A	Parameter setting: F1-Unit F2-Fever alert setting F3-Sound on/off setting F4- Overall temperature offset	Similar, the difference does not affect the determination of substantial equivalence.
Fundamental technology	Infrared technology that converts a user's forehead temperature using the infrared energy emitted in the area around the user's forehead to a reference site equivalent temperature.	Infrared technology that converts a user's forehead temperature using the infrared energy emitted in the area around the user's forehead to a reference site equivalent temperature.	Identical
Performance	Meets ISO 80601-2-56:2017	Meets ISO 80601-2-56:2009	Substantially Equivalent
Electrical Safety	Meets ANSI / AAMI / IEC 60601-1:2012	Meets ANSI / AAMI / IEC 60601-1:2012	Substantially Equivalent
EMC	Meets IEC 60601-1-2:2014	Meets IEC 60601-1-2:2014	Substantially Equivalent
Shelf life	5 years	3 years	Substantially Equivalent

7. Substantial Equivalence – Non-Clinical Evidence

The modifications to the device have been designed and assessed under design control processes compliant with FDA 21 CFR 820. Non-clinical testing has been performed todemonstrate that the safety and efficacy of the device remains substantially equivalent to its predicate.

Model	Bench Tests	Standards	Results	Report File No.
HTD8818A HTD8808C HTD8816C	General requirements for basic safety and essential performance	IEC 60601-1:2005 (Third Edition) + CORP. 1:2006 + CORP. 2:2007	Pass	GZME180100000901
	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	IEC 60601-1-11: 2015	Pass	GZME180100000902
	General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic compatibility	IEC 60601-1-2:2014	Pass	GZME180100001001
	Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement	ISO 80601-2-56:2017	Pass	GZME180100000903
	Medical device software - Software life-cycle processes	IEC 62304：2006+A1:2015	Pass	ZHTF-CE-01-006

Design control activities summary Table

Device Change	Risks	Verification/Validation Method(s)	Acceptance Criteria	Summary of Results
Parameters Information on labeling change	The parameters information on labeling doesn't update on time, that would make user error operation	Labeling and User manual are checked according to IEC 60601-1 clause 7.9 Accompany documents, IEC60601-1-11 clause 7.4 instructions for use, IEC60601-1-2 for EMC declaration, ISO 80601-2-56:2017 clause 201.7.9 Accompany document. Please refer to Appendix 6 and Appendix 7	All applicable items for the devices shall meet the requirements.	All the changes have been added on labeling
Operating environment change	Inaccuracy reading to delay in patient treatment in extended environment	1.Environmental operating conditions-continuous operating conditions test was done by SGS laboratory according to IEC 60601-1-11:2015 Please refer to Appendix 6 2. Clinical accuracy test based on the change was done, which is compliance with ASTM E1965-98 Please refer to Appendix 11	1. Device comply with its specifications and all requirements of standard when operated in normal use within Temperature. 2. The bias of the test thermometer is non-inferior to the bias of the predicate thermometer when compared to the reference thermometer. The repeatability for the test article is less than or equal to ± 0.3°C.	1. The accuracy of laboratory under operating environment were with ±0.3℃ 2. The clinical bias is equal to 0.05°C/0.07° C/-0.04°C with uncertainty of ±0.20/±0.19/±0.18 respectively for group I (Infants), group II (children) and group III (adults). The "Repeatability" is: 0.13. It's considered reasonably small and not to pose a problem for diagnostic purposes.
Storage environment change for HTD8818A	-Inaccuracy reading to delay in patient treatment after storage -Damage to device, device couldn't work.	Environmental transportation and storage test was done by SGS laboratory according to IEC 60601-1-11:2015 Please refer to Appendix 6	Device allowed to return and stabilize at operation conditions of normal use, and provides basic safety and essential performance	After storage with lowest condition and highest condition of transportation and storage, basic safety and essential performance met the requirements of devices.

Measurement Range change	-Inaccuracy reading to delay in patient treatment in extended range, but very low risk as very minor change from 34-42.9℃ to 34-43.0℃, and very low possibility to have high temperature for human	1. Laboratory accuracy test for lower limit and upper limit of measurement range under five different environments combined upper and lower limits of environmental temperature and humidity were done, which is compliance with ISO 800601-2-56:2017 Please refer to Appendix 8 2. Clinical accuracy test based on the change was done, which is compliance with ASTM E1965-98 Please refer to Appendix 11	1. Laboratory accuracy for lower limit and upper limit of measurement range under five different environments shall be within ±0.3℃ 2. The bias of the test thermometer is non-inferior to the bias of the predicate thermometer when compared to the reference thermometer. The repeatability for the test article is less than or equal to ± 0.3°C.	1. The accuracy of laboratory under operating environment were with ±0.3℃ 2. The clinical bias is equal to 0.05° C/0.07°C/-0.04°C with uncertainty of ±0.20/±0.19/±0.18 respectively for group I (Infants), group II (children) and group III (adults). The "Repeatability" is: 0.13. It's considered reasonably small and not to pose a problem for diagnostic purposes.
Temperature range for Accuracy change	-Inaccuracy reading to delay in patient treatment in extended range,	Laboratory accuracy test for lower limit and upper limit of measurement range under five different environments combined upper and lower limits of environmental temperature and humidity were done, which is compliance with ISO 800601-2-56:2017 Please refer to Appendix 8	Laboratory accuracy for lower limit and upper limit of measurement range under five different environments shall be within ±0.3℃	The accuracy of laboratory under operating environment were with ±0.3℃
Feature: Memory change	Decreasing memory size doesn't impact the safety and effectiveness of medical device, so no risk	According to procedure of IEC62304:2015, software was verified and validated from risk analysis, flowchart of procedure, unit testing, integrated testing and system testing. Please refer to Appendix 9 software verification report	The device shall perform right functions, and don't introduce any bug.	The devices perform right functions, and don't introduce any bug.

Feature: parameter setting change	The function isn't related with basic performance, deleting the function doesn't impact the safety and effectiveness of medical device, so no risk	According to procedure of IEC62304:2015, software was verified and validated from risk analysis, flowchart of procedure, unit testing, integrated testing and system testing. Please refer to Appendix 9 software verification report	The device shall perform right functions, and don't introduce any bug.	The devices perform right functions, and don't introduce any bug.
Shelf life change	-The device damage or couldn't work in the prolonged shelf life	Using accelerated aging test to verify the shelf life: 1.Placed samples in the chamber with75℃ and 93%RH condition for 48Hours, then take them out, placed them in the normal working condition for 24 hours for check, that called a cycle 2.Start the second cycle once the first cycle is finished 3. Repeated this cycle until the device some of its function fails work or reaches the former expected life time. Then test is over. Please refer to Appendix 10 Shelf life validation report	All the functions and performance shall meet the requirements after each cycle in the expected shelf-life.	The test from July 3rd, 2017 to October 20th, 2017, totally 107 days and 22 cycles, Total test time is 2112 hours, the accelerated aging test time is 1056 hours under 75℃, 93%RH condition, the life is 5 years after calculation.

8. Substantial Equivalence – Clinical Evidence

The design of the submitted device specifications is substantially the same as the predicate, with minor difference in the measurement range, operating temperature and humidity range, and storage temperature and humidity range. Clinical evidence was not necessary to demonstrate substantial equivalence.

9. Conclusion

The HeTaiDa non-contact infrared body thermometers HTD8818A, HTD8816C and HTD8808C with changes described have similar intended use, principle of operation, and similar technological characteristics as the predicate device identified. The risk analysis and performance testing contained in this submission demonstrates the minor differences in technological characteristics between the subject device and the predicate do not raise different questions of safety and effectiveness. And we have verified that the mitigations based on risk analysis. Thus, in accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part807 and based on the information provided in this premarket notification, HeTaiDa Technology Co., Ltd. concludes that the Infrared Forehead Thermometers HTD8818A, HTD8816C, HTD8808C with changes described in this premarked notification are substantially equivalent to predicate device.