5. 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.

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1. Company making the submission:
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3. Device Name: Non-contact Infrared Body Thermometer
   Trade name: HeTaiDa-Thermometer
   Models: HTD8818A，HTD8816C，HTD8808C
   Common Name: Clinical electronic thermometer
   Classification Name: Thermometer, electronic, clinical
   Regulatory Class: II
   Product Code: FLL
   Type of 510(k) submission: Traditional

4. Predicate Device.

Manufacturer	**Predicate Device**	**510(k) number**
Hangzhou Universal Electronic Co., Ltd.	Non-contact infrared Body thermometer FT-100A	K160802

5. 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' 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.

The thermometers HTD8818A, HTD8816C and HTD8808C infer temperature from the blackbody radiation emitted from the patient. Temperature is calculated from the knowledge of the amount of infrared energy emitted from the human body. The thermometer design consists lens to focus the infrared thermal radiation on to a detector, which converts the radiant power to an electrical signal that can be displayed in units of temperature. This permits temperature measurement from a distance without contact with the object to be measured.

The three models HTD8818A，HTD8816C，HTD8808C are bundled in this one 510k submission based on the Guidance for Industry and FDA Staff: Bundling Multiple Devices or Multiple Indications in a Single Submission. The HTD8818A，HTD8816C，HTD8808C thermometers present scientific and regulatory issues that can be addressed during one review. Their indications for use, safety and performance data, biocompatibility, clinical evaluation data, and electromagnetic compatibility data are identical. The only differences among the HTD8818A，HTD8816C，HTD8808C thermometers are size, weight, shape of enclosure, printed circuit board (PCB) layout and measuring distances.

6. Indication for use.
The HeTaiDa non-contact infrared body thermometers HTD8818A，HTD8816C，HTD8808C are non-sterile, reusable thermometers intended for the intermittent determination of human body temperature measured at the patients' forehead without contact. The devices are intended for use on people of all ages. The HTD8818A，HTD8816C，HTD8808C are intended for use in clinical and home use environment.

7. Similarities/Differences between the subject and predicate device.

Element of Comparison	**Subject Device(s)**	**Predicate Device**	**Comparison**
Type of Thermometer	Non-Contact Infrared forehead thermometer (Models: HTD8818A HTD8816C HTD8808C)	Non-contact Infrared forehead thermometer, (model: FT-100A)	Identical

510(k)	N/A	K160802	N/A
Indication for Use	The HeTaiDa electronic thermometers HTD8818A, HTD8816C and 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 forehead to detect body temperature. The HTD8818A, HTD8816C and HTD8808C are intended for use in the clinical and homecare environment.	The FT-100A Electronic thermometer is an infrared thermometer which uses an infrared sensor to detect human body temperature of patients of all ages. It is intended to be used on forehead to detect body temperature. The FT-100A is intended for home and clinical use.	Identical
Temperature unit	ºC or ºF	ºC or ºF	Identical
Measurement Range	Forehead: 34°C to 42.9°C (93.2°F to 109.2°F) Surface (Object): 0°C to 100°C (32°F to 212°F)	Forehead: 32°C to 43°C (89.6°F to 109.4°F) Object: 0°C to 100°C (32°F to 212°F)	Similar
Operating Temperature	15°C to 35°C (59°F to 95°F)	16°C to 40°C (60.8°F to 104°F)	Similar
Operating humidity	85% RH or less	95% RH or less	Similar
Storage temperature	-20ºC to 55ºC (-4ºF to 131ºF)	-25ºC to 55ºC (-13ºF to 131ºF)	Similar
Storage humidity	93% RH or less	95% RH or less	Similar
Accuracy	FOR BODY MODE: 34.0~34.9℃: ±0.3℃ (93.2-94.8°F: ±0.5°F); 35.0~42.0℃: ±0.2℃ (95.0-107.6°F: ±0.4°F); 42.1~42.9℃: ±0.3℃ (107.8-109.2°F: ±0.5°F); FOR SURFACE MODE: ± 2°C (± 3.6 °F)	FOR BODY MODE: ±0.2°C (±0.4°F) from 36.0°C (96.8°F) to 39.0°C (102.2°F); ±0.3°C (±0.54°F) from 32.0°C (89.6°F) to 35.9°C (96.6°F) and from 39.1°C (102.4°F) to 43.0°C (109.4°F) FOR OBJECT MODE:	Technological characteristics are similar

		± 4°C (±7.2°F) from 0°C (32°F) to 4.9°C (40.8°F) ± 1°C (±2°F) from 5°C (40.8°F) to 60°C (140°F) ± 4°C (±7.2°F) from 60.1°C (140.1°F) to 100°C (199.9°F)	
Memory capacity	50 measurements	20 measurements	Technological characteristics are similar
Power down time	18s or less	1 min	Similar
Battery type	1.5V AAA x 2	1.5V AAA x 2	Identical
LCD Backlight	Available	Available	Identical
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
Display resolution	0.1°C/0.1°F	0.1°C/0.1°F	Identical

8. Comparison of Technological Characteristics with Predicate Device.

The technological characteristics of the HeTaiDa HTD8818A, HTD8816C and HTD8808C thermometers and the predicate device (FT-100A) are similar. Both convert user's forehead temperature using the infrared energy emitted in the area around the user's forehead to a reference site equivalent temperature. The differences between the HeTaiDa HTD8818A, HTD8816C and HTD8808C thermometers and the predicate device FT-100 do not raise different questions of safety and effectiveness. The HeTaiDa Technology Co., Ltd believes that the non-contact infrared body thermometers HTD8818A，HTD8816C，HTD8808C are substantially equivalent to the (K160802) non-contact infrared body thermometer FT-100A of Universal Electronic Co., Ltd.

9. Safety and Performance Data.

Bench Data are listed in Table as below.

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 + A1:2012	Pass	GZME160 500034301 -01
	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 (First Edition): 2010	Pass	GZME160 500034302 -01
	General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic compatibility	IEC 60601-1-2:2014	Pass	GZME170 100001901
	EMC TEST	CFR 47 FCC Part 15, Subpart B, Class B 2016	Pass	NTC17051 46FV00
	Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement	ISO 80601-2-56:2009 (First Edition) for use in conjunction with IEC 60601-1:2005 (Third edition)	Pass	GZME160 500034303 -01

	Standard specification for infrared thermometers for intermittent determination of patient temperature	ASTM E1965-98 (Reapproved 2009)	Pass	GZME170 100001801

Biocompatibility data are listed in Table as below.

Model	Biocompatibility Tests of Final Finished Device	Standards	Results	Report File No.
HTD8818A HTD8808C HTD8816C	In vitro cytotoxicity with 10% FBS	ISO 10993-5:2009: Biological evaluation of medical devices: part 5: Tests for in vitro cytotoxicity	Pass	SDWH-M201800599-1 (HTD8808C), SDWH-M201800600-1 (HTD8816C), SDWH-M201800601-1 (HTD8818A)
	Skin sensitization 0.9%SC	ISO 10993-10, Biological evaluation of medical device – Part 10: Tests for irritation and skin sensitization.	Pass	SDWH-M201800599-2 and -3 (HTD8808C), SDWH-M201800600-2 and -3 (HTD8816C), SDWH-M201800601-2 and -3 (HTD8818A)
	Skin sensitization Cotton seed oil			
	Skin irritation 0.9%SC	ISO 10993-10, Biological evaluation of medical device – Part 10: Tests for irritation and skin sensitization.	Pass	SDWH-M201800599-4 and -5 (HTD8808C), SDWH-M201800600-4 and -5 (HTD8816C), SDWH-M201800601-4 and -5 (HTD8818A)
	Skin irritation Cotton seed oil			

10. Clinical Data.

A clinical investigation was performed to evaluate the clinical bias, clinical accuracy and clinical repeatability. The four groups of subjects being tested were:

(1) 0 – 3 months, (2) 3 months - 1 year old, (3) 1 – 5 years old, and (4) >5 years older.

Each group of subjects underwent a series of temperature measurement at their forehead using HTD8818A, HTD8816C and HTD8808C non-contact infrared body thermometers. All the subject groups also underwent a series of temperature measurement using a reference contact clinical electronic thermometer BT-21H, which temperatures were measured in the axillary of patients. These temperature measurements were then each compared to the temperature measurements taken by the HeTaiDa non-contact infrared body thermometers. The clinical bias, clinical accuracy and clinical repeatability of the HeTaiDa-thermometers are calculated to be -0.027, ±0.14, and 0.07, respectively, which are within the clinically acceptable range as required by ISO 80601-2-56:2009 and ASTM 1965-68 (Reapproved 2009). These clinical results indicate that the HeTaiDa non-contact infrared thermometers produce effective and accurate temperature measurements.

The design of the submitted device specifications is substantially the same as the predicate, with minor difference in the operating temperature and humidity range, and storage temperature and humidity range.

11. Conclusions.

The HeTaiDa non-contact infrared body thermometers HTD8818A, HTD8816C and HTD8808C have similar intended use, principle of operation, and similar technological characteristics as the predicate device identified. 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. 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 are substantially equivalent to predicate device.

End.