January 22, 2021

Uni-Trend Technology(CHINA) CO.,LTD
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K203656
Trade/Device Name: Non-Contact Forehead Thermometer (UT30H)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical electronic thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: December 7, 2020
Received: December 15, 2020

Dear Dave Yungvirt:

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 M. 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203656

Device Name
Non-Contact Forehead Thermometer, Model: UT30H

Indications for Use *(Describe)*
The Non-Contact Forehead Thermometer (Model: UT30H) is a reusable, infrared thermometer intended for the intermittent measurement of human body temperature on the forehead of people of all ages. It can be used by consumers in the home environment and doctors in the clinic environment as reference.

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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510K summary

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

1. Submitter Information

Sponsor Company Name: UNI-TREND TECHNOLOGY (CHINA) CO.,LTD

- Establishment Registration Number: Applying
- Address: No 6, Gong Ye Bei 1st Road, Songshan Lake National High-Tech Industrial Development Zone, Dongguan City, Guangdong Province, China
- Phone: +86-769 85723888
- Fax: +86-769 85725888
- Contact Person (including title): Mike Mao /Marketing Manager
- E-mail: mike@uni-trend.com.cn

Application Correspondent:

- Company Name: Guangzhou KINDA Biology Technology Co., Ltd.
- Address: 6F, No.1 TianTai road, Science City, LuoGang District, GuangZhou City, China
- Contact Person: Mr. Jet Li/Regulation Manager
- Tel: +86-18588874857
- Email: med-jl@foxmail.com

2. Subject Device Information

Type of 510(k) submission:	Traditional
Common Name:	Clinical Electronic Thermometer
Trade Name:	Non-Contact Forehead Thermometer (UT30H)
Classification Name:	Clinical Electronic Thermometer
Review Panel:	General Hospital
Product Code:	FLL
Regulation Number:	21 CFR 880.2910
Regulation Class:	2

3. Predicate Device Information

Sponsor:	Shenzhen Calibeur Industries Co., Ltd
Common Name:	Clinical electronic thermometer
Trade Name:	Infrared Thermometer (DT-8836T, DT-8836P)
510(k) number:	K191251
Review Panel:	General Hospital
Product Code:	FLL
Regulation Number:	21 CFR 880.2910
Regulation Class:	2

4. Device Description

The Non-Contact Forehead Thermometer (Model: UT30H) is a hand-held, non-sterile, reusable, battery powered device designed to measure human body temperature via body sites: the skin of the forehead.

The Infrared Forehead Thermometer is a battery powered, infrared Thermometer that coverts a user's forehead temperature, using the infrared energy emitted from the area around the user's forehead, to an oral equivalent temperature when placed within 1-5 cm to the subject's forehead with no contact. It uses a thermopile sensor with integrated thermistor for ambient temperature readings.

It composed by a measuring sensor, set buttons, a start button, battery compartment, Buzzer, a LCD and a ABS plastic enclosure, and measuring without probe cover.

The power supply of the thermometer are 3.0V DC, it is supplied by two AAA batteries.

The main functions of Non-Contact Forehead Thermometer are as followings:

- Forehead measure function
- Wide range of temperature readings: from 32.0℃ to 45.0℃（89.6℉-113.0℉）
- The big LCD display showing clear measure result.
- Low battery indicator

5. Indication for use

The Non-Contact Forehead Thermometer (Model: UT30H) is a reusable, infrared thermometer intended for the intermittent measurement of human body temperature on the forehead of people of all ages. It can be used by consumers in the home environment and doctors in the clinic environment as reference.

6. Test Summary

Infrared Thermometer conforms to applicable standards that include:

- ASTM E 1965-98(R)2016 Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature
- AAMI/ANSI ES 60601-1:2005/(R)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 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
- IEC 62304 Edition 1.1 2015-06 Medical Device Software - Software Life Cycle Processes
- IEC60601-1-11:2015 medical electrical equipment - part 1-11: 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
- 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

7. Summary of Clinical Test

The clinical accuracy study for the non-contact thermometer were performed to determine the clinical accuracy. The three groups of subjects being tested were: 1) infant under 1 year old, 2) children between 1 and 5 years old, and 3) patients over 5 years old.

The study included 150 subjects, with More than 30% febrile subjects. For each age group, the ratio of febrile subjects was more than 30%. The study excluded subjects with medical conditions such as inflammation at the measuring sites and subjects using medications known to affect body temperature. From each test site, a total of 150 data sets were collected. The clinical accuracy of the proposed device was evaluated by ISO 80601-2-56 - clinical bias with stated uncertainty and clinical repeatability. The clinical test results showed that the accuracy of the proposed device is within acceptable scope specified in ISO 81061-2-56.

8. Comparison to Predicate Device

Compare with predicate device, the subject device is very similar in design principle, intended use, sensor, measurement mode, measuring range, accuracy and the applicable standards. The differences between subject device and predicate device do not raise and new questions of safety or effectiveness

Elements of Comparison	Subject Device	Predicate Device	Verdict
Manufacturer	UNI-TREND TECHNOLOGY(CHINA) CO.,LTD	Shenzhen Calibeur Industries Co., Ltd.	--
510 (k) Number	Pending	K191251	--
Product Name	Non-Contact Forehead Thermometer	Infrared Thermometer	--
Models	UT30H	DT-8836T, DT-8836P	--
Intended Use	*The Non-Contact Forehead Thermometer (Model: UT30H) is a reusable, infrared thermometer intended for the intermittent measurement of human body temperature on the forehead of people of all ages. It can be used by consumers in the home environment and doctors in the clinic environment as reference.*	The Infrared thermometer is a non-contact infrared thermometer intended for the intermittent measurement of human body temperature from forehead for people of all ages. The device is reusable for home use and clinical use.	SE
Sensor	Infrared Sensor	Infrared Sensor	SE
Measurement Mode	Forehead measurement mode	Forehead measurement mode	SE
Measurement type	Non-contact type	Non-contact type	SE
Measurement Distance	1-5cm	≤3cm	Mirror difference: Note 1
Measuring Range	32.0℃ to 45.0℃ ;	Forehead mode: 32.0° C ~42.5° C (89.6 to 108.5 ° F)	Minor difference Note 2

Elements of Comparison	Subject Device	Predicate Device	Verdict
Accuracy	±0.2℃ /0.4℉ 35. 0℃ -42.0℃ (95.0℉-107.6℉); ±0.3℃ /0.5℉ 32.0℃ -34.9℃ (89.6℉-94.8℉) and 42.1℃ -45.0℃(107.8℉-113.0℉)	Forehead mode: ±0.2°C (0.4°F) within 35.0°C ~ 42.0°C (95.0°F ~ 107.6°F), ±0.3°C(0.5°F) other range	SE
Display Resolution	0.1℃/0.1℉	0.1℃/0.1℉	SE
Signal Output and Display	LCD, Buzzer	LCD	SE
℃/℉ switchable	Yes	Yes	SE
Memory	Last time data for measurement	60 sets	Minor difference Note 3
Power Supply	3.0V DC, offered by o two AAA batteries	Two 1.5V AAA batteries	SE
Low battery indication	Yes	Not identified.	Minor difference Note 4
Operating Conditions	Temperature:15 ℃ -40 ℃ ; Relative humidity: < 90% R.H (non-condensation); Atmospheric pressure: 70-106KPa	10~40°C (50°F ~104 °F) RH 15~95%	Minor difference Note 5
Performance	Compliance with ASTM E 1965; ISO 80601-2-56	Compliance with ASTM E 1965; ISO 80601-2-56	SE

Elements of Comparison	Subject Device	Predicate Device	Verdict
Biocompatibility	All the patient contacting materials are compliance with ISO 10993-5; ISO10993-10 (In Vitro cytotoxicity test, skin irritation, skin sensitization testing)	All the patient contacting materials are compliance with ISO 10993-5; ISO10993-10	SE
Electrical Safety	Compliance with IEC 60601-1	Compliance with IEC 60601-1	SE
EMC	Compliance with IEC 60601-1-2	Compliance with IEC 60601-1-2	SE
Response time	500ms	1s	Minor difference Note 6
Components	It composed by a measuring sensor, set buttons, a start button, battery compartment, Buzzer, a LCD and a ABS plastic enclosure, and measuring without probe cover.	It composed by a measuring sensor, set buttons, a start button, battery compartment, Buzzer, a LCD and a ABS plastic enclosure, and measuring without probe cover.	SE
Materials	ABS for enclosure	ABS for enclosure	SE
Labeling	OTC	OTC	SE

Note 1

There is minor difference for measurement distance, but the subject device clinical accuracy and its performance comply with ISO 80601-2-56 and ASTM E1965. Therefore, this difference does not raise the safety and effectiveness.

Note 2

Although there is minor difference of the measuring range between the subject device and predicate device, the temperature range 32.0℃ to 45.0℃ in subject device is enough for body temperature measurement. And the subject device clinical accuracy comply with ISO 80601-2-56 and ASTM E1965. Therefore, this difference does not raise the safety and effectiveness.

Note 3

Although the memory value of the subject device and predicate device is different, both of them are complied with ASTM E 1965. This difference does not affect the safety and effectiveness.

Note 4

The subject device provided with low battery indicator, it is more helpful for operation and can remind user to replace the battery; and the subject device complied with IEC 60601-1. This difference does not affect the safety and effectiveness.

Note 5

Although Operating environment of the predicate device and subject device is different, but the instruction for use had indicate such operating condition, and the test report ASTM E1965 verifies its performance in such operating condition. The difference does not raise new safety and effectiveness issues.

Note 6

Although there is minor difference of responded time for stable measurement between the predicate device and subject, but the response time do not affect the measurement accuracy and device performance. And the device pass the testing according to ISO 80601-2-56. So the difference does not raise new safety and effectiveness issues.

9. Conclusion

The subject device Non-Contact Forehead Thermometer has all features of the predicate device. The few differences do not affect the safety and effectiveness of the subject device. Thus, the subject device is substantially equivalent to the predicate device.

10. Summary Prepared Date

25 November 2020