December 8, 2021

Honsun (Nantong) Co., Ltd
Iris Du
RA Manager
No.8, Tongxing Road,
Nantong Economic & Technological Development Area
Nantong, Jiangsu 226009
China

Re: K211629
Trade/Device Name: Infrared forehead thermometer LD-FT-100B
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: October 27, 2021
Received: November 8, 2021

Dear Iris Du:

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,

Gang Peng For
Payal Patel
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

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)*
K211629

Device Name
Infrared forehead thermometer LD-FT-100B

Indications for Use *(Describe)*
The infrared forehead thermometer is a nonsterile, reusable clinical thermometer intended for measuring the human body temperature in non-contact mode on the center of the forehead as the measurement site on people of all ages except the age under the 1 year.

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

K211629

1. Submitter

- Company name: HONSUN(NANTONG)Co.,Ltd
- Address:No.8, Tongxing Road, Nantong Economic & Technological development Area,Jiangsu, 226009, China
- Postal Code:226010
- TEL:+86-513-80580127
- Contact person: Xinhua Pan (General Manager) , Iris Du(RA Manager)
- E-mail:dulh@lordmed.com/ sara-xu@lordmed.com
- Preparation Date: 11/17/2021

2. Subject Device Information

- Trade name: Infrared forehead thermometer LD-FT-100B
- Common name:Infrared forehead thermometer
- Regulation name:Clinical Electronic Thermometer
- Model:LD-FT-100B
- Regulation class: II
- Regulation number:880.2910
- Review panel:General Hospital
- Product code:FLL

3. Predicate Device

- Sponsor: Jiangsu Yuyue Medical Equipment & Supply Co.,Ltd.
- Device name: YUWELL Infrared Thermometer
- Model:YT-1, YT-lA, YT-lB, YT-lC, YT-2, YT-2A, YT-2B, YT-2C
- 510(K) number:K201864
- Product code:FLL
- Regulation class: II
- Regulation number:880.2910

4. Device description

The HONSUN infrared forehead thermometer is designed for measuring the body's temperature, is a handheld non-contact infrared thermometer, battery powered, detecting the infrared energy emitted in the forehead area within 0-3 cm (exclude 0 cm) that converts to a body temperature. The measurement site is center of the forehead, while reference body site is the oral.

It is intended to measure the temperature of human body in home and hospital.

It consists of thermopile sensor, printed circuit board, enclosure, button and liquid crystal display. The pressure difference generated by the sensor after receiving the infrared signal is amplified and analyzed then displayed on the LCD screen in digital form. It will be automatically power off if left idle for 20 seconds.

5. Indications for Use

The infrared forehead thermometer is a nonsterile, reusable clinical thermometer intended for measuring the human body temperature in non-contact mode on the center of the forehead as the measurement site on people of all ages except the age under the 1 year.

6. Operation principle

The device is used to measure human body temperature. Once the operator approaches the specific part of the human body (forehead) according to the use method, and presses the measurement key, the infrared radiation receiving sensor can be activated immediately, and the thermal energy generated by the arterial blood flow can be detected through the infrared sensor, and converts to a human body temperature.

7.Substantial equivalence comparison

Item	Subject Device	Predicate Device	Remark
Device name	infrared forehead thermometer	Infrared thermometer	Same
510(K) number	K211629	K201864	/
Product code	FLL	FLL	Same
Regulation No.	880.2910	880.2910	Same
Classification	II	II	Same
Intended use	The infrared forehead thermometer is a nonsterile, reusable clinical thermometer intended for measuring the human body temperature in non-contact mode on the center of the forehead as the measurement site on people of all ages except the age under the 1 year.	The YUWELL infrared forehead thermometer is a nonsterile, reusable clinical thermometer intended for measuring the human body temperature in non-contact mode on the center of the forehead as the measurement site on people of all ages except preterm babies.	Similar Note 1
Patient population	People of all ages except the age under the 1 year.	People of all ages except preterm babies	Similar Note2
Operation	Hand held-manually operated	Hand held-manually operated	Same
Measurement site	Forehead	Forehead	Same
Design method	Using infrared energy conversion	Using infrared energy conversion	Same
Display	LCD digital display	LCD digital display	Same
Operating mode	Adjusted mode	Adjusted mode	Same
Reference body site	Oral	Oral	Same
scale	℃/℉	℃/℉	Same
Measurement range	32℃ to 43℃ (89.6℉ to 109.4℉)	32.5℃ to 43℃ (90.5℉ to 109.4℉)	Similar Note 3

Accuracy	±0.2℃（±0.4℉）from 35.1℃（95.2℉）to 42℃（107.6℉）; ±0.3℃（±0.5℉）from 32℃（89.6℉）to 35℃（95℉）and from 42.1℃（107.8℉） to 43℃（109.4℉）	±0.2℃ (±0.4℉) in the range of 35.0℃～42.0℃ (95.0℉～107.6℉); ± 0.3℃ (± 0.5℉) in the range of 32.5℃～34.9℃ (90.5 ℉ ～ 94.8℉) and 42.1℃～ 43.0℃ (107.8℉～109.4℉)	Similar Note 4
Resolution of display	0.1°C/0.1°F	0.1°C/0.1°F	Same
Operating environment	10°C (50°F) to 40°C (104°F) 15%RH ~85%RH，700hPa~1060hPa	10°C (50°F) to 40°C (104°F), 15%RH ~90%RH (no condensation)	Similar Note5
Storage environment	-10°C (14°F) to 50°C (122°F), 10%RH ~85%RH	-20°C (-4°F) to 55°C (131°F), 10%RH ~85%RH	Similar Note6
Energy source	2 AAA batteries	2 AAA batteries	Same
Measurement distance	Within 0-3 cm (exclude 0 cm)	Within 0-5 cm	Similar Note7
Touch aspect	Non contact	Non contact	Same
Memory Size	32 measurements	No data stored for YT-1 series; Up to 10 sets of data for YT-2 series	Similar Note8
Performance	Meets ISO 80601-2-56	Meets ISO 80601-2-56 ASTM E 1965	Different Note 9
Materials contact the patient	ABS, Acrylic	/	Note 10
Biocompatibility	Meets ISO 10993-1 ISO 10993-5 ISO 10993-10	Meets ISO 10993-1 ISO 10993-5 ISO 10993-10	Same
Electrical safety	Meets IEC 60601-1	Meets IEC 60601-1	Same
EMC	Meets IEC 60601-1-2	Meets IEC 60601-1-2	Same

Discussion of difference:

Note ID	Justification
Note1 and Note2	The HONSUN product has been conducted the clinical accuracy test in accordance of ISO 80601-2-56, and the result met the requirements. The difference does not

	raise new safety and effectiveness questions.
Note3	The measurement range of the subject device is slightly larger (only 0.5℃) than that of the predicate device. The HONSUN product has been conducted the performance test in accordance with ISO 80601-2-56, test results met the requirements. The difference does not raise new safety and effectiveness questions.
Note 4	The accuracy of measurement range of the subject device is similar with that of predicate device and complies with ISO 80601-2-56. The performance test was conducted and the test results met the requirements. The difference does not raise new safety and effectiveness questions.
Note5 and Note6	The difference of operating & storage environment of subject device are different with predicate device. The performance testing shows that the subject device complies with standard ISO 80601-2-56 . The difference does not raise any new issues of safety or efficacy.
Note7	Measurement distance of the subject device is within 0-3 cm (exclude 0 cm), the predicate device's is in the range of 0-5 cm. The manufacturer had conducted performance test to verify measurement accuracy and safety for the patient population according to ISO 80601-2-56 . The test results of subject device show the accuracy met the requirements within the distance range. Therefore, this difference does not raise new safety and effectiveness questions.
Note8	The memory capacity is additional function and will not influence the performance and safety of infrared forehead thermometer. Besides, the HONSUN product was conducted software verification and validation test, the IEC 60601-1 and IEC 60601-1-2 test, the test results met the requirements. Therefore, this difference does not raise new safety and effectiveness questions.
Note9	The subject device performace testing was conducted in accordance with ISO 80601-2-56, IEC 60601-1 and IEC 60601-1-2. The test results met the requirements. All of these standards are applied to clinical thermometers. The difference does not raise new safety and effectiveness questions.
Note10	The parts contact with the patient are palstic enclosure, plastic button and acrylic pannel, the materials are ABS, ABS and Acrylic. All these materials were conducted the biocompatibility tests, including cytotoxicity, skin irritation and skin sensitization. The test results met the requirements.

	The difference does not raise new safety and effectiveness questions.

8. Non-clinical testing

The Infrared Forehead Thermometer is tested per the following standard, to evaluate its performance and safety. The test results demonstrated that the proposed device complies with the standards and guidance.

- IEC 60601-1:2005+AMD1:2012 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 1-11: 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+A1:2018 Medical electrical equipment – Particular requirements for the basic safety and essential performance of clinical thermometers for body temperature measurement
- FDA "Guidance for the content of premarket submissions for software contained in Medical Devices", 2005
- 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

9. Clinical testing

The LD-FT-100B infrared forehead thermometer was conducted the clinical accuracy test in Sept, 2020 according to the ISO 80601-2-56 and following two age groups were selected: older than 1 year and younger than 5 years, and older than 5 years based

on the subject device's intended target population. According to the requirement of clinical test in ISO 80601-2-56, the YUWELL infrared thermometer YT-1 was selected as the reference device. In the subjects, 40 people were over one year old and less than five years old (17 with fever) and 65 people were over five years old (28 with fever).

The temperature was measured at the same measurement site (forehead) of the same subject with the reference thermometer and LD-FT-100B infrared forehead thermometer alternatively , and three values of same site were recorded. The clinical accuracy test results of the subject infrared forehead thermometer met the requirements of ISO 80601-2-56.

10. Conclusion

The subject device HONSUN infrared forehead thermometer LD-FT-100B and predicate device YUWELL Infrared Thermometer have the same intended use and similar technological characteristics. Based on the performance testing, comparison and analysis, the infrared forehead thermometer LD-FT-100B is substantially equivalent to the predicate device (K201864).