March 18, 2022

Sichuan YOUKEDE Medical Equipment Co.,Ltd
Yolanda Lan
Regulatory Affair Consultant
2F, North Wing, No.102 Building, Mianyang Export Processing
Zone, No.261 East Section of Feiyun Road, Mianyang Hi-Tech
Mianyang, SiChuan 621000
China

Re: K210171
Trade/Device Name: Non-contact Infrared Thermometer (Models WL-301, WL-501, WL-601, WL-701)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: February 16, 2022
Received: February 16, 2022

Dear Yolanda Lan:

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)*
K210171

Device Name
Non-contact Infrared Thermometer（Model:WL-301,WL-501,WL-601,WL-701）

Indications for Use *(Describe)*
The Non-contact Infrared Thermometer (Models WL-301, WL-501, WL-601, WL-701) is an electronic thermometer using an infrared sensor to detect human body temperature from forehead on people of one month old and above. The device is reusable for home and clinical 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5 510(K) Summary

1. Prepared Date: 2021/06/18

2. Submitter Information

Name	Sichuan YOUKEDE Medical Equipment Co.,Ltd.
Address	2F, North Wing, No.102 Building, Mianyang Export Processing Zone, No.261 East Section of Feiyun Road, Mianyang Hi-Tech Zone, 621000 Mianyang City, Sichuan Province, P.R.China
Contact person	Sukey Chia
Tel	+86 0816 2296641
E-mail	3004729718@qq.com

3. Submission Correspondent

Contact person	Yolanda Lan
E-mail	yolanda.bleu@foxmail.com
Tel	+86-13713938991

4. Subject Device Information

Proprietary Name	Non-contact Infrared thermometer (Model:WL-301,WL-501,WL-601,WL-701)
Common Name	Infrared thermometer
Model	WL-301, WL-501, WL-601, WL-701
Classification	Thermometer, Electronic, Clinical
Regulation Description	Clinical electronic thermometer
Review Panel	General Hospital
Product Code	FLL
Regulation Number	21 CFR 880.2910
Regulatory Class	II

5. Predicate Device

Infrared Forehead Thermometer, Model DPT-IFT100, (CONMO, K202420)

6. Description

The Infrared thermometers are hand-held, battery powered devices designed to measure human body temperature from the central forehead. Its operation is based on measuring the natural thermal radiation from central forehead.

The thermometers use 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, and an infrared distance sensor for detection of
no-contact use and compensation of the temperature reading.

The device mainly consists of infrared sensor, microprocessor, embedded software (Identified Software version is No: V1), memory, electro-acoustic components, LED display and the device is powered by 2AAA alkaline batteries.

The non-contact infrared thermometer included WL-301, WL-501, WL-601, WL-701. They can be selected calibration mode, body temperature mode and surface mode.

7. Indications for Use

The Non-contact Infrared Thermometer (Models WL-301, WL-501, WL-601, WL-701) is an electronic thermometer using an infrared sensor to detect human body temperature from forehead on people of one month old and above. The device is reusable for home and clinical use.

8. Summary of technological characteristics of device compared to the predicate devices, see the table

A comparison of key similarities and differences between the proposed devices (WL-301, WL-501, WL-601, WL-701) and the predicate devices (K202420) is provided below:

SE Comparisons	Propose device	Predicate device	Note
	YOUKEDE (WL-301, WL-501, WL-601, WL-701)	**CONMO DPT-IFT100**	
510K number	K210171	K202420	--
Regulation number	21 CFR 880.2910	21 CFR 880.2910	Identical
Product code	FLL	FLL	Identical
Indications for use	The Non-contact Infrared Thermometer (Models WL-301, WL-501, WL-601, WL-701) is an electronic thermometer using an infrared sensor to detect human body temperature from forehead on people of one month old and above. The device is reusable for home and clinical use.	The infrared forehead Thermometer DPT-IFT100 is a non-contact thermometer intended for the intermittent measurement of human body temperature from forehead for people of one month old and above. The device is reusable for home use and clinical use.	Different[1]
Measurement Method	Infrared radiation detection	Infrared radiation detection	Identical
Measurement Range	34°C ~42℃	34°C ~43℃	Different, but meets ISO 80601-2-56:2017/Amd.1:2018
Accuracy	34°C～42°C(±0.3°C)	±0.2°C: 35.0°C ~ 42.0°C ±0.3°C: 34.0°C ~ 34.9°C, 42.1°C ~ 43°C	Different[2]
Display	0.1°C (0.1°F)	0.1°C(0.1°F)	Identical

Measurement mode (adjusted/direct mode)	Adjusted	Adjusted	Identical
Measurement distance	3~5cm	3~5cm	Identical
Measurement Site	Forehead	Forehead	Identical
Response time	<6S	1S	Different[3]
Sensor type	Thermopile	Thermopile	Identical
Scale Selection	°C /°F	°C /°F	Identical
Buzzer	No, vibrate instead	Yes	Different[3]
Display screen	LED	LCD	Different[3]
Memory	1sets	60sets	Different[3]
Auto power-off while no operation	Yes	Yes	Identical
Power supply	3.0V DC with 2 AAA batteries	3.0V DC with 2 AAA batteries	Identical
Contact materials	ABS	ABS	Identical
Operation Environment	15~40°C (59°F~104 °F) RH ≤ 95%	10~40°C (50°F~104 °F) 15-85% RH	Different[4]
Storage Environment	-20°C ~+55°C（-4~+131°F） RH≤95%	-20~ +55°C（-4~+131°F） RH≤90%	Different[4]
Dimension	146*35*41 mm	145*38*35mm	Different[5]
Weight	68g	78.2g (with batteries), 56.6g (w/o batteries)	Different[5]

Conformance standard	IEC 60601-1(Safety), IEC60601-1-2(EMC), IEC 60601-1-11 ASTM E1965-98, ISO 10993-1 ISO 10993-5: 2009 ISO 10993-10: 2010	EN60601-1(Safety), IEC60601-1-2(EMC), IEC 60601-1-11 ASTM E1965-98 ISO 10993-1 ISO 10993-5: 2009 ISO 10993-10: 2010	Identical
	ISO80601-2-56(performance), Exceptions: The following clause/collaterals: Clause 201.11.7, Biocompatibility of ME EQUIPMENT and ME SYSTEMS. Clause 201.12.2 and 206, Usability, not evaluated in this report, Refer to IEC 60601-1-6 test Report, Clause 202, EMC, not evaluated in this report, Refer to IEC 60601-1-2 test report. Clause 201.102, Clinical Accuracy VAIDATION, evaluated in ASTM E 1965-98 report.	ISO80601-2-56(performance)	Different[6]

Analysis

From the comparison table, the propose device and predicate device have the same working principle, Measurement place, Measurement Method, Scale selection, Auto power-off while no operation & Conformance standard. There are slightly differences between the devices as follow:

Difference clause	Discussion
Intended Use	The wording for the subject device is slightly different from the predicate device but they are both non-contact thermometers for the intermittent measurement of human body temperature via forehead. The subject device addresses the target population based on the clinical study conducted, and they both conform to the same performance standard - ISO 80601-2-56, Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. The subject device added the “measurement distance” claim, and described detail of the intended use scenario. The above wording differences between the subject device and predicate device will

Measurement Accuracy	Both devices have different measurement accuracy, but they meet the requirements of ISO80601-2-56. And the accuracy of the subjected device has demonstrated through the clinical accuracy trial, which will not affect the device's safety and effectiveness.
Response time/Buzzer/Display screen/ Memory	The response time, buzzer, display screen and memory capability of predicate devices are difference from subject devices, However, the software has been validated according to FDA's software guidance. The performance testing shows that the subject device complies with performance standard during performance testing ISO 80601-2-56 and ASTM E1965-98 and clinical testing. Therefore, we considered that the difference does not raise any issues on the device safety and effectiveness of the subject device.
Operation &Storage Environment	Both devices have slightly different Operation &Storage Environment, but the subject device has been demonstrated to comply with the requirements of standards IEC 60601-1 and ISO 80601-2-56. Therefore, we considered that the difference does not raise any issues on the device safety and effectiveness.
Dimension & Weight	The dimension and weight of subject device is different from the subject device. The difference is caused by their different appearance and construction, but the electrical safety, electromagnetic compatibility, performance of subject device has been evaluated to meet the requirements of the standards IEC 60601-1, IEC 60601-1-2, ASTM E1965-98 and ISO 80601-2-56. Therefore, we considered that the difference does not raise any issues on the device safety and effectiveness.
Conformance standard	Both devices conform to IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11, ASTM E1965-98, ISO 10993-1; though the device not all clauses conform to ISO 80601-2-56, but exceptions was evaluated in the other reports which does not raise issued on the safety and effectiveness of the subject device.

Performance Data

- Compliance to applicable standards includes ISO80601-2-56(not all clauses), as well as IEC 60601-1, IEC 60601-1-2 and IEC60601-1-11 requirements.
- Biocompatibility Evaluation for contacting patient components meets the requirements of ISO 10993-5 and ISO10993-10.
- According to the standard of AAMI TIR30:2011, Effectiveness validation of cleaning method referenced in the User's Manual.
- Shelf-life test result shows the subject device will be safe and effective using under the specified condition within 2 years.
- And then the following performance is verified.
  -Measurement Range& Accuracy
  -Measurement distance
  -Response time

Clinical data

According to the ASTM E 1965-98, the clinical trial was performed for people of one month old and up. Reference clinical thermometer was a Glass thermometer, Model: CRW-23, Yuwell-Jiangsu medical equipment & supply Co. 150 patients were evaluated for both ear and forehead patients.

Conclusion

Based on performance testing and compliance with acceptable voluntary standards, we believe that the Non-contacted Infrared thermometers (WL-301, WL-501, WL-601, WL-701) are substantially equivalent to its predicate devices in K202420.