September 12, 2022

Qingdao Yasee Medical Device Co., Ltd.
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K220084
Trade/Device Name: Infrared Forehead Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: April 17, 2022
Received: May 23, 2022

Dear Prithul Bom:

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
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)*
K220084

Device Name
Infrared Forehead Thermometer

Indications for Use *(Describe)*
Infrared Forehead Thermometers (model1: JA-11A; model2: JA-11S; model3: JA-11C) are non-sterile, reusable, non-contact and handheld devices. They can be used by consumers in homecare environment and doctors in clinic as reference. They are intended for measuring human body temperature of people over one month old by detecting infrared heat from the forehead.

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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510(k) Summary

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

Submitter & Foreign Manufacture Identification

Qingdao Yasee Medical Device Co., Ltd.
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Tel: +86 532 68012805
Submitter's FDA Registration Number: N/A

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Date of Summary: April 14, 2022

Device Name

Trade name	Infrared Forehead Thermometers
Regulation Name	clinical electrical thermometer
Common Name	clinical electrical thermometer
Classification Name	Thermometer, Electronic, Clinical
Device Classification	II
Regulation Number	21 CFR 880.2910
Panel	General Hospital
General Product Code	FLL

Predicate Device Information:

(1) K193253, "Infrared Thermometer", manufactured by "Shenzhen Changkun Technology Co., Ltd."

Trade name	Infrared Thermometer, models: CK-T1501, CK-T1502, CK-T1503
Common Name	clinical electrical thermometer
Classification Name	Thermometer, Electronic, Clinical
Device Classification	II
Regulation Number	21 CFR 880.2910
Panel	General Hospital
Product Code	FLL

Device Description:

Infrared Forehead Thermometers (model1: JA-11A； model2： JA-11S； model3： JA- 11C) are hand-held, battery powered, Infrared Forehead Thermometers that covert a user's forehead temperature, using the infrared energy emitted in the area around the user's forehead to an equivalent temperature when measuring from 1-3 cm of the subject's forehead with no contact.

It is composed of a probe, a display, two buttons (start button and power button), an enclosure and a battery cover.

It is used to measure human body temperature based on the relationship between temperature and measurable infrared radiation. Simply aim the unit's probe toward the surface to be measured to obtain a quick and accurate temperature.

When measuring body temperature, users need to measure in body mode from 1-3 cm from their forehead. Press the measuring key and then release it. The instrument will start measuring the target temperature. After about 1 second, the buzzer emits the corresponding alert sound, the measurement result is displayed on the LCD, and the backlight of the corresponding color is turned on. After about 3 seconds, the backlight is turned off, the unit symbol flashes, and the buzzer beeps shortly. Wait until the key is pressed to measure the temperature again. Start the thermometer without any operation, or no operation after temperature measurement, the thermometer will shut off and LCD go out with one short beep in 60 s ± 20 s.

It can store 32 sets of measurements. Press the【M】button to cycle through them.

User contact components are the enclosure and keys. The materials of the components are ABS plastic.

The thermometer is for intermittent use.

Indications for Use:

Infrared Forehead Thermometers (model1: JA-11A； model2： JA-11S； model3： JA- 11C) are non-sterile, reusable, non-contact and handheld devices. They can be used by consumers in homecare environment and doctors in clinic as reference. They are intended for measuring human body temperature of people over one month old by detecting infrared heat from the forehead.

Testing Summary:

To prove the safety and effectiveness of Infrared Forehead Thermometers, we tested the device according to corresponding standards.

Infrared Forehead Thermometer conforms to the following standards:

ISO 10993-1, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

ISO 10993-5, Biological evaluation of medical devices —Part 5: Tests for in vitro cytotoxicity

ISO 10993-10, Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization

IEC60601-1, Electrical safety

IEC 60601-1-11 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance

IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance

ISO 80601-2-56 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement

Technological Comparison with Predicate Device

The following table shows similarities and differences between our device and the predicate devices.

Table 1: Comparison of Intended Use, Mechanism, and Design

Description	Subject Device	Predicate Device (K193253)	Comparison
Indication For Use	Infrared Forehead Thermometers (model1: JA-11A: model2: JA-11S: model3: JA-11C) are non-sterile, reusable, non-contact and handheld devices. They can be used by consumers in homecare environment and doctors in clinic as reference. They are intended for measuring human body temperature of people over one month old by detecting infrared heat from the forehead.	Infrared Thermometer (model: CK-T1501, CK- T1502, CK-T1503) is a non-sterile, reusable, non-contact and handheld device. It can be used by consumers in homecare environment and doctors in clinic as reference. It is intended for measuring human body temperature of people over one month old by detecting infrared heat from the forehead.	Same
Product Code	FLL	FLL	Same
Classification Name	Clinical Electronic Thermometer	Clinical Electronic Thermometer	Same
Use Environment	at home and hospital	at home and hospital	Same

Patient population	people over one month old	people over one month old	Same
Contact/Non-Contact	Non-Contact	Non-Contact	Same
Biocompatibility	ISO 10993-1 ISO 10993-5 ISO 10993-10	ISO 10993-1 ISO 10993-5 ISO 10993-10	Same
Standards conformance	IEC60601-1 lEC60601-1-2 IEC60601-1-11 ISO80601-2-56	IEC60601-1 lEC60601-1-2 IEC60601-1-11 ISO80601-2-56	Same
Weight	50 g	unknown	Different. The weight does not affect the performance.
Dimensions	149X38.5X38.5 mm	unknown	Different. The dimensions do not affect the performance.
Storage environment	-13 °F - 131 °F (-25 °C - 55 °C) with a relative humidity of up to 85% (non-condensing)	-13 °F - 131 °F (-25°C - 55°C) with a relative humidity of up to 85% (non-condensing)	Same
Operational Environment	10 °C - 40 °C 15 % - 90% RH	10°C - 40 °C 15 % - 90% RH	Same
Display	LCD	LCD	Same
Measurement Range	34 °C - 43 °C	32 °C - 42.5 °C	Similar. Both ranges are sufficient to measure the human body temperature.
C/F switchable	℃/℉ Switchable	℃/℉ Switchable	Same
Measurement Accuracy	34.0 °C - 35.4 °C (93.2 °F - 95.7 °F: ±0.3 °C/±0.5 °F) 35.5 °C - 42.0 °C (95.0 °F - 107.6 °F): ±0.2 °C/±0.4 °F 42.1 °C - 43.0 °C (107.8 °F - 109.4 °F): ±0.3 °C/±0.5 °F	32 °C-34.9 °C: ± 0.3 °C (89.6 °F - 94.8 °F: ±0.5 °F) 35 °C-42 °C: ±0.2 °C/95.0°F-107.6 °F: ±0.4 °F 42.1 °C-42.5 °C: ±0.3 °C/107.8 °F-108.5 °F: ±0.5 °F	Different. In the range of 34.0 °C - 42.0 °C, the measurement accuracy is the same (±0.2°C).
Measurement distance	1-3 cm	3-5 cm	Different. Measurement distance does not affect performance.
Thermometer Type	Infrared Forehead Thermometer	Infrared Forehead Thermometer	Same
Mechanism	Infrared radiation detection	Infrared radiation detection	Same
Anatomy Site	Forehead	Forehead	Same

User Control	Manual On/Off Switch	Manual On/Off Switch	Same
Memory	32 sets	32 sets	Same
Power Source	DC 3V (2 of AAA alkaline batteries)	DC 3V (2 of AA alkaline batteries)	Same
Material	ABS	ABS	Different due to unknown polymerization specifications. It does not affect performance.
Display	LCD	LCD	Same
OTC/Prescription	OTC	OTC	Same

Our device is essentially identical to the predicate device in terms of indications for use, design, mechanism between subject device and the predicate device. The several minor differences do not affect the safety and effectiveness of the device.

Performance Testing

Table 2: Standards Used for Testing

Software	• Software verification and validation per the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005) for a Moderate Level of Concern
Electrical Safety	• Electrical Safety testing per IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
EMC	• Electromagnetic Compatibility and Wireless testing was evaluated per the following: IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance
Medical Electrical Equipment-home health care environment	• 60601-1-11 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance
Device performance	• ASTM 80601-2-56 Medical electrical equipment — Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement • ASTM 1965-98 Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature
Reprocessing/Cleaning	• Validation per the FDA Guidance for Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling (March 17, 2015) confirmed cleaning and disinfection instruction provided in instructions for use
Biocompatibility	• Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing • ISO 10993-5 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity

	• ISO 10993-10 Biological evaluation of medical devices — Part 10: Tests for skin sensitization

Clinical Accuracy Validation

ASTM 1965-98	• Sample size, Patient population age, compared to reference thermometer, reference thermometer, designed per ASTM 1965-98: Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature

Substantial Equivalence Conclusion

Based on the comparison of intended use, design, biocompatibility, and performance, "Infrared Forehead Thermometer (model1: JA-11A； model2： JA-11S； model3： JA-11C)" manufactured by "Qingdao Yasee Medical Device Co., Ltd." is substantially equivalent to its predicate devices.