February 9, 2024

Zhuhai Yueja Medical Device Technology Co.,Ltd.
Feng Yan
Department manager
Room 201, Building 2, No.2 Liushi Road
Tangjiawan Town, High-tech Zone
Zhuhai, Guangdong 519000
China

Re: K232473
Trade/Device Name: Infrared Thermometer: Model YJ600
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: January 11, 2024
Received: January 11, 2024

Dear Feng Yan:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Porsche Bennett

Porsche Bennett
For David Wolloscheck, Ph.D.
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)*
K232473

Device Name
Infrared Thermometer: Model YJ600

Indications for Use *(Describe)*
Infrared Thermometer is intended for the intermittent measurement of body temperature from the forehead on people of all ages. It can be used by consumers in the household environment and by health care providers.

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."

K232473- 510(k) Summary

Device Submitter:	Zhuhai Yueja Medical Device Technology Co.,Ltd. Room 201, Building 2, No.2 Liushi Road, Tangjiawan Town, High-tech Zone, Zhuhai, 519000, China
Contact Person:	Feng Yan Department Manager Phone: +86-18826906029 E-mail: fengy@myzr.com.cn
Date Prepared	February 9, 2024

I Subject Device

Trade Name of Device:	Infrared Thermometer: Model YJ600
Regulation Number:	21 CFR 880.2910
Product Code:	FLL
Regulation Name:	Clinical Electronic Thermometer
Common name	Electronic Thermometer
Regulatory Class	II
Review Panel	General Hospital

II Predicate Device

510k Number	K200471
Trade Name of Device:	Infrared Thermometer, Model: RN-60A, RN-60B
Regulation Number:	21CFR 880.2910
Regulation Name:	Clinical electronic thermometer
Regulatory Class	II
Product Code:	FLL

III Device Descriptions

Infrared Thermometer is mainly composed of infrared probe components, main circuit board components, LCD display components and housing components. The Infrared Thermometer is intended for the intermittent measurement of body temperature from the forehead on people of all ages. Infants and children cannot operate the thermometer; it is recommended that adults take the measurement. The Infrared Thermometer can be used by consumers in the household environment and by healthcare providers. The operator

should be an adult with relevant experience. The operator can replace the battery, transmit data, and measure temperature.

IV Indications for use

Infrared Thermometer is intended for the intermittent measurement of body temperature from the forehead on people of all ages. It can be used by consumers in the household environment and by health care providers.

V Technological Characteristics Comparison

VI-1: Comparison of Subject and Predicate Devices

Device Characteristic	Subject Device	Predicate Device (K200471)	Discussion
Type of Thermometer	Infrared Thermometer: Model YJ600	Infrared Thermometer, Model: RN-60A, RN-60B	-
Product Code	FLL	FLL	Same
Regulation No.	21 CFR 880.2910	21 CFR 880.2910	Same
Class	II	II	Same
Indications for Use	Infrared Thermometer is intended for the intermittent measurement of body temperature from the forehead on people of all ages. It can be used by Consumers in the household environment and by health care providers.	The Infrared thermometer is a non-contact infrared 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
Patient population	All ages	One month old and above	Different 2
Operation Principle	According to the characteristics of natural objects, all objects with temperatures higher than	The Infrared Thermometers RN-60A and RN-60B measure the	Different 3

	zero (-273.15 ℃) are constantly emitting infrared capabilities to the surrounding space. Its radiation characteristics, radiation energy and wavelength distribution are closely related to the surface temperature of the object. The human body, like other organisms, radiates infrared energy around itself, and its wavelength is generally 9-14μm, which is in the infrared band of 0.76-100 μm. Because the light in this wavelength range is not absorbed by air, the infrared radiation from human body has nothing to do with the environmental impact, but only with the energy released by human body. Based on this principle, this product adopts an infrared sensor specially used to detect the infrared radiation energy with the wavelength of 5-14μm released by the human body, and accurately measures the human body temperature through accurate calculation and temperature compensation correction.	temperature by using the principle of receiving infrared. An object with a temperature higher than absolute zero will radiate a certain amount of infrared energy. According to the infrared energy and wavelength, the surface temperature of the object can be determined. The temperature of human forehead is relatively constant, so the temperature of human forehead can be measured according to this principle. The thermometer adopts a new CMOS compatible thermopile sensor with good sensitivity. The pressure difference generated by the sensor after receiving the infrared signal is amplified and analyzed then display on the LCD screen in digital form.	
Prescription/over-the-counter use	over-the-counter use	over-the-counter use	Same
Measurement technology	Infrared radiation detection that converts a user's forehead temperature using	Infrared radiation detection that converts a user's	Same

	the infrared energy emitted in the area around the user's forehead to a reference site equivalent temperature.	forehead temperature using the infrared energy emitted in the area around the user's forehead to a reference site equivalent temperature.	
Measurement site	Forehead	Forehead	Same
Measurement Range	22.0 ℃~42.9 ℃	Forehead mode: 32.0°C ~42.9°C (89.6 to 109.2 ° F)	Different 4
Accuracy	±0.3℃	Forehead mode: ±0.2°C (0.4°F) within (96.8°F ~ 102.2°F),±0.3°C(0.5° F) when ＜36.0℃ (96.8°F) and ＞ 39.0℃(102.2°F)	Different 5
Display resolution	0.1°C	0.1°C(0.1°F)	Same
C/F switchable	Yes	Yes	Same
Measurement distance	1-3 cm	3~5 cm	Different 6
Measurement time	2s	1s	Different 7
Sensor type	high precision infrared sensor	Thermopile	Different 8
Memory	32 sets	60 sets	Different 9
Buzzer	Yes	Yes	Same
Auto power-off while no operation	Yes	Yes	Same
Power supply	2 AAA size batteries	2*AAA battery	Same
Display screen	LCD	LCD	Same
Operation Environment	+15°C~+40C RH<95% non-condesing,70kPa~106kPa	5.0°C∽40.0°C (41°F∽104℉) 15%≤RH≤90% 70.0kPa-106.0kPa	Different 10

Storage Environment	-20°C~+55°℃ humidity<93%, 70kPa~106kPa	-25.0℃∽70.0℉ (-13°F∽158°F) RH≤95% 50.0kPa-106.0kPa	Different 11
Conformance standard	ISO80601-2-56 (performance), IEC60601-1(Safety), IEC60601-1-2(EMC) IEC 60601-1-11(Home use) ASTM E1965-98 IEC60601-1-6(Usability)	ISO80601-2-56 (performance), IEC60601-1(Safety), IEC60601-1-2(EMC) IEC 60601-1-11(Home use) ASTM E1965-98	Same
Patient contact materials	ABS	ABS	Same
Biocompatibility	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	Same

Different 1
There are minor differences in the wording of the indications for use. In addition, the subject device is indicated for people of all ages, while the predicate device is indicated for people one month old and above. Clinical accuracy testing was conducted to ISO80601-2-56. Therefore, the difference does not raise different questions of safety and effectiveness.

Different 2
The subject device is indicated for people of all ages, while the predicate device is indicated for people one month old and above. Clinical accuracy testing was conducted to ISO80601-2-56. Therefore, the difference does not raise different questions of safety and effectiveness.

Different 3
The description of operation principle is different. However, its working principle is the same, both use the principle of receiving infrared rays to measure the temperature of the human body. Therefore, the difference does not raise different questions of safety and effectiveness.

Different 4
The minimum measurement temperature of the subject device is lower than that of the predicate device. Performance testing was conducted to ISO 80601-2-56. Therefore, the difference does not raise different questions of safety and effectiveness.

Different 5
The accuracy is different, however compliant with ISO 80601-2-56. Therefore, the difference does not raise different questions of safety and effectiveness.

Different 6
The measurement distance is different; however, performance testing was conducted to demonstrate the difference does not raise different questions of safety and effectiveness.

Different 7
The measurement time is different; however, performance testing was conducted to demonstrate the difference does not raise different questions of safety and effectiveness.

Different 8
The sensor type is different; however, performance testing was conducted to demonstrate the difference does not raise different questions of safety and effectiveness.

Different 9
The memory is different; however, the difference does not raise different questions of safety and effectiveness.

Different 10
The operation environment is different, however compliant with ISO 80601-2-56. Therefore, the difference does not raise different questions of safety and effectiveness.

Different 11
The storage environment is different, however compliant with ISO 80601-2-56. Therefore, the difference does not raise different questions of safety and effectiveness.

VI Summary of Non-clinical Testing (Bench)

The non-clinical testing for Infrared Thermometer: Model YJ600 was performed to demonstrate verification testing in conformance with the acceptance criteria of test methods and recognized consensus standards shown below.

Table VII-1: Performance testing was conducted on the subject device

Inspecting item		Inspection content and acceptance standard	Result
1. Appearance and structure test	1.1	The shape of the thermometer should be correct, the surface should be smooth and clean, and there should be no obvious scratches, sharp edges, burrs and deformation.	Pass
	1.2	The text and symbols on the thermometer control panel and function keys should be clear, accurate and firm.	Pass
	1.3	The control devices of the thermometer should be flexible and reliable, and the fasteners should not	Pass

		he loose.	
	1.4	The top of the thermometer probe should be smooth and the edges should be free of burrs.	Pass
	1.5	The function keys of the thermometer should be clearly marked, indicating that the function keys of the thermometer should be clearly marked and indicated.	Pass
2. Temperature display range test		In body temperature mode, the temperature display range of the thermometer22.0℃~42.9℃	Pass
3. Maximum allowable error test		The maximum allowable error of the thermometer is ± 0.3° C within the temperature display range of 22.0° C to 42.0°C.	Pass

4. Anti-drop test		The thermometer shall meet the requirements of 6.3.1 after falling freely from a height of 1m in vertical distance to a hard surface with three different initial postures during normal use.	Pass
5. Indicative unit test	5.1 Resolution	The resolution of the indication unit of the thermometer is 0.1°C (0.1° F).	Pass
	5.2 Display	The height of the reading value on the thermometer display is >4mm.	Pass
	5.3 Prompt function	In the body temperature mode, when the measured value of the thermometer is lower than 22.0°C, there should be a prompt sound "Di di" twice and "LO" should be displayed; when the measured value is higher than 42.9°C, a prompt sound " Beep" twice and display "HI".	Pass

	5.4 Low voltage prompt function	The battery voltage of the thermometer is lower than 2.5±0.2V. When the "  " icon flashes on the screen, it means that the battery is low and needs to be replaced.	Pass
	5.5 Mode	a) The thermometer should have a temperature measurement mode. b) The calibration mode for calibration purposes shall be obtained by a conversion technique that directly sets the infrared thermometer to this mode.	Pass
6 Function and performance test	6.1 Unit switching function	The thermometer has a temperature unit switching function, which can switch between "℃" and "F".	Pass
	6.2 Sound Prompt Function	a) In body temperature mode, when the measurement result is in the range of 22° C to 37.4°C, a green backlight will be displayed and a short sound will arise. b) In body temperature mode, when the measurement result is in the range of 37.5° C to 38.4° C, an orange backlight will be displayed and 1 long sound + 3 short sounds will arise. c) In body temperature mode, when the measurement result is in the range of 38.5° C to 42.9° C, a red backlight will be displayed and 1 long sound + 5 short sounds will arise.	Pass
	6.3 Measuring time	The thermometer should complete the temperature measurement within 2s.	Pass

	6.4 Memory query	32 groups of local data can be queried.	Pass
7. Cleaning and disinfection test		After the thermometer is cleaned/disinfected according to the instructions in the instruction manual, it shall meet the requirements of 6.3.1.	Pass
8. Self-inspection function test		All LCDs on the screen should be fully displayed every time the thermometer is turned on.	Pass
9. Automatic shutdown function test		In standby mode, when there is no button action, it will automatically shut down within 20 seconds.	Pass
10. Instruction Manual Inspection		The instructions for use of the thermometer shall at least include the following:	Pass
		a) Temperature display range, temperature unit, maximum allowable error, normal working and storage conditions. b) Conversion method between calibration mode and body temperature mode; c) The clinical accuracy or clinical bias of the subject population, body part and thermometer.	
11. Electrical safety inspection	11.1	Case Leakage Current and Patient Leakage Current:	Pass

Test item		Normal status
Case leakage current		＜100uA
Patient	d.c	＜10uA

		leakage (BF)	a.c	＜100uA	
	11.2	Dielectric Strength: Dielectric strength, apply 500Vd.c., the device under test should not be broken down			Pass
12. Packaging inspection		The actual product is consistent with the packing list, and the content on the nameplate is correct.			Pass

Others test:

ID#	Test	Method	Acceptance Criteria	Conclusion
1	Performance test	ASTM E 1965-98	Meet the requirement of the standard	Pass
		ISO 80601-2-56	Meet the requirement of the standard	Pass
2	Electromagnetic Compatibility and Electrical Safety	IEC 60601-1	Meet the requirement of the standard	Pass
		IEC 60601-1-2	Meet the requirement of the standard	Pass
		IEC 60601-1-11	Meet the requirement of the standard	Pass
		IEC/TR 60601-4-2	Meet the requirement of the standard	Pass
3	Usability Test	IEC 60601-1-6	Meet the requirement of the standard	Pass
4	Biocompatibility Testing (skin contact < 24h)			
4.1	In Vitro Cytotoxicity	ISO 10993-5:2009	Non-cytotoxic	Pass
4.2	Skin Sensitization Test	ISO 10993-10:2010	Non-sensitizer	Pass
4.3	Skin Irritation Test	ISO 10993-10:2010	Non-Irritation	Pass

VII Clinical Test Conclusion

YJ600 was tested to ISO 80601-2-56:2017/Amd 1:2018 Medical electrical equipment — Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement — Amendment 1 and ASTM E1965-98(Reapproved 2016) Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature.

This study included 200 subjects (the age range include 0 up to 3 months, 3 months to one year, older than one year to five years, older than five years, detail groups as below)

Age group	Age Range	Number	Gender distribution		
			Gender	Number	Percentage
A	0 up to 3 months	50	Female	22	44%
			Male	28	56%
B	3 months to one year	50	Female	23	46%
			Male	27	54%
C	older than one year to five years	50	Female	28	56%
			Male	22	44%
D	older than five years	50	Female	28	56%
			Male	22	44%

According to the results, Infrared thermometer: Model YJ600 clinical repeatability of each age group are in the range of plus or minus 0.3℃, meets the clinical repeatability requirement ±0.3℃ of ISO 80601-2-56:2017+A1:2018 and ASTM E1965-98(Reapproved 2016) standards.

VIII Conclusion

The testing conducted demonstrates that the differences in technological characteristics do not raise different questions of safety and effectiveness. The subject device, Infrared Thermometer: Model YJ600 is substantially equivalent to the predicate device, Infrared Thermometer, Model: RN-60A, RN-60B, cleared under K200471.