January 21, 2022

Beijing Choice Electronic Technology Co., Ltd.
Haiying Zhao
Official Correspondent
2nd Floor 3rd Floor and Room 410-412 4th Floor
No. 2 Building No. 9 Shuangyuan Road
Shijingshan District, 100041
Beijing, China

Re: K211752
Trade/Device Name: Infrared Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: December 14, 2021
Received: December 22, 2021

Dear Haiying Zhao:

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)*
K211752

Device Name
Infrared Thermometer

Indications for Use *(Describe)*
Infrared Thermometer is a reusable thermometer intended for the intermittent determination of human body temperature in a non-contact mode using the center of the forehead as the measurement site on people of all ages. It can be used by consumers in the household environment and by healthcare provider.

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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Section II 510(k) Summary

This summary of 510(k) is being submitted in accordance with the requirements of 21 CFR 807.92.

There is no prior submission for the device.

2.1 Submitter Information

- **Manufacturer Name:**

Establishment Registration Number: 3005569927

Beijing Choice Electronic Technology Co., Ltd.

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- **Contact Person:**

Haiying Zhao

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- **Date prepared**：May 25, 2021

2.2 Subject Device Information

Regulation Name: Clinical Electronic Thermometer

Device Trade/Proprietary Name: Infrared Thermometer

Model: CFT-308

Purpose of submission：510（k）

Regulation Number: 21 CFR 880.2910

Product Code: FLL

Class: Ⅱ

Panel: General Hospital

2.3 Predicate Device

510(k) Number: K191829

Regulation Name: Clinical Electronic Thermometer

Device Trade/Proprietary Name: Microlife Non-Contact Infrared Forehead Thermometer

Model: FR1DG1 (NC200)

Product Code: FLL

Regulation Number: 21 CFR 880.2910

Device Class: Ⅱ

Panel: General Hospital

Manufacturer: Microlife Intellectual Property GmbH, Switzerland

2.4 Device Description

The infrared thermometer uses infrared temperature sensor to detect infrared energy radiated from the forehead. The intensity of the emitted energy depends on the temperature of the object. The infrared probe can recognize the emitted energy and transfer it to an electronic signal. The electronic signal can be processed in the Infrared Thermometer to convert to a temperature reading, which is displayed on the screen.

This is a continuous non-invasive method of measuring body temperature. After measuring the forehead temperature with an infrared temperature sensor, the calculated temperature value is obtained.

The device is not sterile and the transducers are reusable and do not need sterilization and re-sterilization.

The device is for over-the-counter use.

The Infrared Thermometer, Model CFT-308, consists of the following parts:

a) Infrared sensor

b) Integrated circuit

c) Microprocessor (with Bluetooth function) (Bluetooth transmission is optional)

d) OLED display

e) Buzzer

f) 2 Buttons (“Start” button, “Measuring” button)

g) Alkaline batteries; size AAA, 2 x 1.5 V

h) Lens

2.5 Comparison list of the technological characteristics

Table II-1 Performance Specification Comparison Table between the Subject Device and Predicate Device

Comparison Elements	**Subject Device**	**Predicate Device**	**Similar or Different**
Item	Infrared Thermometer	Microlife Non-Contact Infrared Forehead Thermometer	-
Model	CFT-308	FR1DG1 (NC200)	-
Regulation No.	21 CFR 880.2910	21 CFR 880.2910	√
Classification	Ⅱ	Ⅱ	√
Regulation Name	Clinical Electronic Thermometer	Clinical Electronic Thermometer	√
Product Code	FLL	FLL	√
Indications for use	Infrared Thermometer is a reusable thermometer intended for the intermittent determination of human body temperature in a non-contact mode using the center of the forehead as the measurement site on people of all ages. It can be used by consumers in the household environment and by healthcare provider.	The Microlife Non-Contact Infrared Forehead Thermometer, Model FR1DG1 (NC200) is intended for the intermittent measurement and monitoring of human body temperature. The device is indicated for use by people of all ages in the home.	Difference 1

Comparison Elements		**Subject Device**	**Predicate Device**	**Similar or Different**
Components		a) Infrared sensor b) Integrated circuit c) Microprocessor (with Bluetooth function) (Bluetooth transmission is optional) d) OLED display e) Buzzer f) 2 Buttons (“Start” button, “Measuring” button) g) Alkaline batteries; size AAA, 2 x 1.5 V h) Lens	a) Thermopile Sensor b) Application-Specific Integrated Circuitry c) Erasable Programmable Read-Only Memory Integrated Circuit d) Capacitance-touch Integrated Circuit e) LCD and Backlight f) 3 buttons (“START/POWER” button, “M” button, “MODE” button) g) Alkaline batteries; size AAA, 2 x 1.5 V h) Lens	Difference 2
Performance Specification	Thermometer type	Infrared thermometer	Infrared thermometer	√
		Non-Contact	Non-Contact	√
	Device Measurement Technology	Infrared	Infrared	√
	Temperature Measurement distance	Appropriate within 1 cm	Appropriate within 5 cm	Difference 3

Comparison Elements		**Subject Device**	**Predicate Device**	**Similar or Different**
	Measuring location(human)	Forehead	Forehead	√
	Physical dimension	151*38*50.2 mm	156.7 * 43 * 47 mm	-
	Power supply	Alkaline batteries; size AAA, 2 x 1.5 V	Alkaline batteries; size AAA, 2 x 1.5 V	√
	Display resolution	0.1℃ or 0.1°F	0.1℃ or 0.1°F	√
	Measuring range	32.0℃ ~ 43.0℃ (89.6°F～109.4°F)	32.0 ~ 43.0℃(89.6-109.4 °F)	√
	Accuracy	±0.2℃: 35.0 ~ 42.0℃ ±0.3℃: 32.0 ~ 34.9℃， ±0.3℃: 42.1 ~ 43.0℃ 0.4°F for 95°F～107.6°F Outside that range ±0.5°F	±0.2℃: 35.0 ~ 42.0℃ ±0.3℃: 34.0 ~ 34.9℃ ±0.3℃: 42.1 ~ 43.0℃ ±0.4 °F: 95.0 ~ 107.6 °F ±0.5 °F: 93.2 ~94.8 °F， 107.8~109.4 °F	√

Comparison Elements		**Subject Device**	**Predicate Device**	**Similar or Different**
	Response Time	1second	3 second	Difference 4
	Shelf life	5 years	5 years	√
	Operating conditions	Body mode: 59°F～104°F (15°C～40°C), Relative humidity：15%~93% (non-condensing)	Body mode: 15~40°C (59°F~104°F), 15-95% relative maximum humidity	Difference 5
	Storage conditions	13°F~158°F（-25℃~70℃） Relative humidity ≤93% (non-condensing) in storage/transport	-25~55℃(-13°F~131°F) 15-95% relative maximum humidity	
	Reference site	Armpit	Oral	Difference 6
	Display	OLED display	LCD display	Difference 7
	Date, time, and beeper setting	Yes	Yes	√
	Memory	10 sets memories	30 sets memories	Difference 8

<table>
<tr><th colspan="2">Comparison Elements</th><th>Subject Device</th><th>Predicate Device</th><th>Similar or Different</th></tr>
<tr><td rowspan="4"></td><td>Automatic Switch-off</td><td>The thermometer shall automatically shut off without manipulating in 30 seconds.</td><td>Approx. 1 minute after last measurement has been taken</td><td>Difference 9</td></tr>
<tr><td>Beeper indication</td><td>Yes</td><td>Yes</td><td>√</td></tr>
<tr><td>Age setting</td><td>Selectable between three age ranges：
0 ~ 3 months (Screen display 0-3 Months)
3 ~ 36 months (Screen display 3-36 Months)
＞36 months (Screen display 36+ Months)</td><td>None</td><td rowspan="2">Difference 10</td></tr>
<tr><td>Fever remind</td><td>If the individual temperature being measured is in the fever range, four “beeps” will be heard and upset face icon ☹ will appear on the screen
Different fever ranges at different ages as below:
<table>
<tr><td>Age range</td><td>Above Normal</td></tr>
<tr><td>0 ~ 1 months</td><td>＞37.4℃(＞99.4℉)</td></tr>
<tr><td>1 ~ 3 months</td><td>＞37.4℃(＞99.4℉)</td></tr>
<tr><td>3 ~ 36 months</td><td>＞37.6℃(＞99.6℉)</td></tr>
</table></td><td>10 short beeps and a red LCD backlight alerts that the temperature equal to or higher than 37.5℃</td></tr>
</table>

Comparison Elements		**Subject Device**	**Predicate Device**	**Similar or Different**
		＞36 months ＞37.7℃(＞99.9℉)		
	Clinical Study Support	Yes. Clinical test report	Yes. Clinical test report	√
Contacting Material	Battery Cover	ABS	ABS	√
	Enclosure			
Performance Testing	Laboratory Testing	ISO80601-2-56:2017 ASTM E1965-98:2016	ISO80601-2-56:2017 ASTM E1965-98:2016	√
	Electrical Safety	IEC60601-1:2020 IEC60601-1-11:2020	IEC60601-1:2012, IEC60601-1-11:2015	Difference 11
EMC and Electrical Safe	Electromagnetic Compatibility	IEC60601-1-2:2014 FCC certification ANSI C63.27-2017	IEC60601-1-2:2014	Difference 12
Biocompatibility	Biocompatibility Testing	ISO 10993-1:2018 ISO 10993-5:2009 ISO 10993-10:2010	ISO 10993-1:2018 ISO 10993-5:2009 ISO 10993-10:2010	√

Comparison Elements	Subject Device	Predicate Device	Similar or Different
Software Validation	FDA November 2005 document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".	FDA November 2005 document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".	√
Risk Management	Risk Management in Compliance with ISO14971:2019	Risk Management in Compliance with ISO14971:2007	Difference 13

- **Difference 1:** The intended uses of subject device and predicate device are similar. They are both used for intermittent measurement on the forehead in a no touch mode, and are intended to be used by all ages. The use environment of subject device and predicate device are home and medical setting. While there are some minor differences, these do not raise different questions of safety and effectiveness. The device has been tested in accordance with the appropriate standards.

- **Difference 2:** The subject device and the predicate device have the similar components. The subject device has the function of Bluetooth transmission (Bluetooth transmission is optional). The safety and effectiveness of the Bluetooth function was tested per FCC Part 15B and Part 15C and ANSI C63.27-2017 American National standard for evaluation of wireless coexistence.

- **Difference 3:** Subject device and predicate device have similar measuring requirements. Both require that the probe be aimed at the center of the forehead during the test and keep a certain distance. Subject device 's distance is ≤ 1cm, predicate device 's distance is ≤ 5cm. It does not affect performance and accuracy which was evaluated in the performance testing. The accuracy of the subject device under this algorithm is demonstrated through the Clinical study. The Clinical Study Report was present in Performance Testing – Clinical. The difference in measurement distance has no impact on the safety of the device and is compliant to IEC60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

- **Difference 4:** Subject device response time is 1s. Tested to be compliant to the Guidance on the Content of Premarket Notification [510(K)] Submissions for Clinical Electronic Thermometers.

- **Difference 5:** Subject device and predicate device have similar operating conditions and storage conditions. The storage and operating environment conditions of subject device meet the IEC60601-1: 2005, AMD1:2012, AMD2:2020 and IEC60601-1-11: 2015, AMD1:2020 standards. The test report is presented in the Electromagnetic Compatibility and Electrical Safety.

- **Difference 6:** Subject device and predicate device have different reference sites. The subject device is developed with reference to armpit test temperature. Through clinical trials, the measured temperature of subject device and armpit thermometers are compared to demonstrate the measurement accuracy of subject device meets its declared accuracy range. The test report is presented in the Performance Testing–Clinical.

- **Difference 7:** Subject device and predicate device have different display type. The subject device display meets the requirement of IEC60601-1: 2005, AMD1:2012, AMD2:2020 and IEC60601-1-2:2014. The test report is presented in the Electromagnetic Compatibility and Electrical Safety.
- **Difference 8:** Subject device and predicate device have same memory type, but the amount of storage is different. This does not affect the safety and effectiveness of the device.
- **Difference 9:** Subject device and predicate device have the same function of automatic switch-off, the difference is the time for automatic shutdown. This does not affect the safety and effectiveness of the device.
- **Difference 10:** Subject device and predicate device have same function of above normal temperature reminder; the difference is subject device can set age range but predicate device not include this function. Because different ages have different definitions of above normal temperatures, this subject device has the function of selecting different age ranges (0-1months,1-3months, 3-36months, and +36months). This does not affect the safety and effectiveness of the device.
- **Difference 11:** Subject device and predicate device utilize the same standard, but the subject device uses the latest standards.
- **Difference 12:** The subject device has Bluetooth function (Bluetooth transmission is optional), so we have conducted testing for the subject device according Bluetooth Wireless Test according to FCC Part 15B and Part 15C and wireless coexistence testing. The test report is presented in the Electromagnetic Compatibility and Electrical Safety.
- **Difference 13:** Subject device and predicate device have same standard, but the subject device uses the latest standards.

2.6 Indications for use

Infrared Thermometer is a reusable thermometer intended for the intermittent determination of human body temperature in a non-contact mode using the center of the forehead as the measurement site on people of all ages. It can be used by consumers in the household environment and by healthcare provider.

2.7 Testing

The Infrared Thermometer CFT-308 was supported by both laboratory and clinical accuracy testing in order to ensure that they were appropriate performance and functional features to fully comply with recognized standards and is substantially equivalent to the predicate device.

Non-clinical Test

The Infrared Thermometer CFT-308 is designed and tested and will be manufactured in accordance with both mandatory and voluntary standards, including:

- IEC60601-1: 2005, AMD1:2012, AMD2:2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC60601-1-11: 2015, AMD1:2020 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.
- IEC60601-1-2:2014 Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- ISO80601-2-56:2017 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
- ASTM E1965-98:2016 Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature
- ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

We have performance tests per FDA guidance “Guidance on the Content of Premarket Notification [510(K)] Submissions for Clinical Electronic Thermometers”.

The Software Validation is in compliance with FDA Guidance “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”.

Compliant to FDA Guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling".

Table II-2 The list of non-clinical test performed on the subject devices.

No.	Test Name
1	System Performance Test
2	Performance Test according to ISO 80601-2-56: 2017
3	Electromagnetic Compatibility Test According to IEC60601-1-2:2014
4	Electrical Safety Test According to IEC60601-1: 2005, AMD1:2012, AMD2:2020
5	Used in the home healthcare environment test according to IEC60601-1-11: 2015, AMD1:2020
6	Bluetooth Wireless Test according to FCC Part 15B and Part 15C
7	Wireless coexistence testing
8	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process ISO 10993-1:2018
9	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity ISO10993-5:2009
10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization ISO10993-10:2010

The test results indicate that the safety and effectiveness of the subject device is substantially equivalent to that of the predicate device.

Clinical Test

Clinical testing was conducted according to ASTM E1965-98(2016) and ISO 80601-2-56:2017. The Clinical Study of CFT-308 was conducted May 29th, 2020 to March 19th, 2021 in the second hospital of Tianjin medical university. The subject device was compared to a reference thermometer (Model Number：CRW-23) for this study.152 subjects were screened, 2 subjects were eliminated, and 150 subjects completed the clinical trial (15 subjects aged 0 to 3 months, 35 subjects aged 3 months to 1-year-old, 50 subjects aged from 1 to 5 years old, 50 subjects aged 5 years and above).

2.8 Determination of substantial equivalence

The subject device of Infrared Thermometer CFT-308 has the same classification information, same intended use, similar components, similar performance effectiveness as the predicated device. The subject device is Substantially Equivalent (SE) to the predicate device which is US legally market device.