January 15, 2021

Shenzhen Xunwei Industrial Co., Ltd.
℅ Yoyo Chen
Consultant
Shenzhen Joyantech Consulting Co.,Ltd.
1713A, Block A, Zhongguan Times Square,
Liuxian Avenue, Xili Town
Shenzhen, 518000
China

Re: K201579
Trade/Device Name: Infrared Thermometer, Model XW-60
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: December 10, 2020
Received: December 18, 2020

Dear Yoyo Chen:

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,

CAPT Alan Stevens
Acting 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)*
K201579

Device Name
Infrared Thermometer, Model XW-60

Indications for Use *(Describe)*
The infrared thermometer, Model XW-60 is intended for the intermittent measurement and monitoring of forehead temperature of human body. The device is indicated for use by people of one month old and above age in the home.

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

This summary of 510(K) safety and effectiveness information is submitted As Required by requirements of SMDA and 21 CFR §807.92.

1. Administrative Information

Submission Date	June 3, 2020
Manufacturer information	Shenzhen Xunwei Industrial Co., Ltd. Address: First floor to fourth, Upper Small Industrial Zone, Jinhua Road, Block 75, Xixiang Street, Baoan District, Shenzhen City, Guangdong, 518102, China. Contact person: Liu Shengcai TEL: +86-755-86191210 E-Mail: richard@szxunwei.com
Submission Correspondent	Shenzhen Joyantech Consulting Co., Ltd. 1713A, 17th Floor, Block A, Zhongguan Times Square, Liuxian Avenue, Xili Town, Nanshan District, Shenzhen, Guangdong Province, China. Contact person: Ms. Yoyo Chen E-Mail: yoyo@cefda.com; field@cefda.com
Establishment registration number	N/A

2. Device Information

Type of 510(k) Submission:	Traditional
Device Name:	Infrared Thermometer
Model:	XW-60
Classification Name:	Thermometer, Electronic, Clinical
Review Panel:	General Hospital
Device Class:	2
Regulation Number:	880.2910
Product Code:	FLL

3. Predicate Device

Manufacturer	Microlife Intellectual Property GmbH
Device name	Microlife Non-Contact Infrared Forehead Thermometer
Model	FR1DG1 (NC200)
510(K) Number:	K191829
Product Code	FLL

4. Device Description

The device is intended for the intermittent measurement and monitoring of forehead temperature of human body. The device is indicated for use by people of all ages in the home. It has the following features:

- Three button operation;
- Optional mode for Fahrenheit and Celsius;
- Short measurement response time;
- There are 20 measurement data can be memorized and stored;
- Two color backlight display;
- Low and high temperature warning beeps;
- Automatic shutdown feature to save energy;
- Low battery indication;

5. Intended Use/Indication for Use

The infrared thermometer, Model XW-60 is intended for the intermittent measurement and monitoring of forehead temperature of human body. The device is indicated for use by people of one month old and above age in the home.

6. Comparison with predicate device

The subject device infrared thermometer, Model XW-60 is substantially equivalent to the predicate device (K191829). This conclusion is based upon comparison on intended use, technological characteristics and applicable safety standards. Any difference in the technological characteristics does not raise any new issues or concerns of safety or effectiveness.

Items	Subject Device (XW-60)	Predicate Device (K191829)	Comparison
Product code	FLL	FLL	Same
Regulation number	880.2910	880.2910	Same
Device class	2	2	Same
Intended use	The infrared thermometer, Model XW-60 is intended for the intermittent measurement	The Microlife Non-Contact Infrared Forehead Thermometer, Model	Different (Note 1)

Items	Subject Device (XW-60)	Predicate Device (K191829)	Comparison
	and monitoring of forehead temperature of human body. The device is indicated for use by people of one month old and above age in the home.	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.	
Prescription or OTC	OTC	OTC	Same
Prescription or OTC	OTC	OTC	Same
Thermometer type	Infrared thermometer Non-contact	Infrared thermometer Non-contact	Same
Device Measurement Technology	Infrared	Infrared	Same
Measurement location	Forehead	Forehead	Same
Measurement Range	Body mode: 32.0°C ~43.0°C (89.6°F ~109.4°F);	Body mode: 34.0°C - 43.0 °C (93.2-109.4 °F);	Different (Note 2)
Measurement accuracy	±0.2°C :35.0°C ~42.0°C ± 0.3°C: 32.0°C ~34.9°C, 42.1°C ~43.0°C ±0.4°F:95.0°F ~107.6°F ±0.5°F:89.6°F ~94.8°F, 107.8°F ~109.4°F	±0.2 °C: 35.0 ~ 42.0 °C ±0.3 °C: 34°C ~ 34.9°C, 42.1°C ~43°C, ±0.4 °F: 95.0 ~ 107.6 °F, ±0.5 °F: 93.2 ~94.8 °F，107.8~109.4 °F	Different (Note 2)
Temperature Measurement distance	3cm~5cm	Appropriate within 5 cm	Similar
Display Type	LCD Display	LCD Display	Same
Display resolution	0.1°C (0.1°F)	0.1°C (0.1°F)	Same
Power supply	d.c.3.0V (2pcs AAA batteries)	d.c.3.0V (2pcs AAA batteries)	Same
Measurement	1second	3 second	Different

Items	Subject Device (XW-60)	Predicate Device (K191829)	Comparison
time			(Note 3)
Measurement data memories	20 sets memories	30 sets memories	Different (Note 4)
Beeper setting	Yes	Yes	Same
Date and time setting	No	Yes	Different (Note 5)
Backlight	Green and orange backlight according to the measured temperature;	Green and red backlight according to the measured temperature;	Similar
Auto-off time	Approx. 1 minute after last measurement has been taken	Approx. 1 minute after last measurement has been taken	Same
Operation Condition	Temperature: 50°F～104°F (10°C～40°C) Relative Humidity: 15%~95% Atmospheric Pressure: 70kPa～106kPa	Ambient Temperature: 15°C~40°C （59°F~104°F）; Relative humidity: 15%~95%RH	Different (Note 6)
Storage and transportation condition	Temperature: -4°F～131°F (-20°C～55°C) Relative Humidity: 15%~95% Atmospheric Pressure: 70kPa～106kPa	Ambient Temperature: -25°C~55°C (-13°F～131°F); Relative humidity: 15%~95%RH	Different (Note 6)
Protection against electric shock	Internally power supply, Type BF	Internally power supply, Type BF	Same
IP Class	IP22	IP22	Same
Mode of operation	Continuous	Continuous	Same
Error	Display Err when system has malfunction	Display Er0 or Er6 when system has malfunction	Different (Note 7)
High temperature alarm	3 short beeps and LCD display " Hi " while equal to or higher than 37.5°C	10 short beeps and a red LCD backlight alerts that the temperature equal to or higher than 37.5°C	Different (Note 8)
Auto measurement	No	The device can take a measurement automatically when the device detects the distance is appropriate within 5 cm.	Different (Note 9)

Items	Subject Device (XW-60)	Predicate Device (K191829)	Comparison
Sensor type	HMSK1C1F5.5	TPS336	Different (Note 10)
Housing material	ABS/AG15A1-H	ABS/PA 707	Different (Note 11)
Patient-contact button material	ABS/AG15A1-H	PMMA	Different (Note 11)
IC (Integrated Circuitry)	HY11P54	HY11P14	Different (Note 12)
Signal processing	24 bit analog-to digital converter	24 bit analog-to digital converter	Same
Algorithms	FR Algorithm	PH15.0Algorithm	Different (Note 12)
Physical Dimensions	140*38*40mm	156.7*43*47 mm	Different (Note 13)
Weight	70g (Battery excluded)	68.5 g (Battery excluded)	Similar
Expected Service Life	5 year	5 year	Same
Safety & Performance	IEC 60601-1:2005+AMD 1: 2012; IEC 60601-1-2:2014; IEC 60601-1-11:2015; ISO 80601-2-56: 2017; ASTM E1965-98.	IEC 60601-1:2005+AMD 1: 2012; IEC 60601-1-2:2014; IEC 60601-1-11:2015; ISO 80601-2-56: 2017; ASTM E1965-98.	Same
Biocompatibility	Cytotoxicity, ISO 10993-5 Skin Irritation, ISO 10993-10 Skin Sensitization, ISO 10993-10	Cytotoxicity, ISO 10993-5 Skin Irritation, ISO 10993-10 Skin Sensitization, ISO 10993-10	Same
Clinical Study Support	Yes	Yes	Same

(1). Note 1: Indication for use

The subject device is intended to be measuring for the people of one month and above age in the home. This is different from the predicate device. However, we believe this different this does not raise a safety and effectiveness issue. A clinical study was carried out on the subject device for the intended population.

(2). Note 2: Measurement Range and Accuracy

Compared with the predicate device, the subject device has a wide measurement range and different measurement accuracy. They both meet the standard requirement of ASTM E1965-98 reapproved 2016 and ISO 80601-2-56:2018. Therefore, we believe this different will not raise any new safety and effectiveness issues.

(3). Note 3: Measurement time

The measurement time of subject device is much quick than predicate device, but the accuracy of measurement has been validated during performance testing in according to the standard requirement of ASTM E1965-98 reapproved 2016 and ISO 80601-2-56:2018. Therefore, we considered that the difference does not raise any issues on the device safety and effectiveness.

(4). Note 4: Measurement data memories

The functional purpose of measurement data memories is intended to record previous readings. The difference does not raise new questions of safety and effectiveness. This function has been verified during software verification.

(5). Note 5: Date and time setting

Although there is no date and time setting functions for the subject device, both of subject devices and predicate device meet the basic safety requirement of IEC 60601-1:2015, ASTM E1965-98 reapproved 2016, and ISO 80601-2-56:2018. The difference does not raise any new questions of safety and effectiveness.

(6). Note 6: Operation Condition, Storage and transportation condition

Both of subject devices and predicate device are meet the basic safety requirement of IEC 60601-1:2015, ASTM E1965-98 reapproved 2016, ISO 80601-2-56:2018, IEC60601-1-11. The difference does not raise any new questions of safety and effectiveness.

(7). Note 7: Error

Both subject device and the predicate device have self-test function. The principle of self-test is the same. Devices can perform a self-test every time when it is switched on to verify the specified accuracy of any measurement. When an error is detected, it will display an error message. Subject device will display icon “Err” and the predicate device will display icon “Er0” and “Er6”. Although the icons are different, the intended functions are the same.The icon has been defined in the user manual. The differences do not raise new questions of safety and effectiveness.

(8). Note 8: High temperature alarm

Both subject device and the predicate device have high temperature alarm function, when the reading temperature equal to or higher than 37.5°C, in the meantime the device will keep beeping. Even though the beeping time is different, the purposes are the same. It does not affect device’s safety and effectiveness.

(9). Note 9: Auto measurement

This purpose of auto measurement of predicate device is to test the body temperature. However, for the subject device, the user can read the body temperature by aiming the probe

at the center of the forehead with any distance of no more than 3~ 5cm and pressing the “Start “button. The purpose of body temperature measurement can be achieved for subject device and predicate device. Therefore, we considered that the difference does not raise any issues on the device safety and effectiveness.

(10). Note 10: Sensor type and IC

Although the sensor type and IC of subject devices are different with predicate device, but these devices are all tested to conform with same safety and performance standard IEC 60601-1:2015, ASTM E1965-98 reapproved 2016, and ISO 80601-2-56:2018. Otherwise, a clinical study was carried out on the subject device for febrile and afebrile human subjects. It demonstrates the subject device is reliable under clinical use.

(11). Note 11: Housing material, patient-contact button material

Although the housing material and patient-contact button material for subject device and predicate devices are different, but they are all compliance with the biocompatibility standards ISO 10993-5 and ISO 10993-10. Therefore, we considered that the difference does not raise any issues on the device safety and effectiveness.

(12). Note12：Algorithms

Although the algorithms for subject device and predicate devices are different, but they are all complied with performance standards ISO 80601-2-56: 2017 and ASTM E1965-98. In addition, a clinical study is carried out to validate the clinical accuracy of subject devices. Therefore, we considered that the difference does not raise any issues on the device safety and effectiveness.

(13). Note13: Physical Dimensions

The difference is caused because of their different appearance, but the difference does not raise any new safety and effectiveness questions. This has been tested and confirmed according to IEC 60601-1-2 EMC, IEC60601-1, and ISO 80601-2-56 standards. Therefore, we considered that the difference does not raise any issues on the device safety and effectiveness.

7. Non-Clinical Test Summary

7.1. Electromagnetic Compatibility and Electrical Safety Test

The subject device has passed safety testing in according to following standards.

1) AAMI/IEC 60601-1:2005+AMD 1: 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2) 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
3) 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

7.2. Biocompatibility Test

The subject device has passed biocompatibility tests in according to following standards.

1) ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
2) ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

7.3. Performance Test-Bench

The subject device has passed performance testing in according to following standard.

1) ISO 80601-2-56:2017+AMD2018 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
2) ASTM E1965-98 (Reapproved 2016) Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature

8. Clinical Study

Clinical study was conducted in according to ASTM E1965-98(Reapproved 2016). This clinical study is a randomization, simple blind homologous control, pairing design of clinical investigation, consisting of 150 subjects, of which 50 subjects are one month to one year old, 50 subjects are one year to five years old, and 50 subjects are > 5 years old. The clinical test report demonstrated that the clinical data, represented by clinical bias and clinical repeatability, met the acceptance criteria of the clinical study protocol.

9. Conclusion

The Infrared Thermometer (Model XW-60) is substantially equivalent to the predicate device (K191829). This conclusion is based upon comparison on intended use, technological characteristics and applicable standards. Any differences in the technological characteristics do not raise new questions of safety or effectiveness.