September 19, 2022

Jiaxing Shangjia Intelligence Technology Co., Ltd.
% You Yijie
Manager
Qimmiq Medical Consulting Service Co., Ltd.
RM.1711, Building K, NO.101 Science Ave
International Creative Valley
Guangzhou, Guangdong 510663
China

Re: K213038
Trade/Device Name: Infrared Forehead Thermometer, model: HS-9802D
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical electronic thermometer
Regulatory Class: Class II
Product Code: FLL

Dear You Yijie:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated March 10, 2022. Specifically, FDA is updating this SE Letter typo in the trade name as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Payal Patel, OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices, 240-402-6029, payal.patel@fda.hhs.gov.

Sincerely,

David Wolloscheck, Ph.D.
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

March 10, 2022

Jiaxing Shangjia Intelligence Technology Co., Ltd.
You Yijie
Manager
Qimmiq Medical Consulting Service Co., Ltd.
RM.1711, Building K, NO.101 Science Ave
International Creative Valley
Guangzhou, Guangdong 510663
China

Re: K213038
Trade/Device Name: Infrared Forehead Thermometer, model: HS-98020
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: January 31, 2022
Received: January 31, 2022

Dear You Yijie:

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

Section 4: Indications for Use Statement (Form FDA 3881)

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)*

K213038

Device Name

Infrared Forehead Thermometer, model: HS-9802D

Indications for Use *(Describe)*

Infrared Forehead Thermometer, model: HS-9802D 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.

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. Submitter's Information

Establishment Registration Information

Name: Jiaxing Shangjia Intelligence Technology Co., Ltd.
Address: Room 102 and Room 202, Building No.9, Jiaxing Intelligence & Innovation Park, No.36, South Changsheng Road, Jiaxing, Zhejiang, China

Contact Person of applicant

Name: Lou Yongwei
Address: Room 102 and Room 202, Building No.9, Jiaxing Intelligence & Innovation Park, No.36, South Changsheng Road, Jiaxing, Zhejiang, China
TEL: +86 0573 89978800
Email: 100831552@qq.com

Contact Person of the Submission:

Name: Yijie You
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TEL: +86 020-8224 5821
FAX: +86 020-8224 5821
Email: Jet.you@qimmiq-med.com

Date prepared: Sep. 8, 2021

2. Device Information

Device Common Name: Clinical electronic thermometer

Trade Name:	Infrared Forehead Thermometer
Model:	HS-9802D
Regulation name:	Clinical electronic thermometer
Review Panel:	General Hospital
Product Code:	FLL
Regulation Class:	II
Regulation Number:	880.2910

3. Predicate Device Information

510(k) submitter/holder:	Microlife Intellectual Property GmbH, Switzerland.
510(K) Number:	K191829
Trade Name:	Microlife Non-Contact Infrared Forehead Thermometer

Model: FR1DG1 (NC200)
Classification name: Clinical electronic thermometer
Review panel: General Hospital
Product code: FLL
Regulation Class: II
Regulation Number: 880.2910

4. Device description

Infrared Forehead Thermometer, model: HS-9802D is a hand-held, battery powered, infrared thermometer that measures human body temperature from forehead. The reference body site is oral. The device measures temperature from center of the forehead.

Principle of operation:

Infrared Forehead Thermometer, model: HS-9802D is an electronic thermometer uses IR sensor (thermopile) to detect infrared radiation emitting from forehead, after then, the IR sensor outputs electrical signal which is fed to circuit for amplification and then being inputted to MCU, the MCU captures the temperature measured from center of forehead. The measured temperature will finally appear on LCD display.

5. Indications for Use

Infrared Forehead Thermometer, model: HS-9802D 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.

6. Summary of technological characteristics of device compared to the predicate device

SE Comparisons	**Subject device** (Infrared Forehead Thermometer, model: HS-9802D)	**Primary predicate device** (K191829, Microlife Non-Contact Infrared Forehead Thermometer, Model: FR1DG1 (NC200))	**Discussion of difference**
Classification	21CFR 880.2910	21CFR 880.2910	**Same**
Product Code	FLL	FLL	**Same**
FDA Class	II	II	**Same**
Intended Use	Infrared Forehead Thermometer, model: HS9802D 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.	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.	**Same**

Principle of operation	Measure temperature by reading infrared radiation emitting from the forehead when the	Measure temperature by reading infrared radiation emitting from the forehead when	**Same**
	thermometer is placed within few centimeters of forehead.	the thermometer is placed within few centimeters of forehead.	
target population	people of all ages	people of all ages	**Same**
Measurement site	forehead	forehead	**Same**
Material of Patient contact components	Probe: ABS Cap: PS Liquid crystal display (LCD): Glass ON/Scan button: ABS Battery Cover (shell has same material): ABS Memory button: Silica gel	Housing and battery cover material: ABS707 Patient-Contact Button material: PMMA	**Different** (Discussion is indicated in D1)
Biocompability testing	Meets ISO 10993- 5 ISO 10993-10	Meets ISO 10993- 5 ISO 10993-10	**Same**
Environment	home	home	**Same**
Design	Handheld	Handheld	**Same**
Measurement method	Infrared radiation detection	Infrared radiation detection	**Same**
Display Type	LCD	LCD	**Same**
Measurement Mode	Forehead mode	Forehead mode	**Same**
Reference site	Oral	Oral	**Same**
Key	Two buttons (ON/Scan button, Memory button)	Two buttons (M-button, START I/O button)	**Same**
Scale selection	°C/°F	°C/°F	**Same**
Display unit	°C/°F	°C/°F	**Same**
High temperature warning	Yes	Yes	**Same**
Low battery indicator	Yes	Yes	**Same**
Sensor Type	Thermopile	Thermopile	**Same**
Performance Testing	Meets ASTM E1965-98 and ISO 80601-2-56	Meets ASTM E1965-98 and ISO 80601-2-56	**Same**
Electrical Safety	ANSI AAMI ES60601-1	ANSI AAMI ES60601-1	**Same**

EMC Meets	IEC 60601-1-2	IEC 60601-1-2	**Same**
Measuring Range	34.0 to 42.0 °C (93.2 to 107.6 °F).	32.0-43.0 °C (89.6-109.4 °F)	**Different** (Discussion is indicated in D2)
Display resolution	0.1°F (0.1ć)	0.1eF (0.1ć)	**Same**
Measuring accuracy	±0.3°C (0.5°F): 34.0 to 42.0 °C (93.2 to 107.6 °F).	±0.2 °C: 35.0 ~ 42.0 °C ±0.3 °C: 34.0 ~ 34.9 °C, 42.1 ~ 43.0 °C	**Different** (Discussion is indicated in D3)
Measuring Distance	< 2.5cm	< 5cm	**Different** (Discussion is indicated in D4)
Measurement data memories	6 sets memories	30 sets memories	**Different** (Discussion is indicated in D5)
Backlight	Yes	Yes	**Same**
Auto-off time	15 seconds	Approx. 1min second after last measurement has been taken	**Different** (Discussion is indicated in D6)
Beeper indication	Yes	Yes	**Same**
Operation Condition	5-40ć; 20%-95%R.H., noncondensing	Ambient Temperature: 15°C~40°C (59°F~104°F) Relative humidity: 15%~95%RH (noncondense)	**Different** (Discussion is indicated in D7)
Storage and transportation condition	-20 - 50ć; 10%-95%R.H., noncondensing, 70-106kPa	-25 ~ 55 °C (-13°F ~131°F) 15-95 % relative maximum humidity	**Different** (Discussion is indicated in D8)
Physical dimension	134x76.5x38 mm	156.7 x 43 x 47 mm	**Different** (Discussion is indicated in D9)
High temperature alarm	Yes	Yes	**Same**
Power source	3 V d.c. (2X AAA batteries)	3.0V DC with 2 AAA batteries	**Same**

The discussion of differences exist between the subject and predicate device is listed in following:

D1: The proposed device has been validated for cytotoxicity per ISO 10993- 5 and Irritation as well as Sensitization per ISO 10993-10. The difference will not affect the safety and effectiveness.

D2&D3: The proposed device conducted performance testing in accordance with ASTM E1965-98, ISO 80601-2-56 to demonstrate the difference does not affect the safety and effectiveness.

D4: The Measuring Distance range of proposed device is in the range of the predicate device. The difference will not affect the safety and effectiveness.

D5: The different memory number will not affect the safety and effectiveness.

D6: The different Auto-off time will not affect the safety and effectiveness.

D7: The operating condition of subject device has passed the safety test and comply with the requirement of ASTM E1965-98, and the subject device complies the standard IEC 60601-1-11, so the difference between the operating conditions of subject device and predicate device will not affect the safety and effectiveness.

D8: The operating condition of subject device has passed the tests of ASTM E1965-98 and ISTA 2A, so the difference between the operating conditions of subject device and predicate device will not affect the safety and effectiveness.

D9: The different dimension will not affect the safety and effectiveness.

7. Discussion of Non-Clinical Tests Performed for Safety and effectiveness are as follows

The recognized consensus standards for safety of medical electrical equipment: ANSI AAMI ES60601-1, IEC 60601-1-11 for safety, IEC 60601-1-2 for electromagnetic compatibility, ASTM E 1965-98 and ISO 80601-2-56 for performance and IEC 62304 are complied, and see below table for details:

Standards	Standards Name
ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
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
IEC 60601-1-11: 2015	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests
ISO 80601-2-56: 2017+A1:2018	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

IEC 62304:2006+A1:2015	Medical device software - Software life cycle processes
ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2010	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

Software verification and validation was performed for the subject device in accordance with Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff, May 2005.

8. Discussion of Clinical Accuracy Testing Performed

The clinical accuracy test report and data analysis followed the requirements of the ASTM E 196598 (2016).

The clinical accuracy testing evaluated 105 of subjects, division of all subjects into (1) infants-newborn up to one year, (2) children- greater than one to five years; and (3) adults—greater than five years ol. The test data showed the clinical accuracy of the subject device complied with the requirements of ASTM E1965-98 (2016).

Summary of reference equipment:

Name	Digital Thermometer	Microlife Non-Contact Infrared Forehead Thermometer
Model	KFT-03	FR1DG1 (NC200)
Manufacturer	Kangfu Medical Equipment Factory	Microlife Intellectual Property GmbH, Switzerland
Measuring Method	Contact	Non-Contact Infrared Forehead
K Number	K182652	K191829

9. Conclusions

Based on performance testing, comparison and analysis, the subject device Infrared Forehead Thermometer, model HS-9802D is substantially equivalent to the predicate device.