July 12, 2018

Shenzhen Jiacom Technology Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd.
P.O Box 120-119
Shanghai, 200120 China

Re: K172874
Trade/Device Name: Infrared Thermometer, Model FR800 and FR850
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: June 5, 2018
Received: June 14, 2018

Dear Diana Hong:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Alan M. Stevens -S

Digitally signed by Alan M. Stevens -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300189211, cn=Alan M. Stevens -S
Date: 2018.07.12 14:55:51 -04'00'

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172874

Device Name
Infrared Thermometer
Model: FR800 and FR850

Indications for Use *(Describe)*
Infrared Thermometer is intended to detect body temperature from forehead in the population including infant (above 6 months), child, adolescent, and adult.

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.

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510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K172874

1. Date of Preparation: 6/19/2018

2. Sponsor Identification

Shenzhen Jiacom Technology Co ., Ltd
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4. Identification of Proposed Device

Trade Name: Infrared Thermometer, Model(s): FR800 and FR850
Common Name: Clinical electronic thermometer
Model(s): FR800 and FR850

Regulatory Information

Classification Name: Clinical electronic thermometer
Classification: Class II
Product Code: FLL
Regulation Number: 21 CFR 880.2910
Review Panel: General Hospital

Indications for Use:

Infrared Thermometer is intended to detect body temperature from forehead in the population including infant (above 6 months), child, adolescent, and adult.

Device Description

The proposed device, Infrared Thermometers, which includes model FR800 and FR850 are hand-held, reusable, battery powered device, which are intended to detect body temperature from forehead for infant (above 6 months), child, adolescent, and adult.

The proposed device is intended for non-contacting infrared temperature measurement. The distance of the measurement is 3cm~5cm.

The proposed device uses a temperature sensor, which can detect the object temperature [human body temperature], environment temperature and temperature of sensor itself; these temperatures are then transfer to electronic signal and amplified; and then it is transferred to digital signal by AD module in MCU of the proposed device. MCU will calculate the body temperature, and then transfer to screen for display.

5. Identification of Predicate Device(s)

510(k) Number: K161728
Device Name: Microlife Digital Infrared Forehead Thermometer, Model FR1MN1-1

6. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

ITEM	Proposed device K172874	Predicate Device K161728
Product Code	FLL	FLL
Regulation Number	21 CFR 880.2910	21 CFR 880.2910
Indications for Use	Infrared Thermometer is intended to detect body temperature from forehead in the population including infant	The Microlife Digital Infrared Forehead Thermometer, Model FR1MN1-1 is intended for the

	(above 6 months), child, adolescent, and adult.	intermittent measurement and monitoring of human body temperature. The device is indicated for use by people of all ages in the home.
Measurement Site	Forehead	Forehead
Principle of Operation	Non-contacting, Infrared Temperature Measurement	Non-contacting, Infrared Temperature Measurement
Device features	Display type: LCD	Display type: LCD
	Activation: Scan button	Activation: Scan button
	Have Memory function	Have Memory function
	Have backlight	Have backlight
	Have beeper indication	Have beeper indication
Range	32.0℃-42.9℃	34.0℃-42.2℃
Accuracy	±0.2℃ at 35.0℃-42.0℃ ±0.4°F at 95°F-107.6°F ±0.3℃ at others ±0.5°F at others	0.4 °F, 96.8 ~ 102.2 °F
Display type	LCD	LCD
Activation	Scan button	Scan button
Power requirements	3Vdc	3Vdc.
Electrical Safety	Complied with IEC 60601-1	Complied with IEC 60601-1
EMC	Complied with IEC 60601-1-2	Complied with IEC 60601-1-2
Performance	Complied with ISO 80601-2-56	Complied with ISO 80601-2-56
	Complied with ASTM E 1965 -98 (2003)	Complied with ASTM E 1965 -98 (2003)
Patient-contact component and material	Enclosure: Acrylonitrile Butadiene Styrene (ABS) Color additive: Titanium dioxide	Unknown
Biocompatibility	Complied with ISO 10993-5	Complied with ISO 10993-5
	Complied with ISO 10993-10	Complied with ISO 10993-10

The subject device is used for above 6 months patients. However, the predicate is used for all ages. The user population of the subject device is subset of the predicate. Therefore, this difference does not raise new safety and effectiveness questions.

The measurement range and accuracy of proposed device and predicate device is different.

Measurement range of proposed device is wider than that of the predicate device. Bench test included in this submission demonstrated that the proposed device can measure this range accurately. The measurement accuracy of proposed device is slightly different from that of the predicate device. However, the specifications of the proposed device comply with the current ISO and ASTM Standards. Therefore, these differences do not raise new questions of safety and effectiveness.

Although we do not know the patient-contact component and material of predicate device, the biocompatibility of proposed device meets ISO 10993 and is equivalent to the predicate.

7. Non-Clinical Tests

Non clinical tests were conducted to verify that the proposed device met all design specifications and is Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-5:2009 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
- AAMI / ANSI ES60601-1:2005/(R) 2012 and A1:2012, c1:2009/(R)2012 and A2:2010/(R)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 Compatibility - Requirements And Tests.
- ISO 80601-2-56 First Edition 2009-10-01, Medical Electrical Equipment - Part 2-56: Particular Requirements For Basic Safety And Essential Performance Of Clinical Thermometers For Body Temperature Measurement.
- ASTM E 1965-98 (R 2016), Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature

Software verification and validation data was completed as recommended in the FDA guidance document, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

All the tests results of above tests, complied with the requirements of its pre-defined acceptance criteria and intended uses.

8. Clinical Test Conclusion

Controlled human clinical studies were conducted in accordance with ASTM E 1965-98(2003), clinical bias, clinical uncertainty and clinical repeatability have been evaluated per clinical validation for infrared thermometer. The clinical trial results verify that the clinical accuracy of the proposed device is not inferior to that of predicate device.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate device.