January 2, 2019

Shenzhen Finicare Co., Ltd.
Chao Li
General Manager
Room 201, A Building NO. 1 Qianwan Road
Shengang Cooperative Zone, Qianhai
Shenzhen, 518052
China

Re: K181215
Trade/Device Name: Infrared Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: July 17, 2018
Received: August 13, 2018

Dear Chao Li:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

Geeta K. Pamidimukkala -S

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)*
K181215

Device Name
Infrared thermometer, models FC-IR100, FC-IR101, FC-IR200, FC-IR300, FC-IR400

Indications for Use *(Describe)*
The Infrared Thermometer is intended for the measurement of human body temperatures. The forehead mode is indicated for people of all ages and the tympanic mode is indicated for people above three months old. The device can be used in the home setting and medical institutes.

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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K181215

510(k) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

1. Submitter:

Shenzhen Finicare Co., Ltd.

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Tel.: +86 -755-23013503
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Contact Person: Chao Li

Prepare date: 2018-03-31

2. Device name and classification:

Device Name: Infrared Thermometer

Models: FC-IR100, FC-IR101, FC-IR200, FC-IR300, FC-IR400

Classification Name:

21 CFR 880.2910

Clinical Electronic Thermometers-Temperature Monitor with Probe

Product code: FLL

Regulatory Class: Class II

3. Reason for Submission New Application.

4. Predicate Device(s): Shenzhen Brav Electronic Technologies Co., Ltd., EFT-165 Infrared Thermometer /K171214

5. Device Description:

FC-IR series infrared thermometers (Models: FC-IR100, FC-IR101, FC-IR200, FC-IR300, FC-IR400) measure the body temperature through receiving infrared energy radiation via the ear or forehead. These thermometers have the capability to measure temperature via forehead temperature mode or ear temperature mode, and the temperature is directly shown on the LCD display.

- The device is intended to be used in the home setting and medical institutes.
- The product is mainly composed of infrared temperature sensors, signal receiving processor, buttons, buzzer, LCD display. It is powered by 2 X 1.5 AAA batteries.
- It focuses the infrared energy received from the human's forehead or ear by using the Fresnel lens of the thermometer.

In addition, when measuring the ear temperature, the ear cover must be used by all thermometer models except for the FC-IR200. FC-IR101 model incorporates Bluetooth technology to wirelessly transmit temperature reading to an APP.

Model(s) / Configuration	FC-IR100	FC-IR101	FC-IR200	FC-IR300	FC-IR400
Internal Battery	√	√	√	√	√
°C/°F Transaction	√	√	√	√	√
Forehead Measurement	√	√	√	×	×
Tympanic Measurement	√	√	×	√	√
Ear Cover	√	√	×	√	√
Bluetooth	×	√	×	×	×
High Temperature Hint	√	√	√	√	√
Backlight	√	√	√	√	√

6. Indications for Use:

The Infrared Thermometer is intended for the measurement of human body temperatures. The forehead mode is indicated for people of all ages and the tympanic mode is indicated for people above three months old. The device can be used in the home setting and medical institutes.

7. Predicate Device Comparison

In comparison to the predicate device, the subject device has the same intended use, similar product design, same performance effectiveness, and performance safety as the predicate device.

Please refer to the following table that notes differences between the subject device and predicate device. All the differences do not affect the basic design principle, usage, effectiveness and safety of the subject device. No new questions are raised regarding effectiveness and safety.

Table 1 Comparison between the main predicate device EFT-165 and the subject device

ITEM	**Proposed Device FC-IR series**	**Predicate Device EFT-165/K171214**	**Comparison Result**
Manufacture	Shenzhen Finicare Co., Ltd.	Brav Electronic Technologies Co., Ltd.	---
Indications for Use	The Infrared Thermometer is intended for the measurement of human body temperatures. The forehead mode is indicated for people of all ages and the tympanic mode is indicated for people above three months old. The device can be used in the home setting and medical institutes.	The infrared thermometer is intended for the measurement and monitoring of human body temperature by doctor or customers in the hospital or home.	Different
Operational Specifications			
Operational Principle	Infrared radiation detection	Infrared radiation detection	Same
Measuring Mode	Forehead and ear	Forehead and ear	Same

Measurement Range	32.0°C～42.9°C （89.6°F~109.2°F)	32.0°C～42.9°C （89.6°F~109.2°F)	Same
Measurement Distance	0 cm	0 cm	Same
Accuracy	Body Mode: ±0.2°C(0.4°F)	Body Mode: ±0.2°C(0.4°F)	Same
Memory Data Limit	memorize 20 measurements automatically	memorize 20 measurements automatically	Same
Product configuration	It is mainly composed with infrared sensor, signal receiving processor, buttons, buzzer, LCD display, battery and etc.	It is mainly composed with infrared sensor, signal receiving processor, buttons, buzzer, LCD display, battery and etc.	Same
Temperature unit and conversion	Dual temperature units "°C" and "°F" optional, and the two units can convert by the conversion key automatically	Dual temperature units "°C" and "°F" optional, and the two units can convert by the conversion key automatically	Same
Bluetooth Compatible	YES (FC-IR 101 only)	YES	Same
Applicable Standards	AAMI ANSI ES60601-1, IEC 60601-1-2, IEC 60601-1-11, and ASTM E1965-98, ISO 10993-5, ISO 10993-10	AAMI ANSI ES60601-1, IEC 60601-1-2, IEC 60601-1-11, and ASTM E1965-98, ISO 10993-5, ISO 10993-10	Same
Display	0.1°C/°F, LCD	0.1°C/°F, LCD	Same
Operating Environment	15°C ~ 35°C (59°F to 95 °F) ≤85% moisture condensation	15°C ~ 35°C (59°F to 95 °F) ≤85% moisture condensation	Same
Storage Environment	-20°C~55°C（-4°F~131°F）≤90% moisture condensation	-20°C~55°C（-4°F~131°F）≤90% moisture condensation	Same
Power supply	2 X 1.5V AAA	2 X 1.5V AAA	Same
Physical Specifications			
Weight	70g (without battery)	72 g (without battery)	Different
Dimensions (length x width x height)	FC-IR100: 163 mm *39 mm *39mm FC-IR101: 163 mm *39 mm *39mm FC-IR200: 166 mm *53 mm *41 mm FC-IR300: 122 mm *59 mm *41mm FC-IR400: 161 mm *68 mm *43mm	152mm * 44 mm *30mm	
Biological Specifications			
Patient Contacting Materials	ABS	ABS	Same
Patient Contacting	Surface-contacting, Less than 24 h	Surface-contacting, Less than 24 h	Same

As seen in the comparison tables, the subject and predicate devices have almost the same design features and performance specifications. The only differences between the subject and predicate devices are the indications for use (which link specific age groups with specific modes of temperature reading) and the appearance and operating/storage environment, which do not raise different questions of safety or effectiveness. Moreover, as demonstrated in the non-clinical and clinical testing, the different indications and

technological characteristics do not affect the safety and effectiveness of the FC-IR series Infrared thermometer system.

8. Performance Testing:

Performance data includes "Non-Clinical Data" and "Clinical Data". Summary of the data provided is below:

Non-Clinical Data:

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the FC-IR series Infrared thermometer was conducted in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The worst case of the whole system is considered tissue-contacting for a duration of less than 24 hours. The following tests were conducted:

☐Cytotoxicity

☐Skin Sensitization

☐Skin Irritation

Reprocessing: Cleaning and Disinfection

The sterilization and shelf life information provided are acceptable because the subject devices are non-sterile devices. The validation testing results for cleaning and disinfection of the subject devices are adequate and acceptable.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the FC-IR series Infrared thermometer device, consisting of all the modules and accessories in the system. The system complies with ANSI/AAMI ES60601-1:2005/(R)2012and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 *Medical electrical equipment Part 1: General requirements for basic safety and essential performance* for safety, IEC 60601-1-11: 2010 *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*, and the 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* standard for EMC.

Bench Testing

Bench testing was conducted on the FC-IR series Infrared thermometer device, consisting of all the accessories in the system. The system complies with ISO 80601-2-56: 2009 *Medical electrical equipment — Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement* for performance effectiveness.

Software Verification and Validation Testing

Software documentation including verification & validation was provided in accordance with FDA Guidance: *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* for software with a moderate level of concern.

Risk Analysis

A risk analysis was conducted in accordance with ISO 14971: 2007 – Medical devices — Application of risk management to medical devices.

Clinical data:

Clinical testing was conducted per *ASTM E 1965-98 (2009) Standard Specification for Infrared Thermometers For Intermittent Determination Of Patient Temperature.* This clinical study was randomized, with a simple blind homologous control, which consisted of a minimum of 144 subjects with the various age groups as referenced in Section 201.102 of ISO 80601-2-56.

9. Substantial Equivalence Conclusion:

Differences between the indications for use and technological characteristics of the subject device compared to the predicate do not raise different questions of safety and effectiveness. The performance of the device is supported by non-clinical testing, clinical testing, and risk management activities. The Shenzhen Finicare Co., Ltd. FC-IR Series Infrared Thermometer is Substantially Equivalent (SE) to the Shenzhen Brav Electronic Technologies Co., Ltd., EFT-165 Infrared Thermometer, cleared under K171214.