February 14, 2025

Shenzhen Finicare Co., Ltd.
℅ Boyle Wang
General Manager
Shanghai Truthful Information Technology Co., Ltd.
Room 608, No. 738 Shangcheng Rd., Pudong
Shanghai, 200120
China

Re: K243136
Trade/Device Name: Non-contact Forehead Infrared Thermometer (FC-IR2000, FC-IR205, FC-IR202, FC-IR206, FC-IR207, FC-IR209)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: January 10, 2025
Received: January 15, 2025

Dear Boyle Wang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Porsche Bennett
For David Wolloscheck, Ph.D.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243136

Device Name

Non-contact Forehead Infrared Thermometer (FC-IR2000, FC-IR205, FC-IR202, FC-IR206, FC-IR207, FC-IR209)

Indications for Use *(Describe)*

Infrared Thermometer is a non-sterile, reusable, non-contact and handheld device. It can be used by consumers in homecare environment and doctors in clinic as reference. It is intended for measuring human body temperature of people over one month old by detecting infrared heat from the forehead.

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.

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510(k) Summary

K243136

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR 807.92.

1.0 Submitter's Information

Name: Shenzhen Finicare Co., Ltd.
Address: 201, No.50, the 3rd Industrial Park, Houting Community, Shajing Street, Bao'an District, Shenzhen 518104 China
Tel: 86-755-23013503
Contact: Chao Li

Designated Submission Correspondent

Contact: Mr. Boyle Wang
Name: Shanghai Truthful Information Technology Co., Ltd.
Address: Room 608, No. 738 Shangcheng Rd., Pudong Shanghai, 200120 China
Tel: +86-21-50313932
Email: Info@truthful.com.cn

Date of Preparation: February 14, 2025

2.0 Device Information

Trade name: Non-contact Forehead Infrared Thermometer (FC-IR2000, FC-IR205, FC-IR202, FC-IR206, FC-IR207, FC-IR209)
Common name: Infrared Thermometer
Classification name: Thermometer, Electronic, Clinical
Model(s): FC-IR2000, FC-IR205, FC-IR202, FC-IR206, FC-IR207, FC-IR209
Production code: FLL
Regulation number: 21CFR 880.2910
Classification: Class II
Panel: General Hospital

3.0 Predicate Device Information

Manufacturer: Shenzhen Changkun Technology Co., Ltd.
Trade name: Infrared Thermometer, Model Number CK-T1501, CK-T1502,

CK-T1503

510(k) number: K193253

4.0 Indication for Use Statement

Infrared Thermometer is a non-sterile, reusable, non-contact and handheld device. It can be used by consumers in homecare environment and doctors in clinic as reference. It is intended for measuring human body temperature of people over one month old by detecting infrared heat from the forehead.

5.0 Device Description

The Non-contact Forehead Infrared Thermometer (Model FC-IR2000, FC-IR205, FC-IR202, FC-IR206, FC-IR207, FC-IR209) measures the body temperature based on the infrared energy emitted from the forehead. Users can get measurement results after properly scanning the forehead. The thermometer
of a shell, an LCD, a measure button, a beeper, an infrared temperature sensor, and a Microprocessor.
The device is widely used for home healthcare, medical institutes and many other occasions.

6.0 Comparison to the Predicate Device

The technological characteristics, features, specifications, materials, mode of operation, and intended use of Infrared Thermometer is substantially equivalent to the predicate devices referenced above. The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Item	Subject Device K243136	Predicate Device K193253	Remark
Manufacturer	Shenzhen Finicare Co., Ltd.	Shenzhen Changkun Technology Co., Ltd.	/
Product Name	Forehead Infrared Thermometer (Model FC-IR2000, FC-IR205, FC-IR202, FC-IR206, FC-IR207, FC-IR209)	Infrared Thermometer, model CK-T1501, CK-T1502, CK-T1503	/
Product Code	FLL	FLL	Same
Regulation No.	21 CFR 880.2910	21 CFR 880.2910	Same
Class	II	II	Same
Intended Use/Indication for Use	Infrared Thermometer is a non-sterile, reusable, non-contact and handheld device. It can be used by consumers in homecare environment and doctors in clinic as reference. It is intended for measuring human body temperature of people over one month old by detecting infrared heat from the forehead.	Infrared Thermometer (model: CK-T1501, CK-T1502, CK-T1503) is a non-sterile, reusable, non-contact and handheld device. It can be used by consumers in homecare environment and doctors in clinic as reference. It is intended for measuring human body temperature of people over one month old by detecting infrared heat from the forehead.	Same

Thermometer Type	Infrared Forehead Thermometer	Infrared Forehead Thermometer	Same
Display Circumference	LCD Digital Display	LCD Digital Display	Same
Measurement method	Forehead measure mode	Forehead measure mode	
Measuring range	32.0°C–42.9°C (89.6°F–109.2°F)	32°C ~42.5°C (89.6°F~108.5°F)	Similar
Display resolution	0.1°C/0.1°F	0.1°C/0.1°F	Same
C/F switchable	Yes	Yes	Same
Measuring accuracy	89.6°F–109.2°F (32.0°C–42.9°C)/ ±0.4°F/±0.2°C	32°C~34.9°C ± 0.3°C/ 89.6 °F~94.8°F ±0.5°F 35°C~42°C ±0.2°C/ 95.0°F~107.6°F ±0.4°F 42.1°C~42.5°C ±0.3°C/ 107.8°F~108.5°F ±0.5°F	Similar
Measurement distance	0-3cm	3-5cm	Different
Memory	35 sets.	32 sets.	Different
Power source	DC1.5V×2 (2*AAA alkaline batteries)	DC 3V (2 of AA alkaline batteries)	Same
Operating condition	10°C-40°C (50°F-104°F); 15-95%RH; 86-106 kPa	10°C ~ 40°C; 15% ~ 85%RH; 80kPa ~106kPa	Similar
Patients Contacting Materials	Plastic Case / Key& Battery Cover: ABS LCD: PC	ABS	Same
Electric Safety and EMC	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 ISO 80601-2-56	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 ISO 80601-2-56	Same

Analysis:

1) The “measuring range”, “Measurement distance” and “Measuring accuracy” of the subject device is similar with predicate device, both of them meet the requirement of safety and essential performance standard ISO 80601-2-56. The differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device.
2) The “Memory” and “Operating condition” of subject device is similar with predicate device, the software verification and validation test met the requirements. The performance testing shows that the subject device complies with performance standard.

The differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device.

7.0 Non-Clinical Test Conclusion

Non-Clinical Performance Testing:

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

- IEC 60601-1: 2020 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and essential performance
- IEC 60601-1-2:2020 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: 2017+A1:2018 Medical electrical equipment – Particular requirements for the basic safety and essential performance of clinical thermometers for body temperature measurement.
- IEC 60601-1-11:2020 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

Biocompatibility Testing:

Patient contacting components were subjected to biocompatibility testing in compliance with ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process and FDA guidance “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", Document issued on: September 8, 2023.

Software Information:

Software documentation was provided in accordance with the FDA June 14,2023 document “Content of Premarket Submissions for Device Software Functions”.

8.0 Clinical Test Conclusion

Clinical tests were conducted per ASTM E1965-98(Reapproved 2016) Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature. This clinical study is a randomization, simple blind homologous control, pairing design of clinical investigation, consists of a minimum of 143 subjects which were divided into three group age ranges- A Infant group (Group A1- 0 up to 3 months; Group A2- 3 months up to 1 year), B Child group (Older than 1 to 5 years old) and C group older 5 years old (Above 5 years old). The clinical performance test protocol and data analysis were conducted in accordance with the requirement of ISO 80601-2-56 and ASTM E1965-98 (2023).

Based on the result, it is demonstrated the clinical performance of the subject device complied with the requirement of ASTM E1965-98 (2023).

9.0 Conclusion

The conclusions drawn from the comparison and analysis above demonstrate that the subject device is substantially equivalent to the legally marketed predicated device, cleared under K193253.