October 8, 2021

Kangzhan Communication Electronics Co., Ltd.
Su Baotong
General Manager
No. 1008, songbai road, yangguang community, xili street,
Nanshan District
Shenzhen, 518055
China

Re: K203497
Trade/Device Name: Infrared Thermometer (Model K9)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: August 30, 2021
Received: September 8, 2021

Dear Su Baotong:

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,

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

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)*
K203497

Device Name
Infrared Thermometer (Model K9)

Indications for Use *(Describe)*
The Infrared Thermometer, Model K9 is a non-contact infrared thermometer intended for the intermittent measurement and monitoring of human body temperature from forehead for clinical and home use environments.
It can be used for anybody, e.g. for infant, children and adults (Excluding neonates).
The device does not require sterilization and can be reused.

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."

KANGZHAN

K203497 - 510(K) SUMMARY

This summary of 510(K) safety and effective information is being submitted in accordance with the requirement SMDA and 21 CFR 807.92.

1. Submitter of 510(K):

Date of Prepared:	October 8, 2021
Submitter's Name:	Kangzhan Communication Electronics Co., Ltd.
Address:	4th floor, building F, qihang kechuang industrial park , No. 1008, songbai road, yangguang community, xili street, nanshan district, shenzhen City,China
Contact person:	Mr. Su Baotong
TEL:	0755-88377262/ 13602582167
FAX:	/
Email:	kzs168@126.com

2. Proposed Device and code:

Device Trade Name:	Infrared Thermometer (Model K9)
Common Name:	Clinical Electronic Thermometer
Product Code:	FLL
Regulation Name:	Clinical electronic thermometer
Regulation number	21 CFR 880.2910
Device Class	2

3. Predicate Device:

510(K)	Trade or Proprietary or Model Name	Manufacturer

K191668	Infrared Forehead Thermometer (Model IR-FT)	Comper Chuangxiang (Beijing) technology Co., Ltd.

4. Description of Proposed Device:

The Infrared Thermometer, Model K9 is an electronic thermometer using an infrared sensor to measure infrared energy radiated from the forehead. This energy is collected through the lens and converted to a temperature value.

The device uses CapSense Technology to detect distance this technology is used to assist measurement. The concept of proximity sensor detects human electrical proximity level to transform to distance.

The distance control feature is added to the user interface to identify the measurement distances are in the correct parameter. In other words, the device will enter into measurement mode after the correct measurement distance is detected. This device can take a measurement automatically when the device detects the distance is appropriate within 5 cm.

The Infrared Thermometer, Model K9, consists of the following parts:

a) Thermopile Sensor

b) Application-Specific Integrated Circuitry

c) Erasable Programmable Read-Only Memory Integrated Circuit

d) Capacitance-touch Integrated Circuit

e) LED and Backlight

f) Alkaline batteries; size AAA, 2 x 1.5 V

g) Lens

5. Indications for Use

The Infrared Thermometer, Model K9 is a non-contact infrared thermometer intended for the intermittent measurement and monitoring of human body temperature from forehead for clinical and home use environments. It can be used for anybody, e.g. for infant, children and adults (Excluding neonates). The device does not require sterilization and can be reused.

6. Technical and Performance

The following table compares the device to the predicate device with basic technological characteristics.

Both subject and predicate devices use infrared technology to measure and monitor the body temperature by the site of Forehead.

Infrared Thermometer K9 has been compared to the Infrared Forehead Thermometer Infrared Forehead Thermometer Models: IR-FT (K191668) as a predicate device for substantial equivalence. A table comparing the two devices is provided as follows:

Elements of Comparison	Subject device	Predicate device	Similar or Different
510(k) Number	K203497	K191668	/
Indication for use	The Infrared Thermometer, Model K9 is a non-contact infrared thermometer intended for the intermittent measurement and monitoring of human body temperature from forehead for clinical and home use environments. It can be used for anybody, e.g. for infant, children and adults (Excluding neonates). The device does not require sterilization and can be reused.	This device is a non-sterile, reusable, contact Infrared Forehead Thermometer (Model IR- FT) intended for intermittent determination of human body temperature through a touch on the center of the forehead as the measurement site on people of all ages. The Infrared Forehead Thermometer (Model IR- FT) can be used inclinical and home environments.	Same
Thermometer type	Infrared forehead	Infrared forehead	Same
Components	The product is mainly composed of a temperature sensor, a housing, a circuit board and a battery compartment.	The product is mainly composed of a temperature sensor, a housing, a circuit board and a battery compartment.	Same
Temperature Measurement Technology	The thermoneter uses a thermopile sensor with integrated thermistor for the target reading, a thermistor mounted in the head of the thermometer for ambient temperature readings, and an infrared proximity sensor for detection of contact use and compensation of the temperature reading.	The thermometer uses a thermopile sensor with integrated thermistor for the target reading, a thermistor mounted in the head of the thermometer for ambient temperature readings, and an infrared proximity sensor for detection of contact use and compensation of the temperature reading.	Same
Key Temperature Sensor	High-end Thermopile Detector TU05 manufactured by TE Connectivity inc	Thermopile Sensor OTP-336 manufactured by Oriental system technology inc.	Same
Power requirements	DC 3V(2 AAA batteries)	D.C. 3 V (2 AAA dry batteries)	Same
Materials	Patient contacting materials include ABS+PC (Top cover, battery cover, chamber, button power,front cover) and PC(lens)	Patient contacting materials include PC (Top cover, battery cover, chamber, button power) and ABS+TPU (front cover).	Similar (note 1#)
Temperature range	32.0°C ~42.9°C (89.6°F -109.2°F)	32.0°C ~43.0°C (89.6°F -109.4°F)	Similar (note 2#)
Accuracy for body temperature measurement	≤±0.2°C (0.4°F), for the range 35°C -42°C (95°F -107.6°F); ≤±0.3°C (0.5°F),for the range 32°C -34.9°C (89.6°F -94.8°F) and 42.1-42.9°C (107.8°F -109.2°F).	≤±0.2°C (0.4°F), for the range 35°C -42°C (95°F -107.6°F); ≤±0.3°C (0.5°F),for the range 32°C -34.9°C (89.6°F -94.8°F) and 42.1-43°C (107.8°F -109.4°F).	Same

Contact/non contact use	Non contact use	None contact use	Same
Measurement site	Forehead	Forehead	Same
Measurement distance	Within 3 cm	Within 3 cm	Same
operating mode	adjusted mode	adjusted mode	Same
reference body site	oral	oral	Same
Resolution of display	0.1°C / 0.1°F	0.1°C / 0.1°F	Same
Signal output And display	LED, Buzzer	LCD, Buzzer	Similar (note 3#)
Biocompatibility	ISO 10993-1	ISO 10993-1	Same
Voluntary standards for Clinical Electronic Thermometers	ISO 80601-2-56 ASTM E1965	ISO 80601-2-56 ASTM E1965	Same
Medical Electrical Safety and EMC	IEC 60601-1, IEC 60601-1-2	IEC 60601-1, IEC 60601-1-2	Same

Discussion:

From the comparison table1 and table2, the subject devices and predicate devices have the similar Intended use & Indications for Use, same measurement place, Scale selection, Display screen, Auto power-off while no operation & Conformance standard. There are slightly differences between the devices and predicate devices as follows,through the verification and validation process, it has been shown that the differences do not raise new questions of safety and effectiveness.

Note 1#: Materials:

The subject device and predicate device have both performed biocompatibility tests according to the ISO 10993- 1, both devices meet the requirements of ISO 10993-1. Therefore it is substantially equivalent on biocompatibility risk.

Note 2#: Temperature range

The measurement range of the subject device meets the requirements of ISO 80601-2-56 and ASTM E1965-98.

Note 3#: Signal output and display Meets the requirement of IEC 60601-1

Conclusion:

The subject device Infrared Thermometer (Model K9) has all features of the predicate device. The differences between them do not affect the safety and effectiveness. Thus, the subject device is substantially equivalent to the predicate device.

7. Performance Testing:

Performance data includes “Non-Clinical Data” and “Clinical Data”, brief description of which are shown as below.

7.1 Non-Clinical Data:

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

7.2 Biocompatibility testing

The biocompatibility evaluation for the Non-Contact Infrared Forehead Thermometer were 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 duration of less than 24 hours. And the testing included the following tests:

- Cytotoxicity
- Skin Sensitization
- Skin Irritation

7.3 Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Non-Contact Infrared Forehead Thermometer, consisting of all the modules and accessories in the system. The system complies with the IEC 60601-1: 2012 Medical electrical equipment Part 1: General requirements for basic safety and essential performance for safety 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.

7.4 Bench Testing

Bench testing was conducted on the Non-Contact Infrared Forehead Thermometer, consisting of all the accessories in the system. The system complies with the 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, ISO 80601-2-56 Second edition 2017-03 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. [Including: Amendment 1 (2018)].

7.5 Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.” The software for this device was considered as a “Moderate” level of concern.

7.6 Usability Testing

Usability testing according to following FDA Guidance 1757, Applying Human Factors and

Usability Engineering to Optimize Medical Device Design, was conducted.

7.7 Clinical data:

Clinical testing is conducted per ISO 80601-2-56 Second edition 2017-03 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. [Including: Amendment 1 (2018)]. Sections 201.102 Clinical Accuracy Validation

7.7 Summary

Based on the non-clinical and clinical performance as documented in the device development, the subject devices were found to have a safety and effectiveness profile that is similar to the predicate device.

8. Conclusions:

The proposed device has the same intended use and similar technological characteristics as the predicate device. The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. Based on the conducted performance and safety testing, the Infrared Thermometer (Model: K9) is substantially equivalent (SE) to the Infrared Forehead Thermometer (Model IR-FT) cleared under K191668.