Shandong Zhushi Pharmaceutical Group Co., Ltd.
% Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM. 608, No. 738, Shangcheng Rd., Pudong
Shanghai, Shanghai 200120
China

Re: K203454
Trade/Device Name: Infrared Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: March 26, 2021
Received: March 30, 2021

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 (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,

for Payal Patel
Acting 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)*
K203454

Device Name
Infrared Thermometer

Indications for Use *(Describe)*
Infrared Thermometer (model: ZST-A) 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

(K203454)

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

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Contact: Junhui Zhu
Date of Preparation: Mar.26,2021

Designated Submission Correspondent

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Tel: +86-21-50313932
Email: Info@truthful.com.cn

2.0 Device Information

Trade name: Infrared Thermometer
Common name: Infrared Thermometer
Classification name: Clinical electronic thermometer
Model(s): ZST-A

3.0 Classification

Production code: FLL
Regulation number: 21CFR 880.2910
Classification: Class II
Panel: General Hospital

4.0 Predicate Device Information

Manufacturer: Shenzhen Changkun Technology Co., Ltd.
Device: Infrared Thermometer (Models: CK-T1501, CK-T1502, CK-T1503)
510(k) number: K193253

5.0 Device Description

The Infrared Thermometer, Model ZST-A is a non-contact long-distance infrared thermometer which is specialized in measuring human body temperature. It contains buzzer prompt, memory reading, backlight reminder, temperature offset setting, alarm threshold setting, automatic shutdown and common functions of equipment.

The Infrared Thermometer measures the temperature by using the principle of receiving infrared.

◆ All objects radiate energy to their surroundings.

◆The temperature of an object is directly proportional to the intensity of radiation energy, that is, the higher the temperature, the greater the radiation energy.

◆The energy radiated from human body is mainly infrared radiation. Therefore, human body temperature can be calculated by measuring the intensity of infrared energy radiated from human body to its surroundings.

◆Through the accurate measurement of the weak infrared radiation energy released by the human body, the non-contact infrared thermometer can accurately obtain the human body temperature after complex calculation processing and various compensation correction. The product is composed of built-in infrared detector and related hardware and software, which can receive, analyze and record the measured object and ambient temperature. Therefore, once the user approaches the specific part of the human body (forehead) and presses the measurement key, the infrared sensor can be activated immediately, and the thermal energy generated by the arterial blood flow can be detected quickly through the passive infrared sensor, so as to accurately measure the body temperature of the human body.

The measurement distance of the subject device is 1~5 cm from the middle of the forehead.

6.0 Indication for Use Statement

Infrared Thermometer (model: ZST-A) 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.

7.0 Comparison to the Predicate Device

Item	Subject Device K203454	Predicate Device K193253	Remark
Type of Thermometer	Infrared Thermometer ZST-A	Infrared thermometer 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& Indications for use	Infrared Thermometer (model: ZST-A) 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
Prescription/over-the-counter use	over-the-counter use	over-the-counter use	Same
Measurement technology	Infrared radiation detection that converts a user's forehead temperature using the infrared energy emitted in the area around the user's forehead to a reference site equivalent temperature	Infrared radiation detection	Same
Measurement place	Forehead	Forehead	Same
Measurement Range	Forehead mode: 32.0°C ~43.0°C (89.6 to 109.4 ° F)	32.0°C ~42.5°C (89.6 to 108.5 ° F)	Different 1
Accuracy	±0.2°C (0.4°F) within 33.0°C ~ 39.0°C (91.4°F ~ 102.2°F), ±0.3°C(0.5°F) other range	±0.2°C (0.4°F) within 35.0°C ~ 42.0°C (95.0°F ~ 107.6°F), ±0.3°C(0.5°F) other range	

Display resolution	0.1°C(0.1°F)	0.1°C(0.1°F)	Same
C/F switchable	Yes	Yes	Same
Measurement distance	1~5 cm	3~5 cm	Different 2
Response time	1s	1s	Same
Sensor type	Thermopile	Thermopile	Same
Memory	32 sets	32 sets	Same
Buzzer	Yes	Yes	Same
Auto power-off while no operation	Yes	Yes	Same
Power supply	2*1.5V AA battery	DC 3V (2 of AA alkaline batteries)	Same
Display screen	LCD	LCD	Same
Operation Environment	15.0°C∽40.0°C(59.0°F∽104°F) RH≤90% 70.0kPa-106.0kPa	10°C ~ 40°C; 15% ~ 85%RH; 80kPa~106kPa	Different 3
Storage Environment	-20.0℃∽55.0℉ (-4.0°F∽131.0°F) RH≤90% 70.0kPa-106.0kPa	Not Publicly available	
Dimension	15*9*4cm	Not Publicly available	--
Weight	≤93g	Not Publicly available	--
Materials	User contacting materials are ABS (Device Plastic Case, Button & Battery Cover)	ABS	Same
Conformance standard	ISO80601-2-56, IEC60601-1, IEC60601-1-2, IEC 60601-1-11 ASTM E1965-98	ISO80601-2-56, IEC60601-1, IEC60601-1-2, IEC 60601-1-11 ASTM E1965-98	Same
Biocompatibility	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	Same

Analysis:

From the comparison table, the subject devices and predicate device have the same Intended use & Indications for Use, Measurement place, Display resolution, Display screen, Auto power-off while no operation and

Conformance standard. There are slightly differences between the devices and predicate device as follows:

Different 1: Both devices have different measurement range, but they have the same accuracy and the measurement range of subject devices meet the requirements of ASTME1965-98. The different does not raise new performance questions.

Different 2: Measurement distance of the subject devices is 1-5cm, the predicate device's is 3-5cm. Although the "measurement distance" of subject device is a little different from the predicate devices. The clinical trial report of the subject device demonstrates the device meets the clinical accuracy requirements of the standards ISO 80601-2-56 and ASTM E1965-98 within the distance range, the differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device.

Different 3: Both devices have slightly different Operation &Storage Environment, but the subject devices meet the requirements of IEC60601-1.In conclusion, these differences do not raise any new safety or performance questions.

8.0 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: 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: 2017+A1:2018 Medical electrical equipment – Particular requirements for the basic safety and essential performance of clinical thermometers for body temperature measurement.
- IEC 60601-1-11:2015 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

Biocompatibility Testing:

The biocompatibility evaluation for the ZST-A Infrared Thermometer were conducted in accordance with International Standards ISO 10993-1:2018, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process, ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity, and ISO 10993-10:2010, Biological evaluation of medical devices -- Part 10: Tests for irritation and sensitization, as recognized by FDA, and per FDA guidance document entitled Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,dated on September 4, 2020. The testing conducted included the following:

- Cytotoxicity
- Irritation
- Sensitization

Software Information:

Software validation was conducted in accordance with a moderate level of concern designation in accordance with the FDA November 2005 document “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”

9.0 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 105 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 (greater than 1 to 5 years old) and C Over 5 years old (Above 5 years old). Each group at least has 35 subjects.

Based on the result, it is demonstrated the clinical performance of the subject device complied with the requirement of ASTM E1965-98 (2016).

Based on the result, it is demonstrated the clinical performance of the subject device complied with the requirement of ASTM E1965-98 (2016).

10.0 Conclusion

Performance testing contained in this submission demonstrates the minor differences in technological characteristics between the subject device and the predicate do not raise different questions of safety and effectiveness. And based on the performance testing and compliance with acceptable voluntary standards, we believe the Infrared Thermometer ZST-A are substantially equivalent to its predicate device in K193253.