June 17, 2020

Shenzhen Changkun Technology Co., Ltd.
% Cassie Lee
Official Correspondent
Guangzhou GLOMED Biological Technology Co., Ltd.
2231, Building 1, Rui Feng Center, Kaichuang Road
Huangpu District
Guangzhou, 510000
China

Re: K193253
Trade/Device Name: Infrared Thermometer, Models: CK-T1501, CK-T1502, CK-T1503
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: March 23, 2020
Received: May 18, 2020

Dear Ms. Cassie Lee:

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 Tina Kiang, Ph.D.
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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K193253

Device Name
Infrared Thermometer (Models: CK-T1501, CK-T1502, CK-T1503)

Indications for Use *(Describe)*
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.

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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*"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."*

# 510(k) Summary

## K193253

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

**1. Date of the summary prepared: 2020-05-25**

**2. Submitter's Information**

510(k) Owner's Name: Shenzhen Changkun Technology Co., Ltd.
Establishment Registration Number : Applying
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**Application Correspondent:**

Contact Person: Cassie Lee
Guangzhou GLOMED Biological Technology Co., Ltd.
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Tel: +86 20 8266 2446
Email: regulatory@glomed-info.com

**3. Subject Device Information**

Trade Name: Infrared Thermometer, models: CK-T1501, CK-T1502, CK-T1503
Common Name: Clinical electronic thermometer
Classification name: Thermometer, electronic, clinical
Review Panel: General Hospital
Product Code: FLL
Regulation Class: II
Regulation Number: 21 CFR 880.2910

**4. Predicate Device Information**

Sponsor: Intrinity Global Limited
Trade Name: Non Contact Infrared Forehead Thermometer(model : TVT-200, TVT-200 PLUS)
Common Name: Clinical electronic thermometer
Classification Name: Thermometer, Electronic, Clinical
510(K) Number: K170662
Review Panel: General Hospital
Product Code: FLL
Regulation Number: 880.2910
Regulation Class: II

**5. Device Description**

Infrared Thermometer (model: CK-T1501,CK-T1502,CK-T1503) is a hand-held, battery powered, infrared Thermometer that coverts a user's forehead temperature, using the infrared energy emitted in the area around the user's forehead to an oral equivalent temperature when measure from 3-5 cm of the subject's forehead with no contact.

It uses a thermopile sensor with integrated thermistor for the target reading and a thermistor mounted in the head of the thermometer for ambient temperature readings.

It composed by a measuring sensor, PCB, 4 buttons, a LCD and an enclosure. The functions of the three models are similar. The functions of "Temperature Unit", "Temperature Alarm Point", "Temperature Offset", and "Warning Tone Switch" can be set. When measuring body temperature, users need to measure in body mode from 3-5 cm from their forehead. Press the measuring key, after 0.5 second with the sound of "beep", the measurement is completed and the temperature is displayed on the LCD screen. Without any operation, it will close automatically in 15 sec. The No. and stored value of the stored data are displayed at the bottom of the LCD screen. Press "+" / "-" to view the previous or next stored data, it can store 32 sets of measurements.

User contact components are the enclosure and keys. The materials of the components are ABS plastic.

**6. Intended Use / Indications for Use**

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.

**7. Comparison to predicate device and conclusion**

The technological characteristics, features, specifications, materials, mode of operation, and intended use of Infrared Thermometer is substantially equivalent to the predicate devices quoted above.

The differences between the subject device and predicate devices do not raise new issues of

safety or effectiveness.

| Elements of Comparison | Subject Device | Predicate Device | Verdict |
|---|---|---|---|
| Company | Shenzhen Changkun Technology Co., Ltd. | Intrinity Global Limited | -- |
| Trade Name | Infrared Thermometer | Non Contact Infrared Forehead Thermometer | -- |
| Classification Name | Clinical Electronic Thermometer | Clinical Electronic Thermometer | Same |
| 510(k) Number | K193253 | K170662 | -- |
| Product Code | FLL | FLL | Same |
| Thermometer Type | Infrared Forehead Thermometer | Infrared Forehead Thermometer | Same |
| Intended Use / Indications for Use | 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. | Non Contact Infrared Forehead Thermometer is a non-sterile, reusable, 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 all ranges of people by detecting infrared heat from the forehead. | Similar Note 3 |
| Display | LCD Digital Display | LCD Digital Display | Same |
| Measurement method | Infrared radiation detection | Infrared radiation detection | Same |
| Measurement mode | Forehead measure mode | Forehead measure mode | Same |
| Measuring range | 32°C ~42.5°C (89.6°F~108.5°F) | 32°C to 43°C (89.6°Fto109.4°F) | Similar Note 1 |
| Display resolution | 0.1°C/0.1°F | 0.1°C/0.1°F | Same |
| C/F switchable | YES | YES | Same |
| Measuring | 32°C~34.9°C ± 0.3°C/ | ±0.2°C (0.4°F) | Similar |

| Elements of Comparison | Subject Device | Predicate Device | Verdict |
|---|---|---|---|
| accuracy | 89.6 °F~94.8°F ±0.5°F<br>35°C~42°C ±0.2°C/<br>95.0°F~107.6°F±0.4°F<br>42.1°C~42.5°C ±0.3°C/<br>107.8°F~108.5°F±0.5°F | | Note 1 |
| Measurement distance | 3-5cm | 1cm | Similar<br>Note 1 |
| Display | LCD | LCD | Same |
| Memory | 32 sets. | 16 sets. | Similar<br>Note 2 |
| Power source | DC 3V (2 of AA alkaline batteries) | DC 3V (2 of AA alkaline batteries) | Same |
| Operating condition | 10°C ~ 40°C;<br>15% ~ 85%RH;<br>80kPa ~106kPa | 15°C~ 40°C (59°F~ 104°F);<br>≤95% RH | Similar<br>Note 2 |
| Patient contact materials | ABS | ABS with colorants (pink, grey, orange and purple), Glass and Metal | Same |
| Electric Safety and EMC | IEC 60601-1<br>IEC 60601-1-2<br>IEC 60601-1-11<br>ISO 80601-2-56 | IEC 60601-1<br>IEC 60601-1-2<br>IEC 60601-1-11<br>ISO 80601-2-56 | Same |

**Comparison in Detail(s):**

**Note 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.

**Note 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.

**Note 3:**

Although the "Intended Use / Indications for Use" of subject device is a little different from the predicate devices, but both of subject device and predicate device are meet the clinical accuracy requirements of the standards ISO 80601-2-56 and ASTM E1965-98. Based on the performance evaluation, the differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device.

**8. Summary of Non-Clinical Testing**

**8.1 Non-clinical testing was conducted to verify that the subject devices met all design specifications, demonstrated safety based on current industry standards, and to demonstrate substantial equivalence to the predicate. The following tests were performed:**

A. Electromagnetic Compatibility, Electrical Safety, and Battery Safety:

The subject devices were tested in compliance with the following:

- ANSI/AAMI ES60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-11 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 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

B. Biocompatibility:

- 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, including cytotoxicity (ISO 10993-5), sensitization (ISO 10993-10) and irritation (ISO 10993-10).

C. Software Verification: Software documentation was provided in accordance with FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued May 11, 2005.

D. Performance Testing:

- 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 E1965-98 (2016): Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature

**8.2 Discussion of Clinical Tests Performed**

The clinical performance test protocol and data analysis is conducted as the requirement of ASTM E1965-98 (2009). The test report showed the clinical performance of the subject device complied with the requirement of ASTM E1965-98 (2016).

The clinical tests evaluated 240 of subjects. and the thermometer was evaluated in three age groups including subgroup A1 and A2: A1 – one month up to three month, A2 - three months to one year; B - older than one years and younger than five years; and C - older than five 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 (2016). The test report showed the clinical performance of the subject devices complied with the requirement of ISO 80601-2-56 and ASTM E1965-98 (2016).

**9. Conclusion:**

Based on the performance testing, comparison and analysis in this submission, the subject device Infrared Thermometer (model: CK-T1501, CK-T1502, CK-T1503) is substantially equivalent to the predicate device K170662.