February 17, 2023

Truly Instrument Limited
℅ Kevin Wang
Consultant
Chonconn Medical Device Consulting Co., Ltd.
Room 504, Block C, No. 1029 Nanhai Avenue, Nanshan District
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China

Re: K220276
Trade/Device Name: Infrared Thermometer TET-351
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: January 23, 2023
Received: January 23, 2023

Dear Kevin 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,

David Wolloscheck, Ph.D.
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)*
K220276

Device Name
Infrared Thermometer TET-351

Indications for Use *(Describe)*
The TRULYL Infrared thermometer TET-351 is intended for the intermittent measurement of human body temperature from the auditory canal and from the forehead for people of all ages used in the home setting. The non-contact thermometer detects infrared heat from the forehead at distance of about 1-2cm.

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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K220276 - 510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2023/1/23

1. Submission sponsor

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2. Submission correspondent

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3. Subject Device Information

Trade/Device Name	Infrared Thermometer
Model	TET-351
Common Name	Infrared Thermometer
Regulatory Class	Class II
Classification	21CFR 880.2910 / Clinical electronic thermometer
Product Code	FLL
Submission type	Traditional 510(K)

4. Predicate Device

Joytech Healthcare Co., Ltd. Infrared Ear/Forehead Thermometer, DET-218 under K190873.

5. Device Description

The TRULYL Infrared thermometer TET-351 is a hand-held, battery powered device designed to measure the body temperature through receiving infrared energy radiation via the ear canal or forehead. The thermometer has the capability to measure temperature via forehead temperature mode or ear temperature mode, and the temperature is directly shown on the LCD display. The results measured by TET-351 can also be transmitted to APP to record and display through Bluetooth.

6. Intended use & Indication for use

The TRULYL Infrared thermometer TET-351 is intended for the intermittent measurement of human body temperature from the auditory canal and from the forehead for people of all ages used in the home setting. The non-contact thermometer detects infrared heat from the forehead at distance of about 1-2cm.

7. Comparison to the Predicate Device

Features	**Predicate device K190873 Infrared Ear/Forehead thermometer: DET-218**	**Subject device Infrared thermometer: TET-351**	**Note**
Regulation number	21 CFR 880.2910	21 CFR 880.2910	Same
Product code	FLL	FLL	Same
Intended Use & Indications for use	Infrared Ear/Forehead Thermometer DET-218 is intended for the intermittent measurement of human body temperature by people of all ages. The devices are reusable for home use only. The thermometer detecting infrared heat from non-contact (about 1-2 cm distances) with the forehead.	The TRULYL Infrared thermometer TET-351 is intended for the intermittent measurement of human body temperature from the auditory canal and from the forehead for people of all ages used in the home setting. The non-contact thermometer detects infrared head from the forehead at distance of about 1-2cm.	Same
Measurement Method	Infrared radiation detection	Infrared radiation detection	Same
Rx/OTC	OTC	OTC	Same
Patient Population	Adult, pediatric	Adult, pediatric	Same
Measurement Range	Ear/Forehead mode: 34.0℃ ~43.0℃(93.2℉~109.4℉)	Ear/Forehead mode: 32.0℃ ~43.0℃(89.6℉~109.4℉)	Different
Accuracy	Ear/Forehead mode: ±0.2℃ (0.4℉) during 35.5℃ ~42.0℃ (95.9℉~107.6℉) at 15℃~35℃ (59.0℉~95.0℉) operating temperature range ±0.3℃ (0.5℉) for other measuring and operating temperature range	Ear/Forehead mode: ±0.2℃(0.4° F) (Outside 34~42° C(93.2℉ ~107.6℉) measurement range, accuracy ±0.3° C (0.5℉)).	Different

Features	Predicate device K190873 Infrared Ear/Forehead thermometer: DET-218	Subject device Infrared thermometer: TET-351	Note
Display	0.1°C(0.1°F)	0.1°C(0.1°F)	Same
Measurement Mode	adjusted	adjusted	Same
Measurement place	Forehead Ear	Forehead Ear	Same
Forehead measurement method	non-contact	non-contact	Same
Reference body site	Oral	axillary	Different
Forehead Measurement distance	Not available	1-2cm	Different
Ingress protection rating	IP22	IP22	Same
Time until Auto power-off	60s	60s	Same
Response Time	Approx. 1s	1s	Same
Sensor type	Thermopile	Thermopile	Same
Scale Selection	°C /°F	°C /°F	Same
Signal processing and display	-Internal firmware and local LCD display -Also able to transfer transmit data to mobile device for secondary display	-Internal firmware and local LCD display -Also able to transfer transmit data to mobile device for secondary display	Same
Wireless Interface	Bluetooth Low Energy (BLE)	Bluetooth Low Energy (BLE)	Same
Bluetooth RF characteristics	Not available	operating frequency: 2.4GHz frequency bandwidth: 2402MHz~2480MHz transmission power:8.0 dBm	Different
Memory	Ear/forehead/ object measurements sharing 30 memories	30 sets	Same
Signal transmission	Bluetooth 4.0	Bluetooth 4.1	Different
Buzzer	Yes	Yes	Same

Features	Predicate device K190873 Infrared Ear/Forehead thermometer: DET-218	Subject device Infrared thermometer: TET-351	Note
Auto power-off while no operation	Yes	Yes	Same
Power supply	2 * 1.5V AAA	2 * 1.5V AAA	Same
Display screen	LCD	LCD	Same
Patient contact materials	Enclosure:ABS; Probe: Stainless steel&.ABS;	Enclosure:ABS-750 Probe: cooperl&.ABS;	Different
Biocompatibility	Cytotoxicity, Skin irritation, Skin sensitization	Cytotoxicity, Skin irritation, Skin sensitization	Same
Operation Environment	\	Ambient temperature:10°C~40°C(50 to 104 ° F); Relative humidity :15% to 90%; Atmospheric pressure : 70kPa ~ 106kPa	Not available
Conformance standard	ISO 80601-2-56(Performance) IEC 60601-1(Safety) IEC 60601-1-2(EMC) IEC 60601-1-11 ASTM E1965-98 ISO 10993-5 and ISO 10993-10 (Biocompatibility)	ISO 80601-2-56(Performance) IEC 60601-1(Safety) IEC 60601-1-2(EMC) IEC 60601-1-11 ASTM E1965-98 ISO 10993-5 and ISO 10993-10 (Biocompatibility)	Same

As seen in the comparison tables, the subject and predicate devices have similar design features and performance specifications. The main technological differences between the subject and predicate devices are minor differences, which do not raise different questions of safety or effectiveness.
Moreover, as demonstrated in the non-clinical and clinical testing, the different technological characteristics do not affect the safety and effectiveness of the TET-351 Infrared thermometer.

8. Performance Data

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

Biocompatibility testing

The biocompatibility evaluation for the Infrared thermometer was conducted in accordance with the FDA Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The biocompatibility testing included the following tests:

- Cytotoxicity
- Skin Sensitization
- Irritation

Non-clinical data

The Infrared thermometer has been tested according to the following standards:

- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - 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: Medical electrical equipment – Particular requirements for the basic safety and essential performance of clinical thermometers for body temperature measurement.
- ASTM E1965-98 (Reapproved 2016) Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature

The test was selected to show substantial equivalence between the subject device and the predicate.

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, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Clinical data

Clinical testing is conducted per ASTM E 1965-98 (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 150 subjects, of which 1/3 are infants, 1/3 are children and the rest 1/3 are adults (NOTE: Infants---newborn to one year; Children--- greater than one to five years; Adults---greater than five years old.). The test result demonstrated the clinical performance of the subject device complied with the requirement of standard ASTM E 1965-98 (Reapproved 2016).

9. Conclusion

It has been shown in the 510(k) submission that the difference between the proposed devices and the predicate devices do not raise any new or different questions regarding safety and effectiveness.

Performance testing and compliance with voluntary standards demonstrate that the proposed device is substantially equivalent to the relevant aspects of the predicate devices in terms of design, components, materials, principals of operation, biocompatibility, performance characteristics, and intended use.