October 30, 2024

Guangdong Genial Technology CO., Ltd.
% Klem Hou
RA Manager
Constant Medical Technology Co., Ltd.
No. 2021-6, 2nd Floor, No. 228 Huadi Avenue Middle
Liwan District, Guangzhou
Zhaoqing, Guangdong 526437
China

Re: K240333
Trade/Device Name: Wearable Digital Thermometer (T31)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical electronic thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: September 30, 2024
Received: September 30, 2024

Dear Klem Hou:

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,

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.

510(k) Number *(if known)*
K240333

Device Name
Wearable Digital Thermometer (T31)

Indications for Use *(Describe)*
Wearable Digital Thermometer is a battery-operated electronic device with intended use of measuring and monitoring human armpit temperature continuously via wireless signal transmission of the measuring result. Wearable Digital Thermometer is reusable and intended for armpit temperature monitoring for persons of all age. The temperature data of device is not intended to replace the advice, diagnosis, nor treatment recommendations of doctor. Wearable Digital Thermometer can be used at home and healthcare center.

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."

K240333 - 510(k) Summary

1. Submission sponsor

Name: GUANGDONG GENIAL TECHNOLOGY CO., LTD.

Address: I-6-05-02 11th Road, Area B, Guangfozhao Economic Cooperation Zone, Zhagang Town, Huaiji County, Zhaoqing City, Guangdong Province, 526437, P.R. China Zhaoqing Guangdong 526437 China

Contact person: Jun Yu

Title: Deputy general manager

Tel: +86- 136 0284 9551

Email: admin@genial.cn

2. Submission correspondent

Name: Constant Medical Technology Co., Ltd.

Address: No. 2021-6, 2nd Floor, No. 228 Huadi Avenue Middle, Liwan District, Guangzhou Zhaoqing Guangdong 526437 China

Contact person: Klem Hou

Title: RA manager

Tel: +86 178 7557 1727

Email: pharmaklem@outlook.com

3. Device

Name of Device: Wearable Digital Thermometer

Model(s): T31

Common or Usual Name: Clinical Electronic Thermometer

Classification Name: Clinical Electronic Thermometer

Regulatory Class: II

Product Code: FLL

Regulation Number: 21 CFR 880.2910

4. Predicate device(s)

Manufacturer	Predicate Device	510(k) Number
iWEECARE Co., Ltd.	Temp Pal (Smart Thermometer Patch) Model Number: STP-MB01-1	K222588

5. Device description

The Wearable Digital Thermometer consists of a host, App software and stickers. A comprehensive Android and iOS App are provided to access the host from a smart device. It is used for measuring and monitoring armpit temperature in real-time continuously and remotely via Bluetooth to smart device. The medical double-sided sticker are used to fix and stick the host in the user`s axilla.

The NTC temperature sensor is located closely to the stainless steel sheet that make sure the accuracy of temperature data measured.

The subject device could measure and monitor temperature in real-time continuously and remotely via Bluetooth to smart phone.

The Temp Pal is the combination device of thermometer and Bluetooth communication unit intended to be worn at axilla to monitor the armpit temperature continuously. The subject device is a direct mode clinical thermometer where the output temperature is not adjusted.

For the monitoring operation, switch the thermometer on and stick the thermometer in the user's axilla. The thermometer will make a Bluetooth connection between the thermometer and the receiver automatically (User should setup Bluetooth properly on receiver). Then the thermometer starts to measure the body temperature.

The wireless thermometer uses a rechargeable battery for operation.

When the battery is low, internal circuit will detect the low battery condition automatically and send "low battery" signal through Bluetooth communication unit to receiver.

Power source: Battery 3.0V/10mAh

Operation mode: Direct mode

Measuring results display method: The measuring results are transmitted to smart phone and display by APP.

Data communication method: Wireless 2.4G Bluetooth BLE.

6. Indications for Use

Wearable Digital Thermometer is a battery-operated electronic device with intended use of

measuring and monitoring human armpit temperature continuously via wireless signal transmission of the measuring result. Wearable Digital Thermometer is reusable and intended for armpit temperature monitoring for persons of all age. The temperature data of device is not intended to replace the advice, diagnosis, nor treatment recommendations of doctor. Wearable Digital Thermometer can be used at home and healthcare center.

7. Comparison of Technological Characteristics with the Predicate Device(s)

Wearable Digital Thermometer has the same intended use, mode of action and operational characteristics as the predicate devices. Any minor differences between the subject device and the listed predicate devices do not raise any issues of safety or efficacy. Performance data supports that the device is safe and as effective as the predicate device for its intended use.

Therefore, The Wearable Digital Thermometer may be found substantially equivalent to its predicate devices.

Wearable Digital Thermometer is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance:

1) K222588 (Predicate Device), " Temp Pal (Smart Thermometer Patch) ", manufactured by "

iWEECARE Co., Ltd."

Comparison Elements	Subject Device	Predicate Device (K222588)	Remark
Device name	Wearable Digital Thermometer	Temp Pal (Smart Thermometer Patch)	--
Model	T31	STP-MB01-1	--
Indications for use	Wearable Digital Thermometer is a battery-operated electronic device with intended use of measuring and monitoring human armpit temperature continuously via wireless signal transmission of the measuring result. Wearable Digital Thermometer is reusable and intended for armpit temperature monitoring for persons of all age. The temperature data of device is not intended to replace the advice, diagnosis, nor treatment recommendations of doctor. Wearable Digital Thermometer can be used at home and healthcare center.	Temp Pal is a battery-operated electronic device with intended use of measuring and monitoring human armpit temperature continuously via wireless signal transmission of the measuring result. This system is reusable and intended for armpit temperature monitoring for persons of all age. The temperature data of device is not intended to replace the advice, diagnosis, nor treatment recommendations of doctor. Temp Pal can be used at home and healthcare center.	Same
Principle of Operation	For the monitoring operation, switch the thermometer on and stick the thermometer in the user's axilla. The thermometer will make a Bluetooth connection between the thermometer and the receiver automatically (User should setup Bluetooth properly on receiver). Then the thermometer starts to measure the body temperature by means of testing the NTC resistor's resistance value and calculates the body temperature continuously and sends the temperature data to the receiver through Bluetooth connection.	For the monitoring operation, switch the thermometer on and stick the thermometer in the user's axilla. The thermometer will make a Bluetooth connection between the thermometer and the receiver automatically (User should setup Bluetooth properly on receiver). Then the thermometer starts to measure the body temperature by means of testing the NTC resistor's resistance value and calculates the body temperature continuously and sends the temperature data to the receiver through Bluetooth connection.	Same
Thermometer Type	Clinical Electronic Thermometer	Clinical Electronic Thermometer	Same
Anatomical Application	Patients' armpit	Patients' armpit	Same
Sensor	NTC Resistor	NTC Resistor	Same

Display	iOS device display, Android device display	iOS device display, Android device display	Same
Power Requirements	Non-Rechargeable Battery 3.0V/10mAh	Rechargeable Battery 3.7V/10mAh	Different Note 1
Temperature range (Measurement Range)	68-113°F (20-45°C)	77-113°F (25-45°C)	Different Note 2
Accuracy	±0.1°C (35.00°C or39.00°C) - + 0.18°F (95°F – 102.20°F) ±0.2°C (<35.00°C or >39.00°C) or 0.36°F (<95°F or >102.20°F)	0.09 °F (± 0.05 °C)	Different Note 3
Valid transmission distance	10 meters	Up to 5 meters	Different Note 4
APP Temperature display	Display in either °C or°F	Display in either °C or°F	Same
Operation mode	Direct mode	Direct mode	Same
Reusability	Reusable	Reusable	Same
shelf life	5 years	24 months	Different Note 5
composition of material that contacts to the patients	304 Stainless Steel Probe and double sided medical adhesive	304 Stainless Steel Probe and double sided medical adhesive	Same

Comparison in Detail(s):

Note 1: Power Requirements

The subject device is powered by a non-rechargeable battery while the predicate device is powered by a rechargeable battery. If the low power signal displayed in APP, the subject device should change the battery and the predicate device should be recharged, and both of the subject device and the

predicate device should stop working.

The Power Requirements differences between the subject and predicate devices does not raise new concerns of safety and effectiveness for the clinical use.

Note 2: Temperature range (Measurement Range)

The maximum measured temperature of the subject device and predicate device are same and the minimum measured temperature of the subject device is a little lower than that of predicate device which is not important for that the human body temperature is not nearly close to 20℃.

The Temperature range (Measurement Range) differences between the subject and predicate devices does not raise new concerns of safety and effectiveness for the clinical use.

Note 3: Accuracy

The accuracy of the subject device is higher than that of the predicate device.

The accuracy of the subject device has met the requirement of ISO 80601-2-56:2017 and the accuracy differences between the subject and predicate devices does not raise new concerns of safety and effectiveness for the clinical use.

Note 4: Valid transmission distance

The transmission distance of the subject device is further than that of the predicate device.

The Valid transmission distance differences between the subject and predicate devices does not raise new concerns of safety and effectiveness for the clinical use.

Note 5: Shelf life

The shelf life of the subject device is further than that of the predicate device.

The shelf life differences between the subject and predicate devices does not raise new concerns of safety and effectiveness for the clinical use.

8. Performance Data

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

1) Performance test

The Continuous measurement, Intermittent Determination and Direct clinical thermometer measure meet the specification of the product and the relevant standards are listed below.

- ASTM, E1112-00 (2018), Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature
- 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

2) Electromagnetic Compatibility and Electrical Safety

Electrical safety and EMC testing has been performed to, and passed, the following standards:

- IEC 60601-1 Edition 3.2 2020-08, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 4.1 2020-09, 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 Edition 2.1 2020-07, 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
- ANSI C63.4-2014, FCC Part 15 Subpart B
- ANSI C63.4-2014, FCC Part 15 Subpart C

3) Software Verification and Validation

Software documentation consistent with Basic Documentation Level of concern is submitted in this 510(k). System validation testing presented in this 510(k) demonstrated that all software requirement specifications have been met and all software hazards have been mitigated to acceptable risk levels. The relevant standards and guidance are listed below.

- IEC 62304 Edition 1.1 2015-06, Medical device software - Software life cycle processes
- Content of Premarket Submissions for Device Software Functions-Guidance for Industry and Food and Drug Administration Staff
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions-Guidance for Industry and Food and Drug Administration Staff

4) Biocompatibility

The biocompatibility evaluation for the body-contacting components of the Wearable Digital Thermometer has been conducted in accordance with the "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" : Guidance for Industry and Food and Drug Administration Staff", as recognized by FDA. The testing has been performed to, and passed, including:

- ISO 10993-5:2009, Biological Evaluation of Medical Devices –Part 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10:2010, Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization

5) Shelf life

The Reliability Test of the Wearable Digital Thermometer has been conducted in accordance with relevant guidance and standards. The testing has been performed to, and passed, including:

- Guidance of Shelf Life of Medical Devices (1991)

6) Usability

Usability testing has been performed to, and passed, the following standards:

- IEC 60601-1-6:2020 Medical electrical equipment –Part 1-6: General requirements for safety –Collateral standard: Usability

7) Summary

Based on the above performance as documented in this application, the Wearable Digital Thermometer is found to have a safety and effectiveness profile that is similar to the predicate device.

9. Conclusions

Based on the comparison of intended use, design, materials and performance, the Wearable Digital Thermometer is to be concluded substantial equivalent to its predicate devices.