July 22, 2021

iWEECARE Co., Ltd.
Shao-Chun Chen
Official Correspondent
2625 Middlefield Road, #113
Palo Alto, California 94306

Re: K202603
Trade/Device Name: Temp Pal
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: June 11, 2021
Received: June 21, 2021

Dear Shao-Chun Chen:

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)*
K202603

Device Name
Temp Pal

Indications for Use *(Describe)*
The 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 over two years old.
The device is for home healthcare used by the layperson.

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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# 510(k) Summary

1. **Date Prepared:** 07/22/2021

2. **Type of Submission:** Traditional

3. **Submitter's Name:** iWEECARE Co., Ltd.

   **Address:** 2F, No. 121, Sec. 2, Linong St., Beitou Dist., Taipei City 112, Taiwan, R.O.C.
   **Phone:** +886-2-28213597
   **E-mail:** glen.tseng@iweecare.com
   **Contact:** Mr. Glen Tseng/ General Manager
   **Establishment Registration Number:** N/A

4. **Identification of the Device:**

   **Device Classification Name:** Thermometer, Electronic, Clinical
   **Device Name:** Temp Pal
   **Applicant Contact:** Mr. Glen Tseng/ General Manager
   **Correspondent:** 2625 Middlefield Road, #113, Palo Alto, CA 94306, United States
   **Phone:** +650-8617086
   **Email:** samson@mytracmo.com
   **Correspondent Contact:** Shao-Chun Chen
   **Regulation Number:** 880.2910
   **Classification Product Code:** FLL
   **Device Classification:** II

5. **Predicate Device:**

   **Predicate Device Name:** Wireless Thermometer (Model: WT701)
   **Manufacturer:** Raiing Medical Company
   **510(k) Number or Clearance Information:** K132761

6. **Indications for Use:**

   The 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 over two years old. The device is for home healthcare used by the layperson.

## 7. Device Description:

The Temp Pal is designed for the following:
A comprehensive Android and iOS App are provided to access Temp Pal from a smart device. It is used for measuring and monitoring armpit temperature and transmitting measured results to authorized caregivers via a real-time cloud service.

## 8. Substantial Equivalent Determination

The subject device "Temp Pal" is compared with the predicate device "Wireless Thermometer, WT701" in intended use, principle of operation, safety, and performance. Differences and Equivalences between these devices are cited as below.

| Item | Subject device | Predicate device | Substantial equivalence determination |
|---|---|---|---|
| Device Name | Temp Pal | Wireless Theromometer | |
| Model Name | STP-MB01-1 | WT701 | |
| 510(k) No. | K202603 | K132761 | |
| Product Code | FLL | FLL | ***Same*** |
| Classification | Class II | Class II | ***Same*** |
| Indications for Use | The 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 over two years old. The device is for home | The Wireless Thermometer (WT701) 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 | ***Same*** Both devices are designed to measure and monitor human armpit temperature continuously via wireless signal transmission of the result. |

| | | | |
|---|---|---|---|
| | healthcare used by the layperson. | persons over two years old. | |
| Display Unit Specification | iOS device Display | iOS device Display | ***Same*** |
| Working Voltage | DC3.7V | DC3V | ***Similar***<br>The electrical safety of subject device is verified and met the pre-defined criteria. This difference does not raise new issues of SE. |
| Battery | Rechargeable Battery 3.7V/10mAh | The button battery 3.0V, 210mAh | ***Similar***<br>The electrical safety of subject device is verified and met the pre-defined criteria. This difference does not raise new issues of SE. |
| Measurement Range | 77~113℉ (25~45℃) | 77~113℉ (25~45℃) | ***Same*** |
| Accuracy | ±0.09℉ (0.05℃) | ±0.09℉ (0.05℃), range 95~101.3℉ (35~38.5℃); ±0.18℉ (0.10℃), range <94.9 and >101.3℉ (<35 and >38.5℃) | ***Similar***<br>The measurement accuracy of subject device is verified and met the pre-defined criteria. This difference does not raise new issues of SE. |
| Temperature Unit | ℉ or ℃ | ℉ or ℃ | ***Same*** |
| Signal Transmission | Wireless 2.4G Bluetooth BLE | Wireless 2.4G Bluetooth BLE | ***Same*** |
| Receiver | Smart phone, Tablet with Bluetooth V4.0 running Apple operation system iOS 10.0 or later or Android operating | iPhone 4S, iPhone 5, iPad (3rd generation), iPad (4th generation), iPad mini, iPod touch (5th generation) | ***Similar***<br>The receiver of subject device is verified and met the pre-defined criteria. |

| | | | |
|---|---|---|---|
| | system 5.0 or later | | This difference does not raise new issues of SE. |
| Valid Transmission Distance | Up to 5 meters | Up to 5 meters | ***Same*** |
| Operation Environment | 41~113℉ (5~45℃), 15~95% RH | 41~104℉ (5~40℃), 15~85% RH | ***Similar***<br>The operation environment of subject device is verified and met the pre-defined criteria. This difference does not raise new issues of SE. |
| Standards Met for Bench and Clinical Performance | 1. EN 60601-1;<br>2. EN 60601-1-2;<br>3. 47 CFR FCC Part 15 Subpart B;<br>4. 47 CFR FCC Part 15 Subpart C;<br>5. ASTM E1112;<br>6. EN 12470-4;<br>7. ISO 80601-2-56;<br>8. EN 60601-1-11. | 1. EN 60601-1;<br>2. EN 60601-1-2;<br>3. FCC Part 15 Subpart C test FCC Part 15.247;<br>4. ASTM E1112;<br>5. EN 12470-4. | ***Equivalent***<br>The subject device is verified, validated, and met the pre-defined criteria. This difference does not raise new issues of SE. |
| Operational Principles | 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 | 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 | ***Equivalent***<br>The same mechanism is used in measuring the body temperature by testing NTC resistor’s resistance value.<br>The difference in temperature calculation rate does not raise new issues of SE. |

| | | | |
|---|---|---|---|
| | temperature by means of testing the NTC resistor's resistance value and calculates the body temperature every 10/30/60 seconds continuously and sends the temperature data to the receiver through Bluetooth connection. | measure the body temperature by means of testing the NTC resistor's resistance value and calculates the body temperature every 4 seconds continuously and sends the temperature data to the receiver through Bluetooth connection. | |
| Sensor Type | NTC Resistor | NTC Resistor | ***Same*** |
| Shelf Life | 13 months | 24 months | ***Similar***<br>Validation up to 13 months for subject device. |
| Materials | TPE with Biocompatibility verified and validated | ABS with Biocompatibility verified and validated | ***Equivalent***<br>The material of subject device is verified and met the pre-defined criteria. This difference does not raise new issues of SE. |

## 9. Non-clinical Testing Summary

A series of verification and validation activities were conducted on the subject device as below, and no clinical testing is performed to support the decision of substantial equivalence. All the test results demonstrate the subject device meets the requirement of its pre-defined acceptance criteria and intended use, and these can support the substantial equivalence to the predicate device.

(1) Life Time and Shelf Life,
including the battery cell cycle life test and the supporting shelf life test. The latter is performed by the reliability tests according to in-house standards.

(2) Cleaning Validation,

tested by microorganisms and supported total organic carbon.

(3) Biocompatibility,
including *In Vitro* Cytotoxicity, Skin Irritation, and Skin Sensitization, which are in compliance with EN ISO 10993-5, ISO 10993-10, ISO 10993-12, and ISO 10993-1.

(4) Software Validation,
in compliance with FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices and ISO 14971.

(5) Electromagnetic Compatibility and Electrical Safety,
in compliance with IEC/EN 60601-1, EN 60601-1-2, 47 CFR FCC Part 15 Subpart B and Subpart C, and IEC/EN 60601-1-11.

(6) Performance,
in compliance with EN 12470-4, ASTM E1112, and ISO 80601-2-56.

(7) Human Factor (Usability),
in compliance with EN 60601-1-6 and EN 62366.

## 10. Conclusion

The Temp Pal has been compared with “Wireless Thermometer (WT701)”. The subject device has same intended use, similar technological characteristics/ specification and performance as the predicate device. The subject device has undergone safety and performance tests, and the results complied with the test requests as the predicate device. Although there are some different specifications between the two devices, they do not raise new issues of substantial equivalence.

After analyzing the difference comparison and the non-clinical testing data, it can be concluded that the Temp Pal is substantially equivalent to the predicate device “Wireless Thermometer (WT701)”.