February 17, 2023

iWEECARE Co., Ltd.
Julia Yang
Regulatory Manager
1F., No. 11, Ln. 382, Zhonghe St., Beitou Dist.,
Taipei City, 112
Taiwan

Re: K222588
Trade/Device Name: Temp Pal (Smart Thermometer Patch) Model Number: STP-MB01-1
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: January 18, 2023
Received: January 20, 2023

Dear Julia Yang:

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)*

K222588

Device Name
Temp Pal (Smart Thermometer Patch) Model Number: STP-MB01-1

Indications for Use *(Describe)*
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.

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."

K222588 - 510(k) SUMMARY

5.1 Preparation Date: Feb. 9, 2023

5.2 Submitter:

Address:	iWEECARE Co., Ltd. 1F., No. 11, Ln. 382, Zhonghe St., Beitou Dist., Taipei City 112, Taiwan
Phone:	+886-2-2891-8636
Contact:	Glen Tseng glen.tseng@iweecare.com

5.3 Identification of the Device:

Proprietary/Trade Name:	Temp Pal (Smart Thermometer Patch)
Model Number:	STP-MB01-1
Regulation Name:	Clinical Electronic Thermometer
Review Panel:	General Hospital
Regulation Number:	880.2910
Product Code:	FLL
Device Class:	II

5.4 Identification of the Predicate Device:

Predicate Device Name:	Temp Pal
Model Number:	STP-MB01-1
510(k) Number:	K202603
Manufacturer:	iWEECARE Co., Ltd.
Regulation Number:	880.2910
Product Code:	FLL
Device Class:	Class II

5.5 Intended Use/ Indications for Use of the Device

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.

5.6 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 in real-time continuously and remotely via Bluetooth to smart device.

- 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
  Rechargeable Battery 3.7V/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.

5.7 Substantial Equivalence Determination

The Temp Pal (Smart Thermometer Patch) submitted in this 510(k) file is substantially equivalent in intended use, principles of operation, safety and performance to the cleared Temp Pal (K202603). Differences between the devices are cited.

Item	Subject device	Predicate device	Comparison
	Temp Pal (Smart Thermometer Patch)	Temp Pal	
510(k) No.	K222588	K202603	N/A
Proprietary Name	Temp Pal (Smart Thermometer Patch)	Temp Pal	
Model	STP-MB01-1	STP-MB01-1	
Manufacturer	iWEECARE Co., Ltd.	iWEECARE Co., Ltd.	
Product Code	FLL	FLL	***Same***
Classification	Class II	Class II	***Same***
Indications for use	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.	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.	***Similar*** Both devices are designed to measure and monitor human armpit temperature continuously via wireless signal transmission of the result. The subject device expands the patient population to include child under 2 years old (comparing with predicate device (K202603).
Thermometer	Clinical Electronic	Clinical Electronic	***Same***

Item	Subject device	Predicate device	Comparison
	Temp Pal (Smart Thermometer Patch)	Temp Pal	
Type	Thermometer	Thermometer	
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 every 10 seconds 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 every 10/30/60 seconds continuously and sends the temperature data to the receiver through Bluetooth connection.	***Similar*** Both devices measure the body temperature continuously by Bluetooth connection between the patch and smart device. Subject device keeps only 10 seconds measure frequency.
Anatomical	Patients' armpit	Patients' armpit	***Same***

Item	Subject device	Predicate device	Comparison
	Temp Pal (Smart Thermometer Patch)	Temp Pal	
Application			
Sensor	NTC Resistor	NTC Resistor	***Same***
Signal Transmission	Wireless 2.4G Bluetooth BLE	Wireless 2.4G Bluetooth BLE	***Same***
Display	iOS device display, Android device display	iOS device display, Android device display	***Same***
Working Voltage	DC3.7V	DC3.7V	***Same***
Power Requirements	Rechargeable Battery 3.7V/10mAh	Rechargeable Battery 3.7V/10mAh	***Same***
Materials	TPE, 304 Stainless Steel Probe and double-sided medical adhesive	TPE, 304 Stainless Steel Probe and double-sided medical adhesive	***Same***
Maximum continuous measuring time	24 hours	24 hours	***Same***
Response time	Require up to 5 minutes to reach stable reading	Require up to 5 minutes to reach stable reading	***Same***
Device size	Size: 28.5 x 26.8 x 3.52 mm, Weight: 3.6 g	Size: 28.5 x 26.8 x 3.52 mm, Weight: 3.3 g	***Similar***
Reusability	Reusable	Reusable	***Same***
Temperature range (Measurement Range)	77-113°F (25-45°C)	77-113°F (25-45°C)	***Same***
Operation Environment	41-113°F (5-45°C), 15-95%RH	41-113°F (5-45°C), 15-95%RH	***Same***
Storage condition	-4-131°F (-20-55°C), 15-95%RH	-4-131°F (-20-55°C), 15-95%RH	***Same***
Accuracy	0.09 °F (± 0.05 °C)	0.09 °F (± 0.05 °C)	***Same***
Display	0.01 °F (± 0.01 °C)	0.01 °F (± 0.01 °C)	***Same***

Item	Subject device	Predicate device	Comparison
	Temp Pal (Smart Thermometer Patch)	Temp Pal	
resolution			
Valid transmission distance	Up to 5 meters	Up to 5 meters	***Same***
Shelf Life	24 months	13 months	***Different*** Reliability up to 24 months for subject device is tested.
APP name	Temp Pal APP	Temp Pal APP	***N/A***
APP description	The Temp Pal APP provides an interface to receive and display the temperature data transmitted from the Temp Pal device.	The Temp Pal APP provides an interface to receive and display the temperature data transmitted from the Temp Pal device.	***Same***
APP Operation Platform	iOS and Android	iOS and Android	***Same***
APP Temperature display	Display in either ℃ or℉	Display in either ℃ or℉	***Same***
APP Data Export	Enables temperature data to be exported via e-mail as csv file.	Enables temperature data to be exported via e-mail as csv file.	***Same***
APP Battery Capacity	Display with 5 scale	Display with 5 scale	***Same***
Operation mode	Direct mode	Direct mode	***Same***
Biocompatibility	Biocompatibility, including In Vitro Cytotoxicity, Skin Irritation, and Skin Sensitization,	Biocompatibility, including In Vitro Cytotoxicity, Skin Irritation, and Skin Sensitization,	***Same***

Item	Subject device	Predicate device	Comparison
	Temp Pal (Smart Thermometer Patch)	Temp Pal	
	which are in compliance with EN ISO 10993-5, ISO 10993-10, ISO 10993-12, and ISO 10993-1.	which are in compliance with EN ISO 10993-5, ISO 10993-10, ISO 10993-12, and ISO 10993-1.	
Electric Safety and EMC	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.	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.	***Same***
Performance	In compliance with EN 12470-4, ASTM E1112, ISO 80601-2-56 and IEC 60529.	In compliance with EN 12470-4, ASTM E1112, ISO 80601-2-56 and IEC 60529.	***Same***

5.8 Similarity and Difference

The subject device has similar intended use, principle of operation and device size, and different shelf life, as the predicate device.

The intended use of subject device expands patient population to include child under 2 years old compared with the previous cleared device (K202603). The performance testing was conducted in accordance with ISO 80601-2-56 and the results complied with the standard. In addition, the usability testing was performed and met the requirements. So that this difference does not raise new safety and effectiveness questions.

The principle of operation is similar, both devices measure the body temperature continuously by Bluetooth connection between the patch and smart device. The measuring frequency were every 10/30/60 seconds in predicate device, and the subject device only keeps 10 second measuring frequency. The performance testing has been performed on the subject device, and the results complied with the test requests. So that this difference does not raise new safety and effectiveness questions.

The one difference between the subject device and the predicate devices is the shelf life. The subject device extends the reliability test to 24 months. The shelf life test has been performed on the subject device, and the results complied with the test requests. So that this difference does not raise new safety and effectiveness questions.

Finally, the weight of subject device is increased from 3.3g of predicate device to 3.6g by adding a TPE cover. A series of safety and performance tests have been performed on the subject device, and the results complied with the test requests. So that this difference does not raise new safety and effectiveness questions.

5.9 Non-clinical Testing

A series of safety and performance tests were conducted on the subject device, Temp Pal (Smart Thermometer Patch):

- Shelf life
  - Reliability Test

- Biocompatibility (Temp Pal-Smart Thermometer Patch)
  - In Vitro Cytotoxicity Test
  - Skin Irritation Study in White Rabbit
  - Skin Sensitization Study in Guinea Pigs
- Biocompatibility (Medical Adhesive)
  - In Vitro Cytotoxicity Test
  - MEM Elution
  - Primary Skin Irritation
  - Guinea Pig Sensitization
- Performance test
  - Continuous measurement
  - Intermittent Determination
  - Direct clinical thermometer measure
  - Degrees of protection
- Electromagnetic Compatibility and Electrical Safety
  - General requirements for basic safety and essential performance
  - Electromagnetic Compatibility

Please also find the applied standard for non-clinical testing:

Testing Item	Standards applied
Reliability (Stability)	Guidance of Shelf Life of Medical Devices (1991)
Biocompatibility	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.
Performance	EN 12470-4:2000 + A1:2009, Clinical thermometers - Part 4: Performance of electrical thermometers for continuous measurement

	ASTM, E1112-00 (Reapproved 2011), 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. [Including: Amendment 1 (2018)].
	IEC 60529:1989+A2:2013+C1:2019, and EN 60529:1991+A2:2013+AC:2019. Degrees of protection provided by enclosures (IP Code)
Software	IEC 62304:2006+AMD1:2015, Medical device software – Software life cycle processes
	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices: Guidance for Industry and FDA Staff.
Electromagnetic Compatibility and Electrical Safety	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)
	EN 60601-1-2:2007, 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 Edition 2.0 2015-01, 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
Usability	EN 60601-1-6：2007/ AC:2010, General requirements for basic safety and essential performance – Collateral standard: Usability
	EN 62366：2008, Application of usability engineering to medical devices
Cybersecurity	Content of Premarket Submissions for Management of Cybersecurity in Medical Devices
Wireless Coexistence	Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and Food and Drug Administration Staff
	AAMI, TIR69 Risk Management of Radio-Frequency Wireless Coexistence for Medical Devices and Systems

5.10 Conclusion

After analyzing the intended use, technological characteristics, non-clinical laboratory studies and safety testing data, it can be concluded that Temp Pal (Smart Thermometer Patch) is substantially equivalent to the predicate device.