May 5, 2022

Shenzhen Pango Medical Electronics Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
China

Re: K212346
Trade/Device Name: Infrared Thermometer, Model: PG-IRT1612, PG-IRT1613, PG-IRT1615, PG-IRT1618
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: March 26, 2022
Received: April 5, 2022

Dear Diana Hong:

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
For 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)*
K212346

Device Name
Infrared thermometer, Model: PG-IRT1612, PG-IRT1613, PG-IRT1615, PG-IRT1618

Indications for Use *(Describe)*

PG-IRT1612 & PG-IRT1618
Infrared Forehead Thermometer is intended to measure human body temperature by measuring forehead.
The device can be used on people of all ages at home or in hospital environment.

PG-IRT1613 & PG-IRT1615
Infrared Ear/Forehead Thermometer is intended to measure human body temperature by measuring ear canal or forehead.
The device can be used on people of all ages at home or in hospital environment.

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.

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510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K212346

1. Date of Preparation: 04/22/2022

2. Sponsor Identification

Shenzhen Pango Medical Electronics Co., Ltd.
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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Jinlei Tang (Alternative Contact Person)

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Tel: +86-21-22815850,
Fax: 360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Infrared thermometer
Common Name: Clinical electronic thermometer
Model: PG-IRT1612, PG-IRT1613, PG-IRT1615, PG-IRT1618

Regulatory Information

Classification Name: Clinical electronic thermometer;
Classification: II;
Product Code: FLL;
Regulation Number: 21CFR 880.2910
Review Panel: General Hospital;

Indications for Use:
PG-IRT1612 & PG-IRT1618
Infrared Forehead Thermometer is intended to measure human body temperature by measuring forehead.
The device can be used on people of all ages at home or in hospital environment.

PG-IRT1613 & PG-IRT1615
Infrared Ear/Forehead Thermometer is intended to measure human body temperature by measuring ear canal or forehead.
The device can be used on people of all ages at home or in hospital environment.

Device Description
The proposed device includes 4 models, which are PG-IRT1612, PG-IRT1613, PG-IRT1615 and PG-IRT1618. All models of infrared thermometers are intended for people of all age.

The proposed devices, Infrared Forehead Thermometers, Model PG-IRT1612 and PG-IRT1618, are hand-held, reusable, battery powered device, which are intended to measure human body temperature by measuring forehead. They are non-contact infrared thermometers. The distance of the measurement is 3~5cm.

The proposed devices, Infrared Ear/Forehead Thermometers, Model PG-IRT1613 and PG-IRT1615, are hand-held, reusable, battery powered device, which are intended to measure human body temperature by measuring ear canal or forehead. The ear cavity mode is contact measurement. The forehead mode is non-contact measurement and the measurement distance is 1~5mm.

The proposed devices are operated in adjusted mode. The body site used to reference the adjusted

temperature value displayed on the proposed device of each model is oral.

Principle of operation
The proposed device uses a temperature sensor, which can detect the object temperature (OBJ) [human body temperature], environment temperature (NTC) and temperature of sensor itself (AMB); these temperatures are then transfer to electronic signal and amplified; and then it is transferred to digital signal by AD module (signal conversion module) in MCU (Microcontroller Unit) of the proposed device. MCU will calculate the body temperature based on OBJ, NTC and AMB, and then transfer to screen for display.

5. Identification of Predicate Device

510(k) Number: K182597
Device Name: Infrared Thermometer
Model: PG-IRT1601 Infrared Ear Thermometer
PG-IRT1602 Infrared Forehead Thermometer (selected as predicate device)
PG-IRT1603 Infrared Ear/Forehead Thermometer (selected as predicate device)

6. Comparison of Technological characteristics

Table 1 Comparison of Technology Characteristics of Infrared Forehead Thermometers

ITEM	Proposed Device K212346	Predicate Device K182597	Remark
Model	PG-IRT1612 and PG-IRT1618	PG-IRT1602	/
Product Code	FLL	FLL	Same
Regulation Number	21 CFR 880.2910	21 CFR 880.2910	Same
Indications for Use	PG-IRT1612 & PG-IRT1618 Infrared Forehead Thermometer is intended to measure human body temperature by measuring forehead. The device can be used on people of all ages at home or in hospital environment.	PG-IRT1602 Infrared Forehead Thermometer is intended to measure human body temperature by measuring forehead. The device can be used on people of all ages.	Similar
Principle of Operation	The proposed device uses a temperature sensor, which can detect the object temperature (OBJ) [human body temperature], environment temperature (NTC) and temperature of sensor itself (AMB); these temperatures are then transfer to electronic signal and amplified; and	The proposed device uses a temperature sensor, which can detect the object temperature (OBJ) [human body temperature], environment temperature (NTC) and temperature of sensor itself (AMB); these temperatures are then transfer to electronic signal and amplified; and then it is transferred to	Same

	then it is transferred to digital signal by AD module in MCU of the proposed device. MCU will calculate the body temperature based on OBJ, NTC and AMB, and then transfer to screen for display.	digital signal by AD module in MCU of the proposed device. MCU will calculate the body temperature based on OBJ, NTC and AMB, and then transfer to screen for display.	
Features and characteristics	Non-contacting, Infrared Temperature Measurement	Non-contacting, Infrared Temperature Measurement	Same
Measurement Site	Forehead	Forehead	Same
Measurement Method	Infrared radiation detection	Infrared radiation detection	Same
Measurement Range	34.0℃ ~43.0℃ (93.2 ~ 109.4 °F)	34.0℃ ~43.0℃ (93.2 ~ 109.4 °F)	Same
Accuracy	±0.2℃ (0.4°F) at 35.0℃ ~ 42.0℃ (95.0°F ~ 107.6 °F) Others ±0.3℃ (0.5 °F)	±0.2℃ (0.4°F) at 35.0℃ ~ 42.0℃ (95.0°F ~ 107.6 °F) Others ±0.3℃ (0.5 °F)	Same
Display	0.1℃ (0.1℉)	0.1℃ (0.1℉)	Same
Memory	32 sets	9 sets	Different
Display type	LCD	LCD	Same
Activation	Scan button	Scan button	Same
Measurement distance	3~5cm	3~5cm	Same
Sensor name	Thermal Infrared Detectors 10TP583T manufactured by Semitec Inshizuka Electronics Corporation	Thermal Infrared Detectors 10TP583T manufactured by Semitec Inshizuka Electronics Corporation	Same
Sensor type	Thermopile	Thermopile	Same
Scale Selection	℃/℉	℃/℉	
Auto power-off while no operation	Yes	Yes	Same
Response time	1s	1s	Same
Operation environment	10.0℃ ~ 40.0℃ (50.0 ~ 104.0 °F) 15%~93% RH	10.0℃ ~ 40.0℃ (50.0 ~ 104.0 °F) 15%～93% RH	Same
Storage environment	-25.0℃ ~ +55.0℃ (-13.0 ~ +131.0°F) 0% ~ 93% RH	-25.0℃ ~ +55.0℃ (-13.0 ~ +131.0°F) 0%～93% RH	Same
Service life	5 years	5 years	Same
Power requirements	Two pieces of 1.5V AAA batteries	Two pieces of 1.5V AAA batteries	Same
Safety	Complied with IEC 60601-1	Complied with IEC 60601-1	Same
EMC	Complied with IEC 60601-1-2	Complied with IEC 60601-1-2	Same

Performance	Complied with ISO 80601-2-56	Complied with ISO 80601-2-56	Same
	Complied with ASTM E1965-98	Complied with ASTM E1965 -98	Same
Patient-contact Materials	Shell Material: ABS; lens: PMMA; Button: High density polyethylene (HDPE); Color additives	Shell Material: ABS; lens: PMMA; Button: High density polyethylene (HDPE); Color additives	Same
Biocompatibility	Complied with ISO 10993-5	Complied with ISO 10993-5	Same
	Complied with ISO 10993-10	Complied with ISO 10993-10	Same

Table 2 Comparison of Technology Characteristics of Infrared Ear/Forehead Thermometers

ITEM	Proposed Device K212346	Predicate Device K182597	Remark
Model	PG-IRT1613 and PG-IRT1615	PG-IRT1603	/
Product Code	FLL	FLL	Same
Regulation Number	21 CFR 880.2910	21 CFR 880.2910	Same
Indications for Use	PG-IRT1613 & PG-IRT1615 Infrared Ear/Forehead Thermometer is intended to measure human body temperature by measuring ear canal or forehead. The device can be used on people of all ages at home or in hospital environment.	PG-IRT1603 Infrared Ear/Forehead Thermometer is intended to measure human body temperature by measuring ear canal or forehead. The device can be used on people of all ages.	Similar
Principle of Operation	The proposed device uses a temperature sensor, which can detect the object temperature (OBJ) [human body temperature], environment temperature (NTC) and temperature of sensor itself (AMB); these temperatures are then transfer to electronic signal and amplified; and then it is transferred to digital signal by AD module in MCU of the proposed device. MCU will calculate the body temperature based on OBJ, NTC and AMB, and then transfer to screen for display.	The proposed device uses a temperature sensor, which can detect the object temperature (OBJ) [human body temperature], environment temperature (NTC) and temperature of sensor itself (AMB); these temperatures are then transfer to electronic signal and amplified; and then it is transferred to digital signal by AD module in MCU of the proposed device. MCU will calculate the body temperature based on OBJ, NTC and AMB, and then transfer to screen for display.	Same
Features and characteristics	Non-contacting, Infrared Temperature Measurement	Non-contacting, Infrared Temperature Measurement	Same
Measurement Site	Forehead and eardrum	Forehead and eardrum	Same
Measurement	Infrared radiation detection	Infrared radiation detection	Same

Method			
Measurement Range	34.0℃ ~43.0℃ (93.2 ~ 109.4 °F)	34.0℃ ~43.0℃ (93.2 ~ 109.4 °F)	Same
Accuracy	±0.2℃ (0.4°F) at 35.0℃ ~ 42.0℃ (95.0°F ~ 107.6 °F) Others ±0.3℃ (0.5 °F)	±0.2℃ (0.4°F) at 35.0℃ ~ 42.0℃ (95.0°F ~ 107.6 °F) Others ±0.3℃ (0.5 °F)	Same
Display	0.1℃ (0.1°F)	0.1℃ (0.1°F)	Same
Memory	32 sets	9 sets	Different
Display type	LCD	LCD	Same
Activation	Scan button	Scan button	Same
Measurement distance	Contact (Ear) 1~5mm (Forehead)	0~5mm	Different
Sensor name	Thermal Infrared Detectors 10TP583T manufactured by Semitec Inshizuka Electronics Corporation	Thermal Infrared Detectors 10TP583T manufactured by Semitec Inshizuka Electronics Corporation	Same
Sensor type	Thermopile	Thermopile	Same
Scale Selection	℃/°F	℃/°F	
Auto power-off while no operation	Yes	Yes	Same
Response time	1s	1s	Same
Operation environment	10.0℃ ~ 40.0℃ (50.0 ~ 104.0 °F) 15%~93% RH	10.0℃ ~ 40.0℃ (50.0 ~ 104.0 °F) 15%～93% RH	Same
Storage environment	-25.0℃ ~ +55.0℃ (-13.0 ~ +131.0°F) 0% ~ 93% RH	-25.0℃ ~ +55.0℃ (-13.0 ~ +131.0°F) 0%～93% RH	Same
Service life	5 years	5 years	Same
Power requirements	Two pieces of 1.5V AAA batteries	Two pieces of 1.5V AAA batteries	Same
Safety	Complied with IEC 60601-1	Complied with IEC 60601-1	Same
EMC	Complied with IEC 60601-1-2	Complied with IEC 60601-1-2	Same
Performance	Complied with ISO 80601-2-56	Complied with ISO 80601-2-56	Same
	Complied with ASTM E1965-98	Complied with ASTM E1965 -98	Same
Patient-contact Materials	Shell Material: ABS; lens: PMMA; Button: High density polyethylene (HDPE); Color additives	Shell Material: ABS; lens: PMMA; Button: High density polyethylene (HDPE); Color additives	Same
Biocompatibility	Complied with ISO 10993-5	Complied with ISO 10993-5	Same
	Complied with ISO 10993-10	Complied with ISO 10993-10	Same

Similar - Indications for Use

The Indications for Use for the proposed device is not exactly the same as the predicate device. The

Indication for Use for the proposed device includes the use environment, i.e. at home and hospital. The performance test environment condition complies with standards. It does not affect the measurement function of the proposed device. Therefore, the different will not affect the safety and effectiveness of the proposed device.

Different - Memory

The memory function for the proposed device is different from the predicate device. The memory of the proposed device is 32 sets, while the memory of the predicate device is only 9 sets. The proposed device has more memory than the predicate device, which allows users to access more records to get a better grasp of recent body temperature. Software validation and verification test demonstrate the subject devices performance as intended. The difference does not affect the indications for use. In addition, the working principle and measurement methods and parameters of the proposed device are the same as those of the predicate device. Therefore, the different will not affect the safety and effectiveness of the proposed device.

Different - Measurement distance

The measurement distance for the proposed device is different from the predicate device. The forehead mode of the proposed device is non-contact measurement and the measurement distance is 1~5mm, which can be covered by the predicate device. While the ear cavity mode for the proposed device is contact measurement. However, the biocompatibility test of the human contact part of the proposed device was performed and the results showed no adverse effect. In addition, the performance test and clinical test were performed on the proposed device and the test results demonstrate that the proposed device meets the requirements of ASTM E1965-98 (Reapproved 2016). Therefore, the different will not affect the safety and effectiveness of the proposed device.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications. The test performed on the proposed device include

Biocompatibility testing

The biocompatibility test for the proposed device was conducted in accordance with the FDA guidance "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 items include cytotoxicity, Sensitization and Irritation test, the test result demonstrated that there was no adverse effect, thereby, it can be determined that the device can comply with the following standards:

- 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

Electrical safety and EMC

Electrical safety and EMC testing were conducted on the proposed device and the test result demonstrated that the device can operate normally and did not raise any performance degradation and safety issue, thereby, it can be determined that the device can comply with the following standards:

- IEC 60601-1: 2005+CORR.1(2006)+CORR.2(2007)+AMI(2012) Medical electrical equipment-Part 1: general requirement for basic safety and essential performance
- IEC 60601-1-2:2014 Medical Electrical Equipment- Part 1-2: General Requirements for Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility-Requirements And Tests.
- ISO 80601-2-56: 2017+A1: 2018 Medical Electrical Equipment- Part 1-2: Particular Requirements for Basic Safety And Essential Performance of Clinical thermometers for body temperature measurement
- IEC 60601-1-11: 2015 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

The software verification and validation were conducted in accordance with the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," dated May 11, 2005. The test results demonstrated the software function met the requirements.

8. Clinical Test Conclusion

Controlled human clinical studies were conducted in accordance with ASTM E1965-98 (Reapproved 2016), clinical bias, clinical uncertainty and clinical repeatability have been evaluated per clinical validation for infrared thermometer. The clinical trial results verify that the clinical accuracy of the proposed device is not inferior to that of predicate device.

Total 120 subjects and three age groups, including age 0~1 (40 subjects), age 1~5 (40 subjects) and age above 5 (40 subjects) are included in each clinical study, including febrile and afebrile persons. Compared statistical result of clinical bias and clinical repeatability of two comparison groups, the results of proposed device are not being inferior to that of predicate device. The result of proposed device was not inferior to that of predicate device, and the proposed device complies with ASTM E1965-98 (Reapproved 2016).

9. Conclusion

Based on the performance testing, comparison and analysis above, the proposed devices are substantially equivalent to the predicate device K182597.