April 3, 2019

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

Re: K182597
   Trade/Device Name: Infrared thermometer, Model: PG-IRT1601, PG-IRT1602, PG-IRT1603
   Regulation Number: 21 CFR 880.2910
   Regulation Name: Clinical Electronic Thermometer
   Regulatory Class: Class II
   Product Code: FLL
   Dated: February 27, 2019
   Received: March 6, 2019

Dear Ms. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sapana Patel -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
**Indications for Use**

**510(k) Number (if known)**
K182597

**Device Name**
Infrared Thermometer, PG-IRT1601, PG-IRT1602 and PG-IRT1603

**Indications for Use (Describe)**
PG-IRT1601 Infrared Ear Thermometer is intended to measure human body temperature by measuring ear canal.
PG-IRT1602 Infrared Forehead Thermometer is intended to measure human body temperature by measuring forehead.
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.

**Type of Use (Select one or both, as applicable)**

- [ ] Prescription Use (Part 21 CFR 801 Subpart D)
- [x] Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K182597

1. Date of Preparation: 03/19/2019

2. Sponsor Identification

**Shenzhen Pango Electronic Co., Ltd**
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Email: xie_you_jian@163.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Mr. Chengyu Wang (Alternative Contact Person)

**Mid-Link Consulting Co., Ltd**
P.O. Box 120-119, Shanghai, 200120, China

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(s): PG-IRT1601, PG-IRT1602 and PG-IRT1603

Regulatory Information

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

Indications for Use Statement:
PG-IRT1601 Infrared Ear Thermometer is intended to measure human body temperature by measuring ear canal.
PG-IRT1602 Infrared Forehead Thermometer is intended to measure human body temperature by measuring forehead.
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.

Device Description
The proposed device includes 3 models, which are PG-IRT1601, PG-IRT1602 and PG-IRT1603. It includes infrared thermometers and is intended for people of all age.

The proposed device, Infrared Ear Thermometers, Model PG-IRT1601, is hand-held, reusable, battery powered device, which is intended to measure human body temperature by measuring ear canal.

The proposed device, Infrared Skin Thermometers, Model PG-IRT1602, is hand-held, reusable, battery powered device, which is intended to measure human body temperature by measuring forehead. The distance of the measurement is 3cm~5cm.

The proposed device, Infrared Ear/Forehead Thermometer, Model PG-IRT1603, is hand-held, reusable, battery powered device, which is intended to measure human body temperature by measuring ear canal or forehead. The distance of the measurement is 3~5cm while measuring the forehead temperature.

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 Devices

Predicate Device 1
510(k) Number: K152748;
Device Name: Braun Thermoscan® PRO 6000 Ear Thermometer

Predicate Device 2
510(k) Number: K163516;
Device Name: Braun No Touch + Forehead NTF3000 Thermometer;

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
- ASTM E1965-98 (R 2016), Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature

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.
7. Clinical Test Conclusion

Controlled human clinical studies were conducted on 3 models of proposed device with predicates in accordance with ASTM E1965-98, 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 130 subjects and three age groups, including age 0~1 (50 subjects), age 1~5 (40 subjects) and age above 5 (40 subjects) are included in each clinical study, the amounts of male subjects are the same with that of female subjects, 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.

8. Substantially Equivalent (SE) Comparison

<table>
<thead>
<tr>
<th>TABLE 1 Comparison of Technology Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>ITEM</td>
</tr>
<tr>
<td>---------------------</td>
</tr>
<tr>
<td>Product Code</td>
</tr>
<tr>
<td>Regulation Number</td>
</tr>
<tr>
<td>Intended Use</td>
</tr>
</tbody>
</table>
temperature by measuring ear canal or forehead. The device can be used on people of all ages.

<table>
<thead>
<tr>
<th>Measurement Site</th>
<th>Forehead and/or eardrum</th>
<th>Eardrum</th>
<th>Forehead</th>
<th>Same</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principle of Operation</td>
<td>Non-contacting, Infrared Temperature Measurement</td>
<td>Non-contacting, Infrared Temperature Measurement</td>
<td>Contacting or non-contacting, Infrared Temperature Measurement</td>
<td>Same</td>
</tr>
</tbody>
</table>

**Ear Mode**

<table>
<thead>
<tr>
<th>Range</th>
<th>34.0°C-43.0°C</th>
<th>32.0°C-42.9°C</th>
<th>/</th>
<th>Discussion 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accuracy</td>
<td>±0.2 °C at 35.0 °C -42.0°C Others ±0.3°C</td>
<td>±0.2°C at 35.5°C-42.0°C Others ±0.3°C</td>
<td>/</td>
<td>Same</td>
</tr>
</tbody>
</table>

**Forehead Mode**

<table>
<thead>
<tr>
<th>Measurement distance</th>
<th>3~5cm</th>
<th>/</th>
<th>Unknown</th>
<th>Discussion 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Range</td>
<td>34.0°C-43.0°C</td>
<td>/</td>
<td>34.4°C-42.2°C</td>
<td>Discussion 2</td>
</tr>
<tr>
<td>Accuracy</td>
<td>±0.2 °C at 35.0 °C -42.0°C Others ±0.3°C</td>
<td>/</td>
<td>±0.2°C at 35.0°C-42.0°C ±0.3°C at 31.0°C-35.0°C Above 42.0°C ±0.3°C</td>
<td>Same</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Display type</th>
<th>LCD</th>
<th>LCD</th>
<th>LCD</th>
<th>Same</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activation</td>
<td>Scan button</td>
<td>Scan button</td>
<td>Scan button</td>
<td>Same</td>
</tr>
<tr>
<td>Power requirements</td>
<td>Two pieces of 1.5V AAA (number seven) batteries</td>
<td>Two AA Alkaline Batteries or Custom Nickel Metal Hydride Battery Pack</td>
<td>Two AA batteries</td>
<td>Discussion 3</td>
</tr>
<tr>
<td>Safety</td>
<td>Complied with IEC 60601-1</td>
<td>Complied with IEC 60601-1</td>
<td>Complied with IEC 60601-1</td>
<td>Same</td>
</tr>
<tr>
<td>EMC</td>
<td>Complied with IEC 60601-1-2</td>
<td>Complied with IEC 60601-1-2</td>
<td>Complied with IEC 60601-1-2</td>
<td>Same</td>
</tr>
<tr>
<td>Performance</td>
<td>Complied with ISO 80601-2-56</td>
<td>Complied with ISO 80601-2-56</td>
<td>Complied with ISO 80601-2-56</td>
<td>Same</td>
</tr>
<tr>
<td>-------------</td>
<td>--------------------------------</td>
<td>--------------------------------</td>
<td>--------------------------------</td>
<td>------</td>
</tr>
<tr>
<td>Patient-contact Materials</td>
<td>Shell Material: ABS lens: PMMA Button: High density polyethylene (HDPE) Color additives</td>
<td>Common Materials-including an impact resistant casing. Biocompatible metals and resins.</td>
<td>Patient contacting materials include ABS (device housing / handle and power button) and TPR (temperature button and nose / forehead touch bumper).</td>
<td>Discussion 4</td>
</tr>
<tr>
<td>Biocompatibility</td>
<td>Complied with ISO 10993-5</td>
<td>Complied with ISO 10993-5</td>
<td>Complied with ISO 10993-5</td>
<td>Same</td>
</tr>
<tr>
<td></td>
<td>Complied with ISO 10993-10</td>
<td>Complied with ISO 10993-10</td>
<td>Complied with ISO 10993-10</td>
<td>Same</td>
</tr>
</tbody>
</table>

Discussion 1
The proposed device includes three models which respectively measure temperature by ear, by forehead and by ear or forehead. Predicate device 1 supports ear mode, and predicate device 2 supports forehead mode. The indications of proposed device can be covered by predicate 1 and 2. And the proposed device is also intended for people of all age, which is the same with predicates. The difference does not raise different safety and effectiveness issues.

Discussion 2
The measurement ranges and distance of proposed device are different from that of predicate device. However, the proposed device has been demonstrated to comply with the requirements of performance identified in the standards. The difference does not raise different performance questions.

Discussion 3
The batteries of proposed device are different from that of predicate device. However, the proposed device has been demonstrated to comply with the requirements of electrical safety identified in the standards. The difference does not raise different safety and effectiveness issues.

Discussion 4
The patient-contact materials of proposed device are different from that of predicate device. However, the proposed device has been demonstrated to comply with the requirements of biocompatibility identified in the standards. The difference does not raise different safety and effectiveness issues.
9. Substantially Equivalent (SE) Conclusion

Based on the performance testing, comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.