



May 25, 2018

Shenzhen Pacom Medical Instruments Co., Ltd.  
Liangzhou Zhong  
Manager  
8 Floor, B District, B Building, No. 5  
Industry Five Road, Jianbian Community  
Songgang, Shenzhen, 518105  
CHINA

Re: K172889

Trade/Device Name: Infrared Thermometer  
Regulation Number: 21 CFR 880.2910  
Regulation Name: Clinical Electronic Thermometer  
Regulatory Class: Class II  
Product Code: FLL  
Dated: April 16, 2018  
Received: April 16, 2018

Dear Liangzhou Zhong:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

 Tina Kiang  
-S

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

**Sponsor:** Shenzhen Pacom Medical Instruments Co., Ltd.

**Subject Device:** Infrared Thermometer, model : PC868

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## Indications for Use

510(k) Number (if known): K172889

Device Name: Infrared Thermometer, Model: PC868

Indications for Use:

The Infrared thermometer Model PC868 can measure body temperature from the forehead of infants and adults without contact to the human body, it can be used by consumers in household environment and by doctors in the clinic.

Prescription Use \_\_\_\_\_ AND/OR Over-The-Counter Use ✓  
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Sponsor: Shenzhen Pacom Medical Instruments Co., Ltd.

Subject Device: Infrared Thermometer, model: PC868

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## 510(k) Summary

This summary of 510(K) information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92.

The assigned 510(k) number is: K172889

### 1.0 Information of Submitter and Correspondent

#### Submitter's information:

Shenzhen Pacom Medical Instruments Co., Ltd.

Address: On the 8<sup>th</sup> floor of B District, B Building, No.5, Industry five road, Jianbian Community, Songgang, Shenzhen 518105, China.

Phone: +86-755-32920339

Fax: +86-755-32920339

Contact Person: Mr. Zhong

E-mail: reanny@reanny.com

#### Submission contact information:

Shenzhen Reanny Medical Devices Management Consulting Co., Ltd

Address: Room 2012#, Gebu commercial building, Hongxing community, Songgang street, Baoan district, Shenzhen 518000, China

Contact Person: Reanny Wang; E-mail: reanny@reanny.com

### 2.0 Device Information

|                            |                                           |
|----------------------------|-------------------------------------------|
| Type of 510(k) submission: | Traditional                               |
| Trade Name:                | Infrared Thermometer, Model: PC868        |
| Model:                     | PC868                                     |
| Classification name:       | thermometer, electronic, clinical General |
| Review Panel:              | Hospital                                  |
| Product Code:              | FLL                                       |
| Device Class:              | II                                        |
| Regulation Number:         | 880.2910                                  |

Sponsor: Shenzhen Pacom Medical Instruments Co., Ltd.

Subject Device: Infrared Thermometer, model: PC868

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### 3.1 Predicate Device Information

Sponsor: K-jump Health Co., Ltd.

Device: Non-contact Infrared Thermometer, model KI-8280

510(K) Number: K102947

### 4.0 Device Description

All objects above absolute zero temperature emits certain percentage of infrared radiation energy based on its temperature. The amount of the radiation energy and the distribution of the wavelength have very closely relationship. When human forehead's temperature in 36-37°C, it emits wavelength 9-13um of infrared radiation. Based on this principle, according to the relationship between surface forehead temperature, we are able to measure the human forehead's actual temperature through measuring surface forehead temperature. Therefore, the subject device is able to measure the temperature of a person by the energy the person emits. The predicate device KI-8280, use the same detection principle to measure the patient's temperature.

These thermometers are a kind of measurement device that utilize infrared radiation to measure forehead and object temperature. The Infrared Thermometers main function as following:

- ☐ Forehead and object temperature measure functions
- ☐ Have wide range of temperature readings: from 32.0°C to 42.9°C
- ☐ The big LCD display can clear showing the measure result.
- ☐ Have memory function
- ☐ Low battery indicator
- ☐ Have backlight function
- ☐ Have ambient temperature detection function

The power supply of Infrared Thermometer is DC 3.0 V, which is offered by two AAA batteries.

This thermometer uses thermopile as the temperature sensor. The enclosure cover is made of ABS plastic material. The thermometer mainly includes the following components: MCU, PCB, LCD, Infrared Sensor, Probe, Batteries, Buzzer, Backlight and Enclosure Cover.

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There are only one patient contacting materials: ABS plastic. The material also meet the test requirements of ISO10993-5 (In vitro cytotoxicity) and ISO10993-10 (Irritation and delayed-type hypersensitivity).

The subject device of PC868 also use the focusing design to collect the infrared emitted from nearby area of object surface. This mechanism make the subject device have the ability to detect the object surface temperature.

The compact, small and light-weight design, the Shenzhen Pacom Medical Instruments Co., Ltd. Infrared Thermometer, model PC868, enables to provide safe and reliable result and offers a very good clinical accuracy for human body temperature measurements.

Power requirements:

d.c.3V,twoAAAbatteries,meetstherequirementsofUL544

Sterilization information:

Theinfraredthermometerisnotsoldsterile

Temperature range:

For forehead mode: 32.0°C to 42.9°C; For  
surface mode: 0°C to 100°C

Ambient temperature environment:

Temperature: 10°C-40°C; Relative humidity: 15%-85%RH; Atmospheric  
pressure: 70-106KPa

Storage environment:

Temperature: 0°C-50°C; Relative humidity: 15%-85%RH; Atmospheric  
pressure: 70-106KPa

Accuracy and repeatability: For

forehead mode:

±0.2°C (0.4°F) during 35.5°C-42.0°C; (95.9°F-107.6°F)

±0.3°C (0.5°F) other ranges; For

surface mode:

±1.0°C (1.8°F) during 15.0°C-60.0°C (59°F-140°F);

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±2.0°C(3.6°F) other ranges;

Other capabilities:

- a) LCD display with color changing backlight
- b) Read temperature in Fahrenheit or centigrade
- c) Automatic power saving in 15 seconds
- d) Automatically saves last 99 readings
- e) Battery life span greater than 1000 reads, replaceable batteries

## **5.0 Intended Use**

The Infrared thermometer Model PC868 can measure body temperature from the forehead of infants and adults without contact to the human body, it can be used by consumers in household environment and by doctors in the clinic.

## **6.0 Performance Summary**

The devices conform to applicable standards as follow table:

| Item                        | Description    | FDA recognized consensus standards | Justification |
|-----------------------------|----------------|------------------------------------|---------------|
| Safety                      | IEC 60601-1    | Yes                                | Conform       |
| EMC                         | IEC 60601-1-2  | Yes                                | Conform       |
| Home healthcare environment | IEC 60601-1-11 | Yes                                | Conform       |
| Performance                 | ASTM E 1965-98 | Yes                                | Conform       |
|                             | ISO 80601-2-56 | Yes                                | Conform       |
| Biocompatibility evaluation | ISO 10993-1    | Yes                                | Conform       |
| Biocompatibility test       | ISO 10993-5    | Yes                                | Conform       |
|                             | ISO 10993-10   | Yes                                | Conform       |
| Software                    | IEC 62304      | Yes                                | Conform       |
| Risk management             | ISO 14971      | Yes                                | Conform       |

Sponsor: Shenzhen Pacom Medical Instruments Co., Ltd.

Subject Device: Infrared Thermometer, model: PC868

## 7.0 Comparison to predicate device and conclusion

The subject device is substantially equivalent to predicate devices, K102947, KI-8280. The substantial equivalence chart is provided as follows:

| Elements of Comparison | Predicate Device                                                                                                                                                                                                                | Subject Device                                                                                                                                                                                                                    | Judgment          |
|------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Models                 | KI-8280                                                                                                                                                                                                                         | PC868                                                                                                                                                                                                                             | --                |
| Company                | K-jump Health Co., Ltd.                                                                                                                                                                                                         | Shenzhen Pacom Medical Instruments Co., Ltd.                                                                                                                                                                                      | --                |
| Device Name            | Non-Contact Infrared Thermometer                                                                                                                                                                                                | Infrared Thermometer                                                                                                                                                                                                              | --                |
| 510(k) Number          | K102947                                                                                                                                                                                                                         | Pending                                                                                                                                                                                                                           | --                |
| Intended use           | The non-contact infrared thermometer, Model KI-8280, can measure body temperature for infants and adults without contact to human body, it can be used by consumers in household environment and doctor in clinic as reference. | The thermometers are intended to measure forehead temperature without contact at home or hospital, including anyone, such as infants, children and adults.                                                                        | Similar           |
| Sensor                 | Infrared Sensor                                                                                                                                                                                                                 | Infrared Sensor                                                                                                                                                                                                                   | Same              |
| Measurement method     | Infrared radiation detection                                                                                                                                                                                                    | Infrared radiation detection                                                                                                                                                                                                      | Same              |
| Measurement mode       | Forehead and surface measure mode                                                                                                                                                                                               | Forehead and surface measure mode                                                                                                                                                                                                 | Same              |
| Measurement range      | Forehead mode:<br>32.2°C-43.3°C (90.0°F-109.9°F);<br>Surface mode:<br>0.0°C-100°C (32°F-212°F);                                                                                                                                 | For forehead mode:<br>32.0°C to 42.9°C (89.6°F-107.9°F);<br>For surface mode:<br>0°C to 100°C (32°F-212°F)                                                                                                                        | Similar<br>Note 1 |
| Measuring accuracy     | Forehead mode:<br>±0.2°C (0.4°F);<br>Surface mode:<br>±1°C (1.8°F)                                                                                                                                                              | For forehead mode:<br>± 0.2 °C (0.4°F) during 35.5 °C - 42.0°C; (95.9°F-107.6°F)<br>±0.3°C (0.5°F) other ranges;<br>For surface mode:<br>± 1.0 °C (1.8°F) during 15.0 °C - 60.0°C (59°F-140°F);<br>± 2.0 °C (3.6°F) other ranges; | Similar<br>Note 2 |

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Subject Device: Infrared Thermometer, model: PC868

| Elements of Comparison    | Predicate Device                                                             | Subject Device                                                                   | Judgment          |
|---------------------------|------------------------------------------------------------------------------|----------------------------------------------------------------------------------|-------------------|
| Models                    | KI-8280                                                                      | PC868                                                                            | --                |
| Display resolution        | 0.1°C/0.1°F                                                                  | 0.1°C/0.1°F                                                                      | Same              |
| Response Time             | 1 second                                                                     | 1 second                                                                         | Same              |
| Signal output and display | LCD, Buzzer                                                                  | LCD, Buzzer                                                                      | Same              |
| C/F switchable            | Yes                                                                          | Yes                                                                              | Same              |
| Measurement distance      | 3-8cm                                                                        | 3-5cm                                                                            | Similar<br>Note 3 |
| Memory                    | 10 sets                                                                      | 99sets                                                                           | Similar<br>Note 4 |
| Power supply              | Two 1.5V AAA batteries                                                       | Two 1.5V AAA batteries                                                           | Same              |
| Low battery indication    | Yes                                                                          | Yes                                                                              | Same              |
| Waterproof                | No                                                                           | IP22                                                                             | Similar<br>Note 5 |
| High temperature hint     | Higher than 38°C(100.4°F)                                                    | Higher than 38°C(100.4°F)                                                        | Same              |
| Operation environment     | Temperature:<br>10.0°C~40°C (50.0°F~104.0 °F)<br>Humidity:<br>95%RH or below | Temperature:<br>10.0°C~40°C (50.0°F~104.0°F)<br>Humidity:<br>15%-85% RH or below | Similar<br>Note 6 |
| Storage environment       | Temperature:<br>-25.0°C~55.0°C (-13.0°F~131.0°F)<br>Humidity: 95%RH or below | Temperature: 0°C-50°C(32.0°F ~122.0°F);<br>Relative humidity: 15%-85% RH;        |                   |
| Dimension                 | 138×90×45mm                                                                  | 149×95×45mm                                                                      | Similar           |
| Weight                    | 125g (including batteries)                                                   | 140g (including batteries)                                                       | Similar           |
| Performance               | Compliance with ASTM E 1965-98                                               | Compliance with ASTM E 1965- 98                                                  | Same              |
| Biocompatibility          | All the patient contacting materials are compliance with ISO 10993-1/-5/-10  | All the patient contacting materials are compliance with ISO 10993-1/-5/-10      | Same              |
| Electrical Safety         | Compliance with IEC 60601-1                                                  | Compliance with IEC 60601-1                                                      | Same              |
| EMC                       | Compliance with IEC                                                          | Compliance with IEC 60601-1-2                                                    | Same              |

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| Elements of Comparison | Predicate Device | Subject Device | Judgment |
|------------------------|------------------|----------------|----------|
| Models                 | KI-8280          | PC868          | --       |
|                        | 60601-1-2        |                |          |

**Note 1 and note2 :**

Although the measurement range and measuring accuracy of subject devices are different from predicate device, they both comply with the ASTM E 1965 standard, so the difference will not raise different safety or effectiveness issue.

**Note2 :**

Although the measurement distance of subject devices is different than predicate device, they both comply with the ASTM E 1965 standard and clinical test, so the difference will not raise different safety or effectiveness questions.

**Note 3:**

Although the measurement distance of subject devices is different than predicate device, they both comply with the ASTM E 1965 standard and clinical test, so the difference will not raise different safety or effectiveness questions.

**Note 4:**

The memory of subject devices is less than predicate device, but they both comply with the ASTM E 1965 standard, so the difference will not raise different safety or effectiveness questions.

**Note 5:**

The Waterproof of subject devices is IP22 and this have pass the IEC60601-1 test, will not raise different safety or effectiveness questions.

**Note 6:**

The Storage environment of subject devices is less than predicate device, but they both comply with the ASTM E 1965 and IEC 60601-1 standard, so the difference will not raise different safety or effectiveness questions.

**Final Conclusion:**

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Subject Device: Infrared Thermometer, model: PC868

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The subject devices have all features of the predicate device. The few differences do not affect the substantial equivalence of the subject devices.

Thus, the subject devices are substantially equivalent to the predicate device.

## **8.0 Discussion of Clinical Tests Performed**

The clinical performance test protocol and data analysis is followed the requirements the ASTM E 1965-98. It can conclude that the Thermometer, PC868 is acceptable to measure patient's temperature.

## **9.0 Conclusions**

Infrared Thermometer, Model PC868 has the same intended use and similar characteristics as the predicate device. Moreover, the subject device demonstrates product safety by successful completion of testing to the IEC 60601-1 standard and electromagnetic standard IEC 60601-1-2. The performance test demonstrates the PC868 meets the ASTM E 1965-98 and concludes that any differences in their characteristics does not raise different questions of safety and effectiveness.

Form the above information we conclude the subject device, PC868 is substantially equivalent to the predicate devices.

## **10.0 Summary prepared date**

May 10, 2018