November 22, 2017

Intrinity Global Limited
% Elly Xu
Consultant
Shenzhen Joyantech Consulting Co., Ltd
NO. 55 Shizhou middle road, Nanshan District
Shenzhen, 518000 China

Re: K170662
Trade/Device Name: Non Contact Infrared Forehead Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: October 15, 2017
Received: October 26, 2017

Dear Elly Xu:

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) 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K170662

Device Name
Non Contact Infrared Forehead Thermometer

Indications for Use *(Describe)*
Non Contact Infrared Forehead Thermometer is a non-sterile, reusable, handheld device. It can be used by consumers in homecare environment and doctors in clinic as reference. It is intended for measuring human body temperature of all ranges of people by detecting infrared heat from the forehead.

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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# VOL_05: 001 510(k) Summary

K170662

## 5.1 Administrative Information

| | |
|---|---|
| **Date of Summary prepared** | Nov, 14, 2017 |
| **Manufacturer information** | Intrinity Global Limited<br>Unit 1707, Floor 17, Westley Square, 48 Hoi Yuen Road, Kwun Tong, Hong Kong<br><br>Contact person: Alex Kwok<br>Phone: 852-35231874<br>Fax: 852-37484128<br>E-mail: alex.kwok@intrinity.com.hk |
| **Submission Correspondent** | Shenzhen Joyantech Consulting Co., Ltd.<br>Address: Room 1122, International Mayors Communication Centre, NO. 55 Shizhou middle road , Nanshan District, Shenzhen<br>Contact person: Ms. Elly Xu;  Mr. Field Fu<br>E-Mail: elly@cefda.com; cefda13485@163.com |
| **Establishment registration number** | |

## 5.2 Device Information

| | |
|---|---|
| **Type of 510(k) submission:** | Traditional |
| **Trade Name:** | Non Contact Infrared Forehead Thermometer |
| **Model:** | TVT-200, TVT-200 PLUS |
| **Classification name:** | thermometer, electronic, clinical |
| **Review Panel:** | General Hospital |
| **Product Code:** | FLL |
| **Device Class:** | II |

| | |
|---|---|
| **Regulation Number:** | 880.2910 |

### 5.3 Predicate Device Information

| | |
|---|---|
| **Sponsor:** | KAZ USA, Inc. |
| **Device:** | No Touch + Forehead Thermometer |
| **510(K) Number:** | K134043 |

### 5.4 Device Description

The thermometer measures the temperatures of people by detecting the energy. The external probe plays an important role in the measuring process.

As soon as the thermometer is placed near the body and the radiation sensor is activated, the measurement will be taken instantly by detection of the infrared heat.

The thermometer includes two models: TVT-200, TVT-200 PLUS. The TVT-200 model includes four colors: pink, grey, orange and purple. While TVT-200 PLUS has only orange color.

The Non Contact Infrared Forehead Thermometer is composed by an IR sensor, a Human temperature measurement button, an object temperature button, Battery compartment, Buzzer, °C /°F button, a LCD and an enclosure.

The functions of TVT-200 and TVT-200 PLUS are the same, except the Back Light. The detailed functions see below table:

| **Models** | **Functions** | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **Memory** | **°C/°F** | **Scan Mode** | **LCD** | **Buzzer** | **Fever alert** | **Power off/ Auto Off** | **Back Light** |
| **TVT-200** | ● | ● | ● | ● | ● | ● | ● | ● |
| **TVT-200 PLUS** | ● | ● | ● | ● | ● | ● | ● | ○ |

### 5.5 Intended Use/ Indications for Use

Non Contact Infrared Forehead Thermometer is a non-sterile, reusable, handheld device. It can be used by consumers in homecare environment and doctors in

clinic as reference. It is intended for measuring human body temperature of all ranges of people by detecting infrared heat from the forehead.

### 5.6 Technological characteristics of the subject device compared to the predicate device

| Items | Predicate Device (K134043), KAZ | Subject Device | Remarks |
|---|---|---|---|
| **Indications for use** | The No Touch + Forehead Thermometer (Model NTF3000US) is a non-sterile, reusable clinical thermometer intended for the intermittent determination of human body temperature in a touch and no touch on the centre of the forehead as the measurement site on people of all ages. | Non Contact Infrared Forehead Thermometer is a non-sterile, reusable, handheld device. It can be used by consumers in homecare environment and doctors in clinic as reference. It is intended for measuring human body temperature of all ranges of people by detecting infrared heat from the forehead. | Equivalent: intended use remains unchanged |
| **Measurement method** | Infrared radiation detection | Infrared radiation detection | Same |
| **Measurement mode** | Forehead measure mode | Forehead measurement mode | Same |
| **Measuring range** | Forehead temperature mode:<br>34.4°C -42.2°C (93.9°F - 108°F) | Forehead measurement mode:<br>32° to 43°C (89.6°F to 109.4°F) | Similar (**Note01**) |
| **Display resolution** | 0.1°C (0.1°F) | 0.1°C/0.1°F | Same |
| **C/F switchable** | Yes | Yes | Same |
| **Measuring accuracy** | Forehead temperature mode: ±0.2°C (0.4°F) | Forehead measurement mode:<br>±0.2°C (0.4°F) | Same |
| **Display** | LCD display | LCD display | Same |
| **Measurement distance** | 0-5cm | 1cm | Similar (**Note02**) |
| **Memory** | Not available. | 16 sets. | **(Note03)** |

| Items | Predicate Device (K134043), KAZ | Subject Device | Remarks |
|---|---|---|---|
| **Power source** | Two AA batteries | One 1.5V AAA alkaline battery | Similar **(Note04)** |
| **Low battery indication** | Yes | Yes | Same |
| **Waterproof** | No, IP20 | No, IP22 | Similar (**Note05**) |
| **Operating condition** | 15 °C – 40 °C (59 °F – 104 °F), 15–95% non condensing | 15°C~ 40°C (59°F~ 104°F); ≤95% RH | Similar **(Note06)** |
| **Patient contact materials** | metals and resins | ABS with colorants (pink, grey, orange and purple), Glass and Metal | Different **(Note07)** |
| **Cleaning/ disinfection** | The thermometer casing and the measuring probe are cleaned and disinfected by alcohol (70% Isopropyl). | The thermometer casing and the measuring probe are cleaned and disinfected by 70% alcohol. | Different **(Note08)** |
| **Biocompatibility** | Comply with ISO 10993-5:2009, ISO 10993-10:2010 | Comply with ISO 10993-5:2009, ISO 10993-10:2010 | Same |
| **Electric Safety and EMC** | IEC 60601-1 3rd edition: 2005, IEC 60601-1-2: 2007, IEC 60601-1-11: 2010 | IEC 60601-1: 2005+CORR.1 (2006)+ CORR.2 (2007), IEC 60601-1-2: 2014, IEC 60601-1-11: 2010, ISO 80601-2-56: 2009. | Similar |
| **Performance** | ASTM E1965-98 (2009) | ASTM E1965-98 (2009), ISO 80601-2-56: 2009. | Similar |

**Note 01:**
The measuring range of subject device meet the minimum rated output range of clinical thermometer requirement, from 35°C to 42°C, which is stated in standard ISO 80601-2-56. The differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device.

**Note 02:**
The difference in measurement distance will not affect the safety and effectiveness of the subject device. And the use method are described detailed in IFU.

**Note 03:**

The memory capacity will not affect the safety and effectiveness of the subject device.

**Note 04:**

The main difference between the batteries of the Predicate and the subject device is the size, which will not affect the safety and effectiveness. Furthermore, the electric safety of the battery has been validated with the subject device according to the IEC 60601-1. The differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device.

**Note 05:**

The difference in waterproof will not affect the safety and effectiveness of the subject device, which has passed IEC 60601-1 and IEC 60601-1-11 safety test. The differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device.

**Note 06:**

The operating condition of subject device has passed the safety test, and the Instructions for Use in VOL_13_Labeling provides the operating condition, so the difference between the operating conditions of subject device and predicate device will not affect the safety and effectiveness of subject device.

**Note 07:**

The patient contact materials including colorants (pink, grey, orange and purple) have passed the ISO 10993-1:2009, ISO 10993-5:2009, ISO 10993-10:2010 Biocompatibility Test. The differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device.

**Note 08:**

The cleaning has been validated according to the standards ASTM E2314 - 03(2014). The differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device.

The subject device and the predicate device have the same intended use and similar technological characteristics, they both use infrared radiation detection method to detect human body forehead temperature. Their design is compact, small and light-weight. They are same in measuring accuracy, and similar in measuring range. Thus, the subject device is substantially equivalent to the predicate devices.

### 5.7 Brief discussion of nonclinical tests

Nonclinical tests of the Infrared Thermometer are listed as below table:

| Tests | Test Standards | Results |
|---|---|---|
| Electric Safety | IEC 60601-1:2005+A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance;<br><br>IEC 60601-1-11: 2010, 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 | Pass |
| EMC | 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; | Pass |
| Bench performance | ISO 80601-2-56 First Edition 2009-10-01, Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement | Pass |

| Tests | Test Standards | Results |
|---|---|---|
| | ASTM E1965-98 (Reapproved 2009): Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature | |
| Clinical accuracy | ASTM E1965-98 (Reapproved 2009): Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature | Pass |
| Biological Evaluation | AAMI ANSI ISO 10993-1:2009/(R)2013, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process | Pass |
| *In vitro* Cytotoxicity | ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for *in vitro* cytotoxicity | Pass |
| irritation and skin sensitization | ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization | Pass |

**5.8 Brief discussion of clinical tests**

The clinical performance test protocol and data analysis is conducted as the requirement of ASTM E1965-98 (2009). The test report showed the clinical performance of the subject device complied with the requirement of ASTM E1965-98 (2009).

**5.9 Conclusions**

Based on the above information, we conclude that the subject device, Non Contact Infrared Forehead Thermometer, is substantially equivalent to the predicate device.