November 28, 2018

Alicn Medical (Shenzhen), Inc
% Reanny Wang
Medical Device Consultant
Shenzhen Reanny Medical Devices Management Consulting Co, Ltd
Room 2012 of Gebu commercial building, Hongxing community, Songgang street
Baoan District
Shenzhen, Guangdong 518000
China

Re: K180207
Trade/Device Name: Non-contact Infrared Thermometer, Model: AET-R161, AET-R171, AET-R1D2, AET-R1B1
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: September 9, 2018
Received: October 19, 2018

Dear Reanny Wang:

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,

Geeta K.
Pamidimukkala -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180207

Device Name
Non-contact Infrared Thermometer (Model: AET-R161, AET-R171, AET-R1D2, AET-R1B1)

Indications for Use *(Describe)*
Non-contact Infrared 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 two months and above of people by detecting infrared heat from the center of 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.

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510(k) Summary

K180207

1 Administrative Information

Date of Summary prepared	Nov. 28, 2018
Manufacturer information	Submitter's Name: Alicn Medical (Shenzhen), Inc. Address: 4/F, B Building, Shenfubao Modern Optical Factory, Kengzi Street, Pingshan District, Shenzhen City, China Contact person: Meisong Fang Phone: +86-755-26501548 Fax: +86-755-26504849 E-mail: hans.fang@alicn.com.hk
Submission Correspondent	Name: Reanny Wang Address: Room 2012 of Gebu commercial building, Hongxing community, Songgang street, Baoan district, Shenzhen City, Guangdong Province, China Contact person: Reanny Wang E-Mail: cefdacfda@163.com

2 Device Information

Type of 510(k) submission:	Traditional
Trade Name:	Non-contact Infrared Thermometer
Model:	AET-R161, AET-R171, AET-R1D2, AET-R1B1
Regulation Name:	Clinical electronic thermometer
Review Panel:	General Hospital
Product Code:	FLL
Device Class:	II
Regulation Number:	880.2910

3 Predicate Device Information

Sponsor:	KAZ USA, Inc.

Device:	No Touch + Forehead Thermometer
510(K) Number:	K134043

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 at the center of the forehead or the object with a distance of 15mm-50mm and the radiation sensor is activated, the measurement will be taken instantly by detection of the infrared heat.

The thermometer AET-R161 can be connected with FOND APP through Bluetooth. The FOND APP applies to mobile phones which systems are Android 4.3 and above, or IOS 8.0 and above, and can be downloaded from Google store (for Android 4.3 and above) or iPhone APP Store (for IOS 8.0 and above). The data measured with AET-R161 can be transmitted to the FOND APP, where data can be recorded, saved and shared.

The device principle of operation is described as below:
All object, solid, liquid or gas, emit energy by radiation. The intensity of this energy depends on the temperature of the object. The Infrared Thermometer is therefore able to measure the temperature of a person by the energy the person emits. This measurement can be taken by an external temperature probe on the device for analysis and register the ambient temperature. Therefore, as soon as the operator holds the thermometer near forehead and activates the radiation sensor, the measurement is taken instantly by detection of the infrared heat generated by the arterial blood flow. Body heat can therefore be measured without any interference from the heat of the surrounding environment.

The thermometer includes four models: AET-R161, AET-R171, AET-R1D2, AET-R1B1. They all have the following basic functions:
- Sound alarm if the temperature exceeds 37.8℃.
- LCD back-lighted digital screen.
- Data displayed in Celsius or Fahrenheit.
- Automatic stop (energy saver).

Their detailed functions see below table:

Models	Functions								
	Memory	**C/F**	**LCD**	**Buzzer**	**High temperat-ure indicator**	**Power off/ Auto Off**	**Back light**	**Low battery**	**DATA**
AET-R161	●	●	●	●	●	●	●	●	●
AET-R171	●	●	●	●	○	●	●	●	○
AET-R1D2	●	●	●	●	●	●	●	●	○
AET-R1B1	●	●	●	●	●	●	●	●	○

Note 1:
"●" means "with the function"; "○" means "without the function".
Note 2:
Details of the functions are listed below:
1) Memory: The thermometers can memorize 32 sets of readings;
2) C/F: The thermometer can shift the temperature units between °C and °F;
3) LCD: The readings will be showed on the LCD;
4) Buzzer: At the start-up or during the measurement, the thermometers will emit beeping sounds;
5) High temperature indicating: If the thermometer detects a temperature ≥37.8°C (or 100.0°F) under Forehead mode, the LCD display will be lit by a "Red" light;
6) Power off/Auto Off: Device will automatically power off left idle for more than 60 seconds to extend battery life;
7) Backlight: There are three backlight colors: green, orange and red. The LCD will display different color according to the temperature measurement;
8) **Low battery:** When the battery voltage is less than 2.55V, a low battery capacity sign will be shown on the LCD.
9) **DATA:** The temperature data can be transferred to cell phone via Bluetooth technique.

5 Intended Use/ Indications for Use

Non-contact Infrared 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 two months and above of people by detecting infrared heat from the center of the forehead.

6 Technological characteristics of the subject device compared to the predicate device

Items	Predicate Device (K134043), KAZ	Subject Device (K180207)	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 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 two months and above of people by detecting infrared heat from the center of the forehead.	Similar (**Note 12**)
Measurement method	Infrared radiation detection	Infrared radiation detection	Same
Measurement mode	Forehead measure mode	Forehead measurement mode/ Body mode, which is same with Forehead measure mode	Same
Measuring range	Forehead temperature mode: 34.4°C -42.2°C (93.9°F - 108°F)	Forehead measurement mode/ Body mode: 32.0°C to 42.2°C (89.6°F to 108°F)	Similar (**Note 01**)
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/ Body mode: ±0.2°C (0.4°F)	Same
Display	LCD display	LCD display	Same
Measurement distance	0-5cm	1.5-5.0cm	Similar (**Note 02**)
Memory	Not available.	32 sets.	**Note 03**
Power source	Two AA batteries	Two 1.5V AAA battery	Similar (**Note 04**)

Items	Predicate Device (K134043), KAZ	Subject Device (K180207)	Remarks
Low battery indication	Yes	Yes	Same
Waterproof	No, IP20	No, IP22	Similar (**Note 05**)
Operating condition	15 ℃ – 40 ℃ (59 °F – 104 °F), 15–95% non condensing	10-40°C (50-104°F), 10%-85%RH	Similar **(Note 06)**
Patient contact materials	metals and resins	ABS	Different **(Note 07)**
Cleaning/ disinfection	The thermometer casing and the measuring probe are cleaned and disinfected by alcohol (70% Isopropyl).	The surface of the device is cleaned and disinfected by 70% alcohol.	Different **(Note 08)**
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, lEC 60601-1-2: 2007, IEC 60601-1-11: 2010	IEC 60601-1: 2005+CORR.1 (2006)+ CORR.2 (2007), lEC 60601-1-2: 2014, IEC 60601-1-11: 2010, ISO 80601-2-56: 2009.	Similar **(Note 09)**
Performance	ASTM E1965-98 (2009)	ASTM E1965-98 (2009), ISO 80601-2-56: 2009.	Similar **(Note 10)**
Bluetooth	No	AET-R171, AET-R1D2, AET-R1B1: These three models do not have a Bluetooth module. AET-R161: This model has a Bluetooth module.	AET-R171, AET-R1D2, AET-R1B1: Same with predicate device AET-R161 **(Note 11)**

Note 01:
The measuring range of subject device meets the minimum rated output range of clinical thermometer requirement, from 35°C to 42°C, which is stated in standard ISO 80601-2-56.

Note 02:
The measurement distance of the subject device is within that of the predicate device. Because the both compliance with ISO 80601-2-56 and ASTM E 1965 standards, the measurement accuracy were meet the requirements of performance standards.

Note 03:
The memory is just for storage of measurement data and viewing by users and it will not affect the performance 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 performance. Furthermore, the electric safety of the battery has been validated with the subject device according to the IEC 60601-1.

Note 05:
The difference in waterproof will not affect the performance of the subject device, which has passed IEC 60601-1 and IEC 60601-1-11 safety test.

Note 06:
The operating condition of subject device has passed the performance test, and the Instructions for Use provides the operating condition.

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.

Note 08:
The cleaning has been validated according to the standards ASTM E2314 -03(2014).

Note 09:
The electrical safety of the subject device has passed the IEC 60601-1, IEC 60601-1-11 and ISO 80601-2-56 tests, and the EMC has passed the IEC 60601-1-2 test.

Note 10:
The performance of the subject device meets the requirements of ASTM E1965-98 (2009), ISO 80601-2-56: 2009.

Note 11:

Many legally marketed thermometers contain Bluetooth function to contact an APP. For the Bluetooth function, the subject device (model: AET-R161) has passed the IEC 60601-1, IEC 60601-1-2, 47 CFR PART 15 Subpart C tests, and the hazards, risks have been identified and the risks are controlled.

Note 12:

Although the description of "Indications for use" of subject device is few difference with predicate device. But the patients ages range (all ages) of predicate device covered the patients ages rang (two months and above) of subject device, and the subject device had performed the clinical accuracy test according to the ASTM E 1965-98 and ISO 80601-2-56 standards.

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. The differences noted above between the subject device and the predicate device do not raise new or different performance concerns. Thus, the subject device is substantially equivalent to the predicate device.

7 Brief discussion of nonclinical tests

Nonclinical tests of the Non-contact 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; 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	Pass

Tests	Test Standards	Results
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 ASTM E1965-98 (Reapproved 2009): Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature	Pass
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
QoS testing	47 CFR PART 15 Subpart C, Radio Frequency Devices Subpart C – Intentional Radiators	Pass
Wireless coexistence	47 CFR PART 15 Subpart C, Radio Frequency Devices Subpart C – Intentional Radiators	Pass
Software validation and verification test	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices issued on: May 11, 2005; Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use	Pass

Tests	Test Standards	Results
	in Medical Devices issued on: September 9, 1999	

8 Brief discussion of clinical tests

The clinical performance test protocol and data analysis is conducted as the requirement of ASTM E1965-98 (2009).

In this clinical study for the clinical accuracy validation, we conduct tests with Infrared Thermometer (model: AET-R161) and the RCT (model: WDJ-001) on the presentative patient populations, which include three age groups, i.e. Infants (two months to 1 year old), Children (1 up to 5 years old) and Adults (older than 5 years), and the number of subjects is 38 for Infants, 36 for Children and 42 for Adults.

The test report showed the clinical performance of the subject device complied with the requirement of ASTM E1965-98 (2009). Therefore, the subject device is able to measure patients' temperatures as intended.

9 Conclusions

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