October 29, 2018

JOYTECH Healthcare Co., Ltd.
Yunhua Ren
General Manager
No. 365 Wuzhou Road, Yuhang Economic Development Zone
Hangzhou City
Zhejiang, 311100
China

Re: K181239
Trade/Device Name: Infrared Forehead Thermometer, Infrared Ear/Forehead Thermometer; Models: DET-205, DET-206, DET-305, DET-306, DET-215
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: August 29, 2018
Received: September 28, 2018

Dear Yunhua Ren:

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)*
K181239

Device Name
Infrared Thermometers DET-205,DET-206,DET-305,DET-306,DET-215

Indications for Use *(Describe)*
Infrared Thermometer DET series are intended for the intermittent measurement of human body temperature by people of all ages. The devices are reusable for home use only.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

The assigned 510(k) number is: K181239

1. Date Prepared: 2018.10.25

2. Submitter's Identification:

Name: JOYTECH Healthcare Co.,Ltd.
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3. Name of the Device:

Device Name:Infrared Thermometer

Trade Name:Infrared Forehead Thermometer,Infrared Ear/Forehead Thermometer

Including models:DET-205,DET-206,DET-305,DET-306,DET-215

Classification name:Clinical Electronic Thermometer

4. Classification Information:

Product Code: FLL

Device Class: II

Panel: 80

Regulation number:880.2910

5. Predicate Device Information:

Non-contact Clinical Thermometer,Model THB0F(Radiant Innovation Inc,K121428)

RII Multi-function Infrared Thermometer, Model TH52Z. (Radiant Innovation Inc, K162083)

6. Intended use / Indication for Use:

Infrared Thermometer DET series are intended for the intermittent measurement of human body temperature by people of all ages.The devices are reusable for home use only.

7. Device Description:

The Infrared thermometers are hand-held, battery powered devices designed to measure human body temperature from the auditory canal or forehead. Its operation is based on measuring the natural thermal radiation from the tympanic membrane or forehead.

The thermometers use a thermopile sensor with integrated thermistor for the target reading, a thermistor mounted in the head of the thermometer for ambient temperature readings, a thermopile collect, the infrared energy emitted from the forehead.

The Infrared thermometer included DET-205,DET-206,DET-305,DET-306 and DET-215. DET-205 and DET-206 units are contact Infrared forehead thermometer,DET-305 and DET-306 units are non-contact Infrared forehead thermometer(measurement distance is 2~3cm), DET-215 unit is multifunction infrared thermometer and it can be selected Ear mode or Forehead mode.

In addition,all models have voice function that used to broadcast the measurement temperature results after complete the measurement. It's working principle is that Microcontroller Unit sends voice commands to the voice integrated circuit and then broadcast the measurement temperature results that display on the LCD.The voice function is use English language and actives after each measurement completed.

8.Summary of technological characteristics of device compared to the predicate devices, see the table1 and table2

A comparison of key similarities and differences between the subject devices (Model DET-205,DET-206,DET-305,DET-306,DET-215) and the predicate devices (K121428 and K162083) is provided below.

Table 1

SE Comparison	Subject Device Model DET-205,DET-206, DET-305,DET-306		Predicate device(PD) Radiant THB0F	Note
510k number	Present application		K121428	--
Regulation number	21 CFR 880.2910		21 CFR 880.2910	Same
Product Code	FLL		FLL	Same
Intended Use/ Indications for use	Infrared Thermometer DET series are intended for the intermittent measurement of human body temperature by people of all ages. The devices are reusable for home use only.		The Non-contact Clinical Thermometer, Model THBOF is an infrared thermometer intended for the intermittent measurement of human body temperature in people of all ages.	Similar
Measure Method	Infrared radiation detection		Infrared radiation detection	Same
Measurement Range	Forehead mode:34.0℃~43.0℃ (93.2℉~109.4℉)		Forehead mode: 34~42.2℃(93.2~108℉)	Similar (Note1)
Accuracy	Forehead mode: ±0.2℃ (0.4℉) during 35.5℃ ~42.0℃ (95.9℉~107.6℉) at 15℃~35℃ (59.0℉~95.0℉) operating temperature range ±0.3℃ (0.5℉) for other measuring and operating temperature range		Forehead mode: ±0.2℃ (0.4℉) within 36~39℃(96.8~102℉), ±0.3℃(0.5℉) other range	Similar (Note1)
Display	0.1℃(0.1℉)		0.1℃(0.1℉)	Same
Measurement Place	Forehead		Forehead	Same
Measurement Distance	DET-205, DET-206	Forehead Contact	2-3cm	Different (Note3)
	DET-305, DET-306	Non-contact, 2~3cm	2-3cm	Same
Response Time	Approximately 3 seconds		1s	Similar (Note4)
Sensor Type	Thermopile		Thermopile	Same
Scale Selection	℃/℉		℃/℉	Same
Display screen	LCD		LCD	Same
Memory	Each 10 sets memories for forehead and object measurements		60 Sets	Different (Note4)
Auto power-off	Yes		Yes	Same

while no operation			
Buzzer	Yes	Yes	Same
Voice Function	Yes	Unknown	Different (Note4)
Power Source	DC3V(2×AAA battery)	DC3V(2×AAA battery)	Same
Patient Contact material	Enclosure;ABS Probe:ABS & Glass	Enclosure;ABS Probe:ABS & Glass	Same
Biocompatibility testing	Cytotoxicity, Skin irritation, Skin sensitization	Cytotoxicity, Skin irritation, Skin sensitization	Same
Conformance standard	ISO 80601-2-56(Performance) IEC 60601-1(Safety) IEC 60601-1-2(EMC) ASTM E1965-98 ISO 10993-5 and ISO 10993-10 (Biocompatibility)	ISO 80601-2-56(Performance) IEC 60601-1(Safety) IEC 60601-1-2(EMC) ASTM E1965-98 ISO 10993-5 and ISO 10993-10 (Biocompatibility)	Same

Table 2

SE Comparison	Subject Device Model DET-215	Pridicate Device Radiant Innovation Inc, Model:TH52Z	Note
510k number	Present application	K162083	--
Regulation number	21 CFR 880.2910	21 CFR 880.2910	Same
Product Code	FLL	FLL	Same
Intended Use/ Indications for use	Infrared Thermometer DET series are intended for the intermittent measurement of human body temperature by people of all ages. The devices are reusable for home use only.	The RII Multi-function Infrared Thermometer,Model TH52Z is intended for the intermittent measurement of human body temperatures.The device is intended for the use at home by people of all ages including neonates and it can be selected Ear mode or Forehead mode.	Similar
Measure Method	Infrared radiation detection	Infrared radiation detection	Same
Measurement Range	Ear/Forehead mode: 34.0℃ ~43.0℃(93.2℉~109.4℉)	Ear / Forehead mode: 34.0℃~42.2℃(93.2℉~108℉)	Similar (Note1)
Accuracy	Ear/Forehead mode: ±0.2℃ (0.4℉) during 35.5℃ ~42.0℃ (95.9℉~107.6℉) at 15℃~35℃ (59.0℉~95.0℉)	±0.4℉ (0.2℃) within 95~107.6℉(35~42℃), ±0.5℉ (0.3℃) for other range.	Similar (Note1)

	operating temperature range ±0.3℃ (0.5℉) for other measuring and operating temperature range		
Display	0.1℃(0.1℉)	0.1℃(0.1℉)	Same
Measurement Place	Forehead Ear	Forehead Ear	Same
Response Time	Ear mode/Object mode: Approx. 1s Forehead: Approx. 3s	1s	Similar (Note4)
Sensor Type	Thermopile	Thermopile	Same
Scale Selection	℃/℉	℃/℉	Same
Display screen	LCD	LCD	Same
Memory	Each 10 sets memories for ear,forehead and object measurements	9 Sets	Different (Note4)
Auto power-off while no operation	Yes	Yes	Same
Buzzer	Yes	Yes	Same
Voice Function	Yes	Unknown	Different (Note4)
Power Source	DC3V(2×AAA battery)	CR2032*1	Different (Note2)
Biocompatibility	Cytotoxicity, Skin irritation, Skin sensitization	Cytotoxicity, Skin irritation, Skin sensitization	Same
Conformance standard	ISO 80601-2-56(Performance) IEC 60601-1(Safety) IEC 60601-1-2(EMC) ASTM E1965-98 ISO 10993-5 and ISO 10993-10 (Biocompatibility)	ISO 80601-2-56(Performance) IEC 60601-1(Safety) IEC 60601-1-2(EMC) ASTM E1965-98 ISO 10993-5 and ISO 10993-10 (Biocompatibility)	Same

Analysis

From the comparison table1 and table2, the subject devices and predicate devices have the similar Intended use & Indications for Use, same measurement place, Scale selection, Display screen, Auto power-off while no operation & Conformance standard. There are slightly differences between the devices and predicate devices as follows,through the verification and validation process, it has been shown that the differences do not raise new questions of safety and effectiveness.

Note1	Measurement Range& Accuracy changes	The measurement range and accuracy of subject devices meet the requirements of ISO80601-2-56 and ASTM E1965-98.
Note2	Power Source	Meet the requirement of IEC 60601-1
Note3	Measurement Distance changes	Meet the requirement of ISO 80601-2-56 clinical test
Note4	Response Time changes from 1s to 3s	Our devices have longer response time to measure the temperature,and all tests passed,so such different do not raise new performance questions.
	Memory change from 60 sets/9 sets to 10 sets	Software Validation Passed.
	Add voice function	Software Validation Passed.

9. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Infrared Thermometers conforms to applicable standards that include:

- ASTM E 1965-98 Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature
- IEC 60601-1:2012, Medical Electrical Equipment - Part 1: General Requirements 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
- 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
- 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

- ISO 80601-2-56: 2009 Medical electrical equipment - part 2-56: particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.
- The software verification and validation was provided in accordance with the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," dated May 11, 2005.

12. Discussion of Clinical Tests Performed:

Clinical tests were conducted on the DET-205,DET-206,DET-305,DET-306 and DET-215. The clinical tests evaluated 165 of subjects. Each model was evaluated in three groups 1) infants—newborn to one year; 2) children—greater than one to five years; and 3) adults—greater than five years old.The clinical performance test protocol and data analysis is conducted as the requirement of ASTM E1965-98 (2016). The test report showed the clinical performance of the subject device complied with the requirement of ASTM E1965-98 (2016).

13. Conclusions:

Based on the information provided in this submission, the submit Infrared Thermometers, models: DET-205,DET-206,DET-305,DET-306 and DET-215 are substantially equivalent to the predicate devices.