October 2, 2018

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

Re: K181081
Trade/Device Name: Infrared Ear Thermometer, Model: DET-101, DET-102, DET-103, DET-105
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: August 25, 2018
Received: August 29, 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)*
K181081

Device Name
Infrared Ear Thermometers DET-101,DET-102,DET-103,DET-105

Indications for Use *(Describe)*
Infrared Ear Thermometers 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.

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510(k) Summary

The assigned 510(k) number is: k181081

1. **Date Prepared:** 2018.08.24

2. **Submitter's Identification:**

Name: JOYTECH Healthcare Co.,Ltd.

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3. **Name of the Device:**

	Device	Accessory
Device Name	Infrared Ear Thermometer Models:DET-101,DET-102,DET-103,DET-105	Probe Cover
Trade Name	Infrared Ear Thermometer Models:DET-101,DET-102,DET-103,DET-105	PC11 Probe Cover

4. **Classification Information:**

Product Code: FLL

Device Class: II

Panel: 80

Regulation number:21 CFR 880.2910

Regulation Name: Clinical Electronic Thermometer

5. Predicate Device Information:

Manufacturer: SEJOY ELECTRONICS & INSTRUMENTS CO., LTD.

Device: Infrared Ear Thermometer,Model ET-101H

510k number: K153146

6. Intended use / Indication for Use:

Infrared Ear Thermometers 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:

Infrared Ear Thermometer:

The Infrared Ear Thermometers are electronic thermometers using an infrared detector (thermopile detector) to detect body temperature from the auditory canal. It's operation is based on measuring the natural thermal radiation emanating from the tympanic membrane.DET-103 and DET-105 include probe cover that is optional.

The Infrared Ear Thermometers include probe which used to measure ear canal temperature,plastic enclosure which enclosed the display window,buttons and the battery cover.

Probe Cover:

The probe cover is used as a sanitary barrier between the infrared ear thermometer and the ear canal to prevent any secretions or particulates from being transferred between different people.

8. Comparing to Predicate Device:

Comparisons	SUBJECT DEVICE: Infrared Ear Thermometer Model:DET-101,DET-102,DET-103, DET-105 510k number:K181081		PREDICATE DEVICE: Infrared Ear Thermometer Model:ET-101H 510k number:K153146	Remark
Indications for Use	Infrared Ear Thermometers are intended for the intermittent measurement of human body temperature by people of all ages.The devices are reusable for home use only.		Infrared Ear Thermometers are indicated for the intermittent measurement and monitoring of human body temperature by consumers in a home use environment.It's intended for use on people of all ages.	Same
Measurement method	Infrared radiation detection		Infrared radiation detection	Same
Measuring Site	Ear canal		Ear canal	Same
Principle of operation	The thermometer measures temperature by reading infrared radiation emitting from eardrum tissue .The probe of the thermometer is inserted into the ear canal, where surrounding tissues give off heat. The thermometer converts it into a temperature value.		The thermometer measures temperature by reading infrared radiation emitting from eardrum tissue .The probe of the thermometer is inserted into the ear canal, where surrounding tissues give off heat. The thermometer converts it into a temperature value.	Same
Display	0.1℃(0.1℉)		0.1℃(0.1℉)	Same
Measurement range	DET-101, DET-102,	32.0℃~43.0℃ (89.6℉~109.4℉)	Ear mode: 28.0℃~43.0℃ (82.4℉~109.4℉) Object mode: -20℃~100℃(-4℉~212℉)	Similar (Note1)
	DET-103, DET-105	Ear mode: 32.0℃~43.0℃ (89.6℉~109.4℉) Object mode: 0℃~100℃(32℉~212℉)	Ear mode: 28.0℃~43.0℃ (82.4℉~109.4℉) Object mode: -20℃~100℃(-4℉~212℉)	Similar (Note1)
Accuracy	DET-101, DET-102	±0.2℃ (0.4℉) during 35.0℃~42.0℃ (95.0℉~107.6℉) at 15℃~35℃ (59.0℉~95.0℉) operating	Ear mode: ±0.2℃ (0.4℉) during 35.5℃~42.0℃ (95.9℉~107.6℉) at 15℃~35℃ (59.0℉	Similar (Note1)

		temperature range ±0.3℃ (0.5℉) for other measuring and operating temperature range	~95.0℉) operating temperature range ±0.3℃ (0.5℉) for other measuring and operating temperature range Object mode: ±4% or ±2℃(4℉) whichever is greater	
	DET-103, DET-105	Ear 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 Object mode: ±4% or ±2℃(4℉) whichever is greater		
Operating temperature range	10℃~40℃ (50℉~104℉), 15%~85%RH, non-condensing Atmospheric Pressure: 700hPa ~ 1060hPa		10℃~40℃ (50℉~104℉), 15%~85%RH, non-condensing Atmospheric Pressure: 700hPa ~ 1060hPa	Same
Storage and transport environment	-25℃~55℃(-13℉~131℉), 15%~95%RH, non-condensing Atmospheric Pressure: 700hPa~1060hPa		-25℃~ 55℃ (-13℉~131℉), 15%~95%RH, non-condensing Atmospheric Pressure: 700hPa~1060hPa	Same
Power Source	DET-101, DET-102	One CR2032 battery	Two AAA battery	Different (Note2)
	DET-103, DET-105	Two AAA battery	Two AAA battery	Same
Accessory	DET-101, DET-102	No accessory	Probe cover	Different (Note3)
	DET-103, DET-105	Probe cover	Probe cover	Same
Response Time	Approx. One second		Approx. One second	Same
Material	Enclosure;ABS Probe:ABS & Glass Probe Cover:PE		Enclosure;ABS Probe:ABS & Glass Probe Cover:PE	Same
Memory	10 memories		10 memories	Same

Voice	DET-101, DET-102, DET-103	No	No	Same
	DET-105	Yes	NO	Different (Note4)
Biocompatibility	Comply with ISO 10993-5 and ISO 10993-10		Comply with ISO 10993-5 and ISO 10993-10	Same
Electrical Safety	Complied with IEC 60601-1		Complied with IEC 60601-1	Same
EMC	Complied with IEC 60601-1-2		Complied with IEC 60601-1-2	Same

Analysis

From the comparison table, the subject devices and predicate devices have the same Intended use & Indications for Use, 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 and these differences do not raise new performance questions.

Note1	Measurement Range changes from 28.0℃ ~43.0℃ to 32.0℃~43.0℃ & Accuracy changes from ±0.2℃ (0.4℉) during 35.5℃~42.0℃ (95.9℉~107.6℉) to ±0.2℃ (0.4℉) during 35.0℃~42.0℃ (95.0℉~107.6℉)	The changed measurement range and accuracy of subject devices meet the requirements of ISO80601-2-56 and ASTM E1965-98.
Note2	DET-101,DET-102 Power Source changes from Two AAA battery to CR2032 battery	Meet the requirement of IEC 60601-1.
Note3	DET-101,DET-102 accessory changes from have probe cover to no probe cover.	Meet the requirement of ASTM E1965-98.
Note4	DET-105 add voice function	Software Validation passed.

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

Infrared Ear Thermometer 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: 2017 Medical electrical equipment - part 2-56: particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
- Software Validation:FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," issued on May 11, 2005

10. Discussion of Clinical Tests Performed:

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).

11. Conclusions:

Based on the information provided in this submission, we conclude that the submit Infrared Ear Thermometers, models: DET-101, DET-102,DET-103 and DET-105 are substantially equivalent to the predicate thermometer.