July 26, 2019

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

Re: K190873
Trade/Device Name: Infrared Ear/Forehead Thermometer, DET-218
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: June 26, 2019
Received: July 1, 2019

Dear Mr. 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Alan Stevens
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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)*
K190873

Device Name
Infrared Ear/Forehead Thermometer DET-218

Indications for Use *(Describe)*

Infrared Ear/Forehead Thermometer DET-218 is 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: K190873

1. **Date Prepared:** 2019.07.10

2. **Submitter's Identification:**

Name: Joytech Healthcare Co.,Ltd.

Add.: No,365,Wuzhou Road,Yuhang Economic Development Zone,

Hangzhou City,311100 Zhejiang,China

Contact Person: Yunhua Ren

Phone: +86-571-81957767

Fax: +86-571-81957750

Email: renyh@sejoy.com

3. **Name of the Device:**

Device Name:Infrared Ear/Forehead Thermometer

Trade Name:Infrared Ear/Forehead Thermometer

Including models:DET-218

Classification name:Clinical Electronic Thermometer

4. **Classification Information:**

Product Code: FLL

Device Class: II

Panel: 80

Regulation number:880.2910

5. **Predicate Device Information:**

The Infrared Ear/Forehead Thermometer DET-218 is substantially equivalent to the following device:

510k number	model	Product code	manufacturer
K181239	DET-215	FLL	JOYTECH HEALTHCARE CO., LTD.

6. Intended use / Indication for Use:

Infrared Ear/Forehead Thermometer DET-218 is 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 Ear/Forehead Thermometer is a hand-held, battery powered device 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 Infrared Ear/Forehead Thermometer 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 results can be displayed on LCD. And, the results measured by DET-218 can also be transmitted to mobile device (i.e. iPhone) with Bluetooth and the application APP installed on a mobile device using the iOS system or the Android system. The thermometer is reusable for home use on people of all ages with adult supervision. The device can be used with as a stand-alone device or in conjunction with the App on a compatible BLE enabled smartphone.

The purpose of data transfer to a mobile device is convenient for users to view the measured data through the APP. The APP operating system is IOS 9.0+ system , Android 5.0+ system.

The name of APP is “Healthforyou”， it adopts AES+RSA combination to encrypt and decrypt interface parameters and the data transmission between APP and server adopts HTTP+SSL mode to ensure the security of information.

The App only visualizes the Measurements from the device via. bluetooth to smart phone. The APP receives and records data, and displays measurement on smart phone in correspondence with DET-218 Measurement site (Ear/Forehead) set. The App has the following functions:

I. data recording;

II. curve display;

III. alarm functions.

The light bar of DET-218 turns on green light when the measurement is＜38.0℃(100.4℉). The alarm function refers to the light bar of the device DET-218 turns on red light when the measurement is ≥38.0℃(100.4℉), the APP will give an alarm when the measurement received simultaneously from DET-218 displays≥38.0℃.

8.Substantial Equivalence Comparison:

SE Comparison	Subject Device Model:DET-218	Predicate Device Model:DET-215	Note
510k number	K190873	K181239	--
Regulation number	21 CFR 880.2910	21 CFR 880.2910	Same
Product Code	FLL	FLL	Same
Intended Use/ Indications for use	Infrared Ear/Forehead Thermometer DET-218 is intended for the intermittent measurement of human body temperature by people of all ages. The devices are reusable for home use only.	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.	Same
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℃ ~43.0℃(93.2℉~109.4℉)	Same
Accuracy	Ear/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	Ear/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	Same

Display	0.1℃(0.1℉)	0.1℃(0.1℉)	Same
Measurement Place	Forehead Ear	Forehead Ear	Same
Response Time	Approx. 1s	Ear mode/Object mode: Approx. 1s Forehead: Approx. 3s	Different (Note3)
Sensor Type	Thermopile	Thermopile	Same
Scale Selection	℃/℉	℃/℉	Same
Signal processing and display	-Internal firmware and local LCD display -Also able to transfer transmit data to mobile device for secondary display	Internal firmware and local LCD display	Different (Note1)
Wireless Interface	Bluetooth Low Energy (BLE)	None	Different (Note 1)
Memory	Ear/forehead/ object measurements sharing 30 memories	Each 10 sets memories for ear,forehead and object measurements	Different (Note 2)
Signal transmission	Bluetooth 4.0	/	Different (Note 1)
Receiver (mobile terminal)	iOS9.0 or above mobile device Android5.0 or above mobile device	/	Different (Note 1)
Auto power-off while no operation	Yes	Yes	Same
Buzzer	Yes	Yes	Same
Voice Function	No	Yes	Different (Note4)
Power Source	DC3V(2×AAA battery)	DC3V(2×AAA battery)	Same
Patient contact materials	Enclosure:ABS; Probe: Stainless steel&.ABS;	Enclosure:ABS; Probe: Stainless steel&.ABS;	Same
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 table, the subject device and predicate device have the same

Intended use & Indications for Use, same measurement places, unit change, battery source& Auto power-off. There are several differences between the subject device and predicate device as follows:

S/N.	Change from predicate device	Comments
Note1	Add blue tooth data transmission	FCC, EN301489-1, EN301489-17, EN 300328 and wireless coexistence test passed.
Note2	Memory set changes	Software Validation Passed.
Note3	Response time changes	Our device has shorter response time to measure from 3s to 1s the temperature,and all tests passed,so this difference does not raise new performance questions
Note4	No voice function	Software Validation Passed.

The differences between the subject device and predicate device have been analyzed and tests performed accordingly. It has been shown that the differences do not raise new questions of safety and effectiveness for DET-218.

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

The following performance data were provided in support of the substantial equivalence determination:

Performance testing was conducted to validate and verify that Infrared Ear/Forehead Thermometer, DET-218 met all requirements of related international standards, including electrical safety, EMC, biocompatibility, software validation and product specifications. Results of these tests demonstrate compliance to the requirements of the below consensus standards.

Electrical Safety and performance requirements:

- AAMI / ANSI ES60601-1:2005/(R)2012 And A1:2012,C1:2009/(R)2012 And A2:2010/(R)2012 Medical Electrical Equipment
- 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
- ASTM E 1965-98 Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature

Home-used medical equipment requirements and environmental test:

- IEC 60601-1-11:2015 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

Electromagnetic compatibility requirements:

- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- EN300328:Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques;
- ETSI EN 301489-1: Electromagnetic compatibilityand Radio spectrum Matters(ERM); ElectroMagnetic Compatibility (EMC)standard for radio equipment and services;Part 1:Common technical requirements;
- ETSI EN 301489-17: Electromagnetic compatibility and Radio spectrum Matters (ERM);ElectroMagnetic Compatibility (EMC) standard for radio equipment; Part 17: Specific conditions or Broadband Data Transmission Systems;

Biocompatibility Evaluation for patient contacting components:

- ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- ISO10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

Guidance Document:

● Guidance on the content of Premarket Notifications [510(k)] Submissions for clinical electronic thermometers

The software/firmware 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-218.The clinical tests evaluated 150 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 Ear/Forehead Thermometer DET-218 is substantially equivalent to the predicate device.