DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 31, 2016

Sejoy Electronics & Instruments Co., Ltd.
Ren Yunhua
General Manager
Building 2, No. 202, Zhenzhong Road,
West Lake Economy & Technology Zone
Hangzhou, 310030
CHINA

Re: K153146
Trade/Device Name: Infrared Ear Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: February 25, 2016
Received: February 29, 2016

Dear Ren Yunhua:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,


for Erin I. Keith, M.S.
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)*
K153146

Device Name
Infrared Ear Thermometers ET-101D,ET-101H

Indications for Use *(Describe)*

Infrared Ear Thermometers, models ET-101D and ET-101H 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.

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: K153146
Date Prepared: 2015.11.22

## I. Submitter:

Name: Sejoy Electronics & Instruments Co., Ltd.
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Email: renyh@sejoy.com

## II. Device:

Trade Name: Infrared Ear Thermometer,
Including models: ET-101D,ET-101H
Common Name: Infrared Ear Thermometer
Classification name: Clinical Electronic Thermometer

Classification Information:
Product Code: FLL- Clinical Electronic Thermometer
Device Class: II
Panel: 80
Regulation number：880.2910

## III. Predicate Device Information:

Infrared Ear Thermometer ET-101A, K082192
The predicate device is manufactured by Sejoy Electronics & Instruments Co., Ltd.

## IV. Device Description:

The Infrared Ear Thermometers, models ET-101D and ET-101H are electronic thermometers using an infrared detector (thermopile detector) to detect body temperature from the auditory canal. The thermometer's operation is based on measuring the natural thermal radiation emanating from the tympanic membrane and the adjacent surfaces of the patient.

Both thermometer models include probes, which are used to measure ear canal temperature, plastic enclosures enclosing the display window as well as buttons and a battery cover. The disposable probe cover of ET-101H is optional when measuring temperature while ET-101D does not utilize a disposable probe cover.

The Infrared Ear Thermometers measure temperature by reading infrared radiation emitting from the eardrum tissue. The small cone-shape end of the thermometer is inserted into the ear canal, where the eardrum (tympanic membrane) and surrounding tissues give off heat. The thermometer converts the heat into a temperature value using software.

## V. Intended use / Indication for Use:

Infrared Ear Thermometers, models ET-101D and ET-101H are indicated for the intermittent measurement and monitoring of human body temperature by consumers in a home use environment. It is intended for use on people of all ages.

## VI. Comparison of Technological Characteristics with the Predicate Device

| SE Comparisons | SUBJECT DEVICE :<br>Infrared Ear Thermometer<br>Model:ET-101D、ET-101H<br>Manufacturer:<br>SEJOY ELECTRONICS & INSTRUMENTS CO., LTD | | PREDICATE DEVICE:<br>Infrared Ear Thermometer<br>ET-101A (K082192)<br>Manufacturer:<br>SEJOY ELECTRONICS & INSTRUMENTS CO., LTD | Comparison Result | Remark |
|---|---|---|---|---|---|
| Thermometer type | Infrared Ear Thermometer<br>Product code: FLL | | | Identical | / |
| Measuring Site: | Ear canal | | | Identical | / |
| Reference Body Site: | Oral（This thermometer converts the ear temperature to display its "oral equivalent"） | | | Identical | / |
| Intended use(s) | 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. | | | Identical | / |
| Operation mode | Ear mode(Adjusted mode) | | | Identical | / |
| Components & Materials | ET-101H | Case: ABS<br>Probe: Stainless steel & ABS<br>Probe Cover: PE | Case: ABS<br>Probe: Stainless steel & ABS<br>Probe Cover: PE | Identical | ET-101D do not have probe cover |
| | ET-101D | Case: ABS<br>Probe: Stainless steel & ABS | | | |
| Sensor | Infrared Sensor | | | Identical | / |
| Signal processing and display | Transform the analog signals to digital signals, then displays on the LCD | | | Identical | / |

| | | | | | |
|---|---|---|---|---|---|
| Measurement range | ET-101D | 32.0℃~43.0℃(89.6℉~109.4℉) | 32.0℃~43.0℃<br>(89.6℉~109.4℉) | Similar | Meet the requirement of ASTM E1965-98 |
| | ET-101H | Ear mode:<br>28.0℃~43.0℃(82.4℉~109.4℉)<br>Object mode:<br>-20℃~100℃(-4℉~212℉)<br>Room temperature:<br>0℃~50℃(32℉~122℉) | | | |
| Operating temperature range | ET-101D | 10℃~40℃(50℉~104℉),15%~85%RH,non-condensing<br>Atmospheric Pressure:<br>800hPa ~ 1060hPa | 10℃~40℃(50℉~104℉),15%~85%RH,non-condensing<br>Atmospheric Pressure:<br>800hPa ~ 1060hPa | Identical | / |
| | ET-101H | Ear/Object mode:<br>10℃~40℃(50℉~104℉),15%~85%RH,non-condensing<br>Atmospheric Pressure:<br>800hPa ~ 1060hPa | | | |
| Storage and transportation environment | -25℃~55℃(-13℉~131℉)，15%~95%RH,non-condensing<br>Atmospheric Pressure:800hPa ~ 1060hPa | | | Identical | / |
| Precision (Laboratory accuracy) | ET-101D | ±0.2℃ (0.4℉) during 35.0℃~42.0℃(95.0℉~107.6℉) at 15℃~35℃ (59.0℉~95.0℉) Operating temperature range<br>±0.3℃ (0.5℉) for other measuring and operating temperature range | ±0.2℃ (0.4℉) during 35.0℃~42.0℃(95.0℉~107.6℉) at | | |

| | | | | | |
|---|---|---|---|---|---|
| | ET-101H | Ear mode:<br>±0.2℃ (0.4℉) during 35.5℃~42.0℃ (95.9℉~107.6℉) at 15℃~35℃ (59.0℉~95.0℉) operating temperature range<br>±0.3℃ (0.5℉) for other measuring and operating temperature range<br>Object mode:<br>±4% or ±2℃(4℉) whichever is greater<br>Room temperature: ±2℃(±4℉) | 15℃~35℃ (59.0℉~95.0℉) operating temperature range<br>±0.3℃ (0.5℉) for other measuring and operating temperature range | Similar | / |
| Biocompatibility | Complied with the biocompatible requirements of FDA. | | | Identical | / |
| Accessories | ET-101D | No accessory | Storage Case,Probe Cover | Different | / |
| | ET-101H | Storage Case,Probe Cover | Storage Case,Probe Cover | Identical | / |
| Response time | Approximately 1 Second | | | Identical | / |
| Battery Life | ET-101D | Approx. 1 year/3000 readings | Approx. 1 year/3000 readings | Identical | / |
| | ET-101H | Approx. 1 year/6000 readings | Approx. 1 year/3000 readings | Similar | / |
| Clinical Accuracy | ET-101D | Clinical bias: 0.07℃(0.1℉)<br>Clinical repeatability: 0.11(0.2℉)<br>Limits of agreement:0.76℃(1.4℉) | Clinical bias: 0.12℃(0.2℉)<br>Clinical repeatability: 0.12(0.2℉)<br>Limits of agreement :0.8℃(1.4℉) | Similar | / |
| | ET-101H | Clinical bias: 0.08℃(0.14℉)<br>Clinical repeatability: 0.13(0.23℉)<br>Limits of agreement:0.76℃(1.31℉) | | | |
| Power Sources | ET-101D | One CR2032 battery | One CR2032 battery | Different | / |
| | ET-101H | Two AAA batteries | One CR2032 battery | Different | / |

| | | | | | |
|---|---|---|---|---|---|
| Probe Cover | ET-101D | NO | YES | Different | / |
| | ET-101H | Optional | YES | Similar | / |
| Low Battery Detection | YES | | | Identical | / |
| Automatic Power-Off | YES | | | Identical | / |
| Beep Alarm | YES | | | Identical | / |
| ℃/℉ Switchable | YES | | | Identical | / |
| Object temperature mode | ET-101D | NO | NO | Identical | / |
| | ET-101H | YES | NO | Different | / |
| Ambient temperature mode | ET-101D | NO | NO | Identical | / |
| | ET-101H | YES | NO | Different | / |
| Real time clock | ET-101D | NO | NO | Identical | / |
| | ET-101H | YES | NO | Different | / |
| Room Temperature | ET-101D | NO | NO | Identical | / |
| | ET-101H | YES | NO | Different | / |
| Backlight function | ET-101D | One color | NO | Different | / |
| | ET-101H | Three colors in ear mode and one color in object mode | NO | Different | / |
| Memory | ET-101D | 10 sets | 10 sets | Identical | / |
| | ET-101H | Each 10 sets memories for ear and object measurements | 10 sets | Similar | / |
| Probe cover automatic detection function | ET-101D | NO | NO | Identical | / |
| | ET-101H | YES | NO | Different | / |

Summary of technological characteristics / performance

The Infrared Ear Thermometer, Model ET-101D, ET-101H have substantially equivalent indications for use and technological characteristics as the predicate device.

1) ET-101D,ET-101H have the same intended use/indication for use as the predicate device.
2) The same technologies and test principles are used in the ET-101D and ET-101H thermometers as the predicate device.
3) The identified differences in technological characteristics do not raise new or different questions of safety and effectiveness than the predicate devices.
4) Although some specifications are slightly different than the predicate device, ET-101A, changes have been verified and validated as part of performance testing and safety /EMC testing and are included as part of this submission. Performance information and evidence of compliance to recognized standards demonstrate the device is substantially equivalent to the predicate devices.

Based upon the intended use, and upon the similarity of materials, product configuration and administration, it can be concluded the Infrared Ear Thermometer, Model ET-101D and ET-110H devices are substantially equivalent to the identified predicate device.

## VII. Performance Data

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

Performance testing was conducted to validate and verify that Infrared Electronic Thermometers, models ET-101D and ET-101H 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 ES60601-1:2055/(R)2012 and C1:2009/(R)2012 and A2:2010/(R)2012 Medical Electrical Equipment
- ISO 80601-2-56:2099 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
- ASTM E1104-98(Reapproved 2009) Standard Specification for clinical thermometer probe covers and sheaths

Home-used medical equipment requirements and environmental test:

- IEC 60601-1-11:2010 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 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

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.

Discussion of Animal Tests Performed:
No animal testing was performed.

Discussion of Clinical Tests Performed:
Clinical evaluation of Infrared Ear Thermometers was conducted by Sejoy Electronics & Instruments Co., Ltd in compliance with ISO 80601-2-56 and ASTME1965.

## VIII. Conclusions:

The non-clinical data support the safety of the device and the hardware and software verifications and validation demonstrate that the Infrared Ear Thermometers, models: ET-101D and ET-101H should perform as intended in the specified use conditions. Based on the information provided in this submission, the Infrared Ear Thermometers, models: ET-101D, ET-101H are substantially equivalent to the predicate thermometer ET-101A.