DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 27, 2016

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

Re: K153149
Trade/Device Name: Digital Thermometer, Models MT-1027, MT-4127, MT-1032, MT-4132, MT-4333, MT-4326, MT-4726, MT-4335, MT-4735, MT-09, MT-30, MT-31, MT-36
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: April 15, 2016
Received: May 13, 2016

Dear Mr. 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,

Tina Kiang -S

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)*
K153149

Device Name
Digital Thermometer, Models MT-1027, MT-4127, MT-1032, MT-4132, MT-4333, MT-4326, MT-4726, MT-4335, MT-4735, MT-09, MT-30, MT-31, MT-36

Indications for Use *(Describe)*

The Digital Thermometers MT series are intended to measure the human body temperature in regular mode orally, rectally or under the arm. The devices are reusable for clinical or home 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.

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510(k) Summary

The assigned 510(k) number is: K153149

1. Date Prepared:
May 25, 2016

2. Submitter's Identification:
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3. Name of the Device:
Trade Name: Digital Thermometer, Models MT-1027, MT-4127, MT-1032, MT-4132, MT-4333, MT-4326, MT-4726, MT-4335, MT-4735, MT-09, MT-30, MT-31, MT-36

Common Name: Digital Thermometer

Classification name: Clinical Electronic Thermometer

4. **Classification Information:**
Product Code: FLL- Clinical Electronic Thermometer
Device Class: II
Panel: 80
Regulation number: 21 CFR 880.2910

5. Predicate Device Information:
Digital Thermometers Models MT-4119 and MT-4320 manufactured by SEJOY ELECTRONICS & INSTRUMENTS CO., LTD.

510(k) number: K110776

6. Intended use / Indication for Use:
The Digital Thermometers MT series are intended to measure the human body temperature in regular mode orally, rectally or under the arm. The devices are reusable for clinical or home use on people of all ages.

The intended uses/ indication for use of the Digital Thermometers, models: MT series are Identical to the predicate devices, Digital Thermometers, models: MT-4119, MT-4320.

7. Device Description:
Models MT-1027, MT-4127, MT-1032, MT-4132, MT-4333, MT-4335, MT-4326, MT-09, MT-30, MT-31, and MT-36 are non-predictive digital thermometers. Models MT-4726 and MT-4735 are predictive digital thermometers.

Both predictive and non-predictive models include a sensor, buzz films, housing, a stainless steel cap, a LCD display, and a measurement control module. The thermometers include a dustproof case as an accessory.

Additionally, both models do not need to be used in conjunction with a disposable probe cover when taking temperature.

8. Principles of Operation:

The basic principle of the MT series digital thermometers is that a change in thermistor resistance is caused by a change in temperature. The resistance is measured by a microcontroller unit, so that changes in temperature will correspond to changes in resistance.

Compared to the non-predictive thermometers, the following is a description of the predictive thermometer models MT-4726 and MT-4735:

The predictive thermometer models display the temperature results in a short period of time. The displayed temperature is equivalent to the balanced temperature after 5 minutes according to the proprietary algorithm. Therefore, users only need about 5 seconds to take temperature readings. The measurement time may vary depending on the anatomical site of the temperature reading; however the measurement time should remain between 5-10 seconds. If the predictive temperature cannot be measured, the device will take the actual temperature (regular mode) automatically.

9. Modifications to Predicate Device:

The subject device models have each been altered in at least one of the following ways as noted in the table below:

-Addition of predictive algorithm for Models MT-4735 and MT-4726
-New battery type to support added backlight feature
-Modification of labeling including cleaning/disinfection instructions
-Temperature associated color light indication with updated labeling
-Thermometer response time
-Battery life

Technological Characteristics of Comparison	**Subject Device:**		**Predicate Device Model MT-4119 (K110776):**	**Predicate Device Model MT-4320 (K110776)**	**Comparison Result**	**Remark**
Digital thermometers	Models: MT-1027,MT-4127,MT-1032,MT-4132,MT-4333,MT-4326,MT-4726,MT-4335, MT-4735,MT-09,MT-30,MT-31,MT-36		Model：MT-4119 (Rigid tip thermometer)	Model：MT-4320 (Flexible tip thermometer)	/	/
Intended use/ Indication for Use	Measuring the human body temperature in regular mode orally, rectally or under the arm, and the devices are reusable for clinical or home use on people of all ages.				Identical	/
Components	Sensor, buzz film, housing, stainless steel cap, LCD display, measurement control module.				Identical	/
Accessory	Dustproof case				Identical	/
Sensor	Thermistor				Identical	/
Power Requirements	MT-1027,MT-4127 MT-1032,MT-4132 MT-4333,MT-4326, MT-4335,MT-09, MT-30,MT-31,	1.5V d.c（LR41 or SR41,UCC392）	1.5V d.c（LR41 or SR41,UCC392）		Similar	Change in battery type from 1.5V d.c. (LR41 or SR41,UCC392) to 3.0V d.c. (CR2032)
	MT-4726,MT-4735	3.0V d.c(CR2032)				

Backlight function	MT-1027,MT-4127 MT-1032,MT-4132 MT-4333,MT-4326, MT-4335,MT-09, MT-30,MT-31, MT-36	No backlight function	No backlight function		Identical	/
	MT-4726,MT-4735	Yes	No backlight function		Different	/
Material used	MT-1027,MT-4127 MT-1032,MT-4132 MT-09,MT-30, MT-31	Housing: ABS Probe: Stainless steel	Housing: ABS Probe: Stainless steel	Housing: ABS Flexible tip: TPE Probe: Stainless steel	Identical	Flexible tip thermometers are identical to MT-4320 and rigid tip thermometers are identical to MT-4119
	MT-4333,MT-4326, MT-4726,MT-4335, MT-4735,MT-36	Housing: ABS Flexible tip: TPE Probe: Stainless steel				
Measure range	MT-1027,MT-4127 MT-1032,MT-4132 MT-4326,MT-4335, MT-4333,MT-09, MT-30,MT-31, MT-36	32℃~42.9℃ (90℉~109.9℉)	32℃~42.9℃ （90℉~109.9℉）		Similar	Meet the requirement of ASTM E1112
	MT-4726,MT-4735	32℃~42.9℃ (89.6℉~109.2℉)				
	MT-1027,MT-4127 MT-1032,MT-4132 MT-4333,MT-4326,		Direct Mode			

Operating mode	MT-4335,MT-09, MT-30,MT-31, MT-36	Direct Mode		Similar	/
	MT-4726,MT-4735	Adjusted mode : Oral mode/ Rectal mode/ Underarm mode			
		Direct Mode: Bath mode			
Accuracy	±0.1℃ between 35.5℃ to 42.0℃(±0.2℉,95.9℉-107.6℉), ±0.2℃ under 35.5℃ or over 42.0℃(±0.4℉under 95.9℉or over 107.6℉)			Identical	/
Humidity range	15%~95%,non-condensing			Identical	/
Storage Environment	Temperature:-20℃～55℃（-4℉～131℉）			Identical	/
	Humidity:15% ～95% RH; Atmospheric Pressure:800hPa ~ 1060hPa				
Color-temperature light indicators	MT-4132,MT-4333 MT-4335,MT-4735 MT-4726,MT-4326	Different colored lights corresponding to different temperatures.	No this function	Different	/
	MT-1027,MT-4127 MT-1032, MT-09, MT-30,MT-31, MT-36	No this function	No this function	Identical	/
Response time	MT-4326,MT-4127 MT-4132,MT-4333 MT-4335,MT-30	＜45s	＜45s	Identical	/
	MT-1027,MT-1032	＜60s	＜45s	Similar	/

	MT-09,MT-31				
	MT-4726,MT-4735 MT-36	＜10s	＜45s	Similar	/
Software	MT-1027,MT-4127 MT-1032,MT-4132 MT-4333,MT-4335 MT-4326,MT-09, MT-30,MT-31, MT-36	No software	No software	Identical	/
	MT-4726,MT-4735	Have software	No software	Different	/
Battery life	MT-1027,MT-4127 MT-1032,MT-4132 MT-4333,MT-4335 MT-4326,MT-09, MT-30,MT-31, MT-36	Approx 200 hours	Approx 200 hours	Similar	Battery life changes from approx 200 hours to approx 40 hours
	MT-4726,MT-4735	Approx 40 hours			
Biocompatibility	Complied with the biocompatible requirements of FDA			Identical	/
Labeling	Updated cleaning/disinfection instructions, Updated MR Safety labeling		Outdated cleaning/disinfection instructions and MR Safety labeling	Different	/
Where used	Clinical or home			Identical	/
Number of readings stored in Memory	Display of temperature last measured			Identical	/
Precision and repeatability	3 numerical digits, display in 0.1 degree increments			Identical	/
Reference Standards	AAMI / ANSI ES60601-1,IEC 60601-1-2, IEC 60601-1-11,ISO 80601-2-56, ASTM E1112, ISO 10993-5, ISO 10993-10			Identical	/

10. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence:

The Sponsor performed a risk assessment based on the changes made to their predicate device and determined that the following non-clinical testing was necessary to demonstrate that the changes did not introduce any new risks to the subject device.

Laboratory testing was conducted to validate and verify that the thermometers continued to meet all requirements of related international standards, including electrical safety, EMC, software, biocompatibility, and cleaning/disinfection. Results of these tests demonstrated compliance to the requirements of the below consensus standards and FDA Guidance documents. Software validation testing was only performed for predictive Models MT-4726 and MT-4735.

Electrical Safety and Performance: AAMI / ANSI ES60601-1:2005/(R)2012 and C1:2009/(R)2012 and, A2:2010/(R)2012; AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, and C1:2009/(R)2012 and A2:2010/(R)2012; ISO 80601-2-56:2009; ASTM E1112-00(Reapproved 2011)
Medical Electrical Equipment and medical Electrical Systems Used in the Home Healthcare Environment: IEC 60601-1-11:2010
Electromagnetic Compatibility: IEC 60601-1-2:2007 IEC 60601-1-2:2014
Biocompatibility: ISO 10993-5:2009 ISO 10993-10:2010

Cleaning/Disinfection/Reprocessing: ASTM E2314 -03(2014) FDA Guidance: Reprocessing Medical Devices in Health Care Settings – Validation Methods and Labeling
Software: EN 60601-1-4:2000 General Requirements for safety – Collateral Standard: Programmable electrical medical system General Principles of Software Validation – Final Guidance for Industry and FDA Staff
Clinical Electronic Thermometers Guidance: Guidance on the content of Premarket Notification[510(k)] Submission for clinical electronic thermometers

11. Discussion of Clinical Tests Performed:

In order to demonstrate that the subject device did not introduce any new risks in comparison to the subject device a clinical accuracy evaluation has been conducted according to clause 201.102 of ISO 80601-2-56:2009 for predictive models MT-4726 and MT-4735.

12. Conclusions:

Based on the information provided in this submission, the subject digital thermometer MT series is substantially equivalent to the predicate models MT-4119 and MT-4320. The devices are as safe and as effective as the predicate device models.