DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 24, 2017

Mediana Co., Ltd.
℅ Charlie Mack
Principal Engineer
International Regulatory Consultants
2550 Duportail Street M275
Richland, Washington 99352

Re: K160358
Trade/Device Name: DT-100
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: January 18, 2017
Received: January 24, 2017

Dear Charlie Mack:

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,

Michael J. Ryan -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160358

Device Name
DT-100

Indications for Use *(Describe)*
The DT-100 non-contact infrared thermometer is intended to be used to measure the body temperature using infrared sensors. It can detect the body temperature of all ages from human's face. The DT-100 infrared thermometer can be used by consumers in household environment.

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
K160358

Submitter's Identification

Mediana Co., Ltd
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Contact: Min-hye, Kim
Date Summary Prepared: January 15th, 2016

Name of Device

Trade Name:	DT-100
Common Name:	Clinical electronic thermometer
Regulation:	21 CFR 880.2910
Classification:	Class II
Product Code:	FLL

Predicate Device Information

The predicate device for the DT-100 Infrared Thermometer is:

- **SHENZHEN EVERBEST MACHINERY INDUSTRY CO., LTD** Infrared Thermometer Model DT-8806H/DT-8806 cleared by FDA through 510(k) No. **K101736**

Device Description

The DT-100 non-contact infrared thermometer is intended to be used to measure the body temperature using infrared sensors. It can detect the body temperature of all ages from human's face. The operation principle is based on infrared sensor technology. IR sensor can put out different signal when measuring the different object temperature or body temperature. An ASIC can turn the signal from IR sensor to a digital value and display it by LCD. The DT-100 non-contact infrared thermometer can measure body temperature at maximum 40cm between patient and product. The thermometer stores temperature measurement value up to 30, a user can compare prior measurement value and uses an alkaline battery AAA type for operation.

Indications for Use

The DT-100 non-contact infrared thermometer is intended to be used to measure the body temperature using infrared sensors. It can detect the body temperature of all ages from human's face. The DT-100 infrared thermometer can be used by consumers in household environment.

Comparison to Predicated Devices

The infrared thermometer, model DT-100 is substantially equivalent to the SHENZHEN EVERBEST MACHINERY INDUSTRY CO., LTD, infrared thermometer, model DT-8806H/DT-8806, K101736 which has the same intended use and is similar in design to the predicate device.

Characteristics	**Subject Device**	**Predicate Device**
Device name	DT-100	DT-8806H/DT-8806
K number	K160358	K101736
Manufacturer	Mediana Co., Ltd.	Shenzhen Everbest Machinery Industry Co., Ltd.
Measurement method	Infrared radiation detection	*Same as DT-100 infrared thermometer*
Indications for use	The DT-100 non-contact infrared thermometer is intended to be used to measure the body temperature using infrared sensors. It can detect the body temperature of all ages from human's face. The DT-100 infrared thermometer can be used by consumers in household environment.	DT-8806H/DT-8806 Non-contact body infrared thermometer is designed for body surface and forehead temperature measurement for infants and adults without contact to human body.
Physical dimension/weight	Dimensions: 52.3 x 34.3x143.5 (mm) (W×H×L) Weight : 111g (including batteries)	Dimensions: 82 x43x134 (mm) (W×H×L) Weight : 205g
Display	LCD	*Same as DT-100 infrared thermometer*
Device Pictures		
Button	Soft keys	*Same as DT-100 infrared thermometer*
Battery type	Alkaline battery AAA type	Alkaline battery AA type
Voltage	DC 3V (1.5V, 2EA)	*Same as DT-100 infrared thermometer*
Buzzer	- Set the sound on/off function - Inform the temperature measurements and error situations of the environmental conditions	*Same as DT-100 infrared thermometer*
Operating condition	Temperature: 10 to 40°C (50 to 104°F)	Temperature: 10 to 40 °C (50 to 104°F): DT-8806H 0 to 50°C (32 to 122°F): DT-8806
	Relative Humidity: 30 to 95%	Relative Humidity: 10 to 90%
	Altitude: 70 to 106kPa	*N/A*
Storage condition	Temperature: - 20 to 50°C (-68 to 122°F)	Temperature: - 20 to 60°C (-4 to 140°F): DT-8806H 0 to 50°C (32 to 122°F): DT-8806

Characteristics	Subject Device	Predicate Device
	Relative Humidity: 15 to 95%	Relative Humidity: < 85%
	Altitude: 70 to 106kPa	*N/A*
Automatically shutdown	Within 30 seconds	Within 7 seconds
Memory	saves total 30 temperature measurement values	*Same as DT-100 infrared thermometer*
Method	Infrared sensor technology	*Same as DT-100 infrared thermometer*
Unit of measure	Celsius(°C) and Fahrenheit(°F)	*Same as DT-100 infrared thermometer*
Measurement mode	Body temperature mode	*Same as DT-100 infrared thermometer*
Measurement site	Face surface	Forehead
Temperature measurement range	22.0 to 42.4°C (71.6 to 108.3°F)	32.0 to 42.5°C (90 to 108°F)
Temperature measurement accuracy	- 22.0 to 35.9°C (71.6 to 96.6°F) ± 0.3°C (32.5°F) - 36.0 to 39.0°C (96.8 to 102.2°F) ± 0.2°C (32.4°F) - 39.1 to 42.4°C (102.4 to 108.3°F) ± 0.3°C (32.5°F)	± 0.3°C (32.5°F)
Display resolution	0.1°C (0.1°F)	*Same as DT-100 infrared thermometer*
Measurement distance	30 ~ 40 cm	5 ~ 15 cm
Patient contact materials	Case: ABS 780, TPE Mount Cradle: ABS 780, TPE	-
Cleaning/disinfection	cleans the device with a soft cloth dampened with either a commercial, nonabrasive cleaner or one of the solutions listed below. Lightly wipe the surfaces of the thermometer. - 70% Isopropyl alcohol - 10% Chlorine bleach solution	cleans the device with a cotton bud lightly moistened with 70% alcohol
Performance testing	The test results showed that subject device is satisfied with the following test report and conformance standard. - IEC 60601-1 test report (General requirements for safety) - IEC 60601-1-2 test report (General requirements for safety – Collateral standard: Electromagnetic compatibility – requirements and tests) - IEC 60601-1-6, IEC 62366 Usability test report - IEC 60601-1-11 test report (General requirements for basic safety and essential performance-Collateral Standard: Requirements for medical electrical equipment and medical electrical systems	- IEC 60601-1 - IEC 60601-1-2 - ISO 14971 - EN ISO 10993-5 - EN ISO 10993-10

Characteristics	Subject Device	Predicate Device
	used in the home healthcare environment) - IEC 60068-2-27 Drop shock test report - IEC 60068-2-64 Vibration test report - IEC 60068-2-1, IEC 60068-2-2, IEC 60068-2-30, Temperature and humidity for operation/storage test report - ASTM E1965-98 test report (Standard specification for infrared thermometers for intermittent determination of patient temperature) - Atmospheric test report - ISTA 2A test report - Cleaning validation test report - Battery discharge test report - Free fall test report - Verification and validation plan/test report - Verification report - Clinical accuracy validation test report - ISO 10993-5, In Vitro Cytotoxicity test report - ISO 10993-10, Skin Irritation and Sensitization test report	

Discussion of Differences between the Subject Device and the Predicate Device:

The DT-100 non-contact infrared thermometer has substantially equivalent measurement method and technological characteristics as the predicate device. The differences between the subject device and the predicate device are as follows.

Indications for use

- The subject device, Model DT-100 and predicate device, Model DT-8806/DT-8806H are intended to be used to measure the body temperature using infrared sensor. The DT-100 can detect the body temperature of all ages from human's face, while the predicated device, Model DT-8806H/DT-8806 can detect the body temperature for infants and adults from human's forehead.
- The clinical performance test and data analysis for difference between the subject device and the predicate device have performed.
- The repeatability and accuracy of the subject device has complied with the requirements the ASTM 1965 standard in accordance with clinical performance test protocol.
- Therefore the indications for use difference does not affect the safety and effectiveness of the device.

Temperature measurement range and operating/storage condition

- The temperature measurement range and operating/storage condition are satisfied with the requirements the ASTM 1965 standard.

Measurement site and distance

- The operating principle of DT-100 and the predicated device, Model DT-8806/DT-8806H are “the same”. The two devices are designed under the same principle which an electronic thermometer using the infrared sensor to detect human body temperature. The DT-100 design has improved by applying multi-sensors, while the predicated device, Model DT-8806H/DT-8806 has a single sensor. The DT-100 can be measured with wide area (face) using multi-sensors, while the predicated device, Model DT-8806H/DT-8806 can be measured with narrow area (forehead) using single sensor.
- The clinical performance test and data analysis for difference between the subject device and the predicate device have performed.
- The repeatability and accuracy of DT-100 has complied with the requirements the ASTM 1965 standard in accordance with clinical performance test protocol.

Patient contact materials

- The biocompatibility testing of subject device, DT-100, was conducted in accordance with the ISO 10993-5 and ISO 10993-10.

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

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following test report:

- IEC 60601-1 test report (General requirements for safety)
- IEC 60601-1-2 test report (General requirements for safety – Collateral standard: Electromagnetic compatibility – requirements and tests)
- IEC 60601-1-6, IEC 62366 Usability test report
- IEC 60601-1-11 test report (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)
- IEC 60068-2-27 Drop shock test report
- IEC 60068-2-64 Vibration test report
- IEC 60068-2-1, IEC 60068-2-2, IEC 60068-2-30, Temperature and humidity for operation/storage test report
- ASTM E1965-98 test report (Standard specification for infrared thermometers for intermittent determination of patient temperature)
- Atmospheric test report
- ISTA 2A test report
- Cleaning validation test report
- Battery discharge test report
- Free fall test report
- Verification and validation plan/test report
- Verification report
- Clinical accuracy validation test report
- ISO 10993-5, In Vitro Cytotoxicity test report
- ISO 10993-10, Skin Irritation and Sensitization test report

Compliance to applicable standards includes IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-11, IEC 60068-2-27, IEC 60068-2-64, IEC 60068-2-1, IEC 60068-2-2, IEC 60068-2-30, ASTM E1965-98, ISTA 2A, ISO 10993-5, ISO 10993-10 requirements.

The bench test report of this submission showed that substantial equivalence has demonstrated to be suitable for the subject device.

Discussion of Clinical Tests Performed:

The clinical investigation was conducted at Yonsei University Severance Hospital (Accredited by IRB) to evaluate the clinical accuracy and clinical repeatability of DT-100 non-contact infrared thermometer. The clinical bias was calculated as 0.02℃, which are acceptable because data did not exceed accuracy requirement specified in the ASTM E1965-98 standard as follow.

- Temperature range from 36 to 39 °C (96.8 to 102.2 °F), 0.2 °C (0.4 °F)
- Temperatures less than 36 °C (96.8°F) or greater than 39 °C (102.2 °F), 0.3 °C (0.5 ° F)

The *standard deviation*(Δt_i) was calculated from the temperature differences as +0.60℃. The clinical repeatability(S_r) of all participants is 0.12, that may be considered reasonably small and not to pose a problem for diagnostic purposes. As a result of the test, the DT-100 non-contact infrared thermometer is considered a clinically useful thermometer.

Conclusions

The DT-100 non-contact infrared thermometer has the same intended use and similar technological characteristics as the predicated device, model DT-8806H/DT-8806. Moreover, bench testing contained in this submission. Thus, the DT-100 non-contact infrared thermometer is substantially equivalent to predicated device.