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

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
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.

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.
Submitter’s Identification
Mediana Co., Ltd
132, Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do, Republic of Korea
Tel) (82) 33 742 5400    Fax) (82) 33 742 5483
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.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Subject Device</th>
<th>Predicate Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device name</td>
<td>DT-100</td>
<td>DT-8806H/DT-8806</td>
</tr>
<tr>
<td>K number</td>
<td>K160358</td>
<td>K101736</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Mediana Co., Ltd.</td>
<td>Shenzhen Everbest Machinery Industry Co., Ltd.</td>
</tr>
<tr>
<td>Measurement method</td>
<td>Infrared radiation detection</td>
<td>Same as DT-100 infrared thermometer</td>
</tr>
<tr>
<td>Indications for use</td>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td>Physical dimension/weight</td>
<td>Dimensions: 52.3 x 34.3 x 143.5 (mm) (W×H×L) Weight: 111g (including batteries)</td>
<td>Dimensions: 82 x 43 x 134 (mm) (W×H×L) Weight: 205g</td>
</tr>
<tr>
<td>Display</td>
<td>LCD</td>
<td>Same as DT-100 infrared thermometer</td>
</tr>
<tr>
<td>Button</td>
<td>Soft keys</td>
<td>Same as DT-100 infrared thermometer</td>
</tr>
<tr>
<td>Battery type</td>
<td>Alkaline battery AAA type</td>
<td>Alkaline battery AA type</td>
</tr>
<tr>
<td>Voltage</td>
<td>DC 3V (1.5V, 2EA)</td>
<td>Same as DT-100 infrared thermometer</td>
</tr>
</tbody>
</table>
| 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%  
                          Altitude: 70 to 106kPa | Relative Humidity: 10 to 90%  
                          Altitude: N/A |
<p>| 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 |</p>
<table>
<thead>
<tr>
<th>Characteristics</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Relative Humidity</td>
<td>Relative Humidity: 15 to 95%</td>
<td>Relative Humidity: &lt; 85%</td>
</tr>
<tr>
<td>Altitude</td>
<td>Altitude: 70 to 106kPa</td>
<td>N/A</td>
</tr>
<tr>
<td>Automatically shutdown</td>
<td>Within 30 seconds</td>
<td>Within 7 seconds</td>
</tr>
<tr>
<td>Memory</td>
<td>saves total 30 temperature measurement values</td>
<td>Same as DT-100 infrared thermometer</td>
</tr>
<tr>
<td>Method</td>
<td>Infrared sensor technology</td>
<td>Same as DT-100 infrared thermometer</td>
</tr>
<tr>
<td>Unit of measure</td>
<td>Celsius(°C) and Fahrenheit(°F)</td>
<td>Same as DT-100 infrared thermometer</td>
</tr>
<tr>
<td>Measurement mode</td>
<td>Body temperature mode</td>
<td>Same as DT-100 infrared thermometer</td>
</tr>
<tr>
<td>Measurement site</td>
<td>Face surface</td>
<td>Forehead</td>
</tr>
<tr>
<td>Temperature measurement range</td>
<td>22.0 to 42.4°C (71.6 to 108.3°F)</td>
<td>32.0 to 42.5°C (90.0 to 108.0°F)</td>
</tr>
<tr>
<td>Temperature measurement accuracy</td>
<td>- 22.0 to 35.9°C (71.6 to 96.6°F) ± 0.3°C (32.5°F)</td>
<td>± 0.3°C (32.5°F)</td>
</tr>
<tr>
<td></td>
<td>- 36.0 to 39.0°C (96.8 to 102.2°F) ± 0.2°C (32.4°F)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- 39.1 to 42.4°C (102.4 to 108.3°F) ± 0.3°C (32.5°F)</td>
<td></td>
</tr>
<tr>
<td>Display resolution</td>
<td>0.1°C (0.1°F)</td>
<td>Same as DT-100 infrared thermometer</td>
</tr>
<tr>
<td>Measurement distance</td>
<td>30 ~ 40 cm</td>
<td>5 ~ 15 cm</td>
</tr>
<tr>
<td>Patient contact materials</td>
<td>Case: ABS 780, TPE</td>
<td>Mount Cradle: ABS 780, TPE</td>
</tr>
<tr>
<td>Cleaning/disinfection</td>
<td>cleans the device with a soft cloth dampened with a</td>
<td>cleans the device with a cotton bud lightly moistened</td>
</tr>
<tr>
<td></td>
<td>commercial, nonabrasive cleaner or one of the</td>
<td>70% Isopropyl alcohol</td>
</tr>
<tr>
<td></td>
<td>solutions listed below. Lightly wipe the surfaces</td>
<td>10% Chlorine bleach solution</td>
</tr>
<tr>
<td></td>
<td>of the thermometer.</td>
<td></td>
</tr>
<tr>
<td>Performance testing</td>
<td>The test results showed that subject</td>
<td>- IEC 60601-1</td>
</tr>
<tr>
<td></td>
<td>device is satisfied with the following test report</td>
<td>- IEC 60601-1-2</td>
</tr>
<tr>
<td></td>
<td>and conformance standard.</td>
<td>- ISO 14971</td>
</tr>
<tr>
<td></td>
<td>- IEC 60601-1 test report (General requirements for</td>
<td>- EN ISO 10993-5</td>
</tr>
<tr>
<td></td>
<td>safety)</td>
<td>- EN ISO 10993-10</td>
</tr>
<tr>
<td></td>
<td>- IEC 60601-1-2 test report (General requirements</td>
<td></td>
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<tr>
<td></td>
<td>for safety – Collateral standard: Electromagnetic</td>
<td></td>
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<td></td>
<td>compatibility – requirements and tests)</td>
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<tr>
<td></td>
<td>- IEC 60601-1-6, IEC 62366 Usability test report</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- IEC 60601-1-11 test report (General requirements</td>
<td></td>
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<td></td>
<td>for basic safety and essential performance-Collateral</td>
<td></td>
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<tr>
<td></td>
<td>Standard: Requirements for medical electrical</td>
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<td></td>
<td>equipment and medical electrical systems</td>
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<tr>
<td>Characteristics</td>
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<td>Predicate Device</td>
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</tr>
</tbody>
</table>
| used in the home healthcare environment) | - IEC 60068-2-27 Drop shock test report  
- IEC 60068-2-64 Vibration test report  
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 predicted 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


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°C, 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(△tj) was calculated from the temperature differences as +0.60°C. The clinical repeatability(Sr) 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.