DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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May 6, 2016

TaiDoc Technology Corporation
Ms. Sharon Peng
Regulatory Affairs Specialist
6f, No. 127, Wugong 2nd Rd
Wugu District
New Taipei City, 24888
TAIWAN

Re: K152680
Trade/Device Name: TD-1035 Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: March 18, 2016
Received: March 24, 2016

Dear Ms. Peng:

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)*
K152680

Device Name
TD-1035 Thermometer

Indications for Use *(Describe)*
The TD-1035 Thermometer device is a thermometer intended for body temperature measurement at the axillary measurement site. The device is intended for measurement in patients 12 years and older in a home use 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(K) Summary

This is being submitted in accordance with the requirements of 21 CFR 807.92.

The Assigned 510(K) number is: K152680

1. **Submitter Information**

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Prepared Date:	May 05, 2016

2. **Device name:**

Proprietary Name:	TD-1035 Thermometer
Common Name:	Electronic Thermometer
Product Code:	FLL
Review Panel:	General Hospital
Device Class:	Class II
Regulation Number:	21 CFR §880.2910

3. **Predicate Device:**

Proprietary Name:	Omron MC-246
510(K) Number:	K091676

4. Intended Use:

The TD-1035 Thermometer device is a thermometer intended for body temperature measurement at axillary temperature measurement site. The device is intended for measurement in patients 12 years and older in a home use environment.

5. Device Description:

The TD-1035 Thermometer is a wrist band with sensors, which are used to measure axillary temperature. The sensors are located on the inner edge of the wrist band, so when desired the band is removed from the wrist and held under the user's underarm with the sensors contacting the underarm skin directly.

The main function of TD-1035 Thermometer is to measurement the body temperature range easily and accurately. The TD-1035 Thermometer also has a wireless data transmission function which transmits the readings from the TD-1035 Thermometer to a personnel device, such as a smart phone, tablet PC, etc., via Bluetooth pairing.

6. Test Principle:

The TD-1035 Thermometer detects the temperature by thermistor, which provides signals to the microcontroller where the signals are converted into a digital temperature value that is displayed on the LCD screen.

7. Substantial Equivalence Information:

The technological characteristics of the proposed device, TD-1035 Thermometer, are compared to the predicate device (K091676) and summarized in the following table.

Item	**Predicate device**	**Proposed device**	**Comments**
Classification	Class II	Class II	Same
Product Code	FLL	FLL	Same

Item	Predicate device	Proposed device	Comments
Indications for use	The Omron electronic thermometer Models MC-246 is intended to measure the body temperature either oral, axillaries (under arm) and rectal and to be used by medical professionals in clinical and hospital environments and consumers in a home environment. It is intended for use on people of all ages.	The TD-1035 Thermometer device is a thermometer intended for body temperature measurement at axillary temperature measurement site. The device is intended for measurement in patients 12 years and older in a home use environment.	Similar, the subject device is confined to home use, and axillary contact which is within the intended use boundary set forth by the predicate. Safety and effectiveness is not affected because the intended use is limited to boundaries with no new potential hazards.
Environment	Home and professional use	Home use	Similar, the subject device is confined to home use which is within the intended use boundary by the predicate. Safety and effectiveness is not affected because the use environment is limited to boundaries with no new potential hazards.
Thermometer			
Detection method	Temperature is detected by thermistor and calculated.	Temperature is detected by thermistor and calculated.	Same
Accuracy	89.6°F to 107.6°F: ±0.2°F (32.0°C to 42.0°C: ±0.1°C)	68.00°F to 94.98°F: ±0.18°F 95.00°F to 100.40°F: ±0.09°F 100.42°F to 113.00°F: ±0.18°F (20.00°C to 34.99°C: ±0.10°C 35.00°C to 38.00°C: ±0.05°C 38.01°C to 45.00°C: ±0.10°C)	Similar, the claimed accuracy is with the predicate device accuracy tolerance, and is verified per ISO 80601-2-56:2009 requirements.

Item	Predicate device	Proposed device	Comments
Measurement range	89.6°F to 107.6°F (32.0°C to 42.0°C)	68.00°F to 113.00°F (20.00°C to 45.00°C)	Similar, the claimed measurement range includes the range specified by the predicate and is verified per ISO 80601-2-56:2009 requirements.
Resolution	0.1°C / 0.1°F	0.01°C / 0.01°F	Same
Measurement area	Oral, rectum, armpit	armpit	Similar, the measurement area is the same as one area measurable using the predicate device.
Measurement units	˚C or °F	˚C or °F	Same
General			
Power source	one LR42 battery (DC 1.5V)	one 3V CR2032 lithium battery	Similar, electrical safety is verified per recognized standards noted below.
Battery life	Approx. 2 years (3 times measurements / day)	Approx. 25 days (1 time measurement / day)	Different
Beeper	Yes	None	Different, the absence of this function is validated as acceptable via human factors testing.
Operating condition	50°F to 104°F (10°C to 40°C); 30% to 85% R.H.	41°F to 104°F (5°C to 40°C); 15% to 93% R.H.	Similar, this function is verified per ISO 80601-2-56:2009 requirements

Item	Predicate device	Proposed device	Comments
Storage condition	4°F to 140°F (-20°C to 60°C); 10% to 95% R.H.	-13°F to 158°F (-25°C to 70°C); 10% to 95% R.H.	Similar, this function is verified per ISO 80601-2-56:2009 requirements
Data transmission	None	Bluetooth	Different, this function is verified per IEC 62304 requirements.
Appearance			
Dimensions:	132.5 mm (L) x 19.4mm (W) x 10mm (H)	40.5mm (L) x 27.5mm (W) x 11.7mm (H)	Different, the physical features of the device are validated per IEC 60601-1:2012 requirement.
Weight (g)	11g	18g	Different
Outer casing	On/off button, LCD display, protective case, probe cover	On/off button, LCD display, armband	Different
Appearance			Different
Conformance Standard	▪ Safety: EN 60601-1 ▪ EMC: IEC 60601-1-2 ▪ Biocompatibility: ISO10993 ▪ Performance: EN 12470-3	▪ Safety: EN 60601-1 ▪ EMC: IEC 60601-1-2 ▪ Biocompatibility: ISO10993 ▪ Performance: ISO 80601-2-56	Similar, ISO 80601-2-56 is recognized by the FDA

A comparison table that described similarities and modifications is briefly provided and demonstrates that the modified TD-1035 Thermometer is substantially equivalent to the Omron MC-246 (K091676) and does not raise new questions of safety and effectiveness.

8. Performance Data:

The submission included the following performance data for the TD-1035 Thermometer device.

The accuracy study was performed to demonstrate the TD-1035 Thermometer meet the criteria of ISO 80601-2-56:2009. The evaluation study is in compliance with the international standard.

The laboratory testing of electrical safety, electromagnetic compatibility, and shock met the relevant requirements of the applicable recognized standard: IEC/EN 60601-1, IEC/EN 60601-1-11, IEC/EN 60601-1-2 and ISO 80601-2-56.

The software validation was performed to verify and validate the proposed device works functionally and is in compliance with FDA Guidance for the Content of the Premarket Submissions for Software Contained in Medical Devices.

Biocompatibility testing included cytotoxicity, sensitization and irritation studies completed in accordance with ISO 10993, Part 5: Tests for in vitro cytotoxicity, Part 10: Tests for skin irritation and skin sensitization, and Part 12: Sample preparation and reference materials.

9. Conclusion:

The proposed devise of TD-1035 Thermometer has the same classification information, same intended use, same test principle and similar product design and specifications with the predicate device. Based on the information provided in this submission, the TD-1035 Thermometer is substantially equivalent to the predicated Digital Thermometer, model Omron MC-246 (K091676).