October 22, 2018

TaiDoc Technology Corporation
Sylvia Liu
Regulatory Affairs Specialist
B1-7F, No.127, Wugong 2nd Rd., Wugu District
New Taipei City, 24888 Taiwan

Re: K172733
Trade/Device Name: TD-1035 Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: September 14, 2018
Received: September 18, 2018

Dear Sylvia Liu:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Alan M. Stevens -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172733

Device Name
TD-1035 Thermometer

Indications for Use *(Describe)*
TD-1035 Thermometer is a temperature detector which is intended to measure the body temperature on axillary region. The device is intended for population age of six months and above, which is designed for home use.

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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9. 510(k) Summary

This summary of 510(k) information is being submitted in accordance with the requirements of 21 CFR 807.92.

The Assigned 510(k) number is: K172733

1. Submitter Information

Company Name:	TaiDoc Technology Corporation
Contact Person:	Sylvia Liu
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Prepared Date:	October 22, 2018

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:	TD-1035 Thermometer
510(K) no.	K152680

4. Device Description

TD-1035 Thermometer is a temperature detector which is intended to measure the body temperature on axillary region, and transmit data to personnel device via Bluetooth pairing. The design concept is equivalent to the predicate device, K152680. There are two modifications made to the subject device: (1) indication for use (2) an elastic band was added. The elastic band is designed for more suitable and comfortable wearing. Moreover, the detected sensor contacts user skin directly, which is located on the silicone belt. The parts that contact the user are: (1) elastic band (2) sensor head (3) silicone belt.

Principle of Operation

As the Bluetooth (BT) signals the CPU to display the temperature measurement. The thermistor is the type of temperature sensor and the CPU is a control center to process the device function.

The operating principle is based on differential temperature sending the signal to CPU which gets the signal than processes it and calculates the results.

5. Indications for Use

TD-1035 Thermometer is a temperature detector which is intended to measure the body temperature on axillary region. The device is intended for population age of six months and above, which is designed for home use.

6. Technological Characteristics

The concept of design is same as predicate product, **K152680**. There are two modifications were made to the proposed device: (1) indication for use (2) an elastic band was added. The modifications are changing the indication for use for population age of six months and above, which Thermometer is used at home. Also, the elastic band is design for more suitable and comfortable wearing.

Table of Specification Comparison

Item	Predicate device	Proposed device	Comparison
510K Number	**K152680**	**K172733**	
Indication for 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.**	TD-1035 Thermometer is a temperature detector which is intended to measure the body temperature on axillary region. The device is intended for **population age of six months and above, which is designed for home use.**	**Similarity**
Population	**12 years and older**	**Six months and above**	**Difference**
Intended Environment	Home use	Same as the predicate	**Same**

Item	Predicate device	Proposed device	Comparison
510K Number	**K152680**	**K172733**	
Principles of operation	The **Temperature Monitor** detects the body temperature by thermistor which provides signals to the microcontroller where signals are converted into a digital temperature value that displayed in LCD screen. The thermistor is as a temperature sensor and the microcontroller is used for signal processing. The basic operating principle is that a change of thermistor caused by changes of temperature provides a signal to the microcontroller which gets the signal than processes it and calculates the results.	Same as the predicate	**Same**
General Functions			
Low temperature display	< 89.60˚F (32.00˚C): Display: Lo ˚F (Lo ˚C)	Same as the predicate	**Same**
High temperature display	>109.40˚F (43.00˚C):Display: Hi ˚F (Hi ˚C)	Same as the predicate	**Same**
Measurement area	Armpit	Same as the predicate	**Same**
Measurement units	°C or °F	Same as the predicate	**Same**
Power source	one 3V CR2032 lithium battery	Same as the predicate	**Same**
Battery life	Approx. 25 days (1 time measurement/day)	Same as the predicate	**Same**
Beeper	None	Same as the predicate	**Same**
Operating condition	41°F to 104°F (5°C to 40°C);15% to 93% R.H.	Same as the predicate	**Same**

Item	Predicate device	Proposed device	Comparison
510K Number	**K152680**	**K172733**	
Storage condition	-13°F to 158°F (-25°C to 70°C);10% to 95% R.H.	Same as the predicate	**Same**
Data transmission	Bluetooth	Same as the predicate	**Same**
Dimensions (mm)	40.5 (L) x 27.5 (W) x 11.7 (H)	Same as the predicate	**Same**
Weight (g)	18 g	Same as the predicate	**Same**
Outer casing	On/off button, LCD display, armband	Same as the predicate	**Same**
Atmospheric pressure range	700 hPa to 1060 hPa	Same as the predicate	**Same**
Operation altitude	2000 m	Same as the predicate	**Same**
Expected service life	3 years	Same as the predicate	**Same**
Type BF applied part	Type BF Applied part	Same as the predicate	**Same**
Safety	IEC 60601-1	Same as the predicate	**Same**
EMC	IEC 60601-1-2	Same as the predicate	**Same**
Harmonized standard	ISO 80601-2-52:2009	Same as the predicate	**Same**
Water-resistance	IP22	Same as the predicate	**Same**
Material Description			
Top and Bottom Case	ABS	Same as the predicate	**Same**
Battery Cover	ABS	Same as the predicate	**Same**
M-Key	Silicone	Same as the predicate	**Same**
Lens	PC	Same as the predicate	**Same**
Stainless Steel Cap (Patient Contact Part)	SUS304	Same as the predicate	**Same**
Silicone Belt (Patient Contact Part)	Silicone	Same as the predicate	**Same**

Item	Predicate device	Proposed device	Comparison
510K Number	**K152680**	**K172733**	
Elastic Band (Patient Contact Part)	**NA**	**Nylon & Polyester 190D/Polyester 230g**	**Difference**
Biocompatibility Information			
Description	TD-1035 Thermometer detect the temperature by contact to user skin directly, which the contact time shall less than 24 hours. A part of silicone belt which is connected with sensor, without cover of the elastic band, located on the back of device and contact to user skin directly.		
Standard	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-12		
Patient Contact Parts	Stainless Steel Cap, Silicone belt	Stainless Steel Cap, Silicone belt, **Elastic band**	**Similarity**
Patient Contact Material Information			
Stainless Steel Cap	SUS 304	Same as the predicate	**Same**
Silicone Belt	Silicone	Same as the predicate	**Same**
Elastic Band	**NA**	**Nylon & Polyester 190D/Polyester 230g**	**Difference**

Discussion

The conceptual design of the subject device K172733 is similar with the predicate device K152680, which has the additional component of elastic band.
Considering the user individual circumstances which the predicate device (K152680) could cause the risk of uncomfortable wearing under the long-term effects of temperature monitoring because of the silicone belt has fixed holes size and holes number that are fewer armpit adjustment space. Thus, to modify this issue that the additional elastic band design of the proposal device(K172733) has more space for users to adjust the device wearing, and let the thermo-detector effectively contact the user skin.
Additionally, the temperature measurement accuracy of the subject device K172733 have met the criteria of the ISO 80601-2-56 Medical electrical equipment -- Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.
Also, each parts of the subject device materials passed the biocompatibility test.
Furthermore, the clinical trials have demonstrated that the subject device has met the temperature measurement criteria of ISO 80601-2-56. Overall, the performance tests demonstrate the elastic band does not impact device performance.

Conclusions

The concept of design is similar to the predicate device, K152680, which is a detector to measure the body temperature on axillary region, and transmit data to personal device via Bluetooth pairing. There are two modifications were made to the subject device: (1) indication for use (2) an elastic band was added. The elastic band is design for more suitable and comfortable wearing. Moreover, the temperature sensor is still contacting the user skin directly, which is located on the silicone belt.
The material of elastic band has passed the biocompatibility test. Also, the arm girth of elastic band is adjustable for users to apply on the axillary, and more convenient for using on children by guardian. A part of the silicone belt, which is connected with sensor, without cover of the elastic band, located on the back of device and contact to user skin directly. Overall, the performance tests demonstrate that the elastic band does not impact device performance.

7. Performance Data

Attachment	Standard	Title	Intended Use	Acceptance Criteria	Results
A1.1	IEC62304	Medical device software - Software life cycle processes	This validation is to test for product by itself to verify software is safe for patients using the medical device or not.	The pass/fail criteria is to evaluate the safety and effectiveness of software are met the device's indication for use.	PASS
A1.2	IEC 60601-1	General requirements for basic safety and essential performance	This study is to test for the basic safety and essential performance of medical electrical equipment and medical electrical systems which are intended by their manufacturer for use.	The pass/fail criteria is to evaluate the basic safety and essential performance of medical electrical equipment and medical electrical systems.	PASS
A1.3	IEC 60601-1-11	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	This study is to evaluate to the basic safety and essential performance of medical electrical equipment and medical electrical systems which are intended by their manufacturer for use in the home healthcare environment, regardless of whether the medical electrical equipment or medical electrical system is intended for use by a lay operator or by trained healthcare personnel.	The pass/fail criteria is to evaluate the basic safety and essential performance of medical electrical equipment and medical electrical systems for use in the home healthcare environment.	PASS
A1.4	IEC 60601-1-2	EMC Test Report	IEC 60601-1-2:2014 applies to the basic safety and essential performance of Medical Equipment (ME) equipment and ME systems in the presence of electromagnetic disturbances and to	The pass/fail criteria is limited to maintain the Essential Performance and Basic Safety of EMC requirements.	PASS

			electromagnetic disturbances emitted by me equipment and me systems.		
A2.1	ISO 14971	Risk Management Report	The failure of the function resulting in wrong analytical result which may have serious impairment to the health of a patient may happen. Control measures were taken to reduce the risk to as minimum as possible. Safety and effectiveness of use about the system was then verified.	The risk criteria were established when setting the context, the level of risk would against this criteria in order to determine whether the risk is acceptable.	Overall the risks are acceptable

General Performance Test:

Attachment	Standard	Title	Intended Use	Acceptance Criteria	Results
A1.5	ISO 80601-2-56	Storage Test Report	This report is intended to evaluate the accuracy of Thermometer after having been stored or transported within manufacturer's claimed range.	The pass/fail criteria is to simulate the worst case of the transportation and the storage conditions of the device when exposing at -13°F and at 158°F environment. ➢ The greatest calculated error δ should not be greater than 0.09℉ (0.05℃) between the measuring range from 95.00℉ to 100.40℉ (35.00℃ to 38.00℃). ➢ The greatest calculated error δ should not be greater than 0.18℉ (0.10℃) between the measuring range from 68.00℉ to 94.98 ℉ (20.00℃ to 34.99℃) and the measuring range from 100.42.℉ to 113.00℉ (38.01 ℃ to 45.00℃).	When error δ＜0.09℉ (0.05℃) or ＜0.18℉ (0.10℃) PASS
A1.6		Mechanical Shock Test Report	Verify the performance of Thermometer is complied with ISO 80601-2-56:2009 after	➢ The greatest calculated error δ should not be greater than 0.09℉ (0.05℃) between the measuring range from 95.00℉ to	When error δ＜0.09℉ (0.05℃) or

			mechanical shock.	100.40°F (35.00°C to 38.00°C). ➢ The greatest calculated error δ should not be greater than 0.18°F (0.10°C) between the measuring range from 68.00°F to 94.98 °F (20.00°C to 34.99°C) and the measuring range from 100.42.°F to 113.00°F (38.01 °C to 45.00°C).	＜0.18°F (0.10°C) PASS
A1.7		Display Temperature Range	Verify the measuring display range of Thermometer is complied with the manufacture-claimed display temperature range and the FDA recommended standard, ISO 80601-2-56:2009, which has the requirement of covering the minimum display range from 95 °F (35.0°C) to 107.6°F (42.0 °C).	All measurements meet the manufacture-claimed display temperature range which is cover the measuring range from 68°F (20°C) to 113°F (45°C) and it is in accordance with the requirement of ISO 80601-2-56:2009 that the minimum display range shall cover from 95°F (35.0°C) to 107.6°F (42.0°C).	Temperature Range Display
A1.8		Accuracy Test Report	Assess the laboratory accuracy of Thermometer under reference conditions.	A sample-size of 80 measurements, with no single measurement error exceeding the allowable limit, provides a confidence of 99% that at least 95% of all measurement will meet the acceptable criteria.	When error δ＜0.09°F (0.05°C) or ＜0.18°F (0.10°C) PASS
A1.9		Operating Environment Test Report	Verify the operating environment of Thermometer that met the accuracy requirements when operated in an environment of 41°F to 104	To evaluate the maximum errors in the operation environment range of 41°F to 104°F (5°C to 40°C) and a relative humidity of 15% to 93% noncondensing, the environment chambers were used to create the prospective condition.	When error δ＜0.09°F (0.05°C) PASS

			℉ (5°C to 40°C) and a relative humidity of 15% to 93% noncondensing. The operating environment of 41℉ to 104℉ (5°C to 40°C) and a relative humidity of 15% to 93% noncondensing are complied with the requirement of ISO 80601-2-56:2009 international standard that an ambient temperature operating range should at least be from 15°C to 35°C and a relative humidity range of 15% to 85% noncondensing.	Two temperatures of chamber were set as described in the standard.	
A1.11		Accuracy Test Report After Cleaning Procedure	This test is intended to evaluate the accuracy of TD-1035 Thermometer after performing cleaning procedure by the manufacturer instruction.	➢ The greatest calculated error δ should not be greater than 0.09℉ (0.05℃) between the measuring range from 95.00℉ to 100.40℉ (35.00℃ to 38.00℃). ➢ The greatest calculated error δ should not be greater than 0.18℉ (0.10℃) between the measuring range from 68.00℉ to 94.98 ℉ (20.00℃ to 34.99℃) and the measuring range from 100.42.℉ to 113.00℉ (38.01 ℃ to 45.00℃).	When error δ＜0.09℉ (0.05℃) or ＜0.18℉ (0.10℃) PASS

Biocompatibility & Clinical Test Report

Attachment	Standard	Title	Intended Use	Acceptance Criteria	Results
A1.12	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-12	Biocompatibility Test Report for Thermometer	When assessing medical device, the sponsor should specifically state if the medical device does not result in any risk of direct or indirect tissue-contacting components. Thus, performing the biocompatibility test to indicate the safety of device, which includes with Cytotoxicity Test, Skin Sensitization Test, and Irritation Test.	Cytotoxicity Test: If cell viability is reduced to < 70% of the reagent control extract, a cytotoxic potential exists. Skin Sensitization Test: Grades of 1 or greater observed in the test group generally indicated sensitization, provided that grades of less than 1 were observed on the control animals. Irritation Test: For each rabbit, the irritation score for test area was calculated by adding together the scores of erythema and edema at each time point and divide the sum by the total number of observation.	Cytotoxicity Test: ≥95% cell viability PASS Skin Sensitization Test: The test article extracts and the test article showed no evidence of causing delayed dermal contact sensitization. PASS Irritation Test: The Primary irritation index (PII) of the test article was zero. PASS
A1.13		Biocompatibility Test Report for Stainless Steel Cap			
A1.14		Biocompatibility Test Report for Elastic Band			
A1.15		Biocompatibility Test Report for Silicone belt			
A1.16	ISO 80601-2-56	Clinical Test Report	This study is intended to evaluate if the safety and effectiveness of device consistently meet the requirements of the intended use.	Clinical Accuracy of a thermometer is verified by comparing its output with that of a reference device, which has a specified uncertainty for measuring true temperature.	The statistics analysis results have demonstrated that the system accuracy of body temperature measurement in non-febrile and febrile group of subjects, infants (6months and above), children, adults and elderly were met the criteria of 95% limit of agreement and

					within 95% confidence interval requirements.

8. Conclusions

The TD-1035 Thermometer has same test principle, 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 predicate device (K152680).