TaiDoc Technology Corporation
Jacky Chou
Regulatory Affairs Director
6F, No.127, Wugong 2nd Rd., Wugu District
New Taipei City, 24888 TWN

April 5, 2022

Re: K200946
Trade/Device Name: Clever Forehead Thermometer / Clever Medical Forehead Thermometer (TD-1241)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: March 4, 2022
Received: March 7, 2022

Dear Jacky Chou:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Payal Patel
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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)*
K200946

Device Name
Clever Forehead Thermometer/Clever Medical Forehead Thermometer (TD-1241)

Indications for Use *(Describe)*
The Clever Forehead Thermometer/Clever Medical Forehead Thermometer (TD-1241) is an infrared thermometer intended for the non-contact measurement of human body temperature in people of all ages and may be used by medical professionals or by consumers in a home 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary K200946

Submitter information

Manufacturer	TaiDoc Technology Corporation
Address	6F, No. 127, Wugong 2nd Rd. Wugu Dist. New Taipei City, Taiwan 24888
Establishment Registration No.	3004145393
Date Prepared	March 23, 2022
Correspondent	TaiDoc Technology Corporation
Correspondent Contact	Jacky Chou
Title	Regulatory Affairs Director
Phone	+886-2-6625-8188
E-mail	jacky.chou@taidoc.com.tw

Proposed Device Information

Proprietary name	Clever Forehead Thermometer/Clever Medical Forehead Thermometer (TD-1241)
Common name	Clinical Electronic Thermometer
Product code	FLL
Classification panel	General Hospital
Classification	II
Regulation Number	21 CFR §880.2910

Predicate Device Information

Manufacturer	TaiDoc Technology Corporation
Proprietary Name	Caregiver Professional Clinical Thermometer, PRO-TF series (Model PRO-TF300)
Common Name	Clinical Electronic Thermometer
510(k) Number	K131771

Indications for use

The Clever Forehead Thermometer/Clever Medical Forehead Thermometer (TD-1241) is an infrared thermometer intended for the non-contact measurement of human body temperature in people of all ages and may be used by medical professionals or by consumers in a home environment.

Device Description

The Clever Forehead Thermometer/Clever Medical Forehead Thermometer (TD-1241) is a handheld, battery powered, infrared forehead thermometer with a non-contact body temperature measuring function. It detects infrared energy emitted from forehead within 1.2 - 5 cm and converts to a body temperature. This device can be used on people of all ages by medical professionals and consumers in a home environment. The final measured temperature will be displayed on the LCD screen of the device. The users can transmit temperature results from the Clever Forehead Thermometer/Clever Medical Forehead Thermometer to Healthy Check on their mobile devices and Health care management system on pc via Bluetooth. The Healthy check and Health care management system provide an overview of users record with historical data and trend graph.

Principle of Operation

The thermometer measures temperature by reading infrared radiation emitting from the forehead and converts it into a temperature value.

Comparison to the Predicate

The similarities and differences between the predicate and proposed devices are summarized in Table 1 below.

Table 1: Comparison between the Predicate and Proposed Device

Characteristic	**Predicate device:** Caregiver Professional Clinical Thermometer, PRO-TF series (Model PRO-TF300) (K131771)	**Proposed device:** Clever Forehead Thermometer/Clever Medical Forehead Thermometer (K200946)	**Comparison**
Indications for use	Caregiver Professional Clinical Thermometer is an infrared thermometer intended for the measurement of human body temperature in people of all ages without contact to the body and may be used by medical professionals or by consumers in a home environment.	The Clever Forehead Thermometer/Clever Medical Forehead Thermometer (TD-1241) is an infrared thermometer intended for the non-contact measurement of human body temperature in people of all ages and may be used by medical professionals or by consumers in a home environment.	Similar
Components	Power button, temperature measurement button, scanner, 4 side buttons, protective cap, microcontroller, and LCD	Power button, temperature measurement button, scanner, 4 side buttons, protective cap, microcontroller, LCD, and Bluetooth module	Different
Features	Temperatrue measurement Memory feature (10 sets) 3 Measurement modes	Temperatrue measurement Memory feature (30 sets) 3 Measurement modes Bluetooth Apps for data transfer	Different

Characteristic	**Predicate device:** Caregiver Professional Clinical Thermometer, PRO-TF series (Model PRO-TF300) (K131771)	**Proposed device:** Clever Forehead Thermometer/Clever Medical Forehead Thermometer (K200946)	**Comparison**
Principles of operation	Temperatures of a subject and environment are sensed by the thermopile and thermistor respectively, then temperature is transduced into electrical signal and feed to analog signal amplification circuit. The micro-controler consists of ADC (analog to digital signal converter) to process the signals from the amplification circuit, Then, through mathematical process, and the LCD displays the temperature reading on a screen.	Temperatures of a subject and environment are sensed by the thermopile and thermistor respectively, then temperature is transduced into electrical signal and feed to analog signal amplification circuit. The micro-controler consists of ADC (analog to digital signal converter) to process the signals from the amplification circuit, Then, through mathematical process, and the LCD displays the temperature reading on a screen.	Identical
MCU	The MSP430FG42x0 is a microcontroller configuration with a 16-bit timer, a high-performance 16-bit sigma-delta A/D converter, 12-bit D/A converter, two configurable operational amplifiers, 32 I/O pins, and a liquid crystal display driver.	The MSP430FG42x0 is a microcontroller configuration with a 16-bit timer, a high-performance 16-bit sigma-delta A/D converter, 12-bit D/A converter, two configurable operational amplifiers, 32 I/O pins, and a liquid crystal display driver.	Identical

Characteristic	**Predicate device:** Caregiver Professional Clinical Thermometer, PRO-TF series (Model PRO-TF300) (K131771)	**Proposed device:** Clever Forehead Thermometer/Clever Medical Forehead Thermometer (K200946)	**Comparison**
Materials	User contacting materials include ABS (device housing, power button, swithes), PC(lens & protective head cap).	User contacting materials include ABS (device housing, power button, swithes), PC(lens, protective head cap).	Identical
Performance	Meets ASTM E 1965:2016	Meets ASTM E 1965	Identical
Electrical Safety	Meets EN 60601-1:2014	Meets IEC 60601-1	Identical
EMC	Meets IEC 60601-1-2:2014	Meets IEC 60601-1-2	Identical
Measurement time	1 second	1 second	Identical
Measurement distance	1.2 cm – 5 cm	1.2 cm – 5 cm	Identical
Reference body site	Rectal for < 3 years old Oral for > 3 years old	Rectal for < 3 years old Oral for > 3 years old	Identical
Mode of operation	Adjusted mode	Adjusted mode	Identical
Weight	83 g	83 g	Identical
Memory/storage	32kb +256b flash memory 256b ram	32kb +256b flash memory 256b ram	Identical
Biocompatibility	ISO 10993-1	ISO 10993-1	Identical surface material
Probe cover	Yes	Yes	Identical
Sensor	IR Thermopile sensor	IR Thermopile sensor	Identical
Dimension (mm)	150 (L) x 48.48 (W) x 55.16 (H)	150 (L) x 48.48 (W) x 55.16 (H)	Identical

Characteristic	Predicate device: Caregiver Professional Clinical Thermometer, PRO-TF series (Model PRO-TF300) (K131771)	Proposed device: Clever Forehead Thermometer/Clever Medical Forehead Thermometer (K200946)	Comparison
Display Resolution	0.1 °F /0.1°C	0.1 °F /0.1°C	Identical
Measurement unit	°F or °C	°F or °C	Identical
Ambient operation condition	50°F to 104°F (10°C to 40°C)	50°F to 104°F (10°C to 40°C)	Identical
Meter storage/ transportation condition	-4°F to 140°F (-20°C to 60°C)	-4°F to 140°F (-20°C to 60°C)	Identical
Measurement range	Forehead: 94°F to 108°F (34.4°C to 42.2°C)	Forehead: 71.6°F to 111.2°F (22°C to 44°C)	Different
	Ambient: 50°F to 104°F (10℃ to 40℃)	Ambient: 50°F to 104°F (10℃ to 40℃)	Identical
HI/LO Indicator	Forehead: • ≦94°F (34.4°C) LCD Display LO • ≧108°F(42.2°C) LCD Display HI	Forehead: • ≦94°F (34.4°C) LCD Display LO • ≧108°F(42.2°C) LCD Display HI	Identical
	Surface: • < 32°F (0°C) LCD Display LO • > 140°F (60°C) LCD Display HI	Surface: • < 32°F (0°C) LCD Display LO > 140°F (60°C) LCD Display HI	Identical

Characteristic	**Predicate device:** Caregiver Professional Clinical Thermometer, PRO-TF series (Model PRO-TF300) (K131771)	**Proposed device:** Clever Forehead Thermometer/Clever Medical Forehead Thermometer (K200946)	**Comparison**
Accuracy (Forehead)	±0.4°F (±0.2°C) from 96.8°F to 102.2°F (36°C to 39°C) ±0.5°F (±0.3°C) for the range of 71.6°F to 96.7°F (22°C to 35.9°C) or 102.3°F to 108.5°F (39.1°C to 42.5°C)	±0.4°F (±0.2°C) from 96.8°F to 102.2°F (36°C to 39°C) ±0.5°F (±0.3°C) for the range of less than 36 °C (96.8 °F) or greater than 39 °C (102.2 °F)	Similar
Power source	2 x 1.5V AA batteries	2 x 1.5V AA batteries	Identical
Time to Power saving	30 Seconds	30 Seconds	Identical
Signal output and display	LCD, Buzzer	LCD, Buzzer, Bluetooth	Different

Substantial Equivalent Discussion

- **Indications for use**

Indications for use of the Clever Forehead Thermometer/Clever Medical Forehead Thermometer (TD-1241) is similar to its predicate device. The without contact is rephrased to non-contact for more precise wording. No new safety and effectiveness questions were raised.

- **Components**

The modified device has an added Bluetooth module. ES and EMC testing as well as function validation has been implemented to ensure the safety or effectiveness of the device is unaffected. The difference does not raise new safety or effectiveness questions.

- **Features**

The Clever Forehead Thermometer/Clever Medical Forehead Thermometer (TD-1241) increases the memory storage limit to 30 temperature readings and added a Bluetooth transfer function. The Clever Forehead Thermometer/Clever Medical Forehead Thermometer (TD-1241) uses the identical memory component, 32kb +256b flash memory 256b ram, as its predicate device. Both the Bluetooth and the memory features have been validated and tested in ES and EMC to ensure the safety or effectiveness of the device.

An additional application feature is added for Bluetooth data transfer. The application has been verified and validated to ensure the safety or effectiveness of the device is unaffected.

- **Measurement range and Accuracy**

The measurement range and accuracy comply with the ASTM E1965-98 (2016) standards. Laboratory test was conducted, and the test results met the requirements. The difference does not raise new safety and effectiveness questions.

- **Signal output and display**

Bluetooth signal output is added to the Clever Forehead Thermometer/Clever Medical Forehead Thermometer (TD-1241). The device has been validated and tested in ES and EMC to ensure the Bluetooth signal output does not raised safety or effectiveness issue for the device.

Non-clinical and performance testing

The entire Hazard Analysis for the Clever Forehead Thermometer/Clever Medical Forehead Thermometer was evaluated to identify all the risks / hazards that could be affected by the modifications to the Clever Forehead Thermometer/Clever Medical Forehead Thermometer.
These risks were mitigated using planned measures that included testing to recognized FDA consensus standards. Changes in software were verified and validated using the software development process.
The following table, which includes a summary of non-clinical testing data conducted according to FDA recognized consensus standards, is provided in support of the substantial equivalence determination:

Test report	Performance Standard
Electromagnetic compatibility (EMC)	• IEC 60601-1-2:2014, Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances -- Requirements and tests
Electrical Safety	• IEC 60601-1:2014, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance • IEC 60601-1-11:2015, Medical electrical equipment - Part 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
Laboratory accuracy	• ASTM E1965-98:2016, Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature
Clinical accuracy	• ASTM E1965-98:2016, Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature
Storage stability	• ASTM E1965-98:2016, Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature
Shock test	• ASTM E1965-98:2016, Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature
Cleaning procedure	• ASTM E1965-98:2016, Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature
Risk management report	• ISO 14971, Medical devices - Applications of risk management to medical devices

Biocompatibility	• ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
Software and Cybersecurity	• IEC 62304, Medical device software - Software life cycle processes • ISO/IEC 12207, Systems and software engineering Software life cycle processes • Software verification and validation test according to the requirements of the FDA "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)" • Guidance for Industry and FDA Staff: Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, October 2018.

Clinical Testing

A clinical accuracy testing evaluated 250 subjects which were performed on the following three age groups: infants (newborn to one year), children (greater than one to five years), and adults (greater than five years old) in accordance with ASTM standard (E1965-98) to compare the Clever Forehead Thermometer/Clever Medical Forehead Thermometer with the comparator method (WelchAllyn SureTemp PLUS model 690 Thermometer). This clinical accuracy study demonstrated that the temperatures obtained with the Clever Forehead Thermometer/Clever Medical Forehead Thermometer were highly related when compared to the comparator method. The clinical bias with stated uncertainty and clinical repeatability as defined in the ASTM standard (E1965-98) were within clinical acceptability.

Conclusion

The intended use of the subject device, the **Clever Forehead Thermometer/Clever Medical Forehead Thermometer**, is identical to that of the predicate device, the Caregiver Professional Clinical Thermometer, PRO-TF series (Model PRO-TF300), and a risk analysis was performed to identify risks associated with the device modifications. Verification and validation tests have been performed to demonstrate that the identified risks have been mitigated. The testing and analysis demonstrate that the subject device is substantially equivalent to the predicate device