April 16, 2021

Shenzhen Everbest Machinery Industry Co., LTD
% Kevin Wang
Consultant
Chonconn Medical Device Consulting Co., Ltd.
Room 508, Block C, No. 1029 Nanhai Avenue, Nanshan District
Shenzhen, 518067 Cn

Re: K203170
Trade/Device Name: Infrared Thermometer, Models: DT-8806S, DT-8807S
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: March 15, 2021
Received: March 15, 2021

Dear Kevin Wang:

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,

for Payal Patel
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203170

Device Name

Infrared Thermometer, Models: DT-8806S, DT-8807S

Indications for Use *(Describe)*

The Infrared thermometer is intended for the intermittent measurement of human body temperature from forehead for people of all ages. The device is reusable for home use and clinical 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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510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: March 11, 2021

1. Submission sponsor

Name: SHENZHEN EVERBEST MACHINERY INDUSTRY CO., LTD.
Address: 19th Building, 5th Region, Baiwangxin Industrial Park, Songbai Rd., Baimang, Xili, Nanshan, Shenzhen, Guangdong, China 518108
Contact person: Deng Aiguo
Title: Quality Manager
E-mail: dengaiguo@cem-meter.com.cn

2. Submission correspondent

Name: Chonconn Medical Device Consulting Co., Ltd.
Address: Room 508, Block C, No. 1029 Nanhai Avenue, Nanshan District, Shenzhen, Guangdong, P. R. China 518067
Contact person: Kevin Wang
E-mail: kevin@chonconn.com
Tel: +86-755 33941160

3. Subject Device Information

Trade/Device Name	Infrared Thermometer
Model	DT-8806S, DT-8807S
Common Name	Infrared Thermometer
Regulatory Class	Class II
Classification	21CFR 880.2910 / Clinical electronic thermometer / FLL
Submission type	Traditional 510(K)

4. Predicate Device

SHENZHEN EVERBEST MACHINERY INDUSTRY CO., LTD. Infrared thermometer Models: DT-8806, DT-8806H, Regulation 21 CFR 880.2910, Product Code FLL, under K101736.

5. Device Description

The Infrared thermometers are hand-held, battery powered devices designed to measure human body temperature from the central forehead for clinical or home use.

The thermometers are powered by AAA 1.5V×2 alkaline batteries. The results can be displayed on LCD. A thermopile sensor is employed to detect or monitor the infrared thermal energy emitted from the surface of the skin of the forehead, which is converted into temperature measurement with the unit of °C or °F

The Infrared thermometer included DT-8806S, DT-8807S. These two models are identical on hardware and software except the physical dimensions and appearance.

6. Intended use & Indication for use

The Infrared thermometer is intended for the intermittent measurement of human body temperature from forehead for people of all ages. The device is reusable for home use and clinical use.

7. Comparison to the Predicate Device

Features	**Subject device** **Infrared thermometer: DT-8806S, DT-8807S**	**Predicate device K101736** **Infrared thermometer: DT-8806, DT-8806H**	**Note**
Regulation number	21 CFR 880.2910	21 CFR 880.2910	Same
Product code	FLL	FLL	Same
Intended Use & Indications for use	The Infrared thermometer is intended for the intermittent measurement of human body temperature from forehead for people of all ages. The device is reusable for home use and clinical use.	Infrared Thermometer Model: 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.	Different (1)
Measurement Method	Infrared radiation detection, adjusted mode	Infrared radiation detection, adjusted mode	Same
Measurement Range	32.0°C ~42.5°C (89.6 to 108.5 ° F)	32.0°C ~42.5°C (89.6 to 108.5 ° F)	Same
Accuracy	±0.2°C (0.4°F) within 36.0°C ~ 39.0°C, (96.8°F ~ 102.2°F), ±0.3°C(0.6°F) within 32°C ~35.9°C (89.6°F ~96.6°F) and 39.1°C~42.5°C (102.3°F ~108.5°F)	±0.2°C (0.4°F) within 36.0°C ~ 39.0°C, (96.8°F ~ 102.2°F), ±0.3°C(0.6°F) within 32°C ~35.9°C (89.6°F ~96.6°F) and 39.1°C~42.5°C (102.3°F ~108.5°F)	Same
Display	0.1°C(0.1°F)	0.1°C(0.1°F)	Same
Measurement distance	8806S: 1 cm - 10 cm 8807S: 1 cm – 4 cm	5 cm - 15 cm	Different (2)
Measurement place	Forehead Surface	Forehead Surface	Same
Sensor type	Thermopile	Thermopile	Same
Scale Selection	°C /°F	°C /°F	Same
Memory	32 sets	32 sets	Same

Features	Subject device Infrared thermometer: DT-8806S, DT-8807S	Predicate device K101736 Infrared thermometer: DT-8806, DT-8806H	Note
Buzzer	Yes	Yes	Same
Auto power-off while no operation	Yes	Yes	Same
Power supply	2 * 1.5V AAA	2 * 1.5V AAA	Same
Display screen	LCD	LCD	Same
Contact materials	ABS	ABS	Same
Operation Environment	10~40°C (50°F ~104 °F) RH ≤85%	10~40°C (50°F ~104 °F) RH ≤85%	Same
Storage condition	0 to 50°C (32 to 122°F) RH ≤85%	0 to 50°C (32 to 122°F) RH ≤85%	Same
Dimension	128 * 74 * 36 mm	149 * 77 * 43mm	---
Weight	104.5 g	172 g	---
Conformance standard	ISO80601-2-56(performance), IEC60601-1(Safety), IEC60601-1-2(EMC) ASTM E1965-98	ISO80601-2-56(performance), IEC60601-1(Safety), IEC60601-1-2(EMC) ASTM E1965-98	Same
Biocompatibility	Under the condition of this study the device is non-cytotoxic, non-sensitizing and non-irritating.	Under the condition of this study the device is non-cytotoxic, non-sensitizing and non-irritating.	Same
Expected battery life	40000 times measure	40000 times measure	Same
Measuring time	1 second	1 second	Same
Clinical accuracy	Meet the requirements of ISO 80601-2-56:2017, ASTM 1965-98(2016)	Meet the requirements of ISO 80601-2-56:2017, ASTM 1965-98(2016)	Same

Justification of difference:

Different (1): The description of the intended use is different. The population of the subject device is wider than the predicate device. The performance testing can demonstrate that the subject device can meet the requirement on this population. So, the different does not raise different questions of safety and effectiveness.

The subject device is only used to measure the body temperature from forehead. The clinical study report can demonstrate this measuring site. So, the different does not raise different questions of safety and effectiveness.

Different (2): The measurement distance is different. The performance testing can demonstrate that the subject device can meet the requirement on this measurement distance. So, the different does not raise different questions of safety and effectiveness.

8. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the Infrared thermometer was conducted in accordance with the FDA Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

Non-clinical data

The Infrared thermometer has been tested according to the following standards:

- IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and essential performance
- IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- ISO 80601-2-56: Medical electrical equipment – Particular requirements for the basic safety and essential performance of clinical thermometers for body temperature measurement.
- IEC 60601-1-11: 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

The test was selected to show substantial equivalence between the subject device and the predicate.

Clinical data

Clinical testing is conducted per ASTM E 1965-98 (Reapproved 2016) Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature.
This clinical study is a randomization, simple blind homologous control, pairing design of clinical investigation, consists of a minimum of 150 subjects, of which 1/3 are infants, 1/3 are children and the rest 1/3 are adults (NOTE: Infants---newborn to one year; Children--- greater than one to five years; Adults---greater than five years old.). The test result demonstrated the clinical performance of the subject device complied with the requirement of standard ASTM E 1965-98 (Reapproved 2016).

9. Conclusion

Based on the performance testing, comparison and analysis provided it was concluded that the subject device, Infrared Thermometer, Models: DT-8806S, DT-8807S is substantially equivalent to the Infrared Thermometer, Models: DT-8806, DT-8806H cleared under K101736