October 15, 2019

Shenzhen Calibeur Industries Co., Ltd.
% Kevin Wang
Consultant
Chonconn Medical Device Consulting Co., Ltd.
No. A415, Block A, NanShan Medical Devices Industrial Park
Nanshan District
Shenzhen, Guangdong 518067
China

Re: K191251
Trade/Device Name: Infrared Thermometer, Model DT-8836T, DT-8836P
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: September 16, 2019
Received: September 16, 2019

Dear Mr. 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 Geeta Pamidimukkala
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191251

Device Name

Infrared Thermometer (Model DT-8836T, DT-8836P)

Indications for Use *(Describe)*

The Infrared thermometer is a non-contact infrared thermometer 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.

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510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

K191251

Prepared Date: 2019/10/14

1. Submission sponsor

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2. Submission correspondent

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Contact person: Kevin Wang

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Tel: +86-755 33941160

3. Subject Device Information

Trade/Device Name	Infrared Thermometer
Model	DT-8836T, DT-8836P
Common Name	Infrared Thermometer
Regulatory Class	Class II
Classification	21CFR 880.2910 / Clinical electronic thermometer /
Submission type	Traditional 510(K)
Product Code	FLL

4. Predicate Device

510(k) Number: K171578

Manufacturer: Shenzhen Aeon Technology Co., Ltd.

Device name/ Model: Infrared thermometer/ A200

5. Device Description

The Infrared thermometers are hand-held, battery powered devices designed to measure human body temperature from the 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 measurement distance of the subject device is no more than 3cm.

The Infrared thermometer included DT-8836T, DT-8836P. 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 a non-contact infrared thermometer 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 K191251 Infrared thermometer DT-8836T, DT-8836P**	**Predicate device K171578 Infrared thermometer A200**	**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 a non-contact infrared thermometer 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.	The Infrared thermometer model A200 is a non-contact infrared thermometer intended for the intermittent measurement of human body temperature by Forehead mode for people of all ages.	Different [1)]
Measurement Method	Infrared radiation detection	Infrared radiation detection	Same
Measurement Range	Forehead mode: 32.0°C ~42.5°C (89.6 to 108.5 ° F)	Forehead mode: 32.0°C ~42.9°C (89.6 to 109.22 ° F)	Different [2)]
Accuracy	Forehead mode: ±0.2°C (0.4°F) within 35.0°C ~ 42.0°C (95.0°F ~ 107.6°F), ±0.3°C(0.5°F) other range	Forehead mode: ±0.2°C (0.4°F) within 36.0°C ~39.0°C (96.8°F ~102.2°F), ±0.3°C(0.5°F) other range	Same
Display	0.1°C(0.1°F)	0.1°C(0.1°F)	Same
Measurement distance	≤3cm	≤3cm	Same
Measurement place	Forehead	Forehead	Same

Features	Subject device K191251 Infrared thermometer DT-8836T, DT-8836P	Predicate device K171578 Infrared thermometer A200	Note
Response time	1s	1s	Same
Sensor type	Thermopile	Thermopile	Same
Scale Selection	°C /°F	°C /°F	Same
Memory	60 sets	25 sets	Different [3)]
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 15~95%	10~40°C (50°F ~104 °F) RH 15~95%	Same
Storage Environment	-25 ~+55°C（-13~+131°F） RH:15~95%	-25 ~+55°C（-13~+131°F） RH:15~95%	Same
Dimension	153.8*62.4*62.4 mm	170*47*53mm	---
Weight	96g	75g	---
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
Patient contact materials	ABS	ABS	Same
Biocompatibility	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	Same

Justification of difference:

Different 1): Both subject and predicate devices are non-contact infrared thermometer. They are over-the-counter reusable devices for home and clinical use. The difference is the wording change in the statement. They are both intended for intermittent measurement of human body temperature from forehead. Thus, this different does not raise any new safety or performance questions.

Different 2): The measurement range of subject device is different from predicate device. The performance testing shows that the subject device complies with performance standard IEC 80601-2-56. Thus, this difference does not raise any new safety or performance questions.

Different 3): The memory of subject device is different from predicate device. However, the software was validation according to FDA's software guidance. The performance testing shows that the subject device complies with performance standard IEC 80601-2-56. Thus, this difference does not raise any new safety or performance questions.

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 software validation and verification were conducted in accordance with FDA's guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," dated May 11, 2005.

Clinical data

Clinical testing is conducted per ASTM E 1965-98 (Reapproved 2009) 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 2009).

9. Conclusion

Performance testing and compliance with voluntary standards demonstrate that the proposed devices are substantially equivalent to the relevant aspects of the predicate device in terms of design, components, materials, principals of operation, biocompatibility, performance characteristics, and intended use.