December 14, 2022

Zhangzhou Easepal Medical Science And Technology Co.,Ltd.
℅ Jet Li
Regulation Manager
Guangdong Jianda Medical Technology Co., Ltd.
906 Room, Longxiang Garden, Tianhe District
Guangzhou, Guangdong 510630
China

Re: K221800
Trade/Device Name: Infrared Thermometer (Model: Y20001, Y20002)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: November 14, 2022
Received: November 14, 2022

Dear Jet Li:

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,

David Wolloscheck, Ph.D.
For Joyce M. Whang, Ph.D.
Acting 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)*
K221800

Device Name
Infrared Thermometer (Model: Y20001, Y20002)

Indications for Use *(Describe)*
The Infrared Thermometer (Model: Y20001, Y20002) is intended for the intermittent measurement and monitoring of human body temperature from forehead. The device is indicated for use for people of two months and above at homecare and in hospital.

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

K221800

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 870.1130.

Summary Prepared Date:14 December 2022

1. Submitter Information

- Sponsor Company Name: Zhangzhou Easepal Medical Science And Technology Co.,Ltd.
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- Contact Person (including title): Flower Huang/ Engineer
- E-mail: flower@easepal.com.cn

Application Correspondent:

- Guangdong Jianda Medical Technology Co.,Ltd.
- Address: 906 Room, Longxiang Garden, Tianhe district, Guangzhou, China
- Contact Person: Mr. Jet Li
- Tile: Regulation Manager
- Tel: +86- 13512755282
- Email: jianda-lee@foxmail.com

2. Subject Device Information

Common Name:	Infrared Thermometer
Trade Name:	Infrared Thermometer
Model names:	Y20001,Y20002
Classification Name:	Thermometer, electronic, clinical
Review Panel:	General Hospital
Product Code:	FLL
Regulation Number:	21 CFR 880.2910
Regulation Class:	II

3. Predicate Device Information

Sponsor:	SHENZHEN EVERBEST MACHINERY INDUSTRY CO., LTD.
Common Name:	Infrared Thermometer
Trade Name:	Infrared Thermometer
Classification Name:	Clinical Electronic Thermometer
Model names:	DT-8806S, DT-8807S
510(k) number:	K203170
Review Panel:	General Hospital
Product Code:	FLL
Regulation Number:	21 CFR 880.2910
Regulation Class:	II

4. Device Description

Infrared thermometer (Model: Y20001,Y20002) are a hand-held, battery powered, infrared Thermometer that coverts a user's forehead temperature, using the infrared energy emitted in the area around the user's forehead when measure from 1-3cm of the subject's forehead with no contact. The temperature will displayed on the screen, and the reference body site is axilla. Infrared thermometer (Model: Y20001,Y20002) use a thermopile sensor with integrated thermistor for the target reading and a thermistor mounted in the head of the thermometer for ambient temperature readings. The device consists of measuring sensor, PCB, buttons, a LCD and an enclosure.

The difference between two models are size, weight and button settings. Y20001 has four buttons(Test button, °C/°F button, "B/S"button, "M" key) and Y20002 has two buttons(Function button, Measurement button). The functions of the two models are same. Infrared thermometer (Model: Y20001,Y20002) have the following features:

1) The device is intended to be reusable for home use and clinical use.
2) Switching of temperature unit between °C and °F.
3) The latest 32 sets of memory for measuring human body and object; the user can view or delete the previous measurement results.
4) Buzzer on or off to set the prompt tone on or off.

5) Prompt tone function.

6) Low battery indication, and auto power-off

5. Indication for use

The Infrared Thermometer (Model: Y20001, Y20002) is intended for the intermittent measurement and monitoring of human body temperature from forehead. The device is indicated for use for people of two months and above at homecare and in hospital.

6. Comparison to Predicate Device

Elements of Comparison	Subject Device	Predicate Device 1#	Verdict
Manufacturer	Zhangzhou Easepal Medical Science And Technology Co.,Ltd.	SHENZHEN EVERBEST MACHINERY INDUSTRY CO., LTD.	--
510 (k) Number	K221800	K203170	--
Product Name	Infrared Thermometer	Infrared Thermometer	--
Models	Y20001, Y20002	DT-8806S, DT-8807S	--
Intended Use	The Infrared Thermometer (Model: Y20001, Y20002) is intended for the intermittent measurement and monitoring of human body temperature from forehead. The device is indicated for use for people of two months and above at homecare and in hospital.	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.	Different, See Note 1
Measurement Method	Infrared radiation detection, adjusted mode	Infrared radiation detection, adjusted mode	Same
Principle of operation	It detects the radiant energy of infrared radiation emitted by objects or human body and converts it into electrical signals, and eventually into a temperature value	It detects the radiant energy of infrared radiation emitted by objects and converts it into electrical signals, and eventually into a temperature value	Same
Measurement Place	Forehead Surface	Forehead Surface	Same
Sensor type	Thermopile	Thermopile	Same
Measurement Distance	1-3cm	8806S: 1 cm - 10 cm 8807S: 1 cm- 4 cm	Different, See Note 2
Measuring Range	34.0℃ to 42.9℃(93.2 to 109.2 ° F)	32.0°C -42.5°C (89.6 to 108.5 ° F)	Different, See Note 3
Accuracy	±0.3℃/0.5℉	±0.2°C (0.4°F) within 36.0°C - 39.0°C, (96.8°F - 102.2°F),	Different, See Note 4

Elements of Comparison	Subject Device	Predicate Device 1#	Verdict
		±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)	
Display Resolution	0.1℃/0.1℉	0.1°C/0.1°F	Same
Display Screen	LCD	LCD	Same
Buzzer	Yes	Yes	Same
℃/℉ switchable	Yes	Yes	Same
Memory	32 sets	32 sets	Same
Auto power-off Same while no operation	Yes	Yes	Same
Power Supply	2 * 1.5V AAA	2 * 1.5V AAA	Same
Contact materials	ABS	ABS	Same
Operating Conditions	Temperature:10℃-40℃; Relative humidity: ≦95%	Temperature: 10.0℃~40℃ (50.0℉ ~104.0℉); Relative humidity: ≦85%	Different, See Note 5
Storage Conditions	Temperature:-20℃-55℃; Relative humidity: ≦95%RH	0 to 50°C (32 to 122°F) ;RH≦85%	
Dimension	Y20001:145 mm * 93 mm * 38 mm Y20002:155 m m *40 mm *40 mm	128 * 74 * 36 mm	Different, See Note 6
Weight	Y20001: 110 g(excluding batteries) Y20002: 59g (excluding batteries)	104.5 g	
Performance	Compliance with ASTM E 1965; ISO80601-2-56	Compliance with ASTM E 1965; ISO80601-2-56	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
Biocompatibility	All the patient contacting materials are compliance with ISO 10993-1，ISO 10993-5，ISO 10993-10，ISO 10993-23.	All the patient contacting materials are compliance with ISO 10993.	Same
	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.	

Elements of Comparison	Subject Device	Predicate Device 1#	Verdict
Electrical Safety	Compliance with IEC 60601-1	Compliance with IEC 60601-1	Same
EMC	Compliance with IEC 60601-1-2	Compliance with IEC 60601-1-2	Same

Note 1

The population of the predicate device is wider than the subject device. The user population of the subject device is subset of the predicate. Therefore, this difference does not raise new safety and effectiveness questions.

Note 2

The measurement distance is different. But we had conducted clinical accuracy testing on subject device according to ISO 80601-2-56:2017, and the clinical accuracy test result 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.

Note 3

The measurement range of subject device is different from the predicate device. The performance testing shows that the subject device complies with the performance standard ISO 80601-2-56 and ASTM E1965-98. Therefore, this difference does not affect the performance and accuracy.

Note 4

The subject device's accuracy are wider than the predicate device within 36.0°C - 39.0°C, (96.8°F - 102.2°F) ,these are based on device's performance standards. These differences do not affect the performance and accuracy according to our Test Report (ASTM E1965- 98), ISO 80601-2-56 Test Report, and our Clinical Test Report.

Note 5

The operation and storage environment of subject device is different from the predicate device, but the measurement accuracy of subject device has been demonstrated to comply with the requirements of standards IEC 60601-1 and ISO 80601-2-56 in operation and storage environment. Therefore, we considered that the difference does not raise any issues on the device safety and effectiveness.

Note 6

The "Dimensions", "Weight" of subject device is similar with predicate devices, both of them meet the requirement of safety and essential performance standard IEC 60601-1, IEC 60601-1-2 and IEC 60601-1-

11. The differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device.

7. Non-Clinical Test Summary

7.1. Electromagnetic Compatibility and Electrical Safety Test

The subject device has been tested in compliance with the following standards:

1) AAMI/IEC 60601-1:2005+AMD 1: 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

2) 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

3) IEC 60601-1-11:2015 Medical electrical equipment - Part 1-11: General requirementsfor basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

7.2. Biocompatibility Test

The subject device is considered for surface contacting, limited exposure (Less than 24 hours), it has been tested in compliance with the following standards:

1) ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

2) ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

3) ISO 10993-23:2021 Biological evaluation of medical devices - Part 23:Tests for irritation

7.3. Performance Test-Bench

The subject device has been tested in compliance with the following standards:

1) ISO 80601-2-56:2017+AMD2018 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement

2) ASTM E1965-98 (Reapproved 2016) Standard Specification for InfraredThermometers for Intermittent Determination of Patient Temperature

7.4. Software Verification

The software documentation of the subject device was provided in accordance with FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued May 11, 2005.

8. Clinical Accuracy Test Summary

Both models(Y20001,Y20002) have undergone clinical accuracy testing, both clinical studies are based on the requirement of ISO 80601-2-56:2017. The test reports showed the clinical performance of the subject device complied with the requirement of ISO 80601-2-56:2017+AMD2018 .

Each clinical study evaluated 150 subjects, and the infrared thermometer was evaluated for the patient populations for two months and above. All subjects were divided into three age groups with 50 subjects in each group, including (1)Infants –two months to one year, (2)Children - greater than one to five years; (3)Adults - greater than five years old. The proportion of fever patient is more than 30% in each age groups.

9. Conclusion

The subject device Infrared Thermometer (Model: Y20001, Y20002) are substantially equivalent to the predicate device (K203170). This conclusion is based upon comparison of the intended use, technological characteristics and applicable safety standards. Any differences in the technological characteristics do not raise any new issues or different questions of safety or effectiveness.