September 28, 2021

Comper Chuangxiang (Beijing) technology Co., Ltd.
Han Du
Manager
Building 1, Unit 4, Room 102, 103 1st Floor, No.1 Kangding
Street, Beijing Economic Technological Development Area
Beijing, 100176
China

Re: K202481
Trade/Device Name: ThermArt (Model IR-EFT)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: August 17, 2021
Received: August 27, 2021

Dear Han Du:

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
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)*
K202481

Device Name
ThermArt (Model IR-EFT)

Indications for Use *(Describe)*
This device is a non-sterile reusable, contact thermometer, intended for intermittent determination of human body temperature through on the ear canal or forehead as the measurement site on people of all age. The ThermArt (Model IR-EFT) can be used in clinical and 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.

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K202481 510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 28 September, 2021

1. Submitter's Information

The submitter of this pre-market notification is:

Name:	Comper Chuangxiang (Beijing) technology Co., Ltd. Address:
	Room 102-103 1st Floor, Building 4 No.1 Kangding Street, Daxing District Beijing, CHINA 100176
Contact person:	Han Du
Title:	Manager
E-mail:	registration@comper.com
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2. Device Identification

Trade/Device Name:	ThermArt
Models:	IR-EFT
Common Name:	Clinical Electronic Thermometer
Regulation Number:	21 CFR 880.2910
Regulation Name:	Clinical electronic thermometer
Regulation Class:	Class II
Product Code:	FLL

3. Predicate Device

510(K) number:	K190873
Device Name:	Infrared Ear/Forehead Thermometer
Manufacturer:	Joytech Healthcare Co., Ltd.
Regulation Number:	21 CFR 880.2910
Regulation Name:	Clinical electronic thermometer
Regulation Class:	Class II
Product Code:	FLL

4. Device Description

The ThermArt (Model IR-EFT) is a hand-held, battery powered device designed to measure human body temperature. This Thermometer takes the body temperature by measuring the infrared energy emitted from the forehead skin or the ear canal. The ThermArt Thermometer adopts gentle-touch, user friendly and non-invasive measurement design. It instantly displays the accurate reading of the body temperature with just a gentle touch.

5. Indications for use

This device is a non-sterile reusable, contact thermometer, intended for intermittent determination of human body temperature through on the ear canal or forehead as the measurement site on people of all age. The ThermArt (Model IR-EFT) can be used in clinical and home environment.

6. Substantial Equivalence Discussion

Comparison to the predicate devices, the subject device has same indications for use, similarproduct design, same performance effectiveness, performance safety as the predicate device as summarized in the following table

Feature	Subject device	Predicate device	Discussion
510(k) Number	K202481	K190873	/
Regulation number	21 CFR 880.2910	21 CFR 880.2910	Same
Product Code	FLL	FLL	Same
Indications for Use	This device is a non-sterile reusable, contact thermometer, intended for intermittent determination of human body temperature through on the ear canal or forehead as the measurement site on people of all age. The ThermArt (Model IR-EFT) can be used in clinical and home environment.	Infrared Ear/Forehead Thermometer DET-218 is intended for the intermittent measurement of human body temperature by people of all ages. The devices are reusable for home use only.	Our indications for use is different from the description of the predicate device, but the means is essentially the same.
Patient population	people of all ages	people of all ages	Same
Measure Method	Infrared radiation detection	Infrared radiation detection	Same
Key Temperature Sensor	Thermopile Sensor	Thermopile Sensor	Same
Materials	Enclosure: PC; Probe: glass & ABS	Enclosure: ABS; Probe: Stainless steel & ABS;	Different, but both of our device and predicate device have performed the Biocompatibility test according to the ISO 10993-1, both two devices meet the requirements of ISO 10993. therefore it is substantially equivalent on Biocompatibility risk.
Temperature range	32.0°C ~43.0°C (89.6°F - 109.4°F)	34.0°C to 43.0°C (93.2°F to 109.4°F)	Our measurement range is greater than predicate device, but we performed accuracy test according to

			the ASTM E1965, therefore it is substantially equivalent on performance.
Accuracy	±0.4℉/±0.2℃ (95℉ – 107.6 ℉/35.0℃ -42℃) ±0.5°F/±0.3°C (outside this temperature range)	Ear/Forehead mode: ±0.2°C (0.4°F) during 35.5°C ~42.0°C (95.9°F ~107.6°F) at 15°C ~35°C (59.0°F ~95.0°F) operating temperature range ±0.3°C (0.5°F) for other measuring and operating temperature range.	Our accuracy is greater than predicate device, but we performed accuracy test according to the ASTM E1965, therefore it is substantially equivalent on performance.
Operating environment	Temperature: 15℃ -40℃ (59℉ - 104°F) relative humidity: ≤ 95%; atmospheric pressure: 70 kPa~106 kPa	Temperature: 10℃~40℃(50℉~104°F), relative humidity: 15%~85%RH non-condensing Atmospheric Pressure : 700hPa ~ 1060hPa	Our operating temperature and relative humidity are different from predicate device, but we performed accuracy test according to the ISO 80601-2-56 and ASTM E1965, therefore it is substantially equivalent on performance.
Transportation and storage conditions	Temperature: -20℃~+ 55℃(-4℉ -131°F); relative humidity: ≤ 95%; atmospheric pressure: 70 kPa~106 kPa	-25℃~ 55℃ (-13°F~131°F), 15%~95%RH, non-condensing Atmospheric Pressure : 700hPa ~ 1060hPa	Our operating temperature and relative humidity are different from predicate device, but we performed accuracy test according to the ISO 80601-2-56 and ASTM E1965, therefore it is substantially equivalent on performance.
The contact/noncontact use of the device	Contact Ear: the ear probe cover contacts with skin; Forehead: the forehead probe cover contacts with skin	Contact	Same
The use of a probe cover	Ear：use the ear probe cover Forehead: use the forehead probe cover	Ear：use the ear probe cover Forehead: use the forehead cap	Same
Measuring time	1s	1s	Same
Resolution of display	0.1℃ / 0.1℉	0.1℃ / 0.1℉	Same
Measurement Place	Forehead Ear	Forehead Ear	Same
Scale Selection	°C /°F	°C /°F	Same
Signal output and display	LED Transfer transmit data to mobile device for secondary display	-Internal firmware and local LCD display -Also able to transfer transmit data to mobile device for	Different type of screen display, but both of our device and predicate device have performed the

		secondary display	Medical electrical safety test according to the IEC 60601-1 and IEC 60601-1-2, both two devices meet the requirements. therefore it is substantially equivalent on Electrical risk.
Wireless Interface	Not applicable	Bluetooth Low Energy (BLE)	Different , Do not affect the use and precision measurement
Signal transmission	Not applicable	Bluetooth 4.0	Different , Do not affect the use and precision measurement
Receiver (mobile terminal)	Not applicable	iOS9.0 or above mobile device Android5.0 or above mobile device	Different, Do not affect the use and precision measurement
Auto power-off while no operation	Yes	Yes	Same
Power Source	DC3V(2×AAA battery)	DC3V(2×AAA battery)	Same
Biocompatibility	Cytotoxicity, Skin irritation, Skin sensitization	Cytotoxicity, Skin irritation, Skin sensitization	Same
Voluntary standards for Clinical Electronic Thermometers,	ASTM E1965 ISO 80601-2-56	ASTM E 1965 and ISO 80601-2-56	Same
Medical Electrical Safety and EMC	IEC 60601-1, IEC 60601-1-2	IEC 60601-1, IEC 60601-1-2	Same

Discussion

Here is a summary of the difference and the tests performed on these differences to address the safety and effectiveness of the subject device.

No.	**Difference**	**Tests performed**
1.	Materials	Biocompatibility test according to the ISO 10993-1, ISO 10993-5 and ISO 10993-10.
2.	temperature range	Accuracy test according to the ASTM E1965.
3.	accuracy	
4.	operating environment	Accuracy test according to the ISO 80601-2-56 and ASTM E1965.
5.	transportation and storage conditions	
6.	signal output and display	Medical electrical safety test according to the IEC 60601-1 and IEC 60601-1-2.

7.	wireless interface	No test performed because the subject device does not contain these functions.
8.	signal transmission	
9.	receiver (mobile terminal)	

The required testing demonstrated that different do not raise new questions of safety and effectiveness between the subject and the predicate device.

8. Performance Data

Non-clinical data

Cleaning validation:

We performed the cleaning validation according to the method if instruction for use, the validation result shows that the method of cleaning meets the cleaning requirements.

Safety:

1. ANSI/AAMI ES60601-1:(R) 2012 AND A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005,MOD)
2. AAMI/ANSI ES60601-1-2:2014 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 requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Performance:

4. ISO 80601-2-56:2017 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.
5. ASTM E1965 (2016) Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature

Biocompatibility:

6. ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within arisk management process
7. ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitrocytotoxicity
8. ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation andskin sensitization

The tests were selected to show substantial equivalence between the subject device and the predicate.

9. Conclusion

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. Based on the safety and performance testing and compliance with performance

standards, the ThermArt (Model IR-EFT) is substantially equivalent to the Infrared Ear/Forehead Thermometer cleared under K190873 with respect to the indications for use, target populations, treatment method, and technological characteristics.