December 6, 2018

Dongguan SIMZO Electronic Technology Co. Ltd.
Mei Tan
QA Manager
No.81, Tianxin Street, Chongkong, Shijie Town
Dongguan, Guangdong,
China

Re: K173048
Trade/Device Name: Non-contact Forehead Thermometer, Model: HW-2/HW-2S/HW-3/HW-4 /HW-4S/HW-302/HW-303
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: October 22, 2018
Received: October 25, 2018

Dear Mei Tan:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Geeta K.
Pamidimukkala -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K173048

Device Name
Non-contact Forehead Thermometer, Model: HW-2/HW-2S/HW-3/HW-4 /HW-4S/HW-302/HW-303

Indications for Use *(Describe)*
The Non-contact Forehead Thermometer is an infrared thermometer intended for the intermittent measurement of human body temperature in people of all ages.

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

K173048

Prepared Date: 2018/12/4

Submitter Information

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Subject Device Information

Trade name: Non-contact Forehead Thermometer
Model: HW-2/HW-2S/HW-3/HW-4 /HW-4S/HW-302/HW-303
Common name: Non-contact Clinical Thermometer
Classification name: Clinical electronic thermometer
Production regulation: 21 CFR 880.2910
Product code: FLL

Predicate Device

Non-contact Clinical Thermometer, Model THB0F. (Radiant Innovation Inc,K121428)

Description

The Non-contact Forehead Thermometers are hand-held, battery powered devices designed to measure human body temperature. The subject devices are Infrared thermometers that convert a user's forehead temperature using the infrared energy emitted in the area around the user's forehead to an oral equivalent temperature when placed in the distance from subject’s forehead up to 5-8cm(HW-2,HW-2S,HW-3,HW-302 and HW-303) or 1-2cm(HW-4 and HW-4S).

The thermometers use a thermopile sensor with integrated thermistor for the target reading, a thermistor mounted in the head of the thermometer for ambient temperature readings, a parabolic mirror to help focus the infrared energy emitted from the forehead, and an infrared distance sensor for detection with the distance from forehead up to 5~8cm(HW-2,HW-2S,HW-3,HW-302 and HW-303) or 1-2cm(HW-4 and HW-4S) and compensation of the temperature reading.

Indications for Use

The Non-contact Forehead Thermometer is an infrared thermometer intended for the intermittent measurement of human body temperature in people of all ages.

Summary of technological characteristics of device compared to the predicate devices (K121428), see the table1

A comparison of key technological characteristics between the subject devices and predicate device was listed as below:

Table 1

	Subject device(SD) SIMZO HW series	Predicate device(PD) Rdiant THB0F	Note
510K number	K173048	K121428	--
Intended Use& Indication for use	The Non-contact Forehead Thermometer is an infrared thermometer intended for the intermittent measurement of human body temperature in people of all ages.	The Non-contact Clinical Thermometer, Model THB0F is an infrared thermometer intended for the intermittent measurement of human body temperature in people of all ages.	Same
Measurement Method	Infrared radiation detection	Infrared radiation detection	Same
Measurement Range	Forehead mode: 35.5°C ~42.9°C (95.9°F ~109.2°F)	Forehead mode: 34.0°C ~42.2°C (93.2°F ~108.0°F)	Similar
Accuracy	Forehead mode: ±0.2°C (0.4°F) within 35.5°C ~42.9°C (95.9°F ~109.2°F), ±0.3°C(0.5°F) other range	Forehead mode: ±0.2°C (0.4°F) within 36~39°C(96.8~102°F), ±0.3°C(0.5°F) other range	
Display	0.1°C(0.1°F)	0.1°C(0.1°F)	Same
Measurement distance	HW-2/HW-2S/HW-3/HW-302/ HW-303:5-8cm HW-4/HW-4S:1-2cm	2-3cm	Similar
Measurement place	Forehead	Forehead	same
Response time	1S	1S	same

Sensor type	Thermopile	Thermopile	Same
Fever alarm	Yes	Yes	Same
Scale selection	℃ /°F	℃/°F	same
Display screen	LCD	LCD	same
Memory	HW-2/2S:32 sets HW-3/4/4S: 1 set HW-302/303:64 Sets	60sets	Similar
Fever alarm	Yes	Yes	same
Buzzer	Yes	Yes	same
Auto power-off while no operation	Yes	Yes	Same
Power supply	2 x AAA	2 x AAA	Same
Operation Environment	10~40°C(50°F ~104 °F) RH < 85%	10~40°C(50°F ~104 °F) 15-85% RH	Similar
Storage Environment	-25℃-+55℃(-13°F-+131°F) RH≤90%	-20℃-+55(-4°F-+131°F) RH≤90%	
Dimension	93*153*41mm	180.3*47.5*29.2mm	---
Weight	90-125 g	104.7g	---
Conformance standard	EN60601-1(Safety), IEC60601-1-2(EMC) ASTME1965-98(performance)	EN60601-1(Safety), IEC60601-1-2(EMC) ASTM E1965-98	Same

Analysis

From the comparison table1, the subject devices and predicate device have the same Intended use & Indications for Use, Measurement place, Scale selection, Display screen, Auto power-off while no operation & Conformance standard. There are slightly differences between the devices and predicate device as follows.

Difference clause	Discussion
Measurement Range& Accuracy	Both devices have different measurement range,but they have the same accuracy and the measurement range of subject devices meet the requirements of ASTME1965-98
Measurement distance	Measurement distance of the subject devices is 5-8cm or 1-2cm, the predicate device's will be in the range of 2-3cm. But the performance test result of subject device shows the accuracy meets the requirements within the distance range.
Memory	The memory capacity of predicate devices in K121428 is difference from subject devices ,but that does not impact the

	performance of subject devices.
Operation &Storage Environment	Both devices have slightly different Operation &Storage Environment, but the subject devices meet the requirements of IEC60601-1

Non-Clinical Data

The Non-contact Forehead Thermometer has been tested according to the following applicable standards:

Test name	Report description	Result
Electrical Safety	Test report / IEC 60606-1:Medical Electrical Equipment - Part 1: General Requirements for Safety	Pass
EMC	Test report / IEC 60601-1-2 Medical Electrical Equipment-Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests	Pass
Cytotoxicity	Cytotoxicity test report /ISO 10993-5 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity	Pass
Sensitization	Sensitization test report /ISO 10993-10 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization	Pass
Irritation	Irritation test report /ISO10993-10 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization	Pass
Performance test in home healthcare environment	Test report/IEC60601-1-11 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	Pass
Performance（Shock test, Storage test, Laboratory accuracy test）	Test report/ASTM E 1965-98 Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature	Pass
Cleaning and Disinfection	Cleaning and Disinfection validation report /ASTM E 1837 – 96 (Reapproved 2014), Standard Test Method to Determine Efficacy of Disinfection Processes for Reusable Medical Devices (Simulated Use Test)	Pass
Shelf life	Shelf life test report /scanner switch on/off cycles 136875 times(use life 5years)	Pass
Software	Guidance for the Content of Premarket Submissions for	Pass

validation and verification	Software Contained in Medical Devices,dated May 11, 2005	

Clinical data

Clinical tests were conducted on HW-2,HW-2S,HW-3,HW-4,HW-4S,HW-302 and HW-303. The clinical tests evaluated 96 subjects which were divided into three group age ranges-infant (new born to 1 year), children (greater than 1 to 5 years old) and adult(greater than5 years old). Each group has 32 patients and 30% of them got temperature equaling or exceeding 38.0℃.

Based on the result, the clinical performance of the subject device complied with the requirement of ASTM E1965-98 (2016).

Conclusion

Based on the performance testing and compliance with acceptable voluntary standards, we believe that the Non-contact Forehead Thermometer is substantially equivalent to its predicate device in K121428.