March 8, 2021

Andon Health Co., Ltd.
Liu Yi
President
No. 3 Jin Ping Street, Ya An Road, Nankai District
Tianjin, Tianjin 300190
China

Re: K202753
Trade/Device Name: iHealth Wireless No-Touch Forehead Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical electronic thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: February 1, 2021
Received: February 5, 2021

Dear Liu Yi:

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)*
K202753

Device Name
iHealth Wireless No-Touch Forehead Thermometer (PT3SBT)

Indications for Use *(Describe)*

The Wireless No-Touch Forehead Thermometer is intended for the intermittent measurement of body temperature from the forehead on people of all ages. It can transmit the temperature to a smart device with Bluetooth and can be used by consumers in the household environment and by healthcare providers.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K202753

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1.0 submitter's information

Name: Andon Health Co., Ltd.
Address: No 3, Jinping Street Ya An Road, Nankai District, Tianjin, P.R. China
Phone number: 86-22-87611660
Fax number: 86-22-6052 6162
Contact: Liu, Yi
Date of Preparation: 2/11/2021

2.0 Device information

Trade name: iHealth Wireless No-Touch Forehead Thermometer (model: PT3SBT)
Common name: Infrared forehead thermometer
Classification name: Clinical Electronic Thermometer

3.0 Classification

Production code: FLL
Regulation number: 880.2910
Classification: II
Panel: General Hospital

4.0 Predicate device information

Manufacturer: Andon Health Co., Ltd
Device: iHealth Infrared No-Touch Forehead Thermometer (Model: PT3)
510(k) number: K200531

5.0 Indications for Use

The Wireless No-Touch Forehead Thermometer is intended for the intermittent measurement of body temperature from the forehead on people of all ages. It can transmit the temperature to a smart device with Bluetooth and can be used by consumers in the household environment and by healthcare providers.

6.0 Device description

The iHealth PT3SBT Wireless No-Touch Forehead Thermometer is hand-held, reusable, battery operated device, which can measure human body forehead skin temperature without touching patient's skin. Its operation is based on measuring the natural thermal radiation from the central forehead. Put the probe of the thermometer at a measurement distance less than or equal to 1.18 inch (3cm) without touching the skin at the center of the patient's forehead. It uses a thermopile sensor to measure the patient's forehead temperature and convert it to the oral equivalent. Pressing the activation button to start the measurement of proposed infrared radiation. The electrical signal read out from the detector is fed to the circuit for amplification and calculation. The final measured temperature will be appeared on a LED display of the device. The thermometer can also be connected to a smart device through Bluetooth and display the measured temperature result on the smart device.

7.0 Summary comparing technological characteristics with predicate device

Item	Subject Device (K202753)	Predicate Device (K200531)	Comparison
Name and Model	iHealth Wireless No-Touch Forehead Thermometer Model: PT3SBT	iHealth Infrared No-Touch Forehead Thermometer Model: PT3	——
Product code	FLL	FLL	Same
Regulation number	21 CFR 880.2910	21 CFR 880.2910	Same
Manufacturer	Andon Health Co., Ltd	Andon Health Co., Ltd	Same
Indications for Use	The Wireless No-Touch Forehead Thermometer is intended for the intermittent measurement of body temperature from the forehead on people of all ages. It can transmit the temperature to a smart device with Bluetooth and can be used by consumers in the household environment and by healthcare providers.	The Infrared No-Touch Forehead Thermometer is intended for the intermittent measurement of body temperature from the forehead on people of all ages. It can be used by consumers in the household environment and by healthcare providers.	Different 1
Probe contact type	Non-contact; measurement distance: ≤ 1.18 in(3 cm)	Non-contact; measurement distance: ≤ 1.18 in(3 cm)	Same

Sensor	Thermopile	Thermopile	Same
Measurement method	Infrared radiation detection	Infrared radiation detection	Same
Display type	LED	LED	Same
Other feature	1. Vibration when get measurement 2. Can connect to a smart device and display measured temperature result on a smart device.	1. Vibration when get measurement	Different 2
APP name and feature	iHealth MyVitals Pro App Store and show data received from the thermometer through Bluetooth	No App related	Different 3
Measuring range	32- 42.9° C (89.6- 109.2° F)	32- 42.9° C (89.6- 109.2° F)	Same
Accuracy	±0.4°F(±0.2°C) within 93.2°F-107.6°F(34℃-42°C), and±0.5°F(±0.3°C) for other temperature ranges.	±0.4°F (0.2°C) within 95~107.6°F (35~42°C), ±0.5°F (0.3°C) for other range.	Different 4
Measuring response time	1 second	1 second	Same
Low battery indicator	Indicated on LED	Indicated on LED	Same
Temperature unit	°C or °F	°C or °F	Same
Display resolution	0.1℉(0.1℃)	0.1℉(0.1℃)	Same
Power requirements	2X1.5V AAA battery	2X1.5V AAA battery	Same
Operation environment	0-40° C, 15%-95% RH, 70-106kPa	15-40° C, 15%-95% RH, 70-106kPa	Different 5
Storage environment	-20-55° C, 15%-95% RH, 70-106kPa	-20-55° C, 10%-95% RH, 70-106kPa	Different 6
Materials of skin-contacting components	ABS and PMMA	ABS and PMMA	Same
biocompatibility	Comply with ISO 10993-1	Comply with ISO 10993-1	Same
electrical safety	Comply with IEC 60601-1	Comply with IEC 60601-1	same
EMC and performance testing	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Same
Wireless communication	Bluetooth low energy	NA	Different 7

Different 1: The indication for use of the proposed device is slightly different, because it can transmit the temperature to a smart device with Bluetooth. The performance test and the clinical accuracy test complied with standards. The difference does not raise any new performance questions.

Different 2-3: There is App on smart device for the subject device, test result displayed on the thermometer can also be transmited to App on smart device through bluetooth. The software validation demonstrated the difference does not raise any new performance questions.

Different 4: The accuracy of the proposed device is different from the predicate device, the performance test and the clinical accuracy test complied with standards. The difference does not raise any new performance questions.

Different 5: The operation temperature range of the proposed device PT3SBT is different from the predicate device, but the performance test complied with standards. The difference does not raise any new performance questions.

Different 6: The storage humidity range of the proposed device PT3SBT is different from the predicate device, but the performance test complied with standards. The difference does not raise any new performance questions.

Different 7: There is wireless communication with bluetooth low energy on the subject device, the software validation and performance test demonstrated the difference does not raise any new performance questions.

8.0 Discussion of non-clinical and clinical test performed

Non-clinical tests were conducted to verify that the proposed device met all design specifications in order to demonstrate that it is Substantially Equivalent to the predicate device.

Non-clinical Tests

Electrical Safety test was performed according to IEC 60601-1:2005/(R)2012 And A1:2012,C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance.

EMC test was performed according to 60601-1-2:2014, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - requirements and tests.

Performance test was performed according to 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. [Including: Amendment 1 (2018)]. is the applicable standards for this device.

Biocompatibility test (including cytotoxicity, sensitization, irritation) was performed according to (1) ISO 10993-1 Fifth edition 2018-08 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, (2)ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity and (3) ISO 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

Software verification and validation were conducted according to FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", dated May 11, 2005. Cybersecurity testing has been evaluated according to guidance "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices".

Clinical Tests

Clinical investigation and data analysis were performed according to ASTM E1965-98:2016. The test was conducted for 40 subjects in infants group (0-1 year), 40 subjects in children group (1-5 years) and 50 subjects in adults group (>5 years) (Total 130 subjects). The clinical test report demonstrated that the clinical data, represented by clinical bias and uncertainties met the acceptance criteria of the clinical study protocol. The iHealth PT3 Infrared No-Touch Forehead Thermometer complies with the requirement of ASTM E1965-98 (2016).

9.0 Conclusion

Basing on the performance testing, comparison and analysis, the subject device iHealth PT3SBT Wireless No-Touch Forehead Thermometer is substantially equivalent to the predicate device .