



July 15, 2020

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

Re: K200531

Trade/Device Name: iHealth Infrared No-Touch Forehead Thermometer, Model: PT3
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: June 10, 2020
Received: June 15, 2020

Dear Mr. 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,

Sapana Patel -S

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

Indications for Use

510(k) Number (if known)

K200531

Device Name

iHealth Infrared No-Touch Forehead Thermometer (Model: PT3)

Indications for Use (Describe)

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.

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

K200531

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: 7/14/2020

2.0 Device information

Trade name: iHealth Infrared No-Touch Forehead Thermometer (model: PT3)
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: Guangzhou Berrcom Medical Device Co., Ltd.
Device: Infrared Thermometer Model MD-H30
510(k) number: K191570

5.0 Indications for Use

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.

6.0 Device description

The iHealth PT3 Infrared No-Touch Forehead Thermometer is hand-held, reusable, battery operated device, which can measure human body forehead 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 time from start of measurement to display of temperature reading is about 1 second. 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.

7.0 Summary comparing technological characteristics with predicate device

Item	Subject Device (K200531)	Predicate Device (K191570)	Comparison
Models	PT3	MD-H30	Different
Product code	FLL	FLL	Same
Regulation number	21 CFR 880.2910	21 CFR 880.2910	Same
Manufacturer	Andon Health Co., Ltd	Guangzhou Berrcom Medical Device Co., Ltd.	Different
Indications for Use	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.	The infrared thermometer is intended for the intermittent measurement of body temperature from the auditory canal or central forehead skin surface on people of all ages. It can be used by consumers in the household environment and by healthcare providers.	Different
Probe contact type	Non-contact; measurement distance: $\leq$ 1.18 in(3 cm)	Skin contacting	Different
Sensor	Thermopile	Thermopile	Same
Measurement method	Infrared radiation detection	Infrared radiation detection	Same
Display type	LED	LCD	Different

Other feature	Vibration when get measurement	Beep when get measurement Probe cover provided	Different
Measuring range	32- 42.9° C (89.6- 109.2° F)	32- 43° C (89.6- 109.4° F)	different
Accuracy	±0.4°F (0.2°C) within 95~107.6°F (35~42°C), ±0.5°F (0.3°C) for other range.	±0.4°F (0.2°C) within 95~107.6°F (35~42°C), ±0.5°F (0.3°C) for other range.	Same
Temperature unit	°C or °F	°C or °F	Same
Display resolution	0.1°F (0.1°C)	0.1°F (0.1°C)	Same
Power requirements	2X1.5V AAA battery	2X1.5V AAA battery	Same
Operation environment Storage environment	15-40° C, 15%-95% RH, 70-106kPa -20-55° C, 10%-95% RH, 70-106kPa	10°C~40°C; ≤95% RH -20~55°C; ≤95%RH	Different,
Materials of skin-contacting components	ABS and PMMA	ABS	Different.
biocompatibility	Comply with ISO 10993-1	Comply with ISO 10993-1	Same

The manufacturer of the subject device is different from the predicate device, so the model is also different, there is slightly difference in the indications for use because the subject device only takes measurement from the forehead while the predicate device takes measurement from both forehead skin and auditory canal. Moreover, the predicate device is skin contacting when taking forehead temperature measurement while the subject device is non-contact device. Both subject and predicate devices detect the infrared radiation from forehead. The software validation, laboratory accuracy test and clinical accuracy test demonstrated the difference does not raise any new performance questions.

The display component of the new device PT3 is changed from LCD to LED, the software validation and performance test demonstrated the difference does not raise any new performance questions.

When measurement completed, the device will vibrate with results displayed on LED, while the predicate will beep when completed measurement. This feature is different, but the software validation demonstrated the difference does not raise any new performance questions.

The subject device is non-contact when taking measurement, which is different from the predicate device, the performance study and clinical accuracy test

demonstrated the difference does not raise any new performance questions.

The Measuring range is different from the predicate device, the performance test and the clinical accuracy test demonstrated the difference does not raise any new performance questions.

The operation temperature range of the proposed device PT3 is narrow than the predicate device, and the storage humidity range of the proposed device PT3 is also narrow than the predicate device, but the performance test demonstrated the difference does not raise any new performance questions.

The material of skin-contacting components is different, the biocompatibility report conforms that there is no new risk for the proposed device.

8.0 Discussion of non-clinical and clinical test performed

Non-clinical tests were conducted to verify that the proposed device meet 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 , 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.

The 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.

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.

Reprocessing: Cleaning and Disinfection

The subject device is a non-sterile device. The cleaning validation was performed according to the Instructions for Use.

Clinical Data Accuracy Validation Test

Clinical investigation and data analysis have performed according to ASTM E1965-98. The test report shows result of 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) are within acceptable range. Based on the test results, it demonstrates the clinical accuracy of $\pm 0.4^{\circ}\text{F}$ (0.2°C) within $95\sim 107.6^{\circ}\text{F}$ ($35\sim 42^{\circ}\text{C}$), and $\pm 0.5^{\circ}\text{F}$ (0.3°C) for other range. 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 above, the subject device i Health PT3 Infrared No-Touch Forehead Thermometer is substantially equivalent to the predicate device .