January 28, 2022

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

Re: K212598
Trade/Device Name: iHealth infrared Ear thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: December 17, 2021
Received: December 29, 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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212598

Device Name
iHealth Infrared Ear Thermometer (PT5)

Indications for Use *(Describe)*

The Infrared Ear thermometer is intended for the intermittent measurement of body temperature from the ear canal on people of all ages except for babies under 3 months. It is suitable for home use and healthcare facilities use.

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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K212598 510(K) SUMMARY

(In accordance with 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, 300190, P.R. China
Phone Number:	86-22-87611660
Fax Number:	86-22-87612379
Contact:	Mr. Liu Yi
Date of Preparation:	November 15, 2021

2.0 Device Information

Device Name:	iHealth PT5 Infrared Ear Thermometer
Common Name:	Infrared Ear Thermometer
Classification Name:	Clinical Electronic Thermometer

3.0 Classification

Product Code:	FLL
Regulation Number:	21 CFR880.2910
Classification:	II
Review Panel:	General Hospital

4.0 Predicate Device Information

Manufacturer:	Kaz USA, Inc.
Device:	Braun Thermoscan® IRT 4000 series and Braun Thermoscan® PRO 4000 series Clinical Infrared Ear Thermometer
510(k) Number:	K103800
Classification	II
Product Code	FLL

5.0 Intended Use

The Infrared Ear thermometer is intended for the intermittent measurement of body temperature from the ear canal on people of all ages except for babies under 3 months. It is suitable for home use and healthcare facilities use.

6.0 Device Description

The iHealth PT5 Infrared Ear Thermometer is a hand-held, reusable, battery operated device, which can measure human body temperature on one's ear canal. Its operation is based on measuring the natural thermal radiation from the ear canal with a built-in correction algorithm to compensate the influence of ambient temperature using a heated tip. Put the probe of the thermometer into a patient's ear canal, after a self-check, 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. It is recommended that adult take the measurement instead when infants and children cannot use the ear thermometer themselves.

7.0 Comparison of Technological Characteristics with Predicate Device

The following table is the summary of the technological characteristics of the proposed subject device and predicate device.

Item	**Subject Device**	**Predicate Device (K103800) Braun Thermoscan® PRO 4000)**	**Comparison Result**
Device name	Infrared Ear Thermometer	Infrared Ear Thermometer	-----
Models	PT5	Braun Thermoscan® IRT 4000 series and Braun Thermoscan® PRO 4000 series Clinical Infrared Ear Thermometer	----
Product code	FLL	FLL	Same
Regulation number	21 CFR 880.2910	21 CFR 880.2910	Same
Manufacturer (legal)	Andon Health Co., Ltd	Kaz, USA Inc	----
Indications for Use	The Infrared Ear thermometer is intended for the intermittent measurement of body temperature from the ear canal on people of all ages except for babies under 3 months. It is suitable for home use and healthcare facilities use.	The Braun Thermoscan® IRT 4000 series and Braun Thermoscan®PRO 4000 series Clinical Infrared Ear Thermometers is indicated for the intermittent measurement and monitoring of human body temperature by consumers of all ages in a home use/professional use environment respectively. The probe cover is used as a	See Note 1.

		sanitary barrier between the infrared thermometer, and the ear canal.	
Sensor	Infrared	Infrared	Same
Measurement method	Infrared radiation detection	Infrared radiation detection	Same
Dimensions	About 138mm×34mm×27mm (5.43in x 1.34in x 2.24in)	150mm x 45 mm x 30 mm	See Note 2
Measurement range	34- 42.9°C (93.2- 109.2°F)	20- 42.2°C	See Note 3
Accuracy for body temperature measurement	±0.4°F (0.2°C) within 93.2~107.6°F (34~42°C), ±0.5°F (0.3°C) for other range.	±0.2℃ within 35.5℃~42℃ ±0.3℃ for other range	See Note 4
Repeatability	<0.3 deg C	<0.3 deg C	Same
Display resolution	0.1℉(0.1℃)	0.1℉(0.1℃)	Same
Operating temperature	Temperature: 10℃-40℃ (50℉-104℉) Humidity: ≤95%RH, non-condensing	10- 42°C ambient and up to 95% RH	See Note 5
Display	LED	LCD	See Note 6
Response Time	≤ 3s	2-3 sec	See Note 7
Signal input	Button, NTC and The thermopile sensor	Button, NTC and The thermopile sensor	Same
Signal output	LED Display, buzzer and probe heating signal	LCD Display, buzzer and probe heating signal	Similar, see note 6
Presence of heating feature	Yes, probe heat function	Yes, probe heat function	Same
Mode of operation	Adjusted mode	Adjusted mode	Same
Reference body Site	Oral	Oral	Same
Power requirements	2X1.5V AAA battery	2X1.5V AA battery or custom rechargeable Nickel Metal Hydride Battery Pack	See Note 8
Materials of construction for patient contacting component	Shell: ABS Key/button: PMMA Protective cover: PP Probe: TPU	Common Materials including an impact resistant casing. Biocompatible metals and resins.	Similar – validated for cytotoxicity per ISO10993-5 and irritation as well as sensitization per ISO 10993-10, See Note 9

Temperature unit	°C or °F	°C or °F	Same
Accessory	Probe cover	Probe cover	Same
Performance	Meets ASTM E 1965, and ISO80601-2-56	Meets ASTM E 1965	All standards verified and validated for test device and met acceptance criteria.
Electrical Safety	Meets IEC 60601-1	Meets IEC 60601-1	Same
EMC	Meets IEC 60601-1-2	Meets IEC 60601-1-2	Same

DISCUSSION OF DIFFERENCES:

Note No	Difference	Justification
1	Indications for Use	The scope of the applicable group of people has been narrowed down to exclude babies under 3 months. The subject device has a narrower intendedpopulation and it will not raise any new or different safety or effectiveness risks.
2	Dimensions	The software validation and clinical accuracy test demonstrated the difference does not raise any new performance questions.
3	Measurement range	The measurement range of the predicate device is different from that of the subject device. The subject device measurement range is 34°C to 42.9°C. Regarding the predicate's clinical measurement range of 34°C to 42.2°C, the accuracy of the subject device and the predicate device are same or even stricter than the predicate device. And the performance test and clinical accuracy test showed that the subject device do not raise any new questions.
4	Accuracy for body temperature measurement	The accuracy of subject device is same or even stricter than that of predicate device. For measurement range of 35.5℃~42℃, the accuracy of the subject device and the predicate device are same, and for 34℃-35.5℃, the accuracy of the subject device is stricter than that of predicate device, and the accuracy of other ranges are same for subject device and predicate device. And based on the testing, the subject device meets ASTM E1965-98, and ISO 80601-2-56 requirements.
5	Operating temperature	Our operating temperature and relative humidity are different from predicate device, but we performed test according to ISO 80601-2-56 and ASTM E1965-98, and it is demonstrated that it is substantially equivalent on performance.
6	Display	Different, the display component of the new device PT5 is changed from LCD to LED, the software validation and performance test demonstrated the difference does not raise any new performance questions.
7	Response Time	Both subject device and the predicate device can get measurement within 3s,

		the software validation showed that the difference does not raise any new performance questions.
8	Power requirements	Power supply of the subject device is different from the predicate device, the electrical safety and EMC test demonstrated the difference does not raise any new performance questions.
9	Materials of construction for patient contacting component	The materials used for subject device and predicate device are similar, and it is validated for cytotoxicity per ISO10993-5 and irritation as well as sensitization per ISO 10993-10, and it is demonstrated that the subject device does not raise any new questions.

8.0 Discussion of Non-Clinical & Clinical Testing

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 tests were 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)].

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.

9.0 Clinical Accuracy Validation Test

Clinical testing have performed according to ASTM F1965-98. The clinical accuracy validation test report included temperature readings of 129 subjects divided into three group age ranges- Infant group (3 months up to 1 year), Children group (1-5 years) and Over 5 years old (＞ 5 years). Based on the result, it is demonstrated the the clinical performance of iHealth PT5 Infrared Ear Thermometer complies with the requirement of ASTM E1965-98 (2016).

10. Comparison to the Predicate Device and Conclusion

The conclusion drawn from the nonclinical tests and clinical test demonstrate that the subject device Infrared Ear Thermometer is very similar with its predicate device in the intended use, design principle, performance and applicable standards. And the tests in this submission demonstrate that the differences compared to the predicate device do not raise any new questions of safety and effectiveness. Therefore, the subject device is substantially equivalent to the legally marketed predicate device (K103800).