January 5, 2021

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

Re: K202791
Trade/Device Name: iHealth Clinical Digital Thermometer (PT1)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: December 4, 2020
Received: December 8, 2020

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,

CAPT Alan M. Stevens
Acting 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)*
K202791

Device Name

iHealth Clinical Digital Thermometer (PT1)

Indications for Use *(Describe)*

The Clinical Digital Thermometer is intended to measure the body temperature oral or axillaries (under the arm) and to be used by consumers in household environments. It is intended for use on adults and children ages 4 and up.

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

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: 86-22-87612379
Contact: Liu Yi
Date of Preparation: 9/18/2020

2.0 Device information

Trade name: iHealth Clinical Digital Thermometer (PT1)
Common name: Clinical Digital 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: Kaz USA, Inc., A Helen of Troy Company
Device: Vicks RapidRead Digital Thermometer
510(k) number: K180131

5.0 Intended use

The Clinical Digital Thermometer is intended to measure the body temperature oral or axillaries (under the arm) and to be used by consumers in household environments. It is intended for use on adults and children ages 4 and up.

6.0 Device description

The iHealth PT1 Clinical Digital Thermometer is hand-held, predictive, thermistor-based, stick thermometer capable of measuring temperature in about 30 seconds. The thermometer uses a negative temperature coefficient thermistor embedded in a measurement tip that is in contact with the measurement site. As the thermistor changes temperature, the resistance of the thermistor also changes, which is measured by the thermometer and converted to a measurement of the temperature of the tip of the thermometer. This temperature, following the use of the predictive algorithm, is then displayed to the end user. Because the thermometer displays the measurement for the physiological site at which it is used, it does not need to convert this temperature via clinical offset.

7.0 Summary comparing technological characteristics with predicate device

Item	Subject Device	Predicate Device (K180131)	Comparison
Device name	iHealth PT1 Clinical Digital Thermometer	Vicks® VDT972 RapidRead™ Digital Thermometer	N/A
Manufacturer (legal)	Andon Health Co., Ltd	Kaz USA, Inc., a Helen of Troy Company	N/A
Contract manufacturer	Andon Medical Co., Ltd	Microlife Corporation	N/A
Thermometer Type	Axillary / Oral, Predictive Digital Thermometer	Axillary / Oral / Rectal, Predictive Digital Thermometer	Different note 1
Models	PT1	Vicks® VDT972 RapidRead™ Digital Thermometer	N/A
510K number	K202791	K180131	N/A
Indications for Use	The Clinical Digital Thermometer is intended to measure the body temperature oral or axillaries (under the arm) and to be used by consumers in household environments. It is intended for use on adults and children ages 4 and up.	The Vicks® VDT972 RapidRead™ Digital Thermometer is a handheld, battery-powered, predictive, digital stick thermometer intended for the intermittent determination of human body temperature orally, rectally, or under the arm, in a home-use environment for people of all ages (infants, children, and adults). It is intended to be	Similar note 2

		used with a single use, disposable probe cover for all measurements.	
User population	Children (ages 4 and up) and adults	Infants, children, and adults	Different note 3
Labeling	Instructions for use, package / box, and rating label	Instructions for use, package / box, and rating label	Similar note 4
Components	On / Off Button, sensor head, microcontroller, & LCD	On / Off Button, Site Selection Button, sensor head, protective cover, microcontroller, & LCD	Different note 5
Sensor	Thermistor	Thermistor	Same
Principles of operation	The thermometer uses a negative temperature coefficient thermistor embedded in a measurement tip that is in contact with the measurement site. As the thermistor changes temperature, the resistance of the thermistor also changes, which is measured by the thermometer and converted to a measurement of the temperature of the tip of the thermometer. This temperature, following the use of the predictive algorithm, is then displayed to the end user. Because the thermometer displays the measurement for the physiological site at which it is used, it does not need to convert this temperature via clinical offset.	The thermometer uses a negative temperature coefficient thermistor embedded in a measurement tip that is in contact with the measurement site. As the thermistor changes temperature, the resistance of the thermistor also changes, which is measured by the thermometer and converted to a measurement of the temperature of the tip of the thermometer. This temperature, following the use of the predictive algorithm, is then displayed to the end user. Because the thermometer displays the measurement for the physiological site at which it is used, it does not need to convert this temperature via clinical offset.	Same
Measurement range	89.6℉-109.4℉（32℃-43℃）	34- 43° C (93.2- 109.4° F)	Different note 6
Accuracy	89.6℉～102.2℉（32℃ -39℃）±0.2℉ 102.3℉～109.4℉（39.1℃ -43℃）±0.3℉	± 0.1°C / 0.2°F within measurement range (34.0°C to 43.0°C /93.2°F to 109.4°F) at room temperature of 71°F	Different note 7
Display resolution	0.1℉(0.1℃)	0.1℉(0.1℃)	Same

Response time	Predictive mode: 30 seconds Monitor mode: 3 minutes	2 to 8 seconds	Different note 8
Signal output and display	LCD, Buzzer	LCD, Buzzer	Same
Operating Environment	temperature: +41°F～+104°F（5°C-40°C） humidity: ≤85% RH	15.0°C to 40.0°C / 59.0°F to 104.0°F; ≤ 95% Relative Humidity	Different note 9
Storage Environment	temperature: -4°F～+131°F（-20°C-55°C） Humidity: ≤95% RH	-25.0°C to 60.0°C / -13.0°F to 140.0°F; ≤ 95% Relative Humidity	Different note 10
Power supply	One 3V CR1632 button	One 3V CR2032 button	Different note 11
Battery life	Approx 1000 measurement for predictive mode About 200 times for other mode	More than 400 measurements or approximately 2 years if used every other day.	Different note 12
Materials	User contacting materials include ABS (shell, battery door and On / Off Button), PET(LCD lens and protective film), PP(probe protective cover and SUS(sensor tip)	User contacting materials include ABS (sensor head, battery door and On / Off Button), TPR (probe and Site Selection Button), PMMA (LCD lens and protective cover), and stainless steel (sensor tip)	Different note 13
Performance	Meets ASTM E1112-00:2011 and ISO 80601-2-56:2017	Meets ASTM E1112-00:2011 and ISO 80601-2-56:2017	Same
Biocompatibility	Meets ISO 10993 and FDA bluebook memo G95-1	Meets ISO 10993 and FDA bluebook memo G95-1	Same
Electrical Safety	Meets IEC 60601-1	Meets IEC 60601-1	Same
EMC	Meets IEC 60601-1-2	Meets IEC 60601-1-2	Same

Note 1: The subject device is not labeled for rectal use. This technological difference does not raise new questions of safety or efficacy.

Note 2: There is a difference in the indication for use because the subject device only takes intermittent measurement of body temperature on children and adults, and no disposable probe cover is provided for all measurements. Testing was not conducted with a probe cover. The software validation and clinical accuracy test demonstrated the difference does not raise any new performance questions.

Note 3: While the user population is different, the clinical accuracy test demonstrated the difference does not raise any new performance questions because it performs effectively in the labeled population of use.

Note 4: The labeling is similar and both of them comply with consensus standards.

Note 5: There is no separate Site Selection Button on the subject device and the on/off button is used as site and mode selection button, which is different from the predicate device. The performance test and software validation demonstrated the difference does not raise any new performance questions.

Note 6: The Measuring range of the subject device is different from the predicate device. The performance test and the clinical accuracy test demonstrated the difference does not raise any new performance questions.

Note 7: The accuracy of the subject device is different from the predicate device. The performance test and the clinical accuracy test demonstrated the difference does not raise any new performance questions, and it is consistent with ISO 80601-2-56.

Note 8: Response time of the subject is different from the predicate device, the clinical accuracy test demonstrated the difference does not raise any new performance questions.

Note 9: The operating environment of the new device PT1 is changed, the performance test demonstrated the difference does not raise any new performance questions.

Note 10: The storage environment of the new device PT1 is changed, the performance test demonstrated the difference does not raise any new performance questions.

Note 11: Power supply and lens filter function 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.

Note 12: Battery life of the new device is different from the predicate device, the electrical safety test, EMC test and performance test demonstrated the difference does not raise any new performance questions.

Note 13: The material contacted is different. The biocompatibility 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 meets all design specifications in order to demonstrate that it is Substantially Equivalent to the predicate device.

Non-clinical Tests

Electrical Safety testing 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 testing 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 testing 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)]. This is the applicable standard 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.

Clinical Accuracy Validation Test

Clinical investigation and data analysis have performed according to ISO 80601-2-56. The test report shows result of 40 subjects in children group (4-5 year) and 70 subjects in adults group (>5 years) (Total 110 subjects) are within acceptable range. Based on the test results, the clinical bias is ≤ 0.03 and the repeatability is ≤ 0.07, which is equivalent to the predicate device.

9.0 Conclusion

Basing on the performance testing, comparison and analysis above, the subject device iHealth PT1 Clinical Digital Thermometer is substantially equivalent to the predicate device.