September 9, 2021

Putian Hanjiang Huafeng Plastic Co., Ltd.
% Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd
Rm. 912, Building #15, XiYueHui, No.5, YiHe North Rd.,
FangShan District
Beijing, 102401
China

Re: K211352
Trade/Device Name: Electronic Thermometer (XHF2001, XHF2002)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: August 6, 2021
Received: August 10, 2021

Dear Ray Wang:

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
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)*
K211352

Device Name
Electronic Thermometer (XHF2001, XHF2002)

Indications for Use *(Describe)*
The Electronic Thermometer (XHF2001, XHF2002) is intended to measure the body temperature under the arm and to be used by consumers in household environments for the people of one month of age and above.

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.

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K211352 - 510(k) Summary

1. Date of Preparation: 09/09/2021

2. Sponsor Identification

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4. Identification of Proposed Device

Trade Name: Electronic Thermometer
Model(s): XHF2001, XHF2002
Common Name: Clinical Electronic Thermometer

Regulatory Information
Classification Name: Clinical electronic thermometer
Classification: Class 2
Product Code: FLL
Regulation Number: CFR 880.2910
Review Panel: General Hospital

5. Identification of Predicate Device(s)
510(k) Number: K202791
Product Name: iHealth Clinical Digital Thermometer

Model Name: PT1
Manufacturer: Andon Health Co., Ltd.

6. Indications For Use Statement:

The Electronic Thermometer (XHF2001, XHF2002) is intended to measure the body temperature under the arm and to be used by consumers in household environments for the people of one month of age and above.

7. Device Description

The Electronic Thermometer is hand-held, predictive, thermistor-based, stick thermometer capable of measuring temperature. 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 Electronic Thermometer comprises a probe which includes a thermistor for getting temperature signal, a buzzer for sounding effect, an build-in software for processing the target temperature digitally, battery compartment with cover, a LCD for displaying the temperature result and indicator information, and a Power (On/Off) switch key.
There are two models of Electronic Thermometer, XHF2001 and XHF2002. The two models share same specification, main components (such as LCD, probe, electric circuit and CPU), the only differences are size and appearance.
The size XHF2001 is 105 x 22 x 12 mm, and the XHF2002 is 125 x 18 x 9.5 mm.

8. Non-Clinical Test Conclusion
The test results demonstrated that the proposed device complies with the following standards:

a. ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
b. IEC 60601-1-2 Edition 4.0 2014-02, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests.
c. ISO 80601-2-56 Second edition 2017-03 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)].
d. ASTM E1112-00 (R2011) Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature
e. ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
f. ISO 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

The software verification and validation were conducted in accordance with the "Guidance for the

Content of Premarket Submissions for Software Contained in Medical Devices," dated May 11, 2005. The test results demonstrated the software function met the requirements.

9. Clinical Test Conclusion

Controlled human clinical studies were conducted on proposed device with predicates in accordance with ISO 80601-2-56, clinical bias, clinical consistency and clinical repeatability have been evaluated per clinical validation for the thermometer.

Total 110 subjects and three age groups, including age 1 month - 1 year (35 subjects), age 1~5 years (35 subjects) and age above 5 years (40 subjects) are included in each clinical study, including febrile and afebrile persons. Compared statistical result of clinical bias and clinical repeatability of two comparison groups, the results of proposed device meet the performance parameters claimed in user manual, and the proposed device complies with ISO 80601-2-56.

10. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	Proposed Device (K211352)	Predicate Device (K202791)	Remark
Device name	Electronic Thermometer (XHF2001, XHF2002)	iHealth Clinical Digital Thermometer PT1	/
Indications For Use	The Electronic Thermometer (XHF2001, XHF2002) is intended to measure the body temperature under the arm and to be used by consumers in household environments for the people of one month of age and above.	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.	Similar (Analysis 1)
Principle 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.	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.	SAME
Measurement Site	Axillary	Oral and Axillary	Similar (Analysis 2)
Main Components	On/Off Button, Sensor, Microcontroller, LCD	On/Off Button, Sensor, Microcontroller, LCD	SAME
Sensor	Thermistor	Thermistor	SAME
Measurement Range	32℃～42.9℃ (89.6℉～109.22℉)	32℃～43℃ (89.6℉～109.46℉)	Similar (Analysis 3)

Accuracy	32 ～ 36.9℃±0.2℃(89.6℉～98.42℉) 37 ～ 39℃±0.1℃(98.6℉～102.2℉) 39.1 ～ 42.9℃±0.2℃(102.38℉～109.22℉)	89.6℉～102.2℉（32℃-39℃）±0.2℉ 102.3℉～109.4℉（39.1℃-43℃）±0.3℉	Different (Analysis 4)
Display Resolution	0.1℉(0.1℃)	0.1℉(0.1℃)	SAME
Signal output and display	LCD, Buzzer	LCD, Buzzer	SAME
Operating Environment	Temperature: +41℉～+104℉（5℃-40℃） Humidity: 15-95%RH	Temperature: +41℉～+104℉（5℃-40℃） Humidity: ≤85%RH	Similar (Analysis 5)
Storage Environment	Temperature: -4℉～+140℉（-20℃-60℃） Humidity: ≤85%RH	Temperature: -4℉～+131℉（-20℃-55℃） Humidity: ≤95%RH	Similar (Analysis 6)
Power Supply	One 1.5V LR41 button	One 3V CR1632 button	Different (Analysis 7)
Measuring Time	32 seconds	30 seconds	Similar (Analysis 8)
Patient Contacting Materials	ABS + Stainless Steel	ABS, PET, PP and SUS	Different (Analysis 9)
Biocompatibility	ISO10993-5&ISO10993-10	ISO10993-5&ISO10993-10	SAME
Electrical Safety	IEC60601-1	IEC60601-1	SAME
EMC	IEC60601-1-2	IEC60601-1-2	SAME
Performance	ISO 80601-2-56 ASTM E1112	ISO 80601-2-56 ASTM E1112	SAME

Difference & Similar Analysis

Analysis 1

There is a minor difference in the indications for use because the proposed device is used for the people of one month of age and above, we have conducted the clinical accuracy testing in accordance with ISO 80601-2-56, the clinical bias, clinical consistency and clinical comply with the standard. We believe the differences

do not raise new or different performance questions.

Analysis 2

The measurement site of the subject device and predicate is different. The measurement site of the subject device is subset of the predicate device. We have conducted the clinical accuracy testing in accordance with ISO 80601-2-56, the clinical bias, clinical consistency and clinical repeatability comply with the standard. We believe the differences do not raise new or different performance questions.

Analysis 3

The measuring range of proposed device is similar with the predicate device. The performance testing and clinical accuracy testing conducted demonstrated the difference does not raise any new performance concerns. It complies with ISO 80601-2-56.

Analysis 4

The accuracy of the proposed device is different from the predicate device. The performance testing and the clinical accuracy testing were conducted to demonstrate the difference does not raise any new performance concerns, and it is consistent with ISO 80601-2-56.

Analysis 5

The operating environment of the proposed device is different from the predicate device. The performance test demonstrated the difference does not raise any new performance concerns.

Analysis 6

The storage environment of the proposed device is different from the predicate device. The performance test demonstrated the difference does not raise any new performance concerns.

Analysis 7

The Power supply of the proposed device is different from the predicate device. The electrical safety and EMC test were conducted to demonstrate the difference does not raise any new performance or safety concerns.

Analysis 8

The Measuring Time of the proposed device is similar with the predicate device, the difference between them is minor, and this specification has been validated by the testing per ISO 80601-2-56. The difference does not raise any new performance or safety concerns.

Analysis 9

The Patient Contacting materials of the proposed device is different from the predicate device. The biocompatibility tests were conducted in accordance with ISO 10993 series to demonstrate the difference does not raise any new performance or safety concerns.

11. Substantially Equivalent (SE) Conclusion

The differences between the predicate and the subject device do not raise any new or different questions of safety and effectiveness. Based on the safety and performance testing and compliance with voluntary standards, we believe that the Electronic Thermometer (XHF2001, XHF2002) is substantially equivalent to the predicate device (K202791).