December 18, 2020

HuBDIC Co., Ltd.
% Peter Chung
President
Plus Global
300 Atwood
Pittsburgh, Pennsylvania 15213

Re: K191978
Trade/Device Name: Fever Garde, Model: HMT-100
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: November 16, 2020
Received: November 16, 2020

Dear Peter Chung:

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 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)*
K191978

Device Name
Fever Garde, Model: HMT-100

Indications for Use *(Describe)*
The Bluetooth Wearable Thermometer, model HMT-100 is a battery-operated electronic device with an intended use of measuring human armpit temperature and transmitting wireless signal of the measuring results to a mobile device, monitoring armpit body temperature for home use.
This product is a non-invasive and re-usable electronic device for multiple patients at home.
This product is intended for non-urgent ambulatory continuous armpit body temperature monitoring from ages 29 days and older.

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

510(k) Summary

K191978

[as required by 807.92(c)]

1. Applicant

1) Company : HuBDIC Co., Ltd.
2) Address : 301, 53, jeonpa-ro, Manan-gu, Anyang-si, Gyeonggi-do Korea, 14084
3) Tel : +82-31-441-8637
4) Fax : +82-31-442-4994
5) Contact person : Peter Chung, 412-512-8802
6) Contact person address : 300, Atwood Street, Pittsburgh, PA, 15213, USA
7) Date Prepared: December. 08, 2020

2. Device Information

1) Trade Name: Fever Garde, Model HMT-100
2) Common Name : Bluetooth Wearable Thermometer
3) Classification Name : Clinical Electronic Thermometer
4) Product Code : FLL
5) RegulationNumber: 21 CFR 880.2910
6) Class of device: Class II
7) Panel : General Hospital

3. The legally marketed device to which we are claiming equivalence:

K181013, Fever Scout™Continuous Monitoring Thermometer

4. Device description :

The Bluetooth Wearable Thermometer is a contact electronic thermometer using a sensor to measure armpit temperature. The Sensor detects heat and measures the temperature using a resistance that changes with heat. Displays the highest temperature among consecutive temeprature readings. Its software performs a calculation that factors in room temperature, and then a calculated temperature is displayed on the mobile device.

This product is in conjunction with the App, and information can be checked through a mobile device.

Application Name: H-Health

The control unit transmits the measurement data to the application wirelessly through the antenna at intervals of 20 seconds. The application displays the corresponding data on a mobile device. In addition, the application alerts the user by sound or vibration when the temperature is below the user-set minimum temperature or above the maximum temperature.

5. Indications for Use:

The Bluetooth Wearable Thermometer, model HMT-100 is a battery-operated electronic device with an intended use of measuring human armpit temperature and transmitting wireless signal of the measuring results to a mobile device, monitoring armpit body temperature for home use. This product is a non-invasive and re-usable electronic device for multiple patients at home. This product is intended for non-urgent ambulatory continuous armpit body temperature monitoring from ages 29 days and older.

6. Comparison of technological characteristics with the predicate device

The comparison of features and operation principles between the subject device Fever Garde (HMT-100) and predicate device Fever Scout™Continuous Monitoring Thermometer is listed as follows:

Proprietary	Subject Device	Predicate Device Fever Scout™Continuous Monitoring Thermometer	Substantially Equivalent or Not Substantially Equivalent
510(k) Number	K191978	K181013	N/A
Common Name	Bluetooth Wearable thermometer	Armpit thermometer	N/A
Trade Name	Fever Garde, Model HMT-100	Fever Scout™Continuous Monitoring Thermometer	N/A
Manufacturer	HuBDIC Co., Ltd.	VivaLNK Inc.	N/A
Product Classification	II	II	Same
Indications for use	The Bluetooth Wearable Thermometer, model HMT-100 is a battery-operated electronic device with an intended use of measuring human armpit temperature and transmitting wireless signal of the measuring results to a mobile device, monitoring armpit body temperature for home use. This product is a non-invasive and re-usable electronic device for multiple patients at home. This product is intended for non-urgent ambulatory continuous armpit body temperature monitoring from ages 29 days and older.	The wireless Fever Scout Continuous Monitoring thermometer is a non-invasive and re-usable electronic device for home use. This product in intended for non-urgent ambulatory continuous armpit body temperature monitoring from ages 29 days and older	Similar 1
Display Use Specification	Apple device and Android device display	Apple device and Android device display	Same
Working Voltage	3.7 V DC	3.0 V DC	Different 1
Battery	Lithium-polymer Rechargeable Battery 3.7V	MS Lithium Rechargeable Battery 3.0V	Different 2
Measurement Range	34~42℃	35~42℃	Similar 2
Accuracy	±0.1℃	±0.1℃ From 37~39℃ ±0.2℃ From 35~37℃ and 39~42℃	Same
Signal Transmission	Wireless 2.4G Bluetooth BLE	Wireless 2.4G Bluetooth BLE	Same
Contact area	Skin(Surface device)	Skin(Surface device)	Same

Contact duration	A-Limited(<24hours)	A-Limited(<24hours)	Same
Receiver	Bluetooth: 4.2+/ IOS system: IOS 8.0 +/ Android system: 5.0(lollipop)+)	Wireless 2.4G Bluetooth BLE enabled smart devices running Apple devices: iPhone 5S+ or later, and iOS 8.0 or later, and Android device: 4.3 or later.	Different 3
Anatomical Application	Axillary(armpit) temperature measuring and monitoring	Axillary(armpit) temperature measuring and monitoring	Same
Principle of operation	The Sensor detects heat and measures the temperature using a resistance that changes with heat. Displays the highest temperature among consecutive temeprature readings.	The Sensor detects heat and measures the temperature using a resistance that changes with heat. Displays the highest temperature among consecutive temeprature readings.	Same
Re-useable Band	Re-useable Band	Re-useable Band	Same
Device major components	Contact Skin Band	Contact Skin Band	Same
Patient contain materials	Silicone and Acrylate	Silicone and Acrylate	Same
Specification including operation environment temperature and humidity level	10~40℃/15~90%	10~40℃/15~85%	Different 4
Transmission distance	3~5m	4.9ft	Different 5
Response time	170 Seconds	8 minutes	Different 6
Biocompatibility	Conformed to ISO 10993-1, ISO10993-5,and ISO10993-10	Conformed to ISO 10993-1, ISO 10993-5, and ISO 10993-10	Same
Electrical Safety	Conformed to IEC 60601-1	Conformed to IEC 60601-1	Same
Electromagnetic Compatibility	Conformed to IEC 60601-1-2	Conformed to IEC 60601-1-2	Same

• Similar 1

The indications for use of the subject device Fever Garde, Model HMT- 100 is similar to the predicate device. Both subject device and predicate contain characteristics of data transferring, battery-operated and home use. The indications for use of the subject device includes these characteristics but not described in the predicate device. The difference does not affect safety and effectiveness.

• Similar 2

The measuring range of the subject device and the predicate device is similar. The measuring range of the subject device is 1℃ wider that complies with performance standard. It does not affect safety and effectiveness.

• Different 1

The rated voltage is 0.7V higher than the predicate device, but the IEC60601-1 electric sfety test was conducted, and it does not affect safety and effectiveness.

• Different 2

Although the battery specifications are different, the subject device has passed the IEC60601-1 test and it does not affect safety and effectiveness.

• Different 3

Reciever's specifications are different, the subject passed the test according to EN 300 328 and EN 62479 standards, and it does not affect safety and effectiveness.

• Different 4:

The operating temperature is the same, but the operating humidity is different. The operating humidity range of the subject device is wider than the predicate device. The performance test was conducted within the operating environment for the subject device. The difference does not affect safety and effectiveness.

• Different 5:

The monitoring distance of the subject device is longer than the predicate device. The subject device passed the test according to the standards of EN 300 328 and EN 62479, and it does not affect safety and effectiveness.

• Different 6:

The response time of the subject device is shorter than the predicate. The subject device has been tested for response time according to IEC60601-1. The difference does not affect safety and effectiveness.

7. Non-Clinical Testing

No.	Test Identification	Test method	
		Test Criteria	Test result
1	Evaluation and Testing	ISO 10993-1: Evaluation and testing	Pass
2	Cytotoxicity MEM Elution Method (Cytotoxicity)	ISO 10993-5: Tests for Cytotoxicity, in vitro Methods	
		Cytotoxicity: 0 Interpretation: Noncytotoxic	Not cytotoxic (Pass)
3	Sensitization	ISO 10993-10: Test for Irritation and sensitization 6.2 Maximization sensitization test	
		Grading scale: 0 Patch test reaction: No visible change	No evidence (Pass)
4	Acute Intracutaneous Reactivity	ISO 10993-10: Test for Irritation and sensitization 5.4 Intracutaneous reactivity test	
		The requirements of the test are met If the difference between the test sample and the vehicle blank mean score is 1.0 or less	No evidence (Pass)

- IEC60601-1 Medical electrical equipment Part1: General requirements for safety and essential performance

- IEC60601-1 Medical electrical equipment Part1-6 – General requirements for safety and essential performance – Collateral Standard: Usability

- IEC60601-1 Medical electrical equipment Part1-11 - General requirements for safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

- ISO80601-2-56 Medical electrical equipment – Part2-56: Particular requirements for basic safety

and essential performance of clinical thermometers for body temperature measurement

- IEC60601-1-2 Medical electrical equipment General requirements for basic safety and essential performance collateral standard Electromagnetic compatibility Requirements and tests

No.	Title	Results summary
1	Display	Measured value displayed
2	Charging operation	Device not operating
3	Communication failure	Notification indicated
4	Temperature notification	High and Low indication displayed
5	Internal battery status	Internal battery status displayed
6	Laboratory Accuracy	Rated Output Range: 34~42°C Equation(0.1°C)
7	Time Response-heating transient time	171.3 Seconds
8	Time Response –cooling transient time	113.8 Seconds
9	Movement test	
9-1	Before the test	Within 30s without moving the sample, H-Health application alarm sounded
9-2	During the test	While the sample was moving, H-Health application alarm not sounded
9-3	After the test	Within 30s without moving the sample, H-Health application alarm sounded
10	Adhesion Test	The product was attached to the armpit with an adhesive band for 24 hours and checked to ensure that it did not fall.
11	Monitoring Distance Test	After moving the product and mobile device to a distance of 3m, it was confirmed that the connection was not disconnected for 24 hours, and the product and mobile device were not disconnected for all participants.
12	Data Transfer Test	After attaching the product, it was checked the body temperature data was transmitted to all participants.

Software Verification and Validation Testing

Software verification and validation testing were conducted in accordance with FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software of the subject device was considered as a "moderate" level of concern.

Cybersecurity Testing

Cybersecurity testing was performed for the subject device. This testing confirmed that appropriate information security controls are implemented to preserve the integrity, confidentiality, and availability of its information based on considerations of FDA's Guidance for Industry and FDA Staff, "Guidance for Industry and Food and Drug Administration Staff: Content of Premarket Submissions for Management of Cybersecurity in Medical Devices".

8. Conclusion:

Based on the performance testing, comparison, and analysis, the subject is substantially equivalent to the predicate device.