February 7, 2025

Hetaida Technology Co., Ltd.
Tom Chen
General Manager
Rm 801, 802, 803, 804, 901, 2# Bldg Scientific Research Ctr
Songhu Intelligent Valley, No.6 Minfu Road, Liaobu Town
Dongguan City, Guangdong 523423
China

Re: K243661
Trade/Device Name: Electronic Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: January 13, 2025
Received: January 13, 2025

Dear Tom Chen:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Robert T. Kazmierski -S

for

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243661

Device Name

Electronic Blood Pressure Monitor

Indications for Use *(Describe)*

This product is intended to measure systolic and diastolic blood pressure and pulse on upper arm of population over 12 years old in household or medical facilities. (Not suitable for neonate, pregnancy or pre-eclampsia).

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

[As required by 21 CFR 807.92]

1. Submission Information

510(k) Number:	K243661
Date:	November 26th, 2024
Type of 510(k) Submission:	Special 510(k)
Submitter/Manufacturer:	Hetaida Technology Co., Ltd. Room 801, 802, 803, 804, 901, 2# Building Scientific Research Center, Songhu Intelligent Valley, No.6 Minfu Road, Liaobu Town, Dongguan City, Guangdong Province, P.R.China Tel: +86-0769-83326886 E-mail: tomchen@hetaida.com.cn
Contactor:	Tom Chen Hetaida Technology Co., Ltd. Room 801, 802, 803, 804, 901, 2# Building Scientific Research Center, Songhu Intelligent Valley, No.6 Minfu Road, Liaobu Town, Dongguan City, Guangdong Province, P.R.China E-mail: tomchen@hetaida.com.cn Tel: +86-0769-83326886

2. Device Description

Proprietary Name:	Electronic Blood Pressure Monitor
Model Name:	D6606US, D6607US
Classification Name:	Noninvasive Blood Pressure Measurement System
Product Code:	DXN
Device Class:	2
Regulation Number:	21 CFR § 870.1130
Review Panel:	Cardiovascular
Indications for use:	This product is intended to measure systolic and diastolic blood pressure and pulse on upper arm of population over 12 years old in household or medical facilities. (Not suitable for neonate, pregnancy or pre-eclampsia).
Device Description:	Electronic blood pressure monitor is a Noninvasive Blood Pressure Measurement System that is intended to measure blood pressure through oscillation mensuration. The proposed device will automatically start to take measurements after the inflation of the cuff is finished, the results will show the systolic pressure and diastolic pressure with pulse rate. The blood pressure monitor will store the measurements automatically; The record may be revisited. It measures blood pressure and pulse rate through inflating cuff which rounding the upper arm of patients. The electronic blood pressure monitor is small, portable and used in home or medical facilities environment. It consists of two parts: main unit and cuffs. The electronic blood pressure monitor is composed of PCBA, crystal oscillator, pump, valve, enclose, and LCD. Cuffs including cuff of size 22cm~32cm and cuff of size 22cm~42cm.

3. Predicate Device Identification

510(k) Number:	K223170
Product Name:	Electronic Blood Pressure Monitor
Model Name:	HTD6602US
Submitter:	Hetaida Technology Co., Ltd.

4. Substantially Equivalent Comparison

Parameters		Subject Device	Predicate Device	Remark
1.	510(k) Number:	K243661	K223170	--
2.	Marketing clearance date	Applying	December 5, 2023	--
3.	Device Name	Electronic Blood Pressure Monitor	Electronic Blood Pressure Monitor	--
4.	Model	D6606US, D6607US	HTD6602US	--
5.	510(k) Owner	Hetaida Technology Co., Ltd.	Hetaida Technology Co., Ltd.	Same
6.	Classification	Class II Device, DXN (21 CFR § 870.1130)	Class II Device, DXN (21 CFR § 870.1130)	Same
7.	Classification Panel	Cardiovascular	Cardiovascular	Same
8.	Type of use	Over-The-Counter Use	Over-The-Counter Use	Same
9.	Indications for Use	This product is intended to measure systolic and diastolic blood pressure and pulse on upper arm of population over 12 years old in household or medical facilities. (Not suitable for neonate, pregnancy or pre-eclampsia).	This product is intended to measure systolic and diastolic blood pressure and pulse on upper arm of population over 12 years old in household or medical facilities. (Not suitable for neonate, pregnancy or pre-eclampsia).	Same
10.	Patient Population	Population over 12 years old	Population over 12 years old	Same
11.	Intended Environment	Home or medical facilities	Home or medical facilities	Same
12.	Design	Table type	Table type	Same
13.	Design Method	Oscillometric	Oscillometric	Same
14.	Measurement Site	Upper Arm	Upper Arm	Same
15.	Cuff Circumference	22cm~32cm; 22cm~42cm.	22cm~32cm; 22cm~42cm.	Same
16.	Inflation Method	Automatic by electronic pump	Automatic by electronic pump	Same
17.	Deflation Method	Automatic Pressure Release Valve	Automatic Pressure Release Valve	Same
18.	Display	Backlight LCD Digital Display	Backlight LCD Digital Display	Same
19.	Memory Size	Two users, 2 × 99 groups	180 groups	Different Note 1
20.	Blood Pressure Indication Range	DIA: 30 mmHg~195mmHg SYS: 60 mmHg~255mmHg	DIA: 30 mmHg~195mmHg SYS: 60 mmHg~255mmHg	Same
21.	Measurement Pressure Range	0~299mmHg (0~39.9kPa)	0~299mmHg (0~39.9kPa)	Same
22.	Range Accuracy	±3mmHg (±0.4kPa)	±3mmHg (±0.4kPa)	Same
23.	Measurement Pulse Range	40~180 beats/min	40~180 beats/min	Same
24.	Pulse Accuracy	±5% of reading value	±5% of reading value	Same
25.	Pressurization Source	Automatic Internal Pump	Automatic Internal Pump	Same
26.	Pressure Sensor	Semiconductor Pressure Sensor	Semiconductor Pressure Sensor	Same
27.	Operating Environment	Ambient temperature: +5ºC ~+40ºC Relative humidity (RH): ≤85% Atmospheric pressure: 800hPa~1050hPa	Ambient temperature: +5ºC ~+40ºC Relative humidity (RH): ≤85% Atmospheric pressure: 800hPa~1050hPa	Same
28.	Storage Environment	Ambient temperature: -20ºC~+55ºC Relative humidity (RH): 10%~93% Atmospheric pressure: 800hPa~1050hPa	Ambient temperature: -20ºC~+55ºC Relative humidity (RH): 10%~93% Atmospheric pressure: 800hPa~1050hPa	Same

29.	Energy Source	Internal power supply DC 6V (4X1.5V (AA) Alkaline battery/ IEC Type LR06); External power supply: USB interface DC 5V 1A	Internal power supply DC 6V (4X1.5V (AA) Alkaline battery/ IEC Type LR06); External power supply: USB interface DC 5V 1A	Same
30.	Display Content	1, User 1 icon, User 2 icon 2, Over pressure Alarm 3, Low battery symbol 4, Unit mmHg 5, WHO (icon) 6, Pulse Rate 7, Unit kPa 8, Memory 9, Average of last 3 measurements 10, Pulse signal 11, Body movement 12, Cuff inflation abnormal 13, Irregular pulse icon 14, Diastolic pressure 15, Systolic pressure 16. Memory group 17. Voice on/off icon	1. User Group 2. Over pressure Alarm 3. Low battery symbol 4. Unit mmHg 5. WHO (icon) 6. Pulse Rate (Measuring mode), Memory group (Memory mode) 7. Unit kPa 8. Memory 9. Average of last 3 measurements 10. Pulse signal 11. Body movement 12. Cuff inflation abnormal 13. Pulse Rate (Memory mode) 14. Diastolic pressure 15. Systolic pressure	Different Note 2
31.	Controls	Set button Start/Stop button Memory button	Set button Start/Stop button Memory button	Same
32.	Performance	ISO 81060-2 IEC 80601-2-30	ISO 81060-2 IEC 80601-2-30	Same
33.	Biocompatibility	ISO 10993-1, FDA Guidance, Tests included Cytotoxicity, Sensitization and Intracutaneous Reactivity	ISO 10993-1, FDA Guidance, Tests included Cytotoxicity, Sensitization and Intracutaneous Reactivity	Same
34.	Electrical Safety	IEC60601-1	IEC60601-1	Same
35.	EMC	IEC60601-1-2	IEC60601-1-2	Same
36.	Usability	IEC 60601-1-6	IEC 60601-1-6	Same
37.	Home Use	IEC 60601-1-11	IEC 60601-1-11	Same
38.	Material of Patient contact components	Bottom Cover: ABS757 Battery door: ABS757 Window cover: PMMA Female connector: ABS757 Start/Stop button: ABS757 Set button: ABS757 Memory button: ABS757 Cuff connector: ABS757 Cuff: 1. cuff: Two layers of 210D raw silk cloth; 2.air bag: PVC; 3.Velcro: nylon; 4.Ring: metal; 5.air tube: PVC.	Top Cover: ABS757 Bottom Cover: ABS757 Battery door: ABS757 Window cover: PMMA Female connector: ABS757 Start/Stop button: ABS757 Set button: ABS757 Memory button: ABS757 Decoration ring(button): ABS757 Cuff connector: ABS757 Cuff: 1. cuff: Two layers of 420Dl Polyester; 2.air bag: PVC; 3.Velcro: nylon; 4.Ring: metal; 5.air tube: PVC.	Different Note 3
39.	Patient Interface	Cuff, button	Cuff, button	Same
40.	Dimensions	116mm×110mm×50mm (Length×Width×Height)	141mm×106mm×70mm (Length×Width×Height)	Different Note 4
41.	Weight	Approximate 278g. (Without battery)	Approximate 323g. (Without battery)	Different Note 5
42.	Principle of operation	Oscillometric Measuring method	Oscillometric Measuring method	Same
43.	Software	Embedded	Embedded	Same

The discussion of differences exist between the subject device and predicate devices is listed as follows:

Note 1: The Memory Size of subject device is different with predicate device HTD6602US (K223170) will not affect the safety and effectiveness.

Note 2: The Display Content between subject device and predicate device is that excluding the same parts, the Display Content of subject device additionally includes “User 1 icon, User 2 icon, Irregular pulse icon, Voice on/off icon” which are not included by predicate device, since the subject device meets the requirements of IEC 80601-2-30:2018, therefore, the difference of subject device with predicate device HTD6602US (K223170) will not affect the safety and effectiveness.

Note 3: The Material of Patient contact components of subject device is same as predicate device, only the cuff has changed the cuff fabric, and the cuff has been validated for Cytotoxicity though testing against ISO 10993- 5, for Sensitization and Irritation though testing against ISO 10993-10 tested, and all test results are positive, the difference of subject device with predicate device HTD6602US (K223170) do not raise new questions of safety and effectiveness.

Note 4: The Dimensions of subject device is different with predicate device HTD6602US (K223170) will not affect the safety and effectiveness.

Note 5: The Weight of subject device is different with predicate device HTD6602US (K223170) will not affect the safety and effectiveness.

5. Discussion of Non-Clinical Tests Performed are as follows:

To demonstrate safety and effectiveness of Electronic Blood Pressure Monitor: D6606US, D6607US and to show substantial equivalence to the predicate device, Hetaida Technology Co., Ltd completed the following non-clinical tests. Results confirm that the design inputs, acceptance criteria for the device are met. The device passed the testing in accordance with internal requirements, national standards, and international standards shown below, supporting its safety and effectiveness, and its substantial equivalence to the predicate device:

- ANSI AAMI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012+A2:2021 (Cons. Text) [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)];
- ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021] Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests [Including Amendment 1 (2021)];
- ANSI AAMI HA60601-1-11:2015 [Including AMD1:2021] Medical Electrical Equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral Standard: Requirements for medical electrical equipment and medical electrical equipment and medical electrical systems used in the home healthcare environment (IEC 60601-1-11:2015 MOD) [Including Amendment1 (2021)];
- IEC 60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems;
- IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability;
- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes;
- IEC 80601-2-30: Edition 2.0 2018-03 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers;

- ISO 10993-5 Third Edition 2009-06-01, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 Third Edition 2010-08-01, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization,

6. Discussion of Clinical Accuracy Testing Performed

The subject device has the same specification as predicated device HTD6602US (K223170), including: intended use, method of measurement, measure type, critical components (ex. Air pump, sensor, cuff…) and algorithm etc., so clinical study results can be transferred from the predicated device HTD6602US (K223170) to the subject device.

In ISO 81060-2 Third edition 2018-11 [Including: Amendment 1 (2020)] Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type, all the relevant activities were performed by designate individual(s) and the results demonstrated that the predetermined acceptance criteria were fully met. Therefore, repeated clinical testing in accordance with the standard ISO 81060-2 Third edition 2018-11 [Including: Amendment 1 (2020)] for subject device is not warranted.

7. Conclusion

The subject device has the same indication for use as the predicate device as well as technical characteristics, and the minor differences do not raise new or different questions of safety and effectiveness, as determined through a risk assessment and well-established test methods. The D6606US and D6607US of subject device are same, only the model number is different. Therefore, the subject device is substantially equivalent to the predicate device.