December 5, 2023

HeTaiDa Technology Co., Ltd.
% You Yijie
Manager
Qimmiq Medical Consulting Service Co., Ltd.
RM.406, Building C, Run Science Park, No.18 Shenzhou Road,
Huangpu, Guangzhou, Guangdong 510663
China

Re: K223170
Trade/Device Name: Electronic Blood Pressure Monitor, model: HTD6602US
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: November 14, 2023
Received: November 14, 2023

Dear You Yijie:

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.

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,

Stephen C. Browning -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223170

Device Name
Electronic Blood Pressure Monitor, model: HTD6602US

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.

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Section 5: 510(k) Summary

510(k) Number: **K223170**

1. Submitter's Information

Establishment Registration Information

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Establishment registration number: 3017493034

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Date prepared: 11/15/2022

2. Device Information

Device Common Name: Noninvasive Blood Pressure Measurement System

Trade Name: Electronic blood pressure monitor

Model: HTD6602US

Classification name: Noninvasive Blood Pressure Measurement System

Review panel: Cardiovascular

Product code: DXN

Regulation Class: II
Regulation Number: 870.1130

3. Predicate Device Information

510(k) submitter/holder:	Jiangsu Yuyue Medical Equipment & Supply Co., Ltd.
510(K) Number:	K200939
Trade Name:	Electronic blood pressure monitor
Model:	YE680B
Classification name:	Noninvasive Blood Pressure Measurement System
Review panel:	Cardiovascular
Product code:	DXN
Regulation Class:	II
Regulation Number:	870.1130

4. Device description

Electronic blood pressure monitor, model: HTD6602US is a Noninvasive Blood Pressure Measurement System that is intended to measuring 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 maybe revisited.

It measures blood pressure and pulse rate through inflating cuff which rounding the upper arm of patients. The HTD6602US is small, portable and used in home or medical facilities environment. The Electronic blood pressure monitor consists of two parts: main unit and cuffs. The HTD6602US is composed of PCBA, crystal oscillator, pump, valve, enclose, and LCD. Cuffs including cuff of size 22cm~32cm and cuff of size 22cm~42cm.

Principle of operation:

This product uses the Oscillometric Measuring method to detect blood pressure. When the cuff is fully inflated to reach a pressure above systolic pressure, no blood flow occurs through the artery. As the cuff is deflated below the systolic pressure, the reducing pressure exerted on the artery allows blood to flow through it and sets up a detectable vibration in the arterial wall. When the cuff pressure falls below the patient's diastolic pressure, blood flows smoothly through the artery in the usual pulses, without any vibration being set up in the wall. Vibrations occur at any point where the cuff pressure is sufficiently high that the blood has to push the arterial wall open in order to flow through the artery. The vibrations are transferred from the arterial wall, through the air inside the cuff, into a transducer in the monitor that converts the measurements into electrical signals. Hence when it starts inflating the arm cuff, meanwhile, the unit detects pressure oscillations

generated by beat-to-beat pulsatile, which is used to determine the systolic and diastolic pressure, and pulse rate.

5. 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).

6. Summary of technological characteristics of device compared to the predicate devices (K200939)

SE Comparisons	Subject device (Electronic blood pressure monitor, model: HTD6602US)	Predicate device (Electronic blood pressure monitor, Model: YE680B)	Discussion of difference
510K Number	**K223170**	**K200939**	**/**
Model	HTD6602US	YE680B	**/**
Classification	21CFR 870.1130	21CFR 870.1130	**Same**
Product Code	DXN	DXN	**Same**
FDA Class	II	II	**Same**
Indications for Use	This product is intended to measure systolic and diastolic blood pressure and pulse on upper arm.	This product is intended to measure systolic and diastolic blood pressure and pulse on upper arm	**Same**
Patient Population	population over 12 years old	Adult	**Different** (Discussion is indicated in D1)
Environment of Use	Home or medical facilities	Home or medical facilities	**Same**
Design	table type	table type	**Same**
Design Method	Oscillometric	Oscillometric	**Same**
Measurement Site	Upper Arm	Upper Arm	**Same**
Cuff Circumference	22cm~32cm; 22cm~42cm.	22cm~32cm; 22~45cm.	**Different** (Discussion is indicated in D2)
Inflation Method	Inflation Method	Inflation Method	**Same**
Deflation Method	Automatic Pressure Release Valve	Automatic Pressure Release Valve	**Same**
Display	Backlight LCD Digital Display	Backlight LCD Digital Display	**Same**
Memory Size	180 groups	Up to 99x2 sets of data	**Different** (Discussion is indicated in D3)
Blood Pressure Indication Range	DIA: 30 mmHg~195mmHg SYS: 60 mmHg~255mmHg	Diastolic:20~210 mmHg Systolic:40~260 mmHg	**Different** (Discussion is indicated in D4)

Measurement Pressure Range	0~299mmHg (0~39.9kPa)	0 ~ 300 mmHg (0 kPa ~ 40 kPa)	**Same**
Range Accuracy	±3 mmHg (±0.4kPa)	±3 mmHg (±0.4kPa)	**Same**
Measurement Pulse Range	40~180 beats/min	40 ~ 200 beats/min	**Different** (Discussion is indicated in D5)
Pulse Accuracy	±5% of reading value	±5% of reading value	**Same**
Pressurization Source	Automatic Internal Pump	Automatic Internal Pump	**Same**
Pressure Sensor	Semiconductor Pressure Sensor	Semiconductor Pressure Sensor	**Same**
Operating Environment	Ambient temperature: +5℃~ +40℃ Relative humidity (RH): ≤85% Atmospheric pressure: 800 hPa~1050 hPa	Temperature: +5ºC ~ +40 ºC Humidity: 15% RH ~ 90% RH (no condensation)	**Different** (Discussion is indicated in D6)
Storage Environment	Ambient temperature: -20℃~+55℃ Relative humidity (RH): 10%~93% Atmospheric pressure: 800 hPa~1050 hPa	Temperature: -20 ºC ~ +55 ºC Humidity: 15% RH ~ 90% RH (no condensation)	**Different** (Discussion is indicated in D7)
Energy Source	Internal power supply DC 6V (4X1.5V (AA) Alkaline battery/ IEC Type LR06); External power supply: USB interface DC 5V 1A	4 AA batteries or 6V/600mA AC adapter	**Different** (Discussion is indicated in D8)
Display Content	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	Cuff Pressure, Pulse, Date, Time, Systolic/Diastolic Pressure, error message, measurements results in memory, Irregular Heart Beat Feature, Body movement detection, Cuff Wrapping Detection, Dual user switching	**Different** (Discussion is indicated in D9)
Controls	Set button Start/Stop button Memory button	Memory Button, START/PULSE Button, Member Button	**Different** (Discussion is indicated in D10)
Performance	ANSI/IAAMI/ISO81060-2:2013	ANSI/IAAMI/ISO81060-2:2013	**Same**
Performance	IEC80601-2-30	IEC80601-2-30	**Same**

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**
Electrical Safety	IEC60601-1	IEC60601-1	**Same**
EMC	IEC60601-1-2	IEC60601-1-2	**Same**
Usability	IEC 60601-1-6	IEC 60601-1-6	**Same**
Home Use	IEC 60601-1-11	IEC 60601-1-11	**Same**
Material of Patient contact components	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 420D Polyester; 2.air bag: PVC. 3.Velcro: nylon. 4.Ring: metal. 5.air tube: PVC.	Not public	**Different** (Discussion is indicated in D11)
Patient Interface	Cuff, button	Cuff, button	**Same**
Dimensions	141mm×106mm×70mm (Length×Width×Height)	127x93x74 (mm)	**Different** (Discussion is indicated in D12)
Weight	Approximate 323g. (Without battery)	Approx.330g	**Different** (Discussion is indicated in D13)
Principle of operation	Oscillometric Measuring method	Oscillometric Measuring method	**Same**
User Interface	Cuff, button	Cuff, button	**Same**
Software	Embedded	Embedded	**Same**

The discussion of differences exist between the subject and predicate devices is listed in following:

D1: The difference of Patient Population between subject device and predicate device is that the intended age range of subject device is over 12 years old and predicate device is intended for adults, this difference is addressed through clinical trial conducted with subject device and contains population over 12 years old according to ISO 81060-2 Third Edition 2018-11, the results of clinical trial meet the requirements of ISO 81060-2 Third Edition 2018-11, therefore, the difference of subject device with predicate device YE680B (K200939) will not affect the safety and effectiveness.

D2: The difference of Cuff Circumference between subject device and predicate device is that the intended Cuff Circumference range of subject device is 22~42cm and predicate device is 22~45cm, the Cuff Circumference range of subject device is in the range of predicate device, and this difference is also addressed through clinical trial conducted with subject device according to ISO 81060-2 Third Edition 2018-11, the results of clinical trial meet the requirements of ISO 81060-2 Third Edition 2018-11, therefore, the difference of subject device with predicate device YE680B (K200939) will not affect the safety and effectiveness.

D3: The Memory Size of subject device is different with predicate device predicate device YE680B (K200939) will not affect the safety and effectiveness.

D4: The difference of Blood Pressure Indication Range between subject device and predicate device is that the Blood Pressure Indication Range of subject device is DIA: 30 mmHg~195mmHg & SYS: 60 mmHg~255mmHg and predicate device is Diastolic:20~210 mmHg & Systolic:40~260 mmHg, the Blood Pressure Indication Range of subject device is in the range of predicate device and meets the requirements of IEC 80601-2-30: Edition 2.0 2018-03, and this difference is also addressed through clinical trial conducted with subject device according to ISO 81060-2 Third Edition 2018-11, the results of clinical trial meet the requirements of ISO 81060-2 Third Edition 2018-11, therefore, the difference of subject device with predicate device YE680B (K200939) will not affect the safety and effectiveness.

D5: The Measurement Pulse Range of subject device is in the range of predicate device, and this difference is also addressed through clinical trial conducted with subject device according to ISO 81060-2 Third Edition 2018-11, therefore, the difference of subject device with predicate device YE680B (K200939) will not affect the safety and effectiveness.

D6: The operating Environment of subject device are different with predicate device YE680B (K200939), the difference introduces risks mitigated by testing in accordance with IEC 60601-1-11 and ANSI AAMI ES60601-1 provided in this submission, therefore the difference does not raise new questions of safety and effectiveness.

D7: The Storage Environment of subject device is different with predicate device YE680B (K200939), the difference introduces risks mitigated by testing in accordance with IEC 60601-1-11 and ANSI AAMI ES60601-1 provided in this submission, therefore the difference does not raise new questions of safety and effectiveness.

D8: The Energy Source of subject device are different with predicate devices, the difference introduces risks mitigated by the electromagnetic compatibility and electrical safety testing in accordance with IEC 60601-1-2 and ANSI AAMI ES60601-1 provided in this submission, therefore the difference does not raise new questions of safety and effectiveness.

D9: The Display Content between subject device and predicate device is that excluding the same parts, the Display Content of subject device additionally includes “User Group and Average of last 3 measurements” which are not included by predicate device, and the predicate device additionally includes “Cuff Pressure, Date, Time, Irregular Heart, Beat Feature, Dual user switching” which are not included by predicate device, since the subject device meets the requirements of IEC 80601-2-30: Edition 2.0 2018-03 and ISO 81060-2 Third Edition 2018-11, therefore, the difference of subject device with predicate device YE680B (K200939) will not affect the safety and effectiveness.

D10: The Controls of subject device are different with predicate device, the difference does not raise new questions of safety and effectiveness.

D11: The Material of Patient contact components of subject device 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 YE680B (K200939) do not raise new questions of safety and effectiveness.

D12: The Dimensions of subject device is different with predicate device predicate device YE680B (K200939) will not affect the safety and effectiveness.

D13: The Weight of subject device is different with predicate device predicate device YE680B (K200939) will not affect the safety and effectiveness.

7. Discussion of Non-Clinical Tests Performed are as follows

The recognized consensus standards for safety of medical electrical equipment: ANSI AAMI ES 60601- 1: 2005 / (R) 2012 and A1: 2012, IEC 60601-1-11 Edition 2.0 2015-01, IEC 60601-1-8 Edition 2.1 2012-11 for safety, IEC 60601-1-2: 2014 for electromagnetic compatibility, IEC 80601-2-30: Edition 2.0 2018-03, ISO 81060-2 Third Edition 2018-11 for performance, IEC 62304 Edition 1.1 2015-06 for software verification, IEC 62366-1 Edition 1.0 2015-02, IEC 60601-1-6 Edition 3.1 2013-10 for usability and ISO 10993-5:2009 for Cytotoxicity endpoints, ISO 10993-10:2010 for Sensitization and Irritation endpoints are complied. See below table for details:

Standards	Standards Name
ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
IEC 60601-1-2: 2014	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances - Requirements And Tests
IEC 60601-1-11 Edition 2.0 2015-01	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests
IEC 60601-1-8 Edition 2.1 2012-11	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 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 81060-2 Third Edition 2018-11	Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type
IEC 62366-1 Edition 1.0 2015-02	Medical devices - Part 1: Application of usability engineering to medical devices
IEC 60601-1-6 Edition 3.1 2013-10	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2010	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
IEC 62304 Edition 1.1 2015-06	Medical device software - Software life cycle processes

- **Electrical safety and electromagnetic compatibility (EMC)**
  Electrical safety and EMC testing were conducted on the subject device HTD6602US. The system complies with the AAMI ANSI ES60601-1, IEC 60601-1-2, IEC 60601-1-8, IEC 60601-1-11, IEC 80601-2-30: Edition 2.0 2018-03, ISO 81060-2 Third Edition 2018-11, standards for electrical safety and the IEC 60601-1-2 standard for EMC.

- **Software Verification and Validation Testing**
  Software verification and validation was performed for the subject device in accordance with Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff, May 2005.

  Software Description:
  The software for this device was considered as a “moderate” level of concern, since a failure or latent flaw in the software could result in Minor Injury, either to a patient or to a user of the device. The software of the system, on the whole, is accountable for the system scheduler of the device, including Pressure and pulse signal acquisition, calculation and display, the button presses of end user, display the result of the measurement, measurement data storage and average calculation, memory data query, prompt of error message, low battery voltage detection and prompt, measurement Unit conversion, user Account Switching.

  ➢ Programming language
  C Programming Language.

  ➢ Hardware Requirements
  Microprocessors: HME062

8. Discussion of Clinical Accuracy Testing Performed

The clinical accuracy test report and data analysis followed the requirements of the ISO 81060-2 Third Edition 2018-11.

The clinical accuracy testing evaluated 85 of subjects, division of all subjects:

Subjects requirement	**Number specified in ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01**	**Actual number**
Total	A minimum of 85	85
Male	At least 26	38
Female	At least 26	47
Age > 12	100%	100%

arm circumference in the range of 22-27cm;	≥20%	31.76%
arm circumference in the range of 27-32cm;	≥20%	23.53%
arm circumference in the range of 32-37cm;	≥20%	23.53%
arm circumference in the range of 37-42cm;	≥20%	21.18%
arm circumference in the range of 22-24.5cm;	≥10%	21.18%
arm circumference in the range of 39.5-42cm	≥10%	11.76%
subjects shall be tested through the cuff with specified (22-32cm)	At least 25%	32.94%
subjects shall be tested through the cuff with specified (22-42cm)	At least 50%	67.06%
Systolic BP ≤ 100mmHg	≥5%	17.65%
Systolic BP ≥ 160mmHg	≥5%	12.94%
Systolic BP ≥140mmHg	≥20%	30.59%
Diastolic BP ≤ 60mmHg	≥5%	14.12%
Diastolic BP ≥ 100mmHg	≥5%	10.59%
Diastolic BP ≥ 85mmHg	≥20%	27.06%

The test data showed the clinical accuracy of the subject device complied with the requirements of ISO 81060-2 Third Edition 2018-11.

Reference equipment used for measurements:

Name	Sphygmomanometer - Stethoscope health box
Model	A Type
Manufacturer	Jiangsu Yuyue Medical Equipment & Supply Co., Ltd.
Measuring Method	Auscultatory

9. Conclusions

The Electronic blood pressure monitor, model: HTD6602US, have the same intended use and similar characteristics as the cleared predicate device Electronic Blood Pressure Monitor, Model: YE680B. Moreover, bench testing contained in this submission supplied demonstrate that the differences existed between HTD6602US and YE680B do not raise any new questions of safety or effectiveness.

The non-clinical tests support the safety of the device and the hardware and software verification and validation demonstrate that the Electronic blood pressure monitor, model: HTD6602US performs as intended in the specified use conditions are same with predicate device. The clinical performance tests demonstrate that the Electronic blood pressure monitor, model: HTD6602US performs comparably to the predicate device that is currently marketed for the same intended use. Thus, the Electronic blood pressure monitor, model: HTD6602US is Substantially Equivalent (SE) to the predicate device.