August 20, 2020

Jiangsu Yuyue Medical Equipment & Supply Co., Ltd
% Giselle Zhang
Technical Consultant
Emergo Global Consulting , LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, Texas 78746

Re: K200939
Trade/Device Name: Electronic Blood Pressure Monitor: YE620B, YE620D, YE660E, YE660F and YE680B
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: July 21, 2020
Received: July 23, 2020

Dear Giselle Zhang:

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,

LT 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)*
K200939

Device Name
Electronic Blood Pressure Monitor: YE620B, YE620D, YE660E, YE660F and YE680B

Indications for Use *(Describe)*
Electronic blood pressure monitor is intended to measure the blood pressure and pulse rate of adult 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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Special 510(k) Summary

Upper Arm Type Electronic Blood Pressure Monitor Series

1. Submission Sponsor

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Contact: Giselle Zhang
Title: Technical Consultant

3. Date Prepared

07/21/2020

4. Device Identification

Trade/Proprietary Name:	Electronic Blood Pressure Monitor: YE620B, YE620D, YE660E, YE660F and YE680B
Common/Usual Name:	Non-Invasive Blood Pressure Monitor
Classification Name:	Noninvasive blood pressure measurement system
Regulation Number:	870.1130
Product Code:	DXN
Class:	II
Classification Panel:	Cardiovascular

5. Legally Marketed Original Device

Trade/Proprietary Name:	Upper Arm Type Electronic Blood Pressure Monitor Series Electronic Blood Pressure Monitor: YE650A, YE650D, YE660B, YE670A and YE670D

Common/Usual Name:	Non-Invasive Blood Pressure Monitor
Classification Name:	Noninvasive blood pressure measurement system
Regulation Number:	870.1130
Product Code:	DXN
Class:	II
Classification Panel:	Cardiovascular
510(k) Number:	K170605

6. Indication for Use Statement

Electronic blood pressure monitor is intended to measure the blood pressure and pulse rate of adult in household or medical facilities. (Not suitable for neonate, pregnancy or pre-eclampsia).

7. Device Description

The measuring method for the Upper Arm Type Electronic Blood Pressure Monitor Series is oscillation mensuration. The subject devices 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 time, date, blood pressure value and pulse value are included. The record maybe revisited.

8. Substantial Equivalence Discussion

The following table compares the modified device series to the original device series by Jiangsu Yuyue Medical Equipment& Supply Co., Ltd. with respect to indications for use, principles of operation, technological characteristics, materials, and performance, and forms the basis for the determination of substantial equivalence. The subject device does not raise any new questions of safety or effectiveness as compared to the predicate device.

Table 5A – Comparison of Characteristics

Device/Model	YE620B	YE620D	YE660E	YE660F	YE680B	Predicate: YE650A, YE650D, YE660B, YE670A and YE670D (K170605)
Manufacturer	Jiangsu Yuyue Medical Equipment & Supply Co., Ltd.					
General						
Product Code	DXN					
Regulation No.	870.1130					
Classification	II					
Intended Use	Electronic blood pressure monitor is intended to measure the blood pressure and pulse rate of adult in household or medical facilities. (Not suitable for neonate, pregnancy or pre-eclampsia)					
Performance						
Design Method	Oscillometric					
Patient Population	Adult					
Measurement Site	Upper Arm					
Cuff Circumference	Type A (22cm~32cm, 22-45cm optional) Type B (22cm~ 32cm, 22-45cm optional)					Type A (22cm~ 32cm) Type B (22cm~ 32cm)
Inflation Method	Automatic by electronic pump					
Deflation Method	Automatic Pressure Release Valve					
Display	Backlight LCD Digital Display	Backlight LCD Digital Display	LCD Digital Display	Backlight LCD Digital Display	Backlight LCD Digital Display	Backlight LCD Digital Display
Patients Contacting Materials	Patient contact materials are not changed.					

Device/Model	YE620B	YE620D	YE660E	YE660F	YE680B	Predicate: YE650A, YE650D, YE660B, YE670A and YE670D (K170605)
Memory Size	Up to 99 sets of data	Up to 60x2 sets of data	Up to 99 sets of data	Up to 90 sets of data	Up to 99x2 sets of data	YE670A:74 sets, YE670D: 60 sets, YE650A: 60 sets, YE650D: 80 sets, YE660B: 74 sets
Blood Pressure Indication Range	Measuring range: Diastolic:20 – 210 mm Hg Systolic:40 – 260 mmHg					
Measurement Pressure Range	0 ~ 300 mmHg (0 kPa ~ 40 kPa)					0~280mmHg (0-37.3kPa)
Range Accuracy	±3 mmHg (±0.4kPa)					
Measurement Pulse Range	40 ~ 200 beats/min					
Pulse Accuracy	±5% of reading value					
Pressurization Source	Automatic Internal Pump					
Pressure Sensor	Semiconductor Pressure Sensor					
Operating Environment	Temperature: +5ºC ~ +40 ºC Humidity: 15% RH ~ 90% RH(no condensation)					Temperature: +10 ºC ~ +40 ºC Humidity: 15% RH ~ 90% RH(no condensation)
Storage Environment	Temperature: -20 ºC ~ +55 ºC Humidity: 15% RH ~ 90% RH(no condensation)					
Energy Source	4 AA batteries or 6V/600mA AC adapter					4 AA batteries
Display Content	Cuff Pressure, Pulse, Date, Time, Systolic/Diastolic Pressure, error message,	Cuff Pressure, Pulse, Date, Time, Systolic/Diastolic Pressure, error message,	Cuff Pressure, Pulse, Date, Time, Systolic/Diastolic Pressure, error message,	Cuff Pressure, Pulse, Date, Time, Systolic/Diastolic Pressure, error message,	Cuff Pressure, Pulse, Date, Time, Systolic/Diastolic Pressure, error message,	Cuff Pressure, Pulse, Date, Time, Systolic/Diastolic Pressure, error message, measurements results in memory, Irregular Heart Beat Feature, Body movement detection, Cuff Wrapping Detection

Device/Model	YE620B	YE620D	YE660E	YE660F	YE680B	Predicate: YE650A, YE650D, YE660B, YE670A and YE670D (K170605)
	measurements results in memory, Irregular Heart Beat Feature, Body movement detection, Cuff Wrapping Detection	measurements results in memory, Irregular Heart Beat Feature, Body movement detection, Cuff Wrapping Detection, Dual user switching	measurements results in memory, Irregular Heart Beat Feature, Body movement detection, Cuff Wrapping Detection	measurements results in memory, Irregular Heart Beat Feature, Body movement detection, Cuff Wrapping Detection	measurements results in memory, Irregular Heart Beat Feature, Body movement detection, Cuff Wrapping Detection, Dual user switching	
Controls	Memory Button, START/PULSE Button	START/PULSE Button, Memory Button, Member Button	Memory Button, START/PULSE Button	Memory Button, START/PULSE Button	Memory Button, START/PULSE Button, Member Button	SET Button, Plus/Minus Button, START/PULSE Button
Performance	ANSI/IAAMI/ISO81060-2:2013					
Performance	IEC80601-2-30					
Biocompatibility	ISO 10993-1, FDA Guidance, Tests included Cytotoxicity, Sensitization and Intracutaneous Reactivity					
Electrical Safety	IEC60601-1					
EMC	IEC60601-1-2					
Usability	IEC 60601-1-6					
Home Use	IEC 60601-1-11					

9. Non-Clinical Performance Data

To demonstrate safety and effectiveness of Electronic Blood Pressure Monitor: YE620B, YE620D, YE660E, YE660F and YE680B and to show substantial equivalence to the original device, Jiangsu Yuyue Medical Equipment& Supply Co., Ltd completed the following non-clinical tests. Results confirm that the design inputs and performance specifications 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 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD) – Passed
- ANSI AAMI IEC60601-1-2:2014Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests – Passed
- 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 – Passed
- IEC 60601-1-11:2015 Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment – Passed
- ANSI AAMI IEC80601-2-30:2009 & A1:2013 (R2016) Medical Electrical Equipment - Part 2-30: Particular Requirements For The Basic Safety And Essential Performance Of Automated Noninvasive Sphygmomanometers – Passed
- ISO 81060-2 Third Edition 2018-11Non-Invasive Sphygmomanometers - Part 2: Clinical Validation Of Automated Measurement Type – Passed

10. Clinical Performance Data

A clinical validation was conducted to evaluate safety and effectiveness of the Electronic Blood Pressure Monitor: YE620B, YE620D, YE660E, YE660F and YE680Bwhen used according to the indications for use. The study is an auscultatory study conducted with Model YE680B (representative model) according to ISO 81060-2. Eighty-five(85) participants were involved in the study, and three valid blood pressure values are taken for each participant by nurses and the reference device used is a mercury sphygmomanometer. A total 255 blood pressure values are being collected.

Results of the clinical evaluation support the indications for use of the Electronic Blood Pressure Monitor: YE620B, YE620D, YE660E, YE660F and YE680B.The results confirm that the device is safe and effective when used according to the instructions for use.

11. Statement of Substantial Equivalence

The Electronic Blood Pressure Monitor: YE620B, YE620D, YE660E, YE660F and YE680B has the same intended use as the original device, and the same or similar technological characteristics. The minor differences in technological characteristics do not raise new or different questions of safety and effectiveness, as determined through a risk assessment and well-established test methods. Therefore, the Upper Arm Electronic Blood Pressure Monitor: YE620B, YE620D, YE660E, YE660F and YE680B is substantially equivalent to the original Upper Arm Type Electronic Blood Pressure Monitor Series Electronic Blood Pressure Monitor: YE650A, YE650D, YE660B, YE670A and YE670D.