March 27, 2018

Jiangsu Yuyue Medical Equipment & Supply Co., Ltd
Rong Zhong
Quality Assurance
Yunyang Industrial Park
Danyang, Jiangsu, China 212300

Re: K170605
Trade/Device Name: Upper Arm Type Electronic Blood Pressure Monitor Series, Electronic Blood Pressure Monitor: YE650A, YE650D, YE660B, YE670A and YE670D
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: January 11, 2018
Received: February 26, 2018

Dear Rong Zhong:

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. 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); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K170605

Device Name

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

Indications for Use *(Describe)*

Electronic blood pressure monitor is intended to measure the blood pressure and pulse rate of adult at household or medical center. (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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510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

(As Required by 21 CFR 807.92)

1. **Date Prepared [21 CFR 807.92(a)(1)]**
   01/11/2018

2. **Submitter's Information [21 CFR 807.92(a)(1)]**

Company Name:	Jiangsu Yuyue Medical Equipment& Supply Co., Ltd
Company Address:	Yunyang Industrial Park, Danyang, Jiangsu, China
Contact Person:	Rui, Li
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Fax:	0511-86900991
Email:	Lirui@yuyue.com.cn

3. **Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]**

Trade Name:	Upper Arm Type Electronic Blood Pressure Monitor Series, Electronic Blood Pressure Monitor: YE650A, YE650D, YE660B, YE670A and YE670D
Common Name:	Electronic Blood Pressure Monitor Series
Product Code:	DXN
Regulation Number:	870.1130
Device Class:	II

4. **Identification of Predicate Devices(s) [21 CFR 807.92(a)(3)]**

The identification of predicates within this submission is as follow:

Predicate I	OMRON Healthcare (China) Co., Ltd.
Manufacturer:	
Trade Name:	Model HEM-7320
Common Name:	Noninvasive Blood PressureMeasurement System
Product Code:	DXN
Classification Name:	Noninvasive blood pressure measurement
Regulation Number:	21CFR 870.1130
Classification:	Class II
FDA 510 (k) #:	K133383

5. **Description of the Device [21 CFR 807.92(a)(4)]**

The measuring method for the Upper Arm Type Electronic Blood Pressure Monitor Series is oscillation mensuration. The series will automatically starting to take measurements after the inflation of the cuff finished, the results will show the systolic pressure and diastolic pressure and pulse rate. The monitor will store the measurements automatically, which including the time, date, blood pressure and pulse. The record could be revisited. Total 74 sets of data could be stored for YE670A, 60 sets of data for YE670D, 60 sets of data for YE650A, 80 sets of data for YE650D and 74 sets of data for YE660B.

6. Intended Use [21 CFR 807.92(a)(5)]

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

7. Technological Characteristic [21 CFR 807.92(a)(6)]

YE670series, YE650series and YE660B utilize modular design method, It consists of nine main modules: power-on self-test module, system initialization module, sampling data processing and pressure, pulse rate calculation module, display processing module, power detection processing module, data storage module, key scanning processing module, sampling processing module, voice broadcast processing module, and each module communicates through a message queue.

The blood pressure monitor controls the pneumatic flow control module through single-chipped microcomputer to pressurize the cuff module in order to exceed the lower pressure of patients, the blood being pushed against the artery walls; Pneumatic Flow Control Module being directed to release the pressure, while the pressure detection module collect pulse pressure signal and amplify filter; amplified filter signal being read by single-chipped microcomputer for pressure and pulse signal, through unique algorithm to obtain the systolic and diastolic pressure with pulse; Single-chipped microcomputer will control the inflation/deflation module to release the pressure after receive measurements; in the meanwhile, display the measurements results then stored the values with memory module.

8. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92(b)(2)]

Table 1	YE650A	YE650D	YE670A	YE670D	YE660B	Predicate Device
Product Code	DXN	DXN	DXN	DXN	DXN	DXN
Regulation No.	870.1130	870.1130	870.1130	870.1130	870.1130	870.1130
Classification	II	II	II	II	II	II
Intended Use	Electronic blood pressure monitor is intended to measure the blood pressure and pulse rate of adult at household or medical center. (Not suitable for neonate, pregnancy or pre-eclampsia)	Electronic blood pressure monitor is intended to measure the blood pressure and pulse rate of adult at household or medical center. (Not suitable for neonate, pregnancy or pre-eclampsia)	Electronic blood pressure monitor is intended to measure the blood pressure and pulse rate of adult at household or medical center. (Not suitable for neonate, pregnancy or pre-eclampsia)	Electronic blood pressure monitor is intended to measure the blood pressure and pulse rate of adult at household or medical center. (Not suitable for neonate, pregnancy or pre-eclampsia)	Electronic blood pressure monitor is intended to measure the blood pressure and pulse rate of adult at household or medical center. (Not suitable for neonate, pregnancy or pre-eclampsia)	The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population. The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.
510 (k) Number	N/A	N/A	N/A	N/A	N/A	K133383
Design Method	Oscillometric Method	Oscillometric Method	Oscillometric Method	Oscillometric Method	Oscillometric Method	Oscillometric Method

Patient Population	Adult	Adult	Adult	Adult	Adult	Adult
Measurement Site	Upper Arm	Upper Arm	Upper Arm	Upper Arm	Upper Arm	Upper Arm
Cuff Circumference	220mm ～ 320mm	220mm ～ 320mm	220mm ～ 320mm	220mm ～ 320mm	220mm ～ 320mm	220mm ～420mm
Inflation Method	Automatic by electronic pump	Automatic by electronic pump	Automatic by electronic pump	Automatic by electronic pump	Automatic by electronic pump	Automatic by electronic pump
Deflation Method	Automatic Pressure Release Valve	Automatic Pressure Release Valve	Automatic Pressure Release Valve	Automatic Pressure Release Valve	Automatic Pressure Release Valve	Automatic Pressure Release Valve
Display	LCD Digital Display	Backlight LCD Digital Display	LCD Digital Display	LCD Digital Display	LCD Digital Display	LCD Display
Patients Contacting Materials	Patient contact materials of the cuff have been tested in accordance with ISO 10993 and FDA guidance.	Patient contact materials of the cuff have been tested in accordance with ISO 10993 and FDA guidance.	Patient contact materials of the cuff have been tested in accordance with ISO 10993 and FDA guidance.	Patient contact materials of the cuff have been tested in accordance with ISO 10993 and FDA guidance.	Patient contact materials of the cuff have been tested in accordance with ISO 10993 and FDA guidance.	Patient contact material of the cuff have been tested in accordance with ISO 10993 and FDA guidance.
Memory Size	Up to 60sets of data	Up to 80 sets of data	Up to 74 sets of data	Up to 60 sets of data	Up to 74 sets of data	Up to 100 sets of data
Measurement Pressure Range	0 ~ 280 mmHg (0 kPa ~ 37.3 kPa)	0 ~ 280 mmHg (0 kPa ~ 37.3 kPa)	0 ~ 280 mmHg (0 kPa ~ 37.3 kPa)	0 ~ 280 mmHg (0 kPa ~ 37.3 kPa)	0~280mmHg (0-37.3kPa)	0 mmHg ~ 299 mmHg(0 kPa~ 39.9 kPa)
Range Accuracy	±3 mmHg (±0.4kPa)	±3 mmHg (±0.4kPa)	±3 mmHg (±0.4kPa)	±3 mmHg (±0.4kPa)	±3mmHg (±0.4kPa)	±3 mmHg (±0.4kPa)or 2% of reading
Measurement Pulse Range	40 ~ 200 beats/min	40 ~ 200 beats/min	40 ~ 200 beats/min	40 ~ 200 beats/min	40 ~ 200 beats/min	40 ~ 180 beats/min
Pulse Accuracy	±5% of reading value	±5% of reading value	±5% of reading value	±5% of reading value	±5% of reading value	Within ±5%of reading
Pressurization Source	Automatic Pressurize	Automatic Pressurize	Automatic Pressurize	Automatic Pressurize	Automatic Pressurize	Automatic Internal Pump
Pressure Sensor	Semiconductor Pressure Sensor	Semiconductor Pressure Sensor	Semiconductor Pressure Sensor	Semiconductor Pressure Sensor	Semiconductor Pressure Sensor	Semiconductor Pressure Sensor

Operating Environment	Temperature: +10 ºC ~ +40 ºC Humidity: 15% RH ~ 90% RH(no condensation)	Temperature: +10 ºC ~ +40 ºC Humidity: 15% RH ~ 90% RH(no condensation)	Temperature: +10 ºC ~ +40 ºC Humidity: 15% RH ~ 90% RH(no condensation)	Temperature: +10 ºC ~ +40 ºC Humidity: 15% RH ~ 90% RH(no condensation)	Temperature: +10 ºC ~ +40 ºC Humidity: 15% RH ~ 90% RH(no condensation)	Temperature: +10 ºC ~ +40 ºC (50-104 ºF) Humidity: 30% RH ~ 85% RH(no condensation)
Storage Environment	Temperature: -20 ºC ~ +55 ºC Humidity: 15% RH ~ 90% RH(no condensation)	Temperature: -20 ºC ~ +55 ºC Humidity: 15% RH ~ 90% RH(no condensation)	Temperature: -20 ºC ~ +55 ºC Humidity: 15% RH ~ 90% RH(no condensation)	Temperature: -20 ºC ~ +55 ºC Humidity: 15% RH ~ 90% RH(no condensation)	Temperature: -20 ºC ~ +55 ºC Humidity: 15% RH ~ 90% RH(no condensation)	Temperature: -20 ºC ~ +60 ºC Humidity: 10% RH ~ 95% RH(no condensation)
Energy Source	4 AA batteries	4 AA batteries	4 AA batteries	4 AA batteries	4 AA batteries	4 AA batteries or AC Adapter
Display Content	Cuff Pressure, Pulse, Date, Time, Systolic/Diastolic Pressure, error message, measurements results in memory, Irregular Heart Beat Feature, Body movement detection Cuff Wrapping Detection	Cuff Pressure, Pulse, Date, Time, Systolic/Diastolic Pressure, error message, measurements results in memory, Irregular Heart Beat Feature, Body movement detection Cuff Wrapping Detection	Cuff Pressure, Pulse, Date, Time, Systolic/Diastolic Pressure, error message, measurements results in memory, Irregular Heart Beat Feature, Body movement detection Cuff Wrapping Detection	Cuff Pressure, Pulse, Date, Time, Systolic/Diastolic Pressure, error message, measurements results in memory, Irregular Heart Beat Feature, Body movement detection Cuff Wrapping Detection	Cuff Pressure, pulse, Systolic/Diastolic, error message, measurement results in the memory, Date, Time.	Cuff Pressure, Systolic/Diastolic Pressure, pulse rate, error message, measurement results in the memory
Controls	SET Button, Plus/Minus Button, START/PULSE Button	SET Button, Plus/Minus Button, START/PULSE Button	SET Button, Memory Button, START/PULSE Button	SET Button, Memory Button, START/PULSE Button	Memory Button, Start Button	START/STOP button, Date/Tim Setting Button, UP/DOWN Button, USER ID Selections Button
Performance	ANSI/AAMI/ISO 81060-2	ANSI/AAMI/ISO 81060-2	ANSI/AAMI/ISO 81060-2	ANSI/AAMI/ISO 81060-2	ANSI/AAMI/ISO 81060-2	ANSIIAAMI/ISO 81060-2
Performance	IEC 80601-2-30	IEC 80601-2-30	IEC 80601-2-30	IEC 80601-2-30	IEC 80601-2-30	IEC 80601-2-30

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	ISO 10993-1, FDA Guidance, Tests included Cytotoxicity, Sensitization and Intracutaneous Reactivity	ISO 10993-1, FDA Guidance, Tests included Cytotoxicity, Sensitization and Intracutaneous Reactivity	ISO 10993-1, FDA Guidance, Tests included Cytotoxicity, Sensitization and Intracutaneous Reactivity	ISO 10993-1, FDA Guidance, Tests included Cytotoxicity, Sensitization and Intracutaneous Reactivity
Electrical Safety	IEC 60601-1	IEC 60601-1	IEC 60601-1	IEC 60601-1	IEC 60601-1	IEC 60601-1
EMC	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2
Home Use	IEC 60601-1-11	IEC 60601-1-11	IEC 60601-1-11	IEC 60601-1-11	IEC 60601-1-11	IEC 60601-1-11

9. Conclusion [21 CFR 807.92(b)(3)]

The Upper Arm Type Electronic Blood Pressure Monitor650A, 650D, 670A, 670D and 660B are substantially equivalent to predicate device because both devices use identical technology and same intended use, also testing standards are identical with the predicates. The differences between both devices are insignificant in terms of safety and effectiveness.