December 5, 2023

Zhuhai Yueja Medical Device Technology Co.,Ltd.
Feng Yan
Department Manager
Room 201, Building 2, No.2 Liushi Road,
Tangjiawan Town, High-tech Zone
Zhuhai, Guangdong 519000
China

Re: K232814
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: August 30, 2023
Received: September 13, 2023

Dear Feng Yan:

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)*
K232814

Device Name
Electronic Blood Pressure Monitor

Indications for Use *(Describe)*
Electronic Blood Pressure Monitor is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population. It is intended to measure the diastolic, systolic blood pressures and pulse rate through an inflatable cuff wrapped around the arm. It can be used by medical professionals or at home. The cuff circumference is limited to 22-42 cm.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

Section 3 510(k) Summary

I 510(k) Submitter

Device Submitter: Zhuhai Yueja Medical Device Technology Co.,Ltd.
Room 201, Building 2, No.2 Liushi Road, Tangjiawan Town,
High-tech Zone, Zhuhai, 519000, China

Contact Person: Feng yan
Department Manager
Phone: +86-18826906029
E-mail: fengy@myzr.com.cn

II Device

Trade Name of Device:	Electronic Blood Pressure Monitor
Regulation Number:	21 CFR 870.1130
Classification Name:	Electronic Blood Pressure Monitor
Product Code:	DXN
Regulation Number:	Electronic Blood Pressure Monitor
Regulatory Class	II
Review Panel	Cardiovascular

III Predicate Devices

510k Number	K222994
Trade Name of Device:	Electronic Blood Pressure Monitor
Regulation Number:	21 CFR 870.1130
Regulation Name:	Electronic Blood Pressure Monitor
Regulatory Class	II
Product Code:	DXN

IV Device Description

Electronic Blood Pressure Monitor mainly consist of the main body (include screen display, air tube connector, memory button and start/stop button), cuff, USB cable, air tube, and AA batteries.

Electronic Blood Pressure Monitor that uses the oscillometric principle to measure your blood pressure and pulse rate. The radial artery in the arm changes from blocked to open as the pressure in the cuff tied around the arm changes from high to low, causing the pressure in the cuff to be superimposed on a series of small pressure pulses. The sphygmomanometer senses these signals and, after certain calculations, finds the systolic and diastolic pressures of the radial artery in the body.

Electronic Blood Pressure Monitor can be divided into three models (YJ320、YJ321E、

YJ326E) according to their appearance and functions. The differences among these models are shown as below:

Model	Air pumps and air valves	Cuffs	Software Function	Hardware
YJ320	Same	Same	Same	Black and white backlit screen
YJ321E	Same	Same	Removed cuff detection and misoperation prompt functions	Black and white backlit screen
YJ326E	Different	Different	Same	Color backlit screen

V Indications for use

Electronic Blood Pressure Monitor is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population. It is intended to measure the diastolic, systolic blood pressures and pulse rate through an inflatable cuff wrapped around the arm. It can be used by medical professionals or at home. The cuff circumference is limited to 22-42 cm.

VI Technological Characteristics Comparison

VI-1: Comparison of Electronic Blood Pressure Monitor

Device Characteristic	Subject Device	Predicate Device (K222994)	**Discussion**
Type of Blood Pressure Monitor	Electronic Blood Pressure Monitor YJ320、YJ321E、YJ326E	Electronic Blood Pressure Monitor AOJ-33 series	-
Product Code	DXN	DXN	Same
Regulation No.	21 CFR 870.1130	21 CFR 870.1130	Same
Class	II	II	Same
Indications for Use	Electronic Blood Pressure Monitor is a digital monitor intended for use in measuring blood pressure and pulse rate in adult	The Arm Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person via	Same

	patient population. It is intended to measure the diastolic, systolic blood pressures and pulse rate through an inflatable cuff wrapped around the arm. It can be used by medical professionals or at home. The cuff circumference is limited to 22-42 cm.	non-invasive oscillometric technique in which an inflatable CUFF is wrapped around the upper arm at medical facilities or at home.	
Measurement site	Upper arm	Upper arm	Same
Patient Population	Adult	Adult	Same
Measurement Item	SYS, DIA, Pulse Rate	SYS, DIA, Pulse Rate	Same
Principle	Oscillometric	Oscillometric	Same
Blood pressure measurement range	pressure:0 to 295mmHg SYS: 55 to 255 mmHg DIA: 25 to 200 mmHg	30 ~ 255 mmHg	Different 1
Accuracy	± 3 mmHg	± 3 mmHg	Same
Pulse Rate Range	40~199beat/min	40-199 bpm	Same
Accuracy	± 5% of reading	± 5% of reading	Same
Cuff size	22~42cm	22~42cm	Same
Power supply	4 “AA” batteries(d.c.6v） or USB-C INPUT 5V d.c~6V d.c/600mA	Lithium-ion battery, D.C. 3.7V	Different 2
Operation condition	+5℃~+40℃, 15%RH~85%RH 80kPa~105kPa	+5℃~+40℃ 15%RH-90%RH 70 kPa -106 kPa	Different 3
Storage condition	-20℃~+55℃, 15%RH~85%RH, 80kPa~105kPa	-20℃~+55℃ 10%RH-93%RH 70 kPa -106 kPa	Different 4
Patient Contacting	Surface-contacting, Less than 24 h	Surface-contacting, Less than 24 h	Same
Biocompatibility evaluation	Cytotoxicity, skin sensitization and irritation	Cytotoxicity, skin sensitization and irritation	Same

Electrical Safety	IEC 60601-1 IEC 60601-1-11 ISO 80601-2-30	IEC 60601-1 IEC 60601-1-11 ISO 80601-2-30	Same
EMC	IEC 60601-1-2	IEC 60601-1-2	Same
Biocompatibility	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-1 ISO 10993-5 ISO 10993-10	Different 5
Clinical data	ISO 81060-2: 2018	ISO 81060-2: 2018	Same

Different 1- Blood pressure measurement range

The Blood Pressure Range of the subject device includes the blood pressure range of predicate devices and meets the requirements of IEC 80601-2-30. Therefore, the difference will not affect the safety and effectiveness of the subject device.

Different 2- Power supply

The difference between subject device and predicate device (K222994) is the batteries, the predicate device use Lithium-ion battery, D.C. 3.7V while the subject device use 4 “AA” batteries (d.c.6v） or USB-C INPUT 5V d.c~6V d.c/600mA, but the power supply safety of subject device is justified by the IEC60601-1 electricity test reports. Thus this difference will not affect the safety and effectiveness, therefore this item is considered as substantial equivalence.

Different 3- Operation condition

The difference between subject device and predicate device (K222994) is the humidity and Atmospheric pressure, the predicate device is 15%RH-90%RH, 70 kPa -106 kPa, while the subject device is 15%RH-85%RH, 80kPa~105kPa, it is included in predicate device. Therefore, this item is considered as substantial equivalence.

Different 4- Storage condition

The difference between subject device and predicate device (K222994) is the humidity

and Atmospheric pressure, the predicate device is 15%RH-90%RH, 70 kPa -106 kPa, while the subject device is 15%RH-85%RH, 80kPa~105kPa, it is included in predicate device. Therefore, this item is considered as substantial equivalence.

Different 5- Biocompatibility

The predicate device (K222994) was tested by ISO 10993-5, ISO 10993-10, and the testing part included the battery.

While the main part of subject device that comes into contact with the patient is the cuff, the part that comes into contact with the operator is mainly the cover and cuff. The material of cover is ABS, which is a commonly used material in the market. It has Limited contact with intact skin. Per FDA's 2020 guidance document, Use of International Standard ISO 10993-1, ABS materials are exempt from biological testing.

In addition, the cuff has tested by ISO 10993-5 and ISO 10993-10.

Based on the above description, these differences do not affect the achievement of the product's intended use, nor do they compromise the safety of patients and operators.

VII Summary of Non-Clinical Testing and Clinical Testing

Non-Clinical Data:

Non-clinical testing for Electronic Blood Pressure Monitor was performed to demonstrate verification testing in conformance with the acceptance criteria of test methods and recognized consensus standards shown below.

Table VII-1: Performance testing was conducted on the subject device

Inspecting item		Inspection content and acceptance standard	Conclusion
1. Identification requirement		Meets the requirements of IEC 60601-1:2005 in 7.2	Pass
2. life span		After at least 10,000 full scale cycles, the sphygmomanometer should still meet the safety requirements and performance requirements in the standard. A full scale cycle is when the pressure rises from 2.67kPa(20mmHg) or less to a maximum pressure value and then falls to 2.67kPa(20mmHg) or less.	Pass
3. Safety requirements	3.1 Maximum cuff pressure	The sphygmomanometer should have overpressure protection function. When the pressure display exceeds 39.33kPa(295mmHg), the sphygmomanometer's vent valve should be opened, and the gas path pressure should be reduced to less than 2kPa(15mmHg) within 10s. In addition, the equipment should	Pass

		ensure that the cuff pressure is above 2kPa(15mmHg) for no more than 3 minutes.	
	3.2 venting	The sphygmomanometer should provide a simple and clearly marked measure allowing the user to deflate the cuff. When the valve of the charging system is fully open and quickly deflated, the time for the pressure to drop from 34.67kPa(260mmHg) to 2kPa(15mmHg) should not exceed 10s.	Pass
4. Performance index	4.1 Range	A blood pressure monitor has a range of at least 0kPa(0mmHg) to 39.3kPa(295mmHg).	Pass
	4.2 Resolution ratio	The display resolution of the sphygmomanometer should be 0.1kPa/1mmHg.	Pass
	4.3 Repeatability	For a sphygmomanometer, measured at static continuous low pressure, the difference between repeated readings measured at each point within the scale range should be no greater than 0.533 kPa(4mmHg). All readings shall comply with the requirements in 4.4	Pass
	4.4 Pressure sensor accuracy	The maximum error of the pressure measurement in the cuff should be ±0.4kPa(±3mmHg) at any measuring point in the range, regardless of whether the pressure is increased or decreased.	Pass

	4.5 Pulse	（a）The pulse measurement range of the sphygmomanometer should be (40 ~ 199) times/min, and the resolution should be 1 time/min. （b）Pulse accuracy: ±5%.	Pass
5 Requirements for charging sources and pressure control valves.	5.1 Aeration source	The sphygmomanometer inflation source should provide enough air within 10 seconds to reach 40kPa(300mmHg) in a 200(12 cubic inch) container.	Pass
	5.2 Pressure controlled air valve	5.2.1 air leakage The sphygmomanometer valve is closed, and the maximum pressure drop in a container with a volume not exceeding 80 at initial pressures of 33.33kPa(250mmHg), 20kPa (150 MMHG) and 6.67kPa(50mmHg) should not exceed 0.133kPa(1mmHg) for 10s. 5.2.2 Valve/cuff bleed rate When the valve is in the pressure control position, the pressure drop rate from 33.33kPa(250mmHg) to 6.67kPa(50mmHg) should not be less than 0.267kPa/s (2mmHg/s); 5.2.3 Venting The rapid venting of a gas-filled	Pass

		system when the valve is fully open should not take longer than 10s for the pressure to drop from 34.67kPa(260 mmHg) to 2kPa(15mmHg).	
6 Cuff with air bag	6.1 Size	The length of the cuff air bag is about 0.8 times the circumference of the limb measured at the median line of the cuff's intended use area, and the width of the cuff air bag is about half the length;	Pass
	6.2 compression resistance	The cuff, the integrated air bag and the entire pipeline should be able to withstand the internal pressure equal to the maximum pressure expected to be used by the cuff;	Pass
	6.3 Cuff interface, structure	After 1,000 opening and closing cycles and 10,000 40kPa(300mmHg) pressure cycles, the closure and sealing off the cuff and the integrated airbag shall remain intact enough to meet the other requirements of this standard.	Pass
7 System air leakage		The rate of pressure drop caused by air leakage of the entire system of the sphygmomanometer should not be greater than 0.133kPa/s(1mmHg/s).	Pass
8 function	8.1 display function	The liquid crystal display of the sphygmomanometer should be able to display systolic blood	Pass

		pressure, diastolic blood pressure and pulse rate, and there should be "kPa" or "mmHg" blood pressure display form.	
	8.2 Automatic zeroing function	The sphygmomanometer should be able to automatically return to zero after each turn on, and automatically open to test blood pressure.	Pass
	8.3 Error prompt function	The sphygmomanometer should display an incorrect indication if it fails to measure blood pressure correctly or fails to measure pulse rate correctly.	Pass
	8.4 Low voltage prompt function	When the sphygmomanometer is turned on, when the battery voltage is low to 4.2V±0.2V, the battery symbol "▭" should flash on the display screen.	Pass
	8.5 Automatic shutdown function	The sphygmomanometer will automatically shut down if no operation is performed within 2 minutes after the measurement is completed.	Pass
	8.6 memory function	The sphygmomanometer can memory store 2*99 groups of measurement data, 99 groups of users A and B, in the memory state, press the [Start/Stop] key and the [memory/read] key at the same time, 3 seconds later the screen will display CLR, release the double key can clear all the memory data.	Pass
	8.7 Clock setting function	The sphygmomanometer should be able to display time and set time, including year, month, day, hour and minute.	Pass
	8.8	The sphygmomanometer should be	Pass

	Arrhythmia prompt function	able to indicate the irregular heartbeat of the human body and can display the "  " symbol.	
	8.9 Voice broadcast prompt function	In the "mmHg" unit display mode, the sphygmomanometer should have a voice broadcast prompt function.	Pass
	8.10 Cuff detection prompt function	The sphygmomanometer has cuff detection function, and the display screen displays "  " symbol when the cuff is connected correctly, If an exception occurs, the "  " symbol is displayed	Pass
9 Appearance and structure	9.1 Sphygmomanometer shape should be correct, the surface should be bright, clean, color should be uniform.		Pass
	9.2 The characters and symbols of the blood pressure monitor should be clear, accurate and firm.		Pass
	9.3 The function keys of the sphygmomanometer should be flexible and reliable, and the fasteners should not be loose.		Pass
	9.4 The cuff should not be damaged.		Pass
	9.5 There should be no missing strokes in the LCD display process.		Pass
10 Electrical safety requirements		The sphygmomanometer shall meet the requirements specified in IEC 60601-1.	Pass
11 electromagnetic compatibility		The sphygmomanometer should meet the requirements specified in IEC60601-1-2 Medical electrical equipment-Part 1-2:General requirements for basic safety and essential performance-Collateral	Pass

	standard: Electromagnetic compatibility-Requirements and tests.	
12 Environmental test requirements	The environmental test of the sphygmomanometer shall comply with IEC 60601-1-11 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.	Pass

Biocompatibility Testing

The main part of subject device that comes into contact with the patient is the cuff, the part that comes into contact with the operator is mainly the cover and cuff. The material of cover is ABS, which is a commonly used material in the market. It has Limited contact with intact skin. Per FDA's 2020 guidance document, Use of International Standard ISO 10993-1, ABS materials are exempt from biological testing.

In addition, the material of cuff is Nylon, it has Limited contact with intact skin and has tested by ISO 10993-5 and ISO 10993-10.

- Cytotoxicity
- Skin Sensitization
- Skin Irritation

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Electronic Blood Pressure Monitor.

The device complies with the IEC60601-1, IEC60601-1-2, IEC 60601-1-8 and IEC60601-1-11.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Moderate" level of concern.

Performance testing

The Electronic Blood Pressure Monitor were test according to the standard which is IEC 80601-2-30, and the cuff to monitor connector was tested based on IEC 80369-5:2016 + C1:2017, the test result meets the requirements.

Usability

Usability was conducted on the Electronic Blood Pressure Monitor.
The device complies with the IEC60601-1-6.

Clinical data:

YJ320 was tested to ISO 81060-2:2018 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type. the clinical validation data on YJ320 can cover YJ321E、YJ326E. The Same Arm Sequential Method was chosen and performed on YJ320. This study included 86 adult subjects (49 females, 37 male) with an age range of 17 to 76 years. All data's mean error and standard deviation of differences for systolic, diastolic pressure is not over the limits of ISO 81060-2: 2018. No adverse effect and/or complication is found in this study.

VIII Conclusion

The conclusions drawn from the non-clinical tests and clinical test demonstrate that the Electronic Blood Pressure Monitor is as safe as effective, and performs as well as or better than the legally marketed device.