December 11, 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: K232815
Trade/Device Name: Wrist 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)*
K232815

Device Name
Wrist Blood Pressure Monitor

Indications for Use *(Describe)*
Wrist Blood Pressure Monitor is used to measure adult systolic blood pressure. diastolic blood pressure and pulse rate. The values are for diagnostic reference only. Suitable for medical institutions (such as hospitals, clinics, health centers, etc.) and home use.

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 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:	Wrist 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	K223291
Trade Name of Device:	Wrist Blood Pressure Monitor
Regulation Number:	21 CFR 870.1130
Regulation Name:	Electronic Blood Pressure Monitor
Regulatory Class	II
Product Code:	DXN

IV Device Description

Wrist Blood Pressure Monitor mainly consist of pressure sensor, air pump, valve, cuff, main board and plastic case.

Wrist 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.

The Wrist Blood Pressure Monitor include two models: YJ110, YJ111

V Indications for use

Wrist Blood Pressure Monitor is used to measure adult systolic blood pressure. diastolic blood pressure and pulse rate. The values are for diagnostic reference only. Suitable for medical institutions (such as hospitals, clinics, health centers, etc.) and home use.

VI Technological Characteristics Comparison

VI-1: Comparison of Wrist Blood Pressure Monitor

Device Characteristic	Subject Device	Predicate Device (K223291)	**Discussion**
Type of Blood Pressure Monitor	Wrist Blood Pressure Monitor YJ110,YJ111	Wrist Blood Pressure Monitor PG-800A18, PG-800A19, PG-800A28, PG-800A51, PG-800A52, PG-800A11-1, PG-800A36-1 and PG-800A37-1	-
Product Code	DXN	DXN	Same
Regulation No.	21 CFR 870.1130	21 CFR 870.1130	Same
Class	II	II	Same
Indications for Use	Wrist Blood Pressure Monitor is used to measure adult systolic blood pressure. diastolic blood pressure and pulse rate. The values are for diagnostic reference only. Suitable for medical institutions (such as hospitals, clinics, health centers, etc.) and home use.	The Electronic Blood Pressure Monitor is intended to measure the systolie and diastolic blood pressure as well as the pulse rate of adult person via non-invasive oscillometric technique in which an inflatable cuff is wrapped around the wrist. It can be used at medical facilities or at home. The intended wrist circumference is 13.5-19.5 cm.The patient population does not include adolescents aged 12 to <18 years of age. The patient population includes transition adolescent B (18 to < 22 years of age but treated like adult) and adults (at least 22 years of age).	Same
Measurement Type	Wrist	Wrist	Same

Patient Population	Adult	Adult	Same
Measurement Item	Systolic Pressure, Diastolic Pressure, Pulse Rate	Systolic Pressure, Diastolic Pressure, Pulse Rate	Same
Principle	Oscillometric	Oscillometric	Same
Main Component	LCD/Key/Cuff/MCU/Pump/Transducer/ Batteries	LCD/Key/Cuff/MCU/Pump/Transducer/ Batteries	Same
Blood Pressure Range	Pressure:0~295mmHg (0~39.3kPa) SYS: 65 to 230 mmHg DIA: 45 to 160 mmHg	30 ~ 280 mmHg	Different 1
Pulse Rate Range	40~199beat/min	40-199 bpm	Same
Intended wristcir cumference	13.5~19.5cm	13.5cm-19.5cm	Same
Records Quantity	60 sets of memory	Double patients mode: 90/90 records	Different 2
Power supply	d.c.3V (2 AAA size batteries)	Two AAA or LR03 batteries for models PG-800A18, PG-800A19, PG-800A28, PG-800A52 3.7V for models PG-800A51, PG-800A11-1,PG-800A36-1,PG-800A37-1	Different 3
Operation condition	+5℃~+40℃, 15%RH~85%RH 80kPa~105kPa	+5℃~+40℃ 30%RH-80%RH Atmospheric pressure	Different 4
Storage condition	-20℃~+55℃, 15%RH~85%RH,and no condensation 80kPa~105kPa	-20℃~+55℃ 10%RH-93%RH Atmospheric pressure	Different 5
Patient Contact Material	Cuff-Nylon Enclosure-ABS Key-ABS	Cuff-Nylon Enclosure-ABS Key-ABS	Same
Biocompatibility	Comply with ISO10993 series standards No cytotoxicity; No irritation to skin; No significant evidence of sensitization	Comply with ISO10993 series standards No cytotoxicity; No irritation to skin; No significant evidence of sensitization	Same

Electrical Safety	Comply with IEC 60601-1	Comply with IEC 60601-1	Same
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Same
Particular Performance	Comply with IEC 80601-2-30 and ISO 81060-2	Comply with IEC 80601-2-30 and ISO 81060-2	Same

Different 1- Blood Pressure 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- Records Quantity

The records quantity of subject device is 60 while for predicate device is 90/90, yet the subject device adopted same measurement principle and NIBP algorithm as predicate device, software function is justified by the software documents. This difference will not affect the safety and effectiveness.

Different 3- Power supply

The difference between subject device and predicate device (K223291) is the batteries, the predicate device use 2 x 1.5V Batteries (for models: PG-800A18, PG-800A19, PG-800A28, PG-800A52) and Rechargeable Li-ion Battery PL 552233 for model: PG-800A51, PG-800A11-1, PG-800A36-1 and PG-800A37-1 while the subject device use two AAA, 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 4- Operation condition

The difference between subject device and predicate device (K223291) is the humidity, the predicate device is 30%RH-80%RH, while the subject device is 15%RH-85%RH, but the humidity of subject device is meets the requirements of IEC 80601-2-30. therefore, the difference will not affect the safety and effectiveness of the subject device.

Different 5- Storage condition

The difference between subject device and predicate device (K223291) is the humidity, the predicate device is 10%RH-93%RH, while the subject device is 15%RH~85%RH, it is included in predicate device, therefore this item is considered as substantial equivalence.

VII Summary of Non-Clinical Testing

The non-clinical testing for Wrist 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. Appearance and structure test	1.1	The shape of the product should be correct, the surface bright and clean, there should be no obvious scratches, damage and deformation.	Pass
	1.2	The text and logo on the control panel of the product should be accurate, clear and firm.	Pass
	1.3	The function of the product shall be clearly marked and indicated.	Pass
	1.4	The connection of each part of the product should be reliable, the key activity should be free, no card key and affect the operation phenomenon.	Pass
	1.5	The display number of the product should be clearly distinguishable, and there is no missing or breaking phenomenon.	Pass
2. Identification requirement	2.1 Device identification	a) Display enough information for easy traceability and identification. In addition, the following information should also be displayed: b) Use warnings, including a statement that you need to consult a medical professional to interpret the blood pressure value measured. c) Appropriate operating instructions。 d) Instrument performance parameters	Pass

		relevant to the accuracy requirements of this standard。 e) Wrist girth for matching wristbands	
	2.2 External packing	The outer package should include the following information: a) Applicable wrist circumference (can be identified by "cm"); b) Any special requirements for battery-operated equipment shall also be indicated.	Pass
	2.3 Specification	Each piece of equipment should be accompanied by a manual, which should include at least the following: a) Complete instructions for use, including a section summarizing warnings for use. This section should be indexable in the table of contents and direct the user to the relevant section in the information manual; b) A dedicated chapter with information on: how to unpack, install, perform pre-service checks, where to get help, standard operating procedures, general maintenance, recalibration and cleaning frequency recommendations; c)How to contact the manufacturer for after-sales service； d)Whether the device can achieve the claimed performance when common arrhythmias such as atrial premature, ventricular premature, and atrial fibrillation occur; e) Check the accuracy of the wristband pressure sensor/indicator at the time	Pass

		interval specified by the manufacturer, and give suggestions on the validity verification method; f) The detailed measurement method should be indicated, including at least the location of the measurement, the appropriate time to rest before the blood pressure measurement, the applicable wrist circumference, and a statement that the blood pressure value measured should be interpreted by a professional; g) The user is reminded that any blood pressure measurement is affected by the posture of the person being measured as well as his/her physical condition. Other factors that interfere with blood pressure measurement should also be listed; h) A statement that if stored or used outside the manufacturer's specified temperature and humidity ranges, the system may not achieve the claimed performance specifications (Manufacturer's specified temperature and humidity ranges should be given together in the statement); i) Product warranty information; j) It should be indicated that the device is not intended for neonates; k) Risks that may exist when the airbag is overinflated for a prolonged period of time; l) Method of determining display device failure; m) Recommended disinfection procedures; n) A statement regarding the correlation	

		between blood pressure measurements (including systolic, diastolic and mean blood pressure) obtained by this product and measurements obtained using one or two other different independent methods mentioned in this standard;	
	2.4 Low voltage prompt function	2.4.1 Label of the battery powered device The device should be marked with the correct battery model. 2.4.2 Wristband identification The wrist strap should indicate or indicate the range of wrist girth to which it applies.	Pass
3. Safety index	3.1 Maximum band pressure	1) Wrist pressure should not exceed 40kPa (300mmHg); 2) The device should ensure that the wristband pressure is kept above 2kPa (15mmHg) for no more than 3 minutes.	Pass
	3.2 Aerofluxus	The device shall provide a simple and clearly marked measure allowing the user to deflate the wristband. 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	Pressure measurement range: 0kPa (0mmHg) ~39.3kPa (295 mmHg), the maximum pressure does not exceed 40kPa (300mmHg). Pulse measurement range: 40~199 times/min.	Pass
	4.2 Resolution ratio	The pressure display resolution should be 0.133kPa (1mmHg). The pulse display resolution should be 1	Pass

		time/min.	
	4.3 Repeatability	When measured at static continuous low pressure, the difference between the readings measured repeatedly at each point within the scale range should not be greater than 0.533kPa (4mmHg). All readings shall comply with the requirements in 4.4.	Pass
	4.4 Pressure sensor and pulse measurement accuracy	4.4.1 The maximum error of the pressure measurement in the wristband should not be greater than ±0.4kPa (±3mmHg) at any measuring point in the range, whether the pressure is increased or decreased. 4.4.2 Pulse measurement error: ±5%.	Pass
	4.5 Requirements for charging sources and pressure control valves	4.5.1 Aeration source The aeration source should provide enough air to reach a pressure of 40kPa (300mmHg) in a 200cm3 (12 cubic inches) container within 10 seconds. 4.5.2 Pressure controlled air valve 4.5.2.1 air leakage When the valve is closed and the initial pressure is 33.33kPa (250mmHg), 20kPa (150mmHg) and 6.67kPa (50mmHg) respectively, the maximum pressure drop in a container with a volume not exceeding 80cm3 should not exceed 0.133kPa (1mmHg) within 10s. 4.5.2.2 Valve/wristband bleed rate When the valve is in the pressure control position (using the accompanying wristband), the pressure reduction rate from 33.33kPa (250mmHg) to 6.67kPa	Pass

		(50mmHg) should not be less than 0.267kPa/s (2mmHg/s). 4.5.2.3 blow-by The rapid venting of a gas-filled 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).	
	4.6 Airbag and wristband requirements	4.6.1 size The length of the airbag is about 0.4 times that of the covering wrist, and the width of the airbag is about half the length. 4.6.2 compression resistance It should be able to withstand an internal pressure equal to the maximum pressure of 39.3kPa (295mmHg) expected to be used by the wristband.	Pass
	4.7 Wrist strap port/Structure	After 1,000 opening and closing cycles and 10,000 40kPa (300mmHg) pressure cycles, the closure and sealing of the wristband and integrated airbag should still be intact enough to meet other requirements.	Pass
	4.8 System air leakage	The rate of pressure drop caused by air leakage throughout the sphygmomanometer system should not be greater than 0.133kPa/s (1mmHg/s).	Pass
	4.9 Lifetime	After at least 10,000 full scale cycles, the equipment should still meet the safety and performance requirements of the standard. A full scale cycle is when the pressure rises from 2.67 kPa (20 mmHg) or less to a maximum pressure value and then falls to 2.67 kPa (20 mmHg) or less.	Pass

	4.10 Prompt facility	4.10.1 Low battery prompt When the voltage of the sphygmomanometer is d.c. (2.2-2.5) ± 0.1V, there should be a battery symbol indicating that there is one grid of electricity left. When it is lower than 2.2V±0.1V, the battery symbol displays empty power and blinked for three times before automatically shutting down. 4.10.2 Irregular heart rate warning The sphygmomanometer should be able to indicate the irregular heartbeat of the human body and can display the " " symbol.	Pass
	4.11 Clock setting function	The sphygmomanometer should be able to display time and set time, including year, month, day, hour and minute.	Pass
	4.12 Memory function	The sphygmomanometer has memory and deletion functions and can remember 60 sets of measurements.	Pass
	4.13 Automatic shutdown function	No operation automatically shuts down after 3 minutes.	Pass
5 Electromagnetic compatibility		The equipment 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.	
6. Electrical safety	The equipment shall meet the requirements specified in IEC 60601-1.	Pass
7.Environmental test requirements	Climatic and environmental tests 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 Enclosure, key and cuff. The material of Enclosure and key 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, ISO 10993-10 and ISO 10993-23.

- Cytotoxicity
- Skin Sensitization
- Skin Irritation

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Wrist 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 Wrist 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 Wrist Blood Pressure Monitor.
The device complies with the IEC60601-1-6.

VIII Clinical Test Conclusion

YJ110 was tested to ISO 81060-2:2018 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type. the clinical validation data on YJ110 can cover YJ111. The Same Arm Sequential Method was chosen and performed on YJ110. This study included 86 adult subjects (47 females, 39 male) with an age range of 18 to 72 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.

IX Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the Wrist Blood Pressure Monitor is as safe as effective, and performs as well as or better than the legally marketed device.