March 15, 2024

Shenzhen Yuezhongxing Technology Co., Ltd.
Yuchao Chen
Sales Manager
No.2, Zhenye Road, Liulian Community, Pingshan Avenue
Pingshan District
Shenzhen, Guangdong 518015
China

Re: K233799
Trade/Device Name: Wrist Blood Pressure Monitor (222); Wrist Blood Pressure Monitor (222BT); Wrist Blood Pressure Monitor (W1681BL); Wrist Blood Pressure Monitor (W1681BT); Wrist Blood Pressure Monitor (W1681R)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: February 29, 2024
Received: February 29, 2024

Dear Yuchao Chen:

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,
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233799

Device Name

Wrist Blood Pressure Monitor (222);
Wrist Blood Pressure Monitor (222BT);
Wrist Blood Pressure Monitor (W1681BL);
Wrist Blood Pressure Monitor (W1681BT);
Wrist Blood Pressure Monitor (W1681R)

Indications for Use *(Describe)*

The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 5 3/8 inches to 7 2/3 inches (13.5cm to 19.5cm). The device detects the appearance of irregular hearbeats during measurement and gives a warning signal with reading.

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.

510(K) Summary

1. Submitter's Information

The submitter of this pre-market notification is:

Name:	Shenzhen Yuezhongxing Technology Co., Ltd.
Address:	No.2, Zhenye Road, Liulian Community, Pingshan Avenue, Pingshan District, Shenzhen,518015,CHINA
Contact person:	Yuchao Chen
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2. Device Identification

Trade/Device Name:	Wrist Blood Pressure Monitor
Models:	222, 222BT, W1681BL, W1681BT, W1681R
Regulation Number:	21 CFR 870.1130
Regulation Name:	Noninvasive blood pressure measurement system
Common Name:	System, Measurement, Blood-Pressure, Non-Invasive
Regulation Class:	Class II
Product Code:	DXN
Panel:	Cardiovascular

3. Predicate Device

510(K) number:	K211041
Device Name:	Wrist Blood Pressure Monitor
Models:	W1681
Manufacturer:	Shenzhen Yuezhongxing Technology Co., Ltd.
Regulation Number:	21 CFR 870.1130
Regulation Name:	Noninvasive blood pressure measurement system
Common Name:	System, Measurement, Blood-Pressure, Non-Invasive
Regulation Class:	Class II
Product Code:	DXN
Panel:	Cardiovascular

4. Device Description

The Wrist Blood Pressure Monitor,Models: 222,222BT,W1681BL, W1681BT, W1681R are powered by a rechargable Li-ion battery, automatic, non-invasive blood pressure system intended for home use. The devices are intended for use in adult patient population with wrist circumference ranging from 5 3/8 inches to 7 2/3 inches (13.5 cm to 19.5 cm). The devices' wrist cuff inflates using an integral pump and deflates via an electric valve. During deflation, the wrist cuff pressure is monitored and pulse waveform data is extracted. The extracted pulse waveform data is then analyzed by software which determines pulse rate, as well as systolic and diastolic blood pressure. The systolic and diastolic blood pressures are measured using the oscillometric method. The cuff can measure pressure range from 0 to 295 mmHg, and the pulse rate range from 40 to 199 beats/min.

When the device detected irregular rhythms, "  " will display on screen. An irregular heartbeat rhythm is defined as a rhythm that is 25% less or 25% more than the average rhythm detected while your monitor is measuring blood pressure. The WHO blood pressure indicator bar can classify by WHO and ISH recommendation. The devices display the latest blood pressure reading, while up to 2 x 99 readings can be stored in memory.

5. Indication for use

The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 5 3/8 inches to 7 2/3 inches (13.5cm to 19.5cm). The device detects the appearance of irregular hearbeats during measurement and gives a warning signal with reading.

6. Compared to Predicate Device

Compare to the predicate devices, the subject device has same intended use, similar product design, same performance,same safety as the predicate device, the summarized comparison information is listed in the following table

SE Comparisons	Subject device Wrist Blood Pressure Monitor, Model:202	Subject device Wrist Blood Pressure Monitor, Model:202BT	Subject device Wrist Blood Pressure Monitor, Model:W1681 BL	Subject device Wrist Blood Pressure Monitor, Model:W1681 BT	Subject device Wrist Blood Pressure Monitor, Model:W1681 R	Predicate device Automatic Wrist Blood Pressure Monitor, Model: W1681 (K211041)	Note
Indication for use	The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 5 3/8 inches to 7 2/3 inches (13.5cm to 19.5cm). The device detects the appearance of irregular hearbeats during measurement and gives a warning signal with reading.					The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 5 3/8 inches to 7 2/3 inches (13.5cm to 19.5cm). The devices detect the appearance of irregular hearbeats during measurement and gives a warning singal with reading	Same
Environment of use	Home					Home	Same
Patient population	Adult					Adult	Same
Contraindication	The monitor is contraindicated for use in ambulatory environment. The monitor is contraindicated in aircraft. Use of this instrument on patients under dialysis therapy or on anticoagulant, antiplatelets, or steroids could cause internal bleeding.					The monitor is contraindicated for use in ambulatory environment. The monitor is contraindicated in aircraft.	Note 1
Principle of operation	Cuff oscillometric method					Cuff oscillometric method	Same
Measurement range	Cuff Pressure: 0-295 mmHg, Pulse: 40-195/minute, Diastolic Pressure: 30-180mmHg,					Cuff Pressure: 0-295 mmHg, Pulse: 40-195/minute,	Same

SE Comparisons	Subject device Wrist Blood Pressure Monitor, Model:202	Subject device Wrist Blood Pressure Monitor, Model:202BT	Subject device Wrist Blood Pressure Monitor, Model:W1681 BL	Subject device Wrist Blood Pressure Monitor, Model:W1681 BT	Subject device Wrist Blood Pressure Monitor, Model:W1681 R	Predicate device Automatic Wrist Blood Pressure Monitor, Model: W1681 (K211041)	Note
	Systolic Pressure: 50-270mmHg					Diastolic Pressure: 30-180mmHg, Systolic Pressure: 50-270mmHg	
Pressure sonsor	Semiconductor pressure sensor					Semiconductor pressure sensor	Same
Wrist circumference	13.5-19.5 cm					13.5-19.5 cm	Same
Accuracy	Cuff Pressure: ±3mmHg Pulse: ±5% of reading The accuracy of diastolic and systolic pressure meets the requirements of ISO 81060-2:2018					Cuff Pressure: ±3mmHg Pulse: ±5% of reading The accuracy of diastolic and systolic pressure meets the requirements of ISO 81060-2:2018	Same
Inflation method	Automatic inflation with piezoelectric pump					Automatic inflation with piezoelectric pump	Same
Deflation method	Automatic rapid deflation valve					Automatic rapid deflation valve	Same
Screen	LED	LED	LCD	LCD	LCD	LCD	Note 2
Power source	Rechargeable Li-ion battery. 3.7Vdc300mAh Charged by Adapter, Input:100-240V 50/60Hz 0.2A,Output:5.0Vdc 1.0A					2 x AAA batteries	See Note 3
Bluetooth	No	Yes	No	Yes	No	No	Note 4

SE Comparisons	Subject device Wrist Blood Pressure Monitor, Model:202	Subject device Wrist Blood Pressure Monitor, Model:202BT	Subject device Wrist Blood Pressure Monitor, Model:W1681 BL	Subject device Wrist Blood Pressure Monitor, Model:W1681 BT	Subject device Wrist Blood Pressure Monitor, Model:W1681 R	Predicate device Automatic Wrist Blood Pressure Monitor, Model: W1681 (K211041)	Note
Operation condition	+5℃~+40℃,15%~80%RH, 70~106kPa					+5℃~+40℃, 15%~80%RH, 80~106kPa	See Note 5
Storage condition And Transportation condition	-20~+55°C,10%~ 93%RH, 70~106kPa					-20~+55°C, 10%~93%RH	See Note 6
Irregular heart beat feature	Yes					Yes	Same
Hypertension indication	Yes					Yes	Same

Note 1:The subject devices have additional contraindication, the subject device are prohibited use for patients under dialysis therapy or on anticoagulant, antiplatelets, or steroids could cause internal bleeding.This does not impact the safety and effectiveness.

Note 2: The subject devices 202 and 202BT employ LED screen.This does not impact the safety and effectiveness.

Note 3: The predicate device is powered by AAA battery, the subject devices are powered by rechargable Li-ion battery, and are charge by an AC adapter.The subject devices, Li-ion battery and AC adapter were conducted IEC 60601-1:2005+A1:2012+A2:2020 tests, the results showed meet safety requirements. So this does not impact the safety and effectiveness.

Note 4: The subject devices 202BT and W1681BT have bluetooth function, can connect to Smartphone App. The EMC, Wirelesscoexist and Cybersecurity are evaluated. So this does not impact the safety and effectiveness.

Note 5: The subject devices comply with IEC 60601-1: 2005+A1:2012, no energy risk and mechanical risk arise. The subject devices can be operated in operation conditions manufacture specified.

Note 6: The subjected devices comply with IEC 60601-11:2015, they can be transported and stored in transport and storage conditions manufacture specified, and the conditions are indicated in user manual.

8. Performance Data

Clinical test:

We performed a clinical study to verify clinical accuracy of the subject devices in accordance with ISO 81060-2:2018. The study was conducted by Shenzhen Cihai Hospital.

The quantity of clinical investigation subjects is 86 subjects. Of these, 44 are men and 42 are women, with a minimum age of 16 and a maximum age of 87. The patient's Wrist size is required between 22 cm and 32cm.

We selected auscultatory method (mercury sphygmomanometer) as the reference standard to determine the clinical accuracy by calculating the mean value and standard deviation according to ISO 81060-2:2018.

86 subjects were selected and 344 valid paired blood pressure values of systolic and diastolic data were obtained.

According to the method of criterion 1 in ISO81060-2 : 2018, 5.2.4. 1.2 . The mean value of the differences of systolic blood pressure between the sphygmomanometers-under-test and mercury sphygmomanometer was 1.0, and the standard deviation was 3.1. The mean value of the differences of diastolic blood pressure between test and mercury sphygmomanometer was 0.9 and the standard deviation was 3.4.

According to the method of criterion 2 in ISO 81060-2 : 2018,5.2.4. 1.2 , the standard deviation of systolic blood pressure of sphygmomanometers-under-test and mercury sphygmomanometer is 2.4 . The standard deviation of diastolic blood pressure for test and mercury sphygmomanometer is 2.6 in table 1.

The statistical analysis results were within the ISO 81060-2-2018 standard acceptance standard, compared with the results of the mercury sphygmomanometer, determine that the subject device have enough clinical accuracy.

Non-clinical data

The Wrist Blood Pressure Monitor comply with:

Safety and performance:

1. IEC 60601-1:2005+ A1:2012+A2:2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
2. 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
3. IEC 80601-2-30:2018 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

Electromagnetic Compatibility:

4. IEC 60601-1-2:2014 Medical electrical equipment-Part1-2: General requirements for basic safety and essential performance-Collateral Standard: Electromagnetic disturbances-Requirements and tests

Biocompatibility:

5. ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

6. ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

Software Verification and Validation:

FDA software validation guidance “General Principles of Software Validation; Final Guidance for Industry and FDA Staff, Document issued on: January 11, 2002”.

Software documentation for moderate level of concern per the FDA Guidance Document “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

9. Conclusion

The conclusions drawn from the nonclinical tests and clinical tests demonstrate that the subject devices are as safe, as effective, and performs as well as the predicate device (K211041).