August 30, 2021

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

Re: K211041
Trade/Device Name: Wrist Blood Pressure Monitor (model: W203, W202, W1681)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: July 7, 2021
Received: July 27, 2021

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 (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,

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)*
K211041

Device Name
Wrist Blood Pressure Monitor (model: W203,W202,W1681)

Indications for Use *(Describe)*
The device are digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging form 5 3/8 inches to 7 2/3 inches (13.5cm to 19.5cm) .
The devices detect the appearance of irregular heartbeats during measurement and gives a warning signal with readings.

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.

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"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."

510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: March 18, 2021

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

510(K) number:	K211041
Trade/Device Name:	Wrist Blood Pressure Monitor
Models:	W203,W202,W1681
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:	K190693
Device Name:	HEM-6410T-ZL Wrist Blood Pressure Monitor
Manufacturer:	Omron Healthcare, Inc.
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 (model: W203,W202,W1681) are battery-powered, automatic, non-invasive blood pressure system intended for home use.The Wrist Blood Pressure Monitor (model: W203,W202,W1681) 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). These devices are powered by 2× AAA battery. The device wrist cuff inflates using an integral pump and deflates via an electric valve. During inflation, 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 195 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 2×99 readings can be stored in memory.

5. Indication for use

The devices are 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 signal with reading.

6. Comparison to Predicate Device

Comparison to the predicate devices, the subject device has same intended use, similar product design, same performance effectiveness, performance safety as the predicate device as summarized in the following table

SE Comparisons	Proposed devices Automatic Wrist Blood Pressure Monitor (model: W203,W202,W1681) K211041	Predicate device Omron HEM-6410 K190693	Note
Indication for use	The devices are 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	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 7.1 to 8.5 inches(18.0cm to 21.5cm) The device detects the appearance of irregular hearbeats during measurement and gives a warning singal with reading	See Note 1
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.	The monitor is contraindicated for use in ambulatory environment. The monitor is contraindicated in aircraft.	Same

Principle of operation	Cuff oscillometric method	Cuff oscillometric method	Same
Measurement range	Pressure:0 to 295 mmHg Pulse rate: 40 to 195 beats/min	Pressure:0 to 299 mmHg Pulse rate: 40 to 180 beats/min	See Note 2
Pressure sonsor	Semiconductor pressure sensor	Semiconductor pressure sensor	Same
Wrist circumference	13.5-19.5 cm	18.0 to 21.5cm	See Note 1
Accuracy of pressure	±3mmHg	±3mmHg	Same
Accuracy of pulse rate	±5% of reading	±5% of reading	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
display	LCD	LCD	Same
Power source	2 x AAA batteries	Rechargeable Li-ion battery	See Note 3
Operation condition	5 to 40°C (41 to 104°F) 15 to 85% RH (non-condensing) 800 to 1060hPa	5 to 40°C (41 to 104°F) 15 to 85% RH (non-condensing) 800 to 1060hPa	Same
Storage condition	-20 to 55°C 10 to 93%RH	-20 to 40°C (-4 to 104°F) 10 to 90%RH (non-condensing)	See Note 4
Transportation condition	-20 to 55°C 10 to 93%RH	-20 to 60°C (-4 to 140°F)10 to 90%RH (non-condensing)	See Note 4

Irregular heart beat feature	Yes	Yes	Same
Body movement detection	No	Yes	See Note 5
Hypertension indication	Yes	Yes	Same
Advanced position sensor	No	Yes	See Note 5

Note 1: Wrist cuff size is different. Do not impact safety or performance of device.

Note 2: The measurement range of blood pressure and pulse rate of proposed devices is wider than predicate device, the clinical accuracy tests were conducted on proposed devices, so it is equal to predicate device at safety and effectiveness.

Note 3: Proposed devices are powered by 2 x AAA batteries, safety risk is lower than Li-ion battery of predicate device.

Note 4: After conducting simulate transportation test, result shows no risk arise.

Note 5: Proposed devices are without Body movement detection and Advanced position sensor feature, this does not affect the safety and main measurement function.

All the differences don't affect the safety and effectiveness which is concluded after all the required testing, so no safety and effectiveness issues relating to the system come into conclusion.

8. Performance Data

Clinical test:

IEC 80601-2-30:2018 require compliance of clinical accuracy should be checked by application of the tests of ISO 81060-2:2013, we conducted the the clinical study in accordance with this standard.

Non-clinical data

The Wrist Blood Pressure Monitor comply with:

Safety and performance:

1. IEC 60601-1:2005+A1:2012 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

Information included in this premarket notification supports the substantial equivalence of the proposed Wrist Blood Pressure Monitor (model: W203,W202,W1681). The proposed device has the identical indications for use and fundamental technology as the primary predicate device cleared under premarket notification K190693. The results of the testing support a determination of substantial equivalence. The minor differences in wrist strap size and Body movement detection and Advanced position sensor feature have been evaluated and determined to not raise different questions of safety or effectiveness. As such, the proposed devices are substantially equivalent to the predicate device.