February 3, 2025

Guangdong Xinyu Electronic and Technology Co., Ltd.
Rita Long
Official Correspondent
Number 42, CuiCheng Road, Cuiheng New District
Zhongshan, Guangdong 528400
China

Re: K241590
Trade/Device Name: Arm Blood Pressure Monitor (XY-B01, XY-B02, XY-B03, XY-B05, XY-B07, XY-B08, XY-B09)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: January 6, 2025
Received: January 6, 2025

Dear Rita Long:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

for Robert T. Kazmierski -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)*
K241590

Device Name
Arm Blood Pressure Monitor (XY-B01, XY-B02, XY-B03, XY-B05, XY-B07, XY-B08, XY-B09)

Indications for Use *(Describe)*

Arm Blood Pressure Monitor is intended for use by medical professionals or at home to monitor and display diastolic, systolic blood pressure and pulse rate on adult each time, with an air cuff buckled around one's arm according to the instruction in the user's guide manual.

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

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR 807.92.

1. Summary Prepared Date

20 May 2024

2. Submitter's Information

Sponsor

- Company Name: Guangdong Xinyu Electronic and Technology Co., Ltd.
- Address: Number 42, CuiCheng Road, Cuiheng New District Zhongshan Guangdong 528400 China
- Phone: 86-760-88818598
- Contact Person (including title): Ms. Rita Long (Regulatory Manager)
- E-mail: zcy_cg@163.com

Application Correspondent:

- Company Name: Guangdong Xinyu Electronic and Technology Co., Ltd.
- Address: Number 42, CuiCheng Road, Cuiheng New District Zhongshan Guangdong 528400 China
- Phone: 86-760-88818598
- Contact Person (including title): Ms. Rita Long (Regulatory Manager)
- E-mail: zcy_cg@163.com

3. Subject Device Information

- Type of 510(k) submission: Traditional
- Common Name: Noninvasive blood pressure measurement system
- Trade Name: Arm Blood Pressure Monitor
- Model: XY-B01, XY-B02, XY-B03, XY-B05, XY-B07, XY-B08, XY-B09
- Classification Name: System, Measurement, Blood-Pressure, Non-Invasive
- Review Panel: Cardiovascular
- Product Code: DXN
- Regulation Number: 870.1130
- Regulation Class: II

4. Predicate Device Information

- 510(k) number: K222926
- Sponsor: Shenzhen Yuezhongxing Technology Co., Ltd.
- Trade Name: Arm Blood Pressure Monitor
- Classification Name: System, Measurement, Blood-Pressure, Non-Invasive

- Model: 111, B1681, B1682, B1683
- Review Panel: Cardiovascular
- Product Code: DXN
- Regulation Number: 21 CFR 870.1130
- Regulation Class: II

5. Device Description

The Arm Blood Pressure Monitor, including XY-B01, XY-B02, XY-B03, XY-B05, XY-B07, XY-B08, XY-B09, can automatically complete the inflation, deflation and measurement, which can measure systolic and diastolic blood pressure as well as the pulse rate of adult person with arm circumference of 220-320mm through oscillometric method. The initial inflation pressure of the cuff is zero pressure. When start the device, the cuff will be inflated and deflated.
The Arm Blood Pressure Monitor is composed of monitor unit and arm cuff. Of which, the main unit contains main control circuit board, air pump, deflation valve, LCD and shell. The seven models have the same intended use, working principle, measuring range, accuracy, cuff, and conformance standard, except for appearance and power supply. The devices are powered by 4*AA batteries (XY-B02) or 4*AAA batteries (other models). The Arm Blood Pressure Monitor has a memory function that automatically stores 2*60 sets data of the latest measurements.

6. Indications for Use

Arm Blood Pressure Monitor is intended for use by medical professionals or at home to monitor and display diastolic, systolic blood pressure and pulse rate on adult each time, with an air cuff buckled around one's arm according to the instruction in the user's guide manual.

7. Comparison 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:

Elements of Comparison	Subject Device	Predicate Device	Verdict
Manufacturer	Guangdong Xinyu Electronic and Technology Co., Ltd.	Shenzhen Yuezhongxing Technology Co., Ltd.	-
510 (k) Number	-	K222926	
Product name	Arm Blood Pressure Monitor	Arm Blood Pressure Monitor	-
Models	XY-B01, XY-B02, XY-B03, XY-B05, XY-B07, XY-B08, XY-B09	111, B1681, B1682, B1683	-
Product Code	DXN	DXN	Same
Regulation No.	21 CFR 870.1130	21 CFR 870.1130	Same
Class	II	II	Same
Indication for use	Arm Blood Pressure Monitor is intended for use by medical professionals or at home to monitor and display diastolic, systolic blood pressure and pulse rate on adult each time, with an air cuff buckled around one's arm according to the instruction in the user's guide manual.	Arm Blood Pressure Monitor is intended for use by medical professionals or at home to monitor and display diastolic, systolic blood pressure and pulse rate on adult each time, with an air cuff buckled around one's arm according to the instruction in the user's guide manual.	Same
Environment of use	Hospital, Home	Hospital, 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 site	Upper Arm	Upper Arm	Same
Measurement range	Pressure: 0mmHg ～295mmHg(0kPa ～39.33kPa) Pulse rate: 40 to 180 beats/min	Pressure:0 to 280 mmHg Pulse rate: 40 to 199 beats/min	Different Note 1
Pressure sensor	semiconductor pressure sensor	Semiconductor pressure sensor	Same
Arm circumference	22 cm to 32 cm	22 cm to 32 cm	Same
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	4*AA batteries (XY-B02) 4*AAA batteries (other models)	4 x AAA batteries, or AC adapter (input: 100-240V~,50/60Hz,0.2A output:5V DC, 1.0A,5.0W)	Different Note 2
Operation condition	+10° C~ +40° C	5 to 40°C 15 to 93% RH	Different Note 3

Elements of Comparison	Subject Device	Predicate Device	Verdict
	15% ~ 85% RH 860hPa~1060hPa	700 to 1060hPa	
Storage condition	-20 ~ +55℃ 10% ~ 93% RH 500hPa~1060hPa	-25 to 70°C 0 to 93%RH	Different Note 3
Transportation condition	-20 ~ +55℃ 10% ~ 93% RH 500hPa~1060hPa	-25 to 70°C 0 to 93%RH	Different Note 3
Irregular heart beat feature	Yes	Yes	Same
Hypertension indication	Yes	Yes	Same

Note 1

The Blood Pressure Range of the subject device has minor difference with the blood pressure range of predicate devices, the measuring rang of the subject device was validated according to ISO 80601-2-30, the difference does not raise different questions of safety and effectiveness.

The pulse rate of the subject device is within that of the predicate device. The difference between the predicate device and subject device will not affect the safety and effectiveness of the subject device.

Note 2

The difference in power source will not affect the safety and effectiveness of the subject device. IEC 60601-1, IEC 60601-1-11 and IEC 60601-1-2 can demonstrate that the subject device can maintain the safety and performance. Thus, this difference does not raise different questions of safety and effectiveness.

Note 3

All the differences in operation condition and storage/transportation condition don't affect the safety and effectiveness which is concluded after all the required testing, thus, this difference does not raise different questions of safety and effectiveness.

8. Performance Data

Non-clinical data

The Arm Blood Pressure Monitor comply with:

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
4. IEC 60601-1-2:2014+A1:2020 Medical electrical equipment-Part1-2: General requirements for basic safety and essential performance-Collateral Standard: Electromagnetic disturbances-Requirements and tests
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

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

FDA guidance: Content of Premarket Submissions for Device Software Functions, JULY 20, 2023

Clinical test
The clinical test was conducted to verify that the proposed device met the requirements of the ISO 81060-2 : 2018 . The study population consisted of 120 subjects (55 female and 65 male) with an age range of 12 to 85 years. For systolic and diastolic pressures , the mean error shall be + 5mmHg or less , with a standard deviation of 8mmHg or less, all data is not over the limits. No adverse effect and/or complication is found in this study.

9. Conclusion

Based on the nonclinical and clinical tests, the subject device Arm Blood Pressure Monitor is as safe and as effective as the predicated device(K222926).