May 5, 2023

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

Re: K222926
Trade/Device Name: Arm Blood Pressure Monitor, Model Name:111, Arm Blood Pressure Monitor, Model Name: B1681, Arm Blood Pressure Monitor, Model Name: B1682, Arm Blood Pressure Monitor, Model Name: B1683
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: March 29, 2023
Received: March 30, 2023

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,

Robert T. Kazmierski -S

for

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)*
K222926

Device Name
Arm Blood Pressure Monitor (Models: 111,B1681,B1682,B1683)

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.

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:

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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: May 03, 2023

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:	K222926
Trade/Device Name:	Arm Blood Pressure Monitor
Models:	111, B1681, B1682, B1683
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:	K193627
Device Name:	Automatic Upper Arm Blood Pressure Monitor
Models:	BA-801X, BA-802X, BA-803X, BA-805X, BA-806X, BA-811X, BA-812X, BA-813X, BA-821X, BA-822X, BA-823X, BA-826X, BA-818,BA-819
Manufacturer:	DONGGUAN E-TEST 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 Arm Blood Pressure Monitor (model: 111, B1681, B1682, B1683) are battery-powered or DC powered, automatic, non-invasive blood pressure system and intended to be use in hospital environment or at home. The Arm Blood Pressure Monitor (model: 111, B1681, B1682, B1683) are intended for use in adult patient population with arm circumference ranging from 22 cm to 32 cm. These devices are powered by 4 x AAA batteries or an AC adaptor (output:5V DC). The device arm cuff inflates using an integral pump and deflates via an electric valve. During deflation, the arm 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 280 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 2x99 readings can be stored in memory.

5. 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.

6. Comparison to Predicate Device

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

SE Comparisons	Subject devices	Predicate devices K193627	Note
Company	Shenzhen Yuezhongxing Technology Co., Ltd.	DONGGUAN E-TEST TECHNOLOGY CO.,LTD	/
Product Name	Arm Blood Pressure Monitor	Automatic Upper Arm Blood Pressure Monitor	/
Model Name	111, B1681, B1682, B1683	BA-801X, BA-802X, BA-803X, BA-805X, BA-806X, BA-811X, BA-812X, BA-813X, BA-821X, BA-822X, BA-823X, BA-826X, BA-818,BA-819	/
Product Code	DXN	DXN	Same
Regulation name	Noninvasive blood pressure measurement system	Noninvasive blood pressure measurement system	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.	Automatic Upper 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

SE Comparisons	Subject devices	Predicate devices K193627	Note
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:0 to 280 mmHg Pulse rate: 40 to 199 beats/min	Pressure:0 to 280mmHg Pulse rate: 40 to 199 beats/min	Same
Pressure sonsor	Semiconductor pressure sensor	Semiconductor pressure sensor	Same
Arm circumference	22 cm to 32 cm	size A: 17cm-22cm (SMALL ADULT CUFF) size B: 22cm-30cm (ADULT CUFF-1) size C: 24cm-34cm (ADULT CUFF-2) size D: 22cm-42cm (LLARGE ADULT CUFF) size E: 30cm-42cm (LARGE ADULT CUFF) size F: 42cm-50cm (EXTRA LARGE ADULT CUFF)	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	4 x AAA batteries, or	4 x AAA batteries	See Note 2

SE Comparisons	Subject devices	Predicate devices K193627	Note
	AC adapter (input: 100-240V~,50/60Hz,0.2A output:5V DC, 1.0A,5.0W)		
Operation condition	5 to 40°C 15 to 93% RH 700 to 1060hPa	5 to 40 °C 15 to 80% RH 800 to 1050 hPa	See Note 3
Storage condition	-25 to 70°C 0 to 93%RH	-20 to 65 °C 10 to 95% RH 86 kPa to 106 kPa	See Note 3
Transportation condition	-25 to 70°C 0 to 93%RH	-20 to 65 °C 10 to 95% RH 86 kPa to 106 kPa	See Note 3
Irregular heart beat feature	Yes	Yes	Same
Hypertension indication	Yes	Yes	Same

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

Note 2: The subject device can be powered by an AC adaptor (output:5V DC) beside 4 x AAA batteries. IEC 60601-1, IEC 60601-1-11 and IEC 60601-1-2 can demonstrate that the subject device can maintain the safety and performance when is powered by an AC adaptor(output:5V DC). Thus, this difference does not raise different questions of safety and effectiveness.

Note 3: After conducting simulate transportation test, result shows no risk arise.

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:

We performed a clinical study to verify clinical accuracy of the subject devices in accordance with ISO 81060-2:2018. The study was conducted at Wanxiang Xintian Community Health Serve Center,Xixiang Street, Bao'an District, Shenzhen City China by Shenzhen Cihai Hospital.

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.

Subject

Number: A total of 86 subjects voluntarily participated in this study,

Gender:44 of them were male and 42 were female,

Age: ranging in age from 16 to 87 years old.

Race: Asian

Ethnicity: Not Hispanic or Latino

Arm size distribution:

37 (43%) subjects have an arm circumference which lies within the upper half of the specified range of use of the cuff,

49 (57%) subjects have an arm circumference within the lower half of the specified range of use of the cuff,

22 (26%) subjects l have an arm circumference which lies within the upper quarter of the specified range of use of the cuff,

26 (30%) subjects have an arm circumference within the lower quarter of the specified range of use of the cuff;

15 (17%) subjects have an arm circumference which lies within the upper eighth of the specified range of use of the cuff,

and 10(12%) subjects have an arm circumference within the lower eighth of the specified range of use of the cuff.

Procedure:

a. Either arm may be utilized
b. Using the reference sphygmomanometer (mercury sphygmomanometer), have the observers determine the subject’s blood pressure
c. Interchange cuffs and wait at least 60s
d. Use the sphygmomanometer-under-test (subject device) to determine the subject’s blood pressure
e. Clear the sphygmomanometer-under-test memory of the previous determination and then wait at least 60s
f. Do not use the data points obtained in b) and d) in the calculation of accuracy.
g. Using the reference sphygmomanometer (mercury sphygmomanometer), have the observers determine the subject's blood pressure
h. Interchange cuffs and wait at least 60 s.
i. Use the sphygmomanometer-under-test (subject device) to determine the subject's blood pressure

j. Interchange cuffs and wait at least 60 s.

k. Have the observers use the reference sphygmomanometer (mercury sphygmomanometer) to determine the subject's blood pressure reference reading.

l. Interchange cuffs and wait at least 60 s.

m. Repeat i) to l) until the required number of valid reference readings and determinations have been performed.

Result

Blood pressure distribution:

7 (8%) subjects of the reference blood pressure readings have a systolic blood pressure ≤100 mmHg

11 (13%) subjects of the reference blood pressure readings have a systolic blood pressure≥160 mm Hg.

20 (23%) subjects of the reference blood pressure reading have a systolic blood pressure ≥140mmHg.

8 (9%) subjects of the reference blood pressure reading have a diastolic blood pressure ≤ 60 mmHg.

11 (13%) subjects of the reference blood pressure readings have a diastolic blood pressure ≥ 100 mm Hg.

21 (24%)subjects of the reference blood pressure readings have a diastolic blood pressure ≥85 mm Hg.

Adverse effects and complications:

There is no adverse effect and complication was found during study.

Data analysis:

According to the method of criterion 1 in ISO 81060-2:2018,5.2.4.1.2, the mean value of the differences of systolic blood pressure between the sphygmomanometer-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 the sphygmomanometer-under-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 the sphygmomanometer-under-test and mercury sphygmomanometer was 2.4, the standard deviation of diastolic blood pressure of the sphygmomanometer-under-test and mercury sphygmomanometer was 2.6.

Conclusion

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 Arm 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

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe and effective as the predicated device(K193627).