January 19, 2022

Yibin Junxin Electronics Technology Co., Ltd.
% Cassie Lee, Manager
Share Info (Guangzhou) Medical Consultant Ltd.
No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road
Huangpu District
Guangzhou, Guangdong 510700
China

Re: K211532
Trade/Device Name: Arm Blood Pressure Monitor, model OB30, OB31, OB32, OB33
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: December 3, 2021
Received: December 22, 2021

Dear Cassie Lee:

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,

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)*
K211532

Device Name
Arm Blood Pressure Monitor

Indications for Use *(Describe)*
Arm Blood Pressure Monitor is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable cuff is wrapped around the arm of which the circumference includes 22 cm~36 cm.

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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# 510(k) Summary

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

## 1. Submitter's Information

Name: Yibin Junxin Electronics Technology Co., Ltd.
Establishment Registration Number: Applying
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**Application Correspondent:**

Contact Person: Cassie Lee
Share Info (Guangzhou) Medical Consultant Ltd.
Address: No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road, Huangpu District, Guangzhou, China
Tel: +86 20 8200 6973
Email: regulatory@share-info.com

## 2. Date of the summary prepared: December 3, 2021

## 3. Subject Device Information

Type of 510(k): Traditional
Common Name: Systems, measurement, blood pressure, Non-invasive
Classification Name: System, Measurement, Blood-Pressure, Non-Invasive
Trade Name: Arm Blood Pressure Monitor
Model Name: OB30, OB31, OB32, OB33
Review Panel: Cardiovascular
Product Code: DXN
Regulation Number: 870.1130
Regulatory Class: II

## 4. Predicate Device Information

Sponsor: Shenzhen BSX Technology Electronics Co., Ltd.
Trade Name: Arm-type Electronic Blood Pressure Monitor
Classification Name: System, Measurement, Blood-Pressure, Non-Invasive
Common Name: Noninvasive Blood Pressure Measurement System
510(K) Number: K183058
Product Code: DXN
Regulation Number: 870.1130
Regulation Class: II

## 5. Device Description

The Arm Blood Pressure Monitor is a battery powered automatic non-invasive pressure monitor, powered by 4 x1.5V AAA battery.

It can automatically complete the inflation, deflation and measurement, which can measure systolic and diastolic blood pressure and pulse rate of the adult person at upper arm within its claimed range and accuracy via the oscillometric technique. User can select the unit of the measurement: mmHg or kPa. The device has the data storage function for data reviewing. The proposed Arm Blood Pressure Monitor share the same software, measurement principle and NIBP algorithm.

The product is provided non-sterile, and not to be sterilized by the user prior to use.

**6. Intended Use / Indications for Use**

Arm Blood Pressure Monitor is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable cuff is wrapped around the arm of which the circumference includes 22 cm~36 cm.

**7. Comparison to predicate device**

The technological characteristics, features, specifications, materials, mode of operation, and intended use of Arm Blood Pressure Monitor is substantially equivalent to the predicate devices quoted above.
The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

| **Elements of Comparison** | **Subject Device** | **Predicate Device 1** | **Remark** |
|---|---|---|---|
| Company | Yibin Junxin Electronic Technology Co., Ltd. | Shenzhen BSX Technology Electronics Co., Ltd. | -- |
| Product Name | Arm Blood Pressure Monitor | Arm-type Electronic Blood Pressure Monitor | -- |
| Model Name | OB30, OB31, OB32, OB33 | BSX516, BSX523, BSX525, BSX583, BSX593 and BSX595 | -- |
| Classification Name | Systems,Measurement,Blood Pressure,Non-invasive | Systems,Measurement,Blood Pressure,Non-invasive | Same |
| 510(k) Number | Applying | K183058 | -- |
| Product Code | DXN | DXN | Same |
| **Intended Use and Indications for Use** | | | |
| Intended Use / Indications for Use | Arm Blood Pressure Monitor is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable cuff is wrapped around the arm of which the circumference includes 22 cm~36 cm. | The blood pressure monitor is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable CUFF is wrapped around the arm of which the circumference includes 22 cm~32 cm. It is intended to be used in hospital environment or at home. | Same |
| **Electrical requirement** | | | |

| | | | |
|---|---|---|---|
| Power Supply | 4x1.5V AAA Alkaline Battery | 4x1.5V AAA Alkaline Battery (BSX516, BSX525, BSX583, BSX593 and BSX595)<br>3.7V 400mAh Li-ion Battery (BSX523) | Same |
| **Performance specification** | | | |
| Measurement Site | Upper Arm | Upper Arm | Same |
| Measuring scope | Pressure: 0mmHg~260 mmHg;<br>Pulse: 40 bpm~199 bpm | Pressure: 0mmHg~299 mmHg<br>Pulse: 40 bpm ~180 bpm | Similar Note 1 |
| Pressure resolution | 1 mmHg or 0.1kPa | 1 mmHg or 0.1kPa | Same |
| Measuring accuracy | Pressure: ±3mmHg (±0.4kPa)<br>Pulse: ±5% | Pressure: ± 3mmHg<br>Pulse: ±5% | Same |
| Cuff Circumference | 22~36cm | 22~32cm | Similar Note |
| Inflation and Deflation | Automatic | Automatic | Same |
| Measuring Method | Non-invasive Oscillometric | Non-invasive Oscillometric | Same |
| Patient Population | Adult | Adult | Same |
| Display | LCD | LCD | Same |
| Operation condition | Temperature: +5 to +40 °C,<br>Humidity: 15 to 80%<br>Atmospheric Pressure: 80 kPa~105 kPa | Temperature: +5 to +40 °C,<br>Humidity: 15 to 85%<br>Atmospheric Pressure: 80 kPa~106 kPa | Similar Note 1 |
| Transport/storage environment | Temperature: -20°C ~ +50°C,<br>Humidity: 15%～93%<br>Atmospheric Pressure: 80 kPa~105 kPa | Temperature: -20°C~+55 °C,<br>Humidity: 10 to 93%<br>Atmospheric Pressure: 70 kPa~106 kPa | Similar Note 1 |
| Safety | IEC 60601-1<br>IEC 60601-1-11<br>IEC 80601-2-30 | IEC 60601-1<br>IEC 60601-1-11<br>IEC 80601-2-30 | Same |
| EMC | IEC 60601-1-2 | IEC 60601-1-2 | Same |
| Biocompatibility | ISO 10993 | ISO 10993 | Same |

**Note1:**
Although “Power Supply”, “Measuring scope”, “Cuff circumference”, “Operation condition and “Transport/storage environment” of the subject device are a little different from the predicate devices, but the difference of subject device is very similar to the K183058. So, these parameters’ differences will not raise any safety or effectiveness issues.

## 8. Performance Data and Test Summary

The following performance data were provided in support of the substantial equivalence determination.

### 8.1 Nonclinical test performed

#### 1) Biocompatibility testing

The biocompatibility evaluation for the Arm Blood Pressure Monitor was conducted in accordance with the FDA Blue Book Memorandum #G95-1 “Use of International Standard ISO-10993, ‘Biological Evaluation of

Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The biocompatibility testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

According to the test results, the subject device is biocompatible for its intended use. And it is complied with biocompatibility standards ISO 10993-5 (Cytotoxicity) and ISO 10993-10 (Irritation and Sensitization).

**2) Electrical safety and electromagnetic compatibility (EMC)**

Electrical safety and EMC testing were conducted on the Arm Blood Pressure Monitor (models: OB30, OB31, OB32, OB33), the device complies with the IEC 60601-1, IEC 60601-1-11, and IEC 80601-2-30 standards for safety and the IEC 60601-1-2 standard for EMC.

**3) Usability Testing**

Usability testing were conducted on the Arm Blood Pressure Monitor (models: OB30, OB31, OB32, OB33), the device complies with IEC 62366-1 and IEC 60601-1-6.

**4) 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, since a malfunction of, or a latent design flaw in, the Software Device lead s to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury.

**8.2 Clinical performance testing performed**

Clinical performance testing was conducted on the Arm Blood Pressure Monitor (models: OB30, OB31, OB32, OB33) according to the ISO 81060-2.

As this device is for adults only, the testing Included 85 subjects, aged from 22 to 81, 52.9% of participants are male and 47.1% are female, the limb size distribution of all subjects complied with clause 5.1.4 of ISO 81060-2.

The subject devices use the oscillometric method to measure blood pressure, the accuracy of determination depends on the sensor, race and ethnicity differences do not have an effect on the measuring result in the specified measuring scope.

During the testing, there were no adverse effects and complications occurred, and the results both meet criterion 1 and criterion 2 of ISO 81060-2.

**9. Final Conclusion:**

The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device K183058.