October 27, 2023

Shenzhen Jumper Medical Equipment Co., Ltd.
Danyin Li – Regulatory Affairs Specialist
D Building, No. 71, Xintian Road, Fuyong Street, Baoan,
Shenzhen, Guangdong, China 518103

Re: K231310
Trade/Device Name: Electronic Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: May 5, 2023
Received: May 5, 2023

Dear Danyin Li:

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,
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)*
K231310

Device Name
Electronic Blood Pressure Monitor

Indications for Use *(Describe)*
The Electronic Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person via non-invasive oscillometric technique at medical facilities or at home. The intended wrist circumference is 13.5-21.5 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.**

**Section 5** **510(K) Summary**

**1. Prepared Date: 2023-02-14**

**2. Submitter Information [807.92(a)(1)]**

| | |
|---|---|
| Name | Shenzhen Jumper Medical Equipment Co., Ltd. |
| Address | D Building, No. 71, Xintian Road, Fuyong Street, Baoan, Shenzhen, Guangdong, China, 518103 |
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**3. Submission Correspondent [807.92(a)(1)]**

| | |
|---|---|
| Contact person | Danyin Li |
| E-mail | ep03@jumper-medical.com |
| Tel | +86-755- 26696279 |

**4. Subject Device Information [807.92(a)(2)]**

| | |
|---|---|
| Proprietary Name | Electronic Blood Pressure Monitor |
| Common Name | Noninvasive blood pressure measurement system |
| Model | HWA11, HWA10 |
| Classification | System, Measurement, Blood-Pressure, Non-Invasive |
| Review Panel | Cardiovascular |
| Product Code | DXN |
| Regulation Number | 870.1130 |
| Regulatory Class | II |

**5. Predicate Device [807.92(a)(3)]**

| K182127, Omron Healthcare, Inc. | |
|---|---|
| Trade/Device Name | Wrist Blood Pressure Monitor |
| Model | BP6100 |
| Regulation Name | Noninvasive Blood Pressure Measurement System |
| Regulatory Class | Class II |

| | |
|---|---|
| Product Code | DXN |

**6. Indications for Use [807.92(a)(5)]**

The Electronic Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person via non-invasive oscillometric technique at medical facilities or at home. The intended wrist circumference is 13.5-21.5 cm.

**7. Device Description [807.92(a)(4)]**

The Electronic Blood Pressure Monitor, is a battery driven automatic non-invasive blood pressure monitor, comprised of the host machine and the wrist cuff. It can measure systolic and diastolic blood pressure and pulse rate of the adult person at wrist via the oscillometric technique. User can select the unit of the measurement: mmHg or kPa. The device can store 199 groups of measurement data for two users.

**8. Summary of technological characteristics of device compared to the predicate devices, see the table**

A comparison of key similarities and differences between the proposed devices (Electronic Blood Pressure Monitor, HWA11, HWA10) and the predicate devices (K182127) is provided below:

| | Propose Device | Propose Device | Predicated Device | Comparison |
|---|---|---|---|---|
| Product Name | Electronic Blood Pressure Monitor | Electronic Blood Pressure Monitor | Wrist Blood Pressure Monitor | / |
| Manufacturer | Shenzhen Jumper Medical Equipment Co., Ltd. | Shenzhen Jumper Medical Equipment Co., Ltd. | Omron Healthcare, Inc. | / |
| Appearance |  |  |  | / |
| Model | HWA11 | HWA10 | BP6100 (K182127) | / |
| Classification | 21 CFR§870.1130, Noninvasive blood pressure measurement system | 21 CFR§870.1130, Noninvasive blood pressure measurement system | 21 CFR§870.1130, Noninvasive blood pressure measurement system | Same |
| Product Code | DXN - Noninvasive blood pressure measurement | DXN - Noninvasive blood pressure measurement | DXN - Noninvasive blood pressure measurement | Same |

| | | | | |
|---|---|---|---|---|
| Indications for Use | The Electronic Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person via non-invasive oscillometric technique at medical facilities or at home. The intended wrist circumference is 13.5-21.5 cm. | The Electronic Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person via non-invasive oscillometric technique at medical facilities or at home. The intended wrist circumference is 13.5-21.5 cm. | 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 inches to 8.5 inches (13.5 cm to 21.5 cm).<br><br>The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings. | Different Note1 |
| Environment of Use | Medical Facilities/Home Use | Medical Facilities /Home Use | Home Use | Different Note1 |
| Patient Population | Adults | Adults | Adults | Same |
| Over-The-Counter (OTC) | Yes | Yes | Yes | Same |
| Measurement method | Cuff oscillometric method | Cuff oscillometric method | Cuff oscillometric method | Same |
| Wrist Cuff Circumference | 13.5-21.5 cm. | 13.5-21.5 cm. | 13.5-21.5 cm. | Same |

| | | | | |
|---|---|---|---|---|
| Measurement Range | Cuff pressure range 0 to 295mmHg<br>Pulse Rate: 40 to 199 beats/min. | Cuff pressure range 0 to 295mmHg<br>Pulse Rate: 40 to 199 beats/min. | Cuff pressure range 0 to 299 mmHg<br>Pulse Rate: 40 to 180 beats/min. | Different<br>Note2 |
| Accuracy | Blood Pressure: Within ±3mmHg<br>Pulse Rate: Within ±5 % of reading | Blood Pressure: Within ±3mmHg<br>Pulse Rate: Within ±5 % of reading | Blood Pressure: Within ±3mmHg<br>Pulse Rate: Within ±5 % of reading | Same |
| Pressure Sensor | Piezo resistance sensor | Piezo resistance sensor | Piezo resistance sensor | Same |
| Inflation Method | Automatic inflation with electric pump | Automatic inflation with electric pump | Automatic inflation with electric pump | Same |
| Deflation Method | Automatic rapid deflation valve | Automatic rapid deflation valve | Automatic rapid deflation valve | Same |
| Display Type | LCD digital display | LCD digital display | LCD digital display | Same |
| Power Source | Two "AAA" batteries | Two "AAA" batteries | Two "AAA" batteries | Same |
| Operating Conditions | 5 to 40 °C (41 to 104 °F)<br>15 to 85 %RH (non-condensing)<br>700 to 1060 hPa | 5 to 40 °C (41 to 104 °F)<br>15 to 85 %RH (non-condensing)<br>700 to 1060 hPa | 10 to 40 °C ( 50 to 104 °F)<br>15 to 90 %RH (non-condensing)<br>800 to 1060 hPa | Different<br>Note3 |

| | | | | |
|---|---|---|---|---|
| Storage/Transport Conditions | -20 to 55 °C (-4 to 131 °F)<br>10 to 93 %RH (non-condensing)<br>700 to 1060 hPa | -20 to 55 °C (-4 to 131 °F)<br>10 to 93 %RH (non-condensing)<br>700 to 1060 hPa | -20 to 60 °C (-4 to 140 °F)<br>10 to 90 %RH (non-condensing) | Different<br>Note3 |
| Dimensions | 61 (W) × 24.1(D) × 87 (H) mm | 61 (W) × 24.1(D) × 87 (H) mm | 93 (W) × 20 (D) × 62 (H) mm | Different<br>Note4 |
| Weight | Approx. 111±5g (without batteries) | Approx. 111±5g (without batteries) | Approx. 86g (3.0 oz) (not including battery) | Different<br>Note4 |

**COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES [807.92(a)(6)]**

The proposed device and the predicate device have similar technological characteristics. Both devices are battery-operated wrist blood pressure monitors intended for home use and employ the oscillometric method for measuring blood pressure and pulse. The devices are intended for the same wrist circumference range of 13.5 cm to 21.5 cm. The devices share the same accuracy range of pressure reading of ±3 mmHg and the same accuracy range for pulse rate reading of ± 5%.

There are minor differences in technical specifications and features between the HWA11, HWA10 proposed device and BP6100 predicate device would be discussed below:

**SUBSTANTIAL EQUIVALENCE**

The proposed Indications for Use for the Electronic Blood Pressure Monitor is like the Indications for Use for the predicate device.

They both intended for use in homecare for blood pressure and pulse rate measurement of adults. And different use environment has been tested by IEC 60601-1 & ISO 80601-2-30 and showed positive result. While the proposed device is designed for household and medical center use and the predicate device is for home use, the difference will not influence the safety and effectiveness of the devices because household environment is more complex.

The proposed device can also detect the appearance of irregular heartbeats during measurement and gives a warning signal with readings, which is mentioned in "Features" and stated as "Indication for irregular heartbeats". So, both devices are identical for this. (Note1)

The pressure range is narrower than the predicate device while the pulse rate of the proposed device are larger than the predicate device. Both contain the blood pressure and pulse range of most people, and the measurement range of proposed device is fully verified according to IEC 80601-2-30. Therefore, the differences do not bring additional risks. (Note 2)

Although the operating atmospheric pressure of the proposed device is slightly broader than the predicate device, while the storage temperature and humidity of the proposed device are little narrower, they all comply with IEC 60601-1, IEC 60601-1-11 and IEC 80601-2-30, so this difference will not raise any safety or effectiveness issue. (Note 3)

Minor differences in the dimensions and weight do not impact the safety or performance of blood pressure or pulse rate measurements (Note4). Any differences in the technological characteristics between the devices do not raise any different questions of safety or effectiveness. Thus, the proposed device is substantially equivalent to the predicate device.

**PERFORMANCE DATA [807.92(b)]**

All necessary bench and clinical testing was conducted on the Electronic Blood Pressure Monitor

Model HWA11, HWA10 to support a determination of substantial equivalence to the predicate device.
[807.92(b)(1)] Nonclinical Testing Summary:
The nonclinical, bench testing included:

- Comparative blood pressure and pulse rate testing to the predicate device
- Performance verification testing to confirm acceptable performance of device features and functions
- Cleaning verification testing to confirm device retains its performance when cuff is cleaned with household detergents as may be required in home use environment

Other nonclinical safety testing included:

- Biocompatibility of patient-contacting materials per ISO 10993-1 requirements
- Electrical safety, electromagnetic compatibility, and electrostatic discharge testing
- Software verification and validation

The collective results of the nonclinical testing demonstrate that the materials chosen, the manufacturing processes, and design of the HWA11 & HWA10 meet the established specifications necessary for consistent performance during its Intended Use. In addition, the collective bench testing results demonstrate that the HWA11 & HWA10 does not raise different questions of safety or effectiveness for blood pressure and pulse rate measurement in a home use environment when compared to the predicate device.

**Clinical Testing Summary [807.92(b)(2)]**
A clinical investigation was conducted with the objective of validating the accuracy of blood pressure measurements by HWA11 based on an oscillometric method as compared to an auscultation method using a calibrated sphygmomanometer by trained medical staff.
This study was conducted in accordance with guideline per ANSI/AAMI/ISO 81060-2:2013 Non-invasive sphygmomanometers — Part 2: Clinical investigation of automated measurement type.
The results demonstrated that BP6100 performed equivalently to the auscultation method and is in conformance with ANSI/AAMI/ISO 81060-2:2013.

**CONCLUSIONS [807.92(b)(3)]**
The conclusions drawn from the nonclinical and clinical tests performed in support of HWA11, HWA10 demonstrate that the device is safe and effective, and performs at least as safely and effectively as the legally marketed K182127 predicate device.

**SUMMARY**
The Electronic Blood Pressure Monitor (Model HWA11, HWA10) is substantially equivalent to the Omron Model BP6100 predicate device(K182127).