October 27, 2025

Shenzhen Jamr Technology Co., Ltd.
Can Liu, RA Manager
A101-301, D101-201, Jamr Science & Technology Park, No. 2
Guiyuan Road, Guixiang Community,Guanlan Street,Longhua Dist
Shenzhen, Guangdong 518100
China

Re: K251331
Trade/Device Name: Blood Pressure Monitor (B73, BE23T)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: September 29, 2025
Received: September 29, 2025

Dear Can Liu:

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,

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251331

Please provide the device trade name(s).

Blood Pressure Monitor (B73, BE23T)

Please provide your Indications for Use below.

The Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate by using the arm cuff. The device can be used in medical facilities or at home, and only for indoor use. It is supplied for OTC use.

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (Part 21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

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.
The assigned 510(k) number is: _____

1. Submitter's information

Submitter's Names: Shenzhen Jamr Technology Co., Ltd.
Address: A101-301, D101-201, Jamr Science & Technology Park, No. 2 Guiyuan Road, Guixiang Community, Guanlan Street, Longhua District, Shenzhen 518100, PEOPLE'S REPUBLIC OF CHINA
Tel: +86-755-85292057
Applicant Contact: Can Liu
Applicant Contact Email:RA.dept@jamrmed.com

2. Device Information

Device Trade Name: Blood Pressure Monitor
Model(s): B73,BE23T
Common Name: Noninvasive blood pressure measurement system
Classification name: System, Measurement, Blood-Pressure, Non-Invasive
Product Code: DXN
Device Class: II
Regulation Number:870.1130

3. Predicate Device Information

510(K) Number: K233146
Trade Name: Blood Pressure Device
Model(s): B23,BA31T,BC31LT
Classification name: System, Measurement, Blood-Pressure, Non-Invasive
Product Code: DXN
Device Class: II
Regulation Number: 870.1130

4. Device Description

The blood pressure monitor is a fully automatic, non-invasive upper arm measurement device using oscillometric methodology to measure systolic pressure, diastolic pressure and pulse rate . The device features an inflatable cuff that wraps around the arm, with a built-in pressure sensor and transducer that analyze arterial pulsations to determine blood pressure values. Measurement results are clearly displayed on the LCD screen.

5. Intended Use/Indication for use

The Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate by using the arm cuff. The device can be used in medical facilities or at home, and only for indoor use. It is supplied for OTC use.

6. Comparisons of technological characteristics with the predicate device

The substantial equivalence chart is provided as follows:

Substantial Equivalence Comparison			
Elements of Comparison	Subject Device	Predicate Device (K233146)	Judgment
Models	B73,BE23T	B23,BA31T,BC31LT	/
Company	Shenzhen Jamr Technology Co., Ltd.	Shenzhen Jamr Technology Co., Ltd.	Same
Device Name	Blood Pressure Monitor	Blood Pressure Monitor	Same
Product code	DXN	DXN	Same
Regulation #	21CFR 870.1130	21CFR 870.1130	Same
Intended use	The Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate by using the arm cuff. The device can be used in medical facilities or at home, and only for indoor use. It is supplied for OTC use.	The Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult by using the arm cuff (22-42cm), it can be used in medical facilities or at home. It is supplied for OTC use.	Similar, refer to Note 1
Anatomical site	Upper arm	Upper arm	Same
Patient population	B73: 12 years above BE23T: 12 years above for cuff size 22-42cm, 32-52cm; 3 years and above for cuff size 15-28cm	Adults	Similar, refer to Note 2
Measurement Item	SYS, DYS, Pulse rate	SYS, DYS, Pulse rate	Same
Principle	Oscillometric	Oscillometric	Same
BP measurement range	Cuff pressure display range:0~295mmHg; Systolic Blood Pressure: 60~260mmHg; Diastolic Blood Pressure: 40~220mmHg	Cuff pressure display range:0~295mmHg; Systolic Blood Pressure: 60~260mmHg; Diastolic Blood Pressure: 40~220mmHg	Same
BP accuracy	±3mmHg	±3mmHg	Same
PR measurement range	40~199 Beats/Min	40~199 Beats/Min	Same
PR measurement accuracy	±5% of reading	±5% of reading	Same

Power supply	For B73: Powered by a) d.c. 6.0V, 4 *1.5V AA batteries; b) AC adapter INPUT: a.c.100 -240V 50/60HZ, OUTPUT:d.c. 5V 1A For BE23T: Powered by a) d.c. 4.5V, 3*1.5V AA alkaline batteries; b) AC adapter INPUT: a.c. 100-240V 50/60HZ, OUTPUT: d.c. 5V 1A	For B23: Powered by a) d.c. 6.0V, 4 x1.5V AAA batteries; b) AC adapter INPUT: a.c.100 -240V 50/60HZ, OUTPUT:d.c. 5V 1A For BA31T: Powered by a) d.c. 4.5V, 3*1.5V AA alkaline batteries; b) AC adapter INPUT:a.c. 100 -240V 50/60HZ, OUTPUT: d.c. 5V 1A. For BC31LT: Powered by a) d.c. 3.7V/ 800mAh lithium battery; b) AC adapter INPUT: a.c. 100-240V 50/60HZ, OUTPUT: d.c. 5V 1A	Same
Degree of protection against electric shock	Type BF applied part	Type BF applied part	Same
Model of operation	Continuous operation	Continuous operation	Same
Cuff size suitable for arm size	B73: 22cm-42cm or 32cm-52cm BE23T: 15cm-28cm, 22cm-42cm or 32cm-52cm	22cm~42cm	Similar, refer to Note 2
Sets of memory	Automatically stores the last 120 measurements for 2 users (total 240)	Automatically stores the last 120 measurements for 2 users (total 240)	Same
Irregular heartbeat detector	Yes	Yes	Same
Voice	Yes	Yes	Same
Operation environment	Temperature: 5°C~40°C; Humidity: 15~90%RH; Atmospheric Pressure:70 kPa~ 106 kPa	Temperature: 5°C~40°C; Humidity: 15~93%RH; Atmospheric Pressure:70 kPa~ 106 kPa	Similar, refer to Note 3
Transport/Storage environment	Temperature: -20°C ~ +60°C, Humidity: 10%RH ~ 93%RH; Atmospheric Pressure:70 kPa~ 106 kPa	Temperature: -20°C ~ +50°C,Humidity: ≤ 93%RH; Atmospheric Pressure:70 kPa~ 106 kPa	Similar, refer to Note 3
Performance	Compliance with Compliance with IEC 80601-2-30	Compliance with Compliance with IEC 80601-2-30	Same
Data transmission and APP	B73:No BE23T:Yes	B23:No BA31T,BC31LT:Yes	Same
Clinical	Compliance with Compliance with ISO 81060-2	Compliance with Compliance with ISO 81060-2	Same
Material	ABS housing and ABS keys	ABS housing and ABS keys	Same

Biocompatibility	All the patient contacting materials are compliance with ISO 10993-1/-5/-10/-23	All the patient contacting materials are compliance with ISO 10993-1/-5/-10/-23	Same
Electrical Safety	Compliance with IEC 60601-1 and IEC 60601-1-11	Compliance with IEC 60601-1 and IEC 60601-1-11	Same
EMC	Compliance with IEC 60601-1-2	Compliance with IEC 60601-1 -2	Same

Note 1:
Although there are minor differences in the "Intended Use" between the subject device and the predicate device, the general meaning remains the same: both are used for measuring blood pressure and pulse rate. Additionally, both devices comply with the standards IEC 60601-1, IEC 60601-1-11, IEC 60601-1-2, and IEC 80601-2-30. These differences do not raise any concerns regarding safety or effectiveness.

Note 2:
While there are differences in patient population and cuff sizes between the subject device and the predicate device, both devices support an arm circumference range of 22-42 cm. The subject device (B73 and BE23T) offers additional cuff sizes (15-28 cm and 32-52 cm) to accommodate a broader range of arm sizes, including pediatric patients (aged 3+) and adolescents (aged 12+). Clinical testing conducted in accordance with ISO 81060-2 and IEC 80601-2-30 confirms that all cuff sizes provide accurate and reliable blood pressure measurements. The performance of B73 and BE23T is consistent with the predicate device, with no significant differences in accuracy or safety.

Note 3:
Although there are slight differences in the "Operation Environment" and "Transport/Storage Environment" between the subject device and the predicate device, both the subject devices and predicate devices meet the requirements of the standards IEC 60601-1, IEC 60601-1-11, IEC 60601-1-2, and IEC 80601-2-30. Relevant test reports demonstrate that these differences do not impact the safety or effectiveness of the devices.

Conclusion:
Based on the comparative analysis provided in this submission, it is concluded that the subject device is substantially equivalent to the predicate device in terms of safety and effectiveness.

7. Brief discussions of the non-clinical tests

Performance testing:

The subject device conforms to the following guidances and standards:

- IEC 60601-1: Medical electrical equipment–Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirement for basic safety and essential performance-Collateral standard: Electromagnetic compatibility – Requirements and tests
- IEC 80601-2-30: Medical electrical equipment-Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers
- IEC 60601-1-11: 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

Biocompatibility testing:

The biocompatibility evaluation for the device was conducted in accordance with the FDA Guidance for Industry and Food and Drug Administration Staff: Use of International Standard

ISO 10993-1, “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process ”.
The biocompatibility testing includes the following tests:

- Cytotoxicity
- Sensitization
- Irritation

8. Brief discussions of clinical tests

The device was tested in accordance with ISO 81060-2:2018+A1:2020 (Non-invasive sphygmomanometers – Part 2: Clinical validation of automated measurement type).

Four clinical studies were conducted using appropriately sized cuffs, enrolling 85, 87, 88, and 98 eligible subjects respectively. The first three studies exclusively included participants aged >12 years, while the fourth study incorporated 35 pediatric subjects (aged 3-12 years).

The mean error and standard deviation of differences in systolic and diastolic blood pressure measurements were all within the limits specified by ISO 81060-2:2020. No adverse effects or complications were reported.

The test results confirm that the Blood Pressure Monitor fully complies with the requirements of IEC 80601-2-30:2018 and ISO 81060-2:2018+A1:2020.

Final Conclusion:

The subject device maintains the same core technology and indications for use as the predicate device (K233146).The minor differences do not affect the safety and effectiveness of the subject device. Thus, the subject device is substantially equivalent to the predicate device (K233146).