August 25, 2023

Shenzhen Jamr Technology Co., Ltd.
℅ Eva Li
Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1401, Dongfang Building, 1500# Century Ave.
Shanghai, 200122
China

Re: K230409
Trade/Device Name: Wrist Type Blood Pressure Monitor (W05,W1101L)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: July 28, 2023
Received: July 28, 2023

Dear Eva 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 (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.

Submission Number *(if known)*

K230409

Device Name

Wrist Type Blood Pressure Monitor (W05，W1101L)

Indications for Use *(Describe)*

This device is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult by using the wrist circumference 12.5-21.5cm, it can be used in medical facilities or at home. It is supplied for OTC use.

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.

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Shenzhen Jamr Technology Co., Ltd.
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005_510(K) Summary

The assigned 510(k) number is: K230409
Data preparation: August 15, 2023

1.0 Information of Submitter

Shenzhen Jamr Technology Co., Ltd.
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Contact person: Haiyu Zhang

2.0 Device Information

Type of 510(k) submission: Traditional
Trade Name: Wrist Type Blood Pressure Monitor
Model(s): W05, W1101L
Classification name: System, Measurement, Blood-Pressure, Non-Invasive
Review Panel: Cardiovascular
Product Code: DXN
Device Class: II
Regulation Number: 21 CFR 870.1130

3.0 Predicate Device Information

Sponsor: Shenzhen Jamr Technology Co., Ltd.
Device: Wrist Type Blood Pressure Monitor
510(K) Number: K220651

4.0 Device Description

The subject device, Wrist Type Blood Pressure Monitor, is a battery driven automatic non-invasive blood pressure monitor. It can automatically complete the inflation, deflation and measurement, which can measure systolic and diastolic blood pressure and pulse rate of adults at wrist within its claimed range and accuracy via the oscillometric technique.
The device has data storage function for data reviewing, including the systolic pressure, diastolic pressure, pulse rate and measurement time. The subject device is intended to be used in medical facilities or at home. And it is provided non-sterile, and not to be sterilized by the user prior to use.
The proposed blood pressure monitor includes two models, which are W05, W1101L. All models contain the same software, measurement principle and NIBP algorithm. The main differences are product appearance, specification of pump and specification of the battery. W05 is alkaline battery driven device and W1101L is lithium battery driven device.

The subject device is used for adult that age is more than 12 years old, and the intended populations are the patients with hypertension or need blood pressure monitoring. It is Not suitable for neonatal and infants； Not suitable for pregnant, including pre-eclamptic patients, not suitable for self-use in public areas, Not intended for use in the emergency medical services environment； Not be used together with HF surgical equipment.

5.0 Indication for use

This device is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult by using the wrist circumference 12.5-21.5cm, it can be used in medical facilities or at home. It is supplied for OTC use.

6.0 Performance Summary

Clinical Test Summary

Testing to ensure clinical accuracy of the device in accordance with ISO 81060-2 Third edition 2018-11 as documented in Clinical Test report. 95 patients (which we adequately accounting for demographic variables, such as age, gender, limb size, blood pressure, population characteristics and measurement site) were invited for the study. Standard auscultation method was used as the reference blood pressure monitor measuring in the arm. Blood pressure measurements were repeated alternatively with the device and auscultation in the same arm according to the sequence in ISO 81060-2 Third edition 2018-11.

Non-Clinical Test Summary

The Subject Device has performed several non-clinical tests to show that all requirement specifications and standard requirements are met. The tests include the follows:
IEC 60601-1:2005+Amd 1:2012+A2:2020
IEC 60601-1-2:2014+A1:2020
IEC 60601-1-11:2015
IEC 80601-2-30:2018

7.0 Comparison to predicate device and conclusion

Elements of Comparison	Subject Device	Predicate device(K220651)	Comparison Result
Device Name	Wrist Type Blood Pressure Monitor	Wrist Type Blood Pressure Monitor	Same
Device Model	W05, W1101L	W1102, W1102A, W02S	——
Manufacturer	Shenzhen Jamr Technology Co., Ltd.	Shenzhen Jamr Technology Co., Ltd.	Same
Indication for Use	This device is intended to measure the systolic and diastolic blood pressure as well as the	The Wrist Type Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the	Same

	pulse rate of adult by using the wrist circumference 12.5-21.5cm, it can be used in medical facilities or at home. It is supplied for OTC use.	pulse rate of adult by using the wrist circumference 12.5-21.5cm, it can be used in medical facilities or at home. It is supplied for OTC use.	
Intended Population	Adults	Adults	Same
Intended Anatomical site	Wrist	Wrist	Same
Prescription & OTC	OTC	OTC	Same
Working Principle	Oscillometric method	Oscillometric method	Same
Internal Power supply	W05: 2- size “AAA” alkaline Batteries W1101L: lithium battery - d.c.3.7V 300mAh	2- size “AAA” alkaline Batteries	Different*1
Memory Function	2×120 memory	2×120 memory	Same
Cuff Size	12.5-21.5cm	12.5-21.5cm	Same
Measuring range	DIA: 40-130mmHg; SYS: 60-230mmHg	Pressure: DIA: 40-130mmHg, SYS:60-230mmHg	Same
	Pulse Rate: 40 to 170 bpm	Pulse Rate: 40-180 bpm	Similar*1
Accuracy	Pressure: ± 3 mmHg Pulse rate:± 5 % BPM	Pressure: ±3mmHg (±0.4kPa); Pulse Rate: ±5% BPM	Same

Discussion：

Different*1：The subject device W05 has the same power source supply with the predicate device. The subject device W1101L has the different power source supply- lithium battery. The W1101L passed the related EMC and electrical safety testing. And the lithium battery also passed the related safety testing. So this different will not raise any safety and effectiveness concerns.

Similar*1：The measuring range 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.

8. 0 Discussion of Clinical Tests Performed

Our blood pressure monitor and cuff have been conducted clinical testing to verify the accuracy according to ISO 81060-2: Third Edition 2018-11, Non-invasive sphygmomanometers- Part 2: Clinical investigation of intermittent automated measurement type. The results of this clinical investigation show that the required limits for mean error and standard deviation are fulfilled by the subject device W1102 in the group of 95 adult subjects which we adequately accounting for demographic variables, such as age, gender, limb size, blood pressure, population characteristics and measurement site with qualified distribution. There was not adverse effects ad complication during clinical testing. Thus, all the relevant activities were performed by designate individual(s) and the results demonstrated that the predetermined acceptance criteria were fully met.

9.0 Discussion of Non-Clinical testing and Clinical Trial

The subject device was tested to evaluate its safety and effectiveness, including the following testing:

Biocompatibility Testing:

The biocompatibility evaluation for the body-contacting component (cuff) was conducted in accordance with the "Use of International Standard ISO 10993-1, Biological Evaluation of Medical Device -- Part 1: Evaluation and Testing Within a Risk Management Process", as recognized by FDA. The cuff has passed the Biocompatibility test by complying with the following standards:

ISO 10993-1:2018, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process;

ISO 10993-5: 2009, Biological Evaluation of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity;

ISO 10993-10:2010, Biological Evaluation of Medical Devices -- Part 10: Tests For Irritation And Skin Sensitization.

Electrical and EMC Safety:

The electrical safety and EMC safety testing have passed by complying with:

IEC 60601-1:2005+Amd 1:2012+A2:2020, Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance;

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;

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

Performance:

The performance testing has passed by complying with the following standards:

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

ISO 81060-2:2018, Non-Invasive Sphygmomanometers -- Part 2: Clinical Validation of Automated Measurement Type;

Accuracy of Blood pressure measurement:

ISO 81060-2 Third edition 2018-11, Non-Invasive Sphygmomanometers -- Part 1: Requirements and Test Methods For Non-Automated Measurement Type

Software:

We have also conducted Software verification and validation test according to the requirements of the FDA “Guidance for Premarket Submissions and for Software Contained in Medical Devices”.

10.0 Conclusions

Wrist Type Blood Pressure Monitor, models W05, W1101L, have the same intended use and similar characteristics as the predicate device. Form the above information, we conclude the subject devices are substantially equivalent to the predicate device, K220651, and any differences in their characteristics do not raise any safety and effectiveness issues.