July 27, 2022

Shenzhen Jamr Technology Co.,Ltd
% Reanny Wang
Senior consultant
Shenzhen Reanny Medical Devices Management Consulting Co Ltd
Room 1407, Jingting Building, Dongzhou Community,
Guangming Street, Guangming District
Shenzhen, Guangdong 518000
China

Re: K220886
Trade/Device Name: Upper Arm Type Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: June 16, 2022
Received: June 27, 2022

Dear Reanny Wang:

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,

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)*
K220886

Device Name
Upper Arm Type Blood Pressure Monitor

Indications for Use *(Describe)*
The Upper Arm Type 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.

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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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: _K220886_

1. Submitter's information

Submitter's Names: Shenzhen Jamr Technology Co., Ltd.

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2. Device Information

Type of 510(k) submission: Traditional

Trade Name: Upper Arm Type Blood Pressure Monitor

Model(s): F1701T, F1701TA

Classification name: System, Measurement, Blood-Pressure, Non-Invasive

Review Panel: Cardiovascular

Product Code: DXN

Device Class: II

Regulation Number: 21 CFR 870.1130

3. Predicate Device Information

510(K) Number: K160019

Trade Name: U80 series Electrical Blood Pressure Monitor

Model(s): U80A, U80AH, U80B, U80BH

Classification name: System, Measurement, Blood-Pressure, Non-Invasive

Review Panel: Cardiovascular

Product Code: DXN

Device Class: II

Regulation Number: 21 CFR 870.1130

4. Device Description

The proposed device, Upper Arm Type Blood Pressure Monitor, is a battery or AC adaptor 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 the adult person at wrist within its claimed range and accuracy via the oscillometric technique.

The device has the data storage function in order for data reviewing, including the systolic pressure, diastolic pressure, pulse rate and measurement time. It has a bar indicating function,

which can indicate the WHO (World Health Organization) Blood Pressure Classification of the measured blood pressure by referencing Diastolic Blood Pressure issued at Journal of Hypertension 1999. Vol 17, No.2.
The proposed 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 2 models, which are F1701T, F1701TA. All models follow the same software, measurement principle and NIBP algorithm. The main difference is the deflation valve.

5. Intended Use/Indication for use

The Upper Arm Type 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.

6. Comparisons of technological characteristics with the predicate device

The subject device is substantially equivalent to predicate device, K212171. The substantial equivalence chart is provided as follows:

Elements of Comparison	Predicate Device (K160019)	Subject Device	Verdict
Device Name	U80 sereis Electrical Blood Pressure Monitor	Upper Arm Type Blood Pressure Monitor	--
Device Model	U80A, U80AH, U80B, U80BH	F1701T, F1701TA	--
Manufacturer	Shenzhen Urion Technology Co., Ltd.	Shenzhen Jamr Technology Co., Ltd.	--
Intended Use/ Indication for Use	U80 Series 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 in which an inflatable cuff is wrapped around the upper arm. It can be used at medical facilities or at home. The intended upper arm circumference is 22-36 cm.	The Upper Arm Type 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.	Same
Intended Population	Adults	Adults	Same
Intended Anatomical site	Upper arm	Upper arm	Same
Prescription & OTC	OTC	OTC	Same

Working Principle	Oscillometric method	Oscillometric method	Same
Power supply	d.c 6.0V, 4*1.5 V AAA batteries	d.c.4.5V AA battery or d.c.5V 1A AC adapter	Same
Cuff Size	22cm~36cm	22cm~42cm	Different
Model of operation	Continuous operation	Continuous operation	Same
Degree of protection against electric shock	Type BF applied part	Type BF applied part	Same
Measuring range	Systolic pressure: 0~299mmHg; Diastolic pressure: 0~299mmHg	Systolic pressure: 60-270mmHg; Diastolic pressure: 40-220mmHg	Different
	Pulse Rate: 40-199 pulses/min	Pulse Rate: 40-180 bpm	Different
Accuracy	Pressure: ±3mmHg (±0.4kPa); Pulse Rate: ±5% BPM	Pressure: ±3mmHg (±0.4kPa); Pulse Rate: ±5% BPM	Same
Bluetooth and APP	No	Yes	Different
Safety and essential performance	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-11; IEC 80601-2-30; ISO81060-2;	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-11; IEC 80601-2-30; ISO81060-2;	Same
Biocompatibility	ISO 10993-1; ISO 10993-5; ISO 10993-10	ISO 10993-1; ISO 10993-5; ISO 10993-10	Same

Remark: the subject device and the predicate device have the same indications for use, intended population, application site and working principle; although “Power supply”, “Function”, “Cuff Size”, “Measuring range” and “Bluetooth and APP” of the subject device are different from the predicate device, but the differences do not raise any new issues of safety and effectiveness based on series tests, trials and validations.

7. Brief discussions of the nonclinical tests

The proposed device conforms to the following standards:

7.1 Biocompatibility evaluation

The biocompatibility evaluations of the proposed device were conducted in accordance with the International Standard ISO 10993-1 “Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process” and FDA biocompatibility guidance, the proposed devices will be classified as external communication devices-tissue contact, and considering the cumulative exposure, the contact time will be permanent. The testing standards include the following:

Standard	Descriptions
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

7.2 Electrical safety, essential performance and EMC tests

-IEC 60601-1:2005+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

-IEC 60601-1-2: 2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

-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 80601-2-30:2018, Medical Electrical Equipment - Part 2-30: Particular Requirements for The Basic Safety and Essential Performance of Automated Non-Invasive Sphygmomanometers

7.3 Wireless and cybersecurity

-Bluetooth test according to FCC CFR Title 47 Part 15 Subpart C.

-ANSI C63.27: 2017: American National Stand for Evaluation of Wireless Coexistence.

-Radio Frequency Wireless Technology in Medical Devices: Guidance for Industry and Food and Drug Administration Staff

-Content of Premarket Submissions for Management of Cybersecurity in Medical Devices

7.4 Software validation

-Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

8. Discussion of Clinical Tests Performed

Clinical studies were conducted to verify the blood pressure accuracy of subject device. The clinical studies were conducted per following standards:

-ISO 81060-2: 2018, Non-Invasive Sphygmomanometers - Part 1: Requirements and Test Methods for Non-Automated Measurement Type.

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 F1701T in the group of 90 adult subjects (60 male and 30 female) with qualified distribution. There was not adverse effects and complications 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. Conclusions

The subject device-Upper Arm Type Blood Pressure Monitor, models of F1701T and F1701TA, 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, K160019, and any differences in their characteristics do not raise any new safety and effectiveness issues.