June 25, 2020

Shenzhen Jamr Technology Co., Ltd.
Luo Fusheng
Management Representative
2nd Floor, A-building, No.2 Guiyuan Road, Guihua community,
Guanlan town, Shenzhen, 518110
CHINA

Re: K200437
Trade/Device Name: 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 12, 2020
Received: May 29, 2020

Dear Luo Fusheng:

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,

LT 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200437

Device Name
Blood Pressure Monitor

Indications for Use *(Describe)*

The Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate by using the oscillometric method during inflation. Measurement position is at human being's upper arm. The intended use of this over-the-counter device is for adults at medical facilities or at home. The intended upper arm circumference is 22-40cm (8.7" – 15.7"). Not suitable for neonatal and infants.

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: K200437

1.0 Information of Submitter and Correspondent

Submitter's information:

Shenzhen Jamr Technology Co., Ltd.
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Contact Person: Luo Fusheng
E-mail: eng201@cigii.net, reanny@reanny.com

2.0 Device Information

Type of 510(k) submission:	Traditional
Trade Name:	Blood pressure monitor
Model:	C02 and F01
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:	Health & Life Co., Ltd.
Device:	Full Automatic (NIBP) Blood Pressure Monitor HL858CL
510(K) Number:	K190507

4.0 Device Description

The blood pressure monitor model C02 and F01 are sphygmomanometers with electronic manometer intended to be used for the indirect (non-invasive) measurement of diastolic, systolic blood pressure and pulse rate using a standard oscillometric method for adults during inflation. The inflatable cuff is wrapped around the upper arm of an individual. The systolic and diastolic blood pressures are transmitted via air pressure and determined by the transducer integrated on the monitor with the oscillometric method. The systolic and diastolic blood pressure values and pulse rate per minute are displayed on the LED panel.

The monitors C02 and F01 have the same measurement principle, specification, structure, intended use and similar software, the main differences are appearance.

5.0 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 oscillometric method during inflation. Measurement position is at human being's upper arm. The intended use of this over-the-counter device is for adults at medical facilities or at home. The intended upper arm circumference is 22-40cm (8.7" – 15.7"). Not suitable for neonatal and infants.

6.0 Performance Summary

Clinical Test Summary

Testing to insure clinical accuracy of the device in accordance with ISO 81060-2 as documented in Clinical Test report.90 patients (42 males and 48 females) 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.

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+Am1:2012
IEC 60601-1-2:2014
IEC 60601-1-11:2015
IEC 80601-2-30:2018
IEC 81060-1:2007

7.0 Comparison to predicate device and conclusion

The subject device is substantially equivalent to predicate devices, K190507, HL858CL.

The substantial equivalence chart is provided as follows:

Elements of Comparison	Predicate Device (K190507)	Subject Device	Judgment
Models	**HL858CL**	**C02 and F01**	**--**
Company	Health & Life Co., Ltd.	Shenzhen Jamr Technology Co., Ltd.	--
Device Name	Full Automatic (NIBP) Blood Pressure Monitor	Blood Pressure Monitor	--
Product code	DXN	DXN	Same
Regulation #	21CFR870.1130	21CFR870.1130	Same
Intended use	HL858CL automatically measures human's Systolic, Diastolic blood pressure and heart rate by using the oscillometric method during inflation. All values can be read out in one LCD panel. Measurement position is at human being's upper arm. The intended use of this over-the-counter device is for adults aged 18 years and older with arm circumference ranging from 9 inches to 22 inches (approx.23 cm to 56 cm) and for home use. HL858CL detects the appearance of irregular heartbeats during measurement; an indicated symbol will appear with measuring reading. And the Risk Category Indicator will show the information with the readings on the screen for the user tracking their blood pressure level. Besides, the device features a built-in "Bluetooth Data Transmission" function, which	The Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate by using the oscillometric method during inflation. Measurement position is at human being's upper arm. The intended use of this over-the-counter device is for adults at medical facilities or at home. The intended upper arm circumference is 22-40cm (8.7" – 15.7").	SE, refer to Remark 1

Elements of Comparison	Predicate Device (K190507)	Subject Device	Judgment
Models	**HL858CL**	**C02 and F01**	**--**
	enables the device automatically transmit measuring results to paired Bluetooth-enabled device. Also, users could simply synchronize the current date and time, and check the battery status of blood pressure monitor by means of DailyChek® application software with the paired Bluetooth-enabled device.		
Measurement type	Upper arm	Upper arm	Same
Patient population	Adults person over 18	Adults person	Same
Measurement Item	SYS, DYS, Pulse rate	SYS, DYS, Pulse rate	Same
Principle	Oscillometric	Oscillometric	Same
Measurement type	During inflation	During inflation	Same
BP measurement range	0-300mmHg Rated Range of Determination: 40~280mmHg	0-295mmHg Rated Range of Determination: SYS:60~255mmHg；DIA：40~200mmHg	SE, refer to Remark 2
BP accuracy	±3mmHg (±0.4kPa)	±3mmHg (±0.4kPa)	Same
PR measurement range	40-199 bpm	40-170 pulses/min	SE, refer to Remark 3
PR measurement accuracy	±5% of reading	±5% of reading	Same
Power supply	6V 1A, 4 × AA/1.5V (LR6) Alkaline batteries, or AC Adapter (Model: SINPRO, HPU15-102 Input: 100-240V AC 47-63Hz / Output: 5.99V, DC, 2A)	d.c. 4.5V, 3*AA batteries; or AC adapter INPUT：100-240VAC 50/60HZ OUTPUT: 5V DC 1A	SE, refer to remark 4

Elements of Comparison	Predicate Device (K190507)	Subject Device	Judgment
Models	**HL858CL**	**C02 and F01**	**--**
Degree of protection against electric shock	Type BF applied part	Type BF applied part	Same
Type of protection against electric shock	Internally power equipment or class II	Internally power equipment or class II	Same
Model of operation	Continuous operation	Continuous operation	Same
Cuff size suitable for arm size	Arm circumference approx. 23~43cm / 9~17 inch (Universal cuff)	cuff: 8.7” – 15.7” (22 - 40 c m)	SE, refer to Remark 5
Sets of memory	2*120, total 240	2*120, total 240	Same
Automatic power off	unknown	Automatically turn off after 60 seconds	Difference, Refer to Remark 6
Operation environment	5℃ ~ 40℃ (41℉~104℉), 15% ~ 93% R.H. 700~1060hPa	5℃-40°C, 15%-93%RH, 70-106kPa	Same
Storage environment	-25℃-70℃, ≦ 93% R.H.	-25℃-70℃, ≦ 93% R.H.	Same
Performance	Compliance with Compliance with ANSI/AAMI/IEC 80601-2-30	Compliance with Compliance with IEC 80601-2-30	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	All the patient contacting materials are compliance with ISO 10993	Same
Electrical Safety	Compliance with IEC 60601-1	Compliance with IEC 60601-1	Same
EMC	Compliance with IEC 60601-1-2	Compliance with IEC 60601-1-2	Same

Remark 1 :

The indication for use of subject device is same as predicate device, only the description is different. The predicate device has irregular heartbeats, risk category indicator function, and Bluetooth data transmission function. The subject device also has irregular heartbeats function, but not shown in this section. It has been shown in section 6 and section 8.3 of user manual. In additional, this indicator is only a caution, not a diagnostic basis. There is not risk category indicator function and Bluetooth data transmission function for our subject device, therefore, this description is not shown. So the difference will not raise any safety or effectiveness issue.

Remark 2:

The blood pressure measurement range and rated range of determination is different between two devices, but they are within the range of predicate device. In additional, the subject device has been passed the testing according to IEC 80601-2-30, ISO 81060-1 and ISO 81060-2 standards. So the difference will not raise any safety or effectiveness issue.

Remark 3:

The PR measurement range of subject device and predicate device is difference, but the range of subject device is within the range of predicate device. In additional, the subject device has been evaluated according to ISO 81060-2 standard. The PR measurement range and accuracy are met the clinical requirements. So the difference will not raise any safety or effectiveness issue.

Remark 4:

The power supply of subject device is d.c. 4.5 V, 3*AA batteries or AC adapter (INPUT：100-240VAC 50/60HZ OUTPUT：5V DC 1A), and the predicate device is 6V 1A, 4 × AA/1.5V (LR6) Alkaline batteries, or AC Adapter (Model: SINPRO, HPU15-102 Input: 100-240V AC 47-63Hz / Output: 5.99V, DC, 2A). They are internal power supply or AC power supply. The subject devices are compliance with IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11, IEC 80601-2-30 and ISO 81060-1 standards. So the difference will not raise any safety or effectiveness issue.

Remark 5:

The intended arm circumferences of the proposed and predicate device are different. This difference is very slight, and the cuff size is appropriate to the claimed intended arm

circumference per IEC 80601-2-30. Therefore, this point is considered as substantially equivalent.

Remark 6:

The time of automatic power off is 60s for subject device, but it is unknown for predicate device. This function is optional; it can be turned off by pressing “on/off” button, and the subject device is compliance with the IEC 80601-2-30 standard, so the difference will not raise any safety or effectiveness issue.

8. 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 C02 in the group of 90 subjects (42 male and 48 female, patient age between 17 to 74) 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. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence is as follows:

The subject device was tested to evaluate its safety and effectiveness, including the Following table:

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 performed and passed the Biocompatibility test. So we have reason to believe that the cuff is safe for the users. The cuff complies 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 InVitro 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 was performed to, and passed, the following standards:

IEC 60601-1:2005, 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, 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 was performed to, and passed, 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

ISO 81060-1:2007, 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 Pre Market Submissions and for Software Contained in Medical Devices” and following standard:

IEC 62304:2015, Medical device software – Software life cycle processes

Other requirement:

The subject device was evaluated its usability and risks according to the following standards:

ISO 14971:2007, Medical devices - Application of risk management to medical devices.(General)

IEC 62366-1:2015, Medical Devices - Part 1: Application Of Usability Engineering To Medical Devices

Summary:

Based on the above performance as documented in this application, the Blood Pressure Monitor was found to have a safety and effectiveness profile that is similar to the predicate device.

8.0 Conclusions

Blood pressure monitor, Model C02 and F01 have the same intended use and similar characteristics as the predicate device. Form the above information we conclude the subject device, C02 and F01 are substantially equivalent to the predicate devices, HL858CL which is manufactured by. Health & Life Co., Ltd. These conclude that any differences in their characteristics do not raise any safety and effectiveness issues.

9.0 Summary_prepared date

May 15, 2020