December 21, 2017

Shenzhen Jamr Medical Technology CO., Limited
% Mei Tan
RA Consultant
Chonconn Medical Device Consulting Co. LTD.
22A, HaiJing Square, No.18 Taizi Road, Nanshan District
Shenzhen, 518067 China

Re: K172171
Trade/Device Name: Digital Blood Pressure Monitor Models: B01, B02, B05 & B06T
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: November 20, 2017
Received: November 20, 2017

Dear Mei Tan:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*
K172171

Device Name
Digital Blood Pressure Monitor Models: B01, B02, B05 & B06T

Indications for Use *(Describe)*
Digital blood pressure monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person. It can be used at medical facilities or at home.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary

Prepared date:2017/11/1

Submitter

Name: Shenzhen Jamr Medical Technology CO., Limited
Address: 2nd Floor, A-building, No.2 Guiyuan Road, Guihua community, Guanlan town, Longhua new district, Shenzhen, P.R.China
Tel: 86-0755-85292057
Fax: 86-0755-61673107
Contact person: Li xue
E-mail: jmr02@cigii.net

Submission Correspondent

Name：Chonconn Medical Device Consulting Co.LTD.
Address：22A,HaiJing Square,No.18 Taizi Road,Nanshan District, Shenzhen,Guangdong,P.R.China,
Contact person：Mei (RA consultant)
E-mail：FDA@chonconn.com/Xinmeitan@chonconn.com
Tel：+86-755-33941160

Device

Trade name: Digital blood pressure monitor Models: B01,B02,B05&B06T
Classification name: System, Measurement, Blood Pressure, Noninvasive
Production regulation: 21CFR 870.1130
Regulatory Class: II
Product code: DXN

Predicate Device

Digital blood pressure monitor, Model: ePA-46B, (K134029, ShenZhen Belter Health Measurement and Analysis Technology Co.,ltd)

Description

The Digital blood pressure monitors, including B01,B02,B05 and B06T, can automatically complete the inflation,deflation and measurement ,which can measure systolic and diastolic blood pressure as well as the pulse rate of adult person with arm circumference ranging from 22 cm to 40cm by the oscillometric technique. User can select the blood pressure unit mmHg or KPa. The initial inflation pressure of the cuff is zero pressure. When start the device, the cuff will be inflated and deflated.

The device consists of the microprocessor, pressure sensor, operation keys, pump, deflation control valve, LCD and cuff. The cuff is made of shelf, inflation bag, Hook, loop

and tube. The B06T is powered by 3.7V-800 mAh lithium battery, other models are powered by 4 AAA alkaline batteries.
The device has a memory function that automatically stores some sets data of the latest measurements. It can also display the latest measurement result. Additionally, the four devices also can read the data through voice broadcast function.

The B06T embeds a Bluetooth that allows it to transport the measurement data to nearby receiving end, and user can take measurement, set device, receive, display store and playback the measurement by the Health care BLE terminal software in receiving end.

The models B01/02/05 also detect the appearance of irregular heartbeats during measurement and give a warning signal with readings.

The four models Digital blood pressure monitors have the same intended use, working principle, measuring range & accuracy, cuff, conformance standard, only in appearance, data transmission and supply power have some difference, but these device have passed testing of IEC60601-1, IEC60601-1-2, ISO80601-2-30, IEC60601-1-11 & ISO81060-2.

Indications for use
Digital blood pressure monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person. It can be used at medical facilities or at home.

Comparison of technological characteristics with the predicate device
The Digital blood pressure monitors and predicate have the same intended use,intended patient,working princple ,accuracy, conformance standard, and so on, both devices have some difference in power supply,measuring range, operation&storage environment, but the subject devices have meet the requirements of IEC60601-1,IEC60601-1-2,IEC60601-1-11&ISO80601-1-30,so this difference can't raise the new problem of safety and effectiveness .

Compared item	Jamr B01, B02, B05, B06T (Present application)	**Belter** ePA-46B (K134029)	**Comment**
Intended use & Indications for Use	Digital blood pressure monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of	The Belter Blood pressure meter is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of	Similar

	adult person. It can be used at medical facilities or at home.	adult person. It can be used at medical facilities or at home. The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.	
Intended patient	Adult	Adult	Same
Prescriptive	OTC	OTC	Same
Environment of use	Medical facilities or home	Medical facilities or home	Same
Operation Principle	Oscillometric	Oscillometric	Same
Measurement Range	Pressure: 0-280mmHg Pulse Rate: 40-199bpm	Pressure: 0-280mmHg Pulse Rate: 40-200bpm	Similar
Accuracy	Pressure :±3mmHg(±0.4kPa) Pulse Rate: ±5%	Pressure :±3mmHg(±0.4kPa) Pulse Rate: ±5%	Same
Display screen	LCD(B01/02/05) Receiving end(B06T)	LCD	Same
Scale Selection	mmHg/KPa	mmHg/KPa	Same
Cuff circumference	22-40 cm	22-40 cm	Same
Memory	2*120sets(B01/02/05) 1*99sets(B06T)	60sets	Similar
Irregular pulse detection	Yes(B01/02/05) No(B06T)	Yes	Same
Power supply	4 AAA batteries(6V DC) -(B01/02/05) Built-in high capacity lithium battery 3.7V 800 mAh-B06T	4 AAA batteries (6V DC)	Same
Operating Environment	Temperature：+5℃～+40℃；Humidity：10～93%RH	Temperature：+10℃～+40℃；Humidity：30～85%RH	Similar

Storage Environment	Temperature：-25℃～+70℃； Humidity：10%～93%	Temperature：-20℃～+50℃； Humidity：20%～95%	
Type of transmission	Transmission by bluetooth (B06T) non-Transmission(B01/02/05)	Transmission by bluetooth	Similar
Conformance standard	IEC 60601-1, IEC 60601-1-2, ISO80601-2-30, IEC60601-1-11, ISO 10993-1,-5,-10	IEC 60601-1, IEC 60601-1-2, ISO80601-2-30, IEC60601-1-11, ISO 10993-1,-5,-10	Same

Performance Data

The following practices were followed and monitored for development of the Digital blood pressure monitor:

- IEC 60601-1 Medical Electrical Equipment-Part 1: General Requirements for Safety, 1988+A1:1991+A2:1995
- IEC 60601-1-2 Medical Electrical Equipment-Part 1-2: General Requirements for Safety -Collateral Standard: Electromagnetic Compatibility-Requirements and Tests, 2007
- IEC60601-1-11 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,2010
- ISO80601-2-30 Medical Electrical Equipment - Part 2-30: Particular Requirements For The Basic Safety And Essential Performance Of Automated Non-Invasive Sphygmomanometers,2013
- ISO 10993-1, Biological evaluation of medical devices-Part 1: Evaluation and testing, 2009
- ISO 10993-5, Biological evaluation of medical devices-Part 5: Tests for In Vitro cytotoxicity, 2009
- ISO 10993-10, Biological evaluation of medical devices-Part 10: Tests for irritation and delayed-type hypersensitivity, 2010
- ISO81060-2 Non-Invasive Sphygmomanometers - Part 2: Clinical Validation Of Automated Measurement Type,2013

Conclusion

From the comparison and analysis above, and the safety & performance test report submitted, we believe that the Digital blood pressure monitor is substantially equivalent to the predicate devices in K134029.