March 3, 2019

Shenzhen Jumper Medical Equipment Co., Ltd.
Jinhui Tang
Regulatory Manager
D Building, No. 71, Xintian Road, Fuyong Street,
Baoan District, Shenzhen, 518103, CHINA

Re: K182495
Trade/Device Name: Electronic Blood Pressure Monitor, models JPD-HA120 and JPD-HA121
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: January 23, 2019
Received: January 28, 2019

Dear Jinhui Tang:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Stephen C. Browning -S5

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)*
K182495

Device Name
Electronic Blood Pressure Monitor, models JPD-HA120 and JPD-HA121

Indications for Use *(Describe)*
The 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 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.

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510(k) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

1. Submitter: Shenzhen Jumper Medical Equipment Co., Ltd.

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Tel.: +86 -755- 2669 2192
Fax: +86 -755- 2685 2025

Contact Person: Jinhui Tang

Prepare date: 2018-09-04

2. Device name and classification:

Device Name: Electronic Blood Pressure Monitor

Models: JPD-HA120 and JPD-HA121

Classification Name:

21 CFR 870.1130

Noninvasive Blood Pressure Measurement System

Product code: DXN

Regulatory Class: Class II

3. Reason for Submission New Application.

4. Predicate Device(s): Shenzhen Pango Electronic Co., Ltd., PG-800B36 Electronic Blood Pressure Monitor / K170151

5. Device Description:

JPD-HA120 and JPD-HA121 Electronic Blood Pressure Monitor is a battery powered 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 upper arm within its claimed range and accuracy via the oscillometric technique. User can select the unit of the measurement: mmHg or kPa.

The device has the data storage function in order for data reviewing, including the systolic pressure, diastolic pressure, pulse rate and measurement time. The proposed JPD-HA120 and JPD-HA121 Electronic Blood Pressure Monitor share the same software, measurement principle and NIBP algorithm. The main differences are product appearance.

The proposed device is intended to be used in medical facilities or at home. And the effectiveness of this sphygmomanometer has not been established in pregnant (including pre-eclamptic) patients.

The product is provided non-sterile, and not to be sterilized by the user prior to use.

6. Indications for Use:

The 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 at medical facilities or at home.

7. Predicate Device Comparison

Comparison to the predicate devices, the subject device has same intended use, similar product design, same performance effectiveness, performance safety as the predicate device.

Please refer to following table to find differences between the subject device and predicate device. All the differences do not affect the basic design principle, usage, effectiveness and safety of the subject device. And no new question is raised regarding the product's effectiveness and safety.

Table 1 Comparison between the predicate PG-800B36 and the subject device

ITEM	Proposed Device JPD-HA120 and JPD-HA121		Predicate Device PG-800B36/ K170151		Comparison Result
Manufacture	Shenzhen Jumper Medical Equipment Co., Ltd.		Shenzhen Pango Electronic Co., Ltd.		---
Intended Use	The 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 at medical facilities or at home.		The 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 arm circumference includes 22 cm~32 cm and 32 cm~42 cm.		Different
Contraindications	Not Known		Not Known		Same
Clinical Use	Medical Facilities and Home Use		Medical Facilities and Home Use		Same
Patient Population	Adult		Adult		Same
Measurement Type	Upper arm		Upper arm		Same
Measurement Principle	Oscillometric		Oscillometric		Same
Components	LCD / Key / Cuff / MCU / Pump / Batteries		LCD / Key / Cuff / MCU / Pump / Batteries		Same
Power Source	4x1.5V		4x1.5V		Same
Physical Dimensions	Approx: 138 mm(Length)x120 mm(Width)x59 mm(Height)		Approx: 140 mm(W)x100 mm(H)x50 mm(D)		Different
Weight	Approx: 483.8 g, excluding battery		Approx: 420 g, excluding battery		
Measurement Range	Blood Pressure	30 ~ 255 mmHg	Blood Pressure	30 ~ 280 mmHg	Different
	Pulse Rate	40-199 bpm	Pulse Rate	40-199 bpm	
Accuracy	Static Pressure	±3 mmHg	Static Pressure	±3 mmHg	Same
	Pulse	±5%	Pulse	±5%	

Arm Circumference	22 cm~36 cm	22 cm~32 cm	Different
Patient Contact Material	Cuff –Terylene Enclosure – ABS Key - PMMA	Cuff –Nylon Enclosure – ABS Key - ABS	Different
Applied Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 80601-2-30:2009 81060-2:2013	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 80601-2-30:2009 81060-2:2013	Same
Operation Environments	+ 5℃~ + 40℃, 15%RH~90%RH Atmospheric Pressure: 70 kPa~106 kPa	+ 5℃~ + 40℃, 15%RH~93%RH Atmospheric Pressure: 50 kPa~106 kPa	Different
Storage Environments	- 20℃~ + 55℃, 10%RH~93%RH Atmospheric Pressure: 70 kPa~106 kPa	- 20℃~ + 55℃, 0%RH~93%RH Atmospheric Pressure: 50 kPa~106 kPa	

As seen in the comparison tables, the subject and predicate devices have almost the same design features and performance specifications. The main technological differences between the subject and predicate devices are minor differences, including the Physical Dimensions, Arm Circumference and Operation &Storage Environments, which do not raise different questions of safety or effectiveness. Moreover, as demonstrated in the non-clinical and clinical testing, the different technological characteristics do not affect the safety and effectiveness of the system.

8. Performance Testing:

Performance data includes “Non-Clinical Data” and “Clinical Data”, brief description of which are shown as below.

Non-Clinical Data:

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the JPD-HA120&JPD-HA121 Electronic Blood Pressure Monitor and the NIBP CUFF 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,” as recognized by FDA. The worst case of the whole system is considered tissue contacting for duration of less than 24 hours. And the battery of testing included the following tests:

- Cytotoxicity
- Skin Sensitization
- Skin Irritation

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the JPD-HA120 and JPD-HA121 Electronic Blood Pressure Monitor, consisting of all the modules and accessories in the system. The system complies with the IEC 60601-1: 2012 *Medical electrical equipment Part 1: General requirements for basic safety and essential performance* for safety and the 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* standard for EMC.

Bench Testing

Bench testing was conducted on the JPD-HA120 and JPD-HA121 Electronic Blood Pressure Monitor, consisting of all the accessories in the system. The system complies with the IEC 60601-1-11: 2010 *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, ISO 80601-2-30: 2009 *Medical electrical equipment — Part 2-56: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers* standards for performance effectiveness.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Clinical data:

Clinical testing is conducted per ISO 81060-2: 2013 *Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type*.

Summary

Based on the non-clinical and clinical performance as documented in the device development, the subject devices were found to have a safety and effectiveness profile that is similar to the predicate device.

9. Conclusion:

Verification and validation testing was conducted on the subject device and all testing passed pre-specified criteria. This premarket notification submission demonstrates that the Jumper Electronic Blood Pressure Monitor is substantially equivalent to the predicate devices.