DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 31, 2017

Shenzhen Pango Electronic Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd.
P.O. Box 120-119
Shanghai, CN 200120

Re: K161845
Trade/Device Name: Electronic Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: July 3, 2017
Received: June 27, 2017

Dear Diana Hong:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161845

Device Name
Electronic Blood Pressure Monitor

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 in which an inflatable cuff is wrapped around the wrist. It can be used at medical facilities or at home. The intended wrist circumference is 13.5-19.5 cm.
The patient population does not include adolescents aged 12 to <18 years of age. The patient population includes transition adolescent B (18 to < 22 years of age but treated like adult) and adults (at least 22 years of age).

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.

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510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K161845

1. Date of Preparation: 7/11/2017

2. Sponsor Identification

Shenzhen Pango Electronic Co.,Ltd.
No.25, 1st Industrial Park, Fenghuang Road, Xikeng, Henggang, Longgang District, Shenzhen, Guangdong, 518115, China.

Establishment Registration Number: 3006792041

Contact Person: Ms. Xiaoyun Yang
Position: Vice General Manager
Tel: +86-755-33825988
Fax: +86-755-33825989
Email:sales@pan-go.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Jing Cheng (Alternative Contact Person)

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: 240-238-7587
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Electronic Blood Pressure Monitor;
Common Name: Wrist Blood Pressure Monitor;
Models: PG-800A25, PG-800A27, PG-800A31, PG-800A32, PG-800A33, PG-800A35, PG-800A36 and PG-800A37

Regulatory Information

Classification Name: Noninvasive blood pressure measurement system

Classification: 2

Product Code: DXN;

Regulation Number: 21 CFR 870.1130;

Review Panel: Cardiovascular;

Intended Use Statement:

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 wrist. It can be used at medical facilities or at home. The intended wrist circumference is 13.5-19.5 cm.

The patient population does not include adolescents aged 12 to <18 years of age. The patient population includes transition adolescent B (18 to < 22 years of age but treated like adult) and adults (at least 22 years of age).

Device Description:

The proposed device, Electronic 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 the adult person at wrist within its claimed range and accuracy via the oscillometric technique. User can select the unit of the measurement: mmHg or Kpa.

The proposed electronic blood pressure monitor has eight models, including PG-800A25, PG-800A27, PG-800A31, PG-800A32, PG-800A33, PG-800A35, PG-800A36 and PG-800A37. All models follow the same software, measurement principle, algorithm and data storage. The main differences are product appearance.

The proposed device is intended to be used in medical facilities or at home.

5. Identification of Predicate Device

510(k) Number: K131569

Product Name: PG-800A Series Electronic Blood Pressure Monitor

Models: PG-800A5, PG-800A5D

Manufacturer: Shenzhen Pango Electronic Co., Ltd

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

IEC 60601-1:2005+ A1:2002, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

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.

IEC 60601-1-2:2007, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Compatibility

IEC 80601-2-30:2009, Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

ISO 81060-2:2013, Non-Invasive Sphygmomanometers - Part 2: Clinical Validation of Automated Measurement Type.

7. Substantially Equivalent

Table 1 Substantially Equivalent Comparison

ITEM	Proposed Device	Predicate Device K131569
Models	PG-800A25, PG-800A27, PG-800A31, PG-800A32, PG-800A33, PG-800A35, PG-800A36 and PG-800A37	PG-800A5, PG-800A5D
Product Code	DXN	DXN
Class	II	II
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 in which an inflatable cuff is wrapped around the wrist. It can be used at medical facilities or at home. The intended wrist circumference is 13.5-19.5 cm. The patient population does not include	The PG-800A Series Electronic Blood Pressure Monitor is intended to measure diastolic, systolic blood pressure as well as the pulse rate of adult person via non-invasive technique in which an inflatable cuff is wrapped around the wrist. It can be used at medical facilities or at home. The intended wrist circumference is 13.5cm~19.5cm.

	adolescents aged 12 to <18 years of age. The patient population includes transition adolescent B (18 to < 22 years of age but treated like adult) and adults (at least 22 years of age).	
Measurement Type	Wrist	Wrist
Patient Population	Adult	Adult
Measurement Item	Systolic Pressure, Diastolic Pressure, Pulse Rate	Systolic Pressure, Diastolic Pressure, Pulse Rate
Principle	Oscillometric	Oscillometric
Component	LCD / Key / Cuff / MCU / Pump /Transducer/ Batteries	LCD / Key / Cuff / MCU / Pump /Transducer/ Batteries
Blood Pressure Range	30 ~ 280 mmHg	30 ~ 280 mmHg
Pulse Rate Range	40-199 bpm	40-199 bpm
Intended wrist circumference	13.5cm~19.5cm	13.5cm~19.5cm
Records Quantity	Double patients mode: 60/60 records	Single patient mode: 90 records for PG-800A5
		Double patient mode: 60/60 records for PG-800A5D
Operating condition	+5 ℃~+40℃; 30%RH~80%RH; Atomospheric pressure	+5 ℃~+40℃; 30%RH~80%RH; Atomospheric pressure
Storage condition	-20℃~+55℃; 10%RH~93%RH; Atomospheric pressure	-20℃~+55℃; 10%RH~93%RH; Atomospheric pressure
Patient Contact Material	Cuff – Nylon Enclosure – ABS Key - ABS	Cuff – Nylon Enclosure – ABS Key - ABS
Bicompatibility	Comply with ISO10993 series standards No cytotoxicity; No irritation to skin; No significant evidence of sensitization	Comply with ISO10993 series standards No cytotoxicity; No irritation to skin; No significant evidence of sensitization
Electrical Safety	Comply with IEC 60601-1	Comply with IEC 60601-1
EMC	Comply with IEC 60601-1-2:2007	Comply with IEC 60601-1-2:2007
Particular Performance	Comply with IEC 80601-2-30:2009 and ISO 81060-2:2013	ANSI/AAMI SP10

Product Comparison Summary

The propoed device and its predicate devices have the similar indented use, mechanism of action, principle of operation, algorithm and cuff. The proposed devices are different than the predicate device in that the proposed device integrates the Key function of both PG-800A5 and PG-800A5D, same Record quantity as that of PG-800A5D, different Product appareance, modified product label

and software which is modified to applicable to the proposed devices; addtitionally the proposed device details the patient populations. The difference between the proposed device and the predicate device do not raise any question regarding its safety and effectiveness.

8. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate device.