June 14, 2023

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

Re: K223291
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: October 19, 2022
Received: October 26, 2022

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. 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,

Robert T. Kazmierski -S

for

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)*

K223291

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.

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Tab # 6 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K223291

1. Date of Preparation: 10/19/2022

2. Sponsor Identification

Shenzhen Pango Medical Electronics Co., Ltd.
No.25 1st Industry Zone, Fenghuang Road, Xikeng Village, Henggang Town, 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. Xingqi Wang (Alternative Contact Person)

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

Tel: +86-21-22815850
Fax: 360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Electronic Blood Pressure Monitor
Common Name: Wrist Electronic Blood Pressure Monitor
Models: PG-800A18, PG-800A19, PG-800A28, PG-800A51, PG-800A52, PG-800A11-1, PG-800A36-1 and PG-800A37-1

Regulatory Information

Classification Name: Noninvasive blood pressure measurement system
Classification: II
Product Code: DXN
Regulation Number: 21 CFR 870.1130
Review Panel: Cardiovascular

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 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 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-800A18, PG-800A19, PG-800A28, PG-800A51, PG-800A52, PG-800A11-1, PG-800A36-1 and PG-800A37-1. 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

Predicate Device
510(k) Number: K161845
Product Name: Wrist Blood Pressure Monitor
Models: PG-800A25, PG-800A27, PG-800A31, PG-800A32, PG-800A33, PG-800A35, PG-800A36 and PG-800A37
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:

- ISO 10993-1:2018 Biological evaluation of medical device- Part 1: Evaluation and testing within a risk management process.
- ISO 10993-5:2009 Biological evaluation of medical Devices-Part 5: Test for in vitro cytotoxicity.
- ISO10993-10:2010 Biological evaluation of medical devices-Part10: Test for irritation and delayed-type hypersensitivity.
- IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012 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 Compatibility - Requirements And Tests
- 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. Comparison of Technological characteristics

Table 1 Comparison for Electronic Blood Pressure Monitor

Item	Proposed Device	Predicate Device K161845	Remark
Product Code	DXN	DXN	Same
Regulation No.	21 CFR 870.1130	21 CFR 870.1130	Same
Class	II	II	Same
Indication 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 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).	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).	Same
Measurement Type	Wrist	Wrist	Same
Patient Population	Adult	Adult	Same
Measurement Item	Systolic Pressure, Diastolic Pressure, Pulse Rate	Systolic Pressure, Diastolic Pressure, Pulse Rate	Same
Principle	Oscillometric	Oscillometric	Same
Main Component	LCD / Key / Cuff / MCU / Pump /Transducer/ Batteries	LCD / Key / Cuff / MCU / Pump /Transducer/ Batteries	Same
Blood Pressure Range	30 ~ 280 mmHg	30 ~ 280 mmHg	Same
Pulse Rate Range	40-199 bpm	40-199 bpm	Same

Intended wrist circumference	13.5cm~19.5cm	13.5cm~19.5cm	Same
Cuff size	Length: 290±5mm Width: 72±5mm	Length: 310±5mm Width: 80±5mm	Analysis 1
Records Quantity	Double patients mode: 90/90 records	Double patients mode: 60/60 records	Analysis 2
Power Supply	Two AAA or LR03 batteries for models PG-800A18, PG-800A19,PG-800A28,PG-800A52	Two AAA or LR03 batteries	Analysis 3
	3.7V for models PG-800A51, PG-800A11-1,PG-800A36-1,PG-800A37-1		
Operating condition	+5℃~+40℃ 30%RH~80%RH Atmospheric pressure	+5℃~+40℃; 30%RH~80%RH; Atomospheric pressure	Same
Storage condition	-20℃~+55℃ 10%RH~93%RH Atmospheric pressure	-20℃~+55℃; 10%RH~93%RH; Atomospheric pressure	Same
Patient Contact Material	Cuff – Nylon Enclosure – ABS Key - ABS	Cuff – Nylon Enclosure – ABS Key - ABS	Same
Biocompatibility	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	Same
Electrical Safety	Comply with IEC 60601-1	Comply with IEC 60601-1	Same
EMC	Comply with IEC 60601-1-2: 2014	Comply with IEC 60601-1-2:2007	Analysis 4
Particular Performance	Comply with IEC 80601-2-30 and ISO 81060-2	Comply with IEC 80601-2-30 and ISO 81060-2	Same

Analysis 1 Cuff size

The cuff size of the proposed device is different from the predicate device. However, the size of the cuff did not affect the function of measuring blood pressure. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

Analysis 2 Records Quantity

For double patient model, the records quantity of proposed device is 90/90 while for predicated device is 60/60, yet the proposed device adopted same measurement principle and NIBP algorithm as predicated device, software function is justified by the software documents. This difference will not affect the safety and effectiveness, therefore this item is considered as substantial equivalence.

Analysis 3- Power supply

The difference between proposed device and predicated device (K161845) is the batteries, the proposed device use 2 x 1.5V Batteries (for models: PG-800A18, PG-800A19, PG-800A28, PG-800A52) and Rechargeable Li-ion Battery PL 552233 for model: PG-800A51, PG-800A11-1, PG-800A36-1 and PG-800A37-1 while the predicate device use two AAA or LR03 batteries, but the power supply safety of proposed device is justified by the IEC60601-1 electricity test reports, and the rechargeable battery of the proposed device meets the requirements of IEC 62133. thus This difference will not affect the safety and effectiveness, therefore this item is considered as substantial equivalence.

Analysis 4- EMC

The difference between proposed device and predicate device (K161845) is the standard version of EMC test. The new version of the standard can override the requirements of the old version of the standard. In addition, the EMC of proposed device is justified by IEC 60601-1-2: 2014. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

8. Summary of Clinical Testing

   The clinical test was conducted to verify that the proposed device met the requirements of the ISO 81060-2:2018. For systolic and diastolic pressures, the mean error shall be ±5mmHg or less, with a standard deviation of 8mmHg or less.

9. Conclusion

   The conclusions drawn from the nonclinical tests and clinical test demonstrate that the proposed device is as safe, as effective, and performs as well as the legally marketed predicate device K161845, Wrist Blood Pressure Monitor.