December 4, 2020

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

Re: K200716
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: November 4, 2020
Received: November 5, 2020

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K200716

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 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.

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 is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: _____

1. Date of Preparation: 2/20/2020

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

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3. Designated Submission Correspondent

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

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4. Identification of Proposed Device

Trade Name: Electronic Blood Pressure Monitor
Common Name: Arm Blood Pressure Monitor;
Models: PG-800B18, PG-800B19, PG-800B19L, PG-800B28, PG-800B29 and PG-800B51

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 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.

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 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. It has a bar indicating function, which can indicate the World Health Organization (WHO) Blood Pressure Classification of the measured blood pressure by referencing Diastolic Blood Pressure issued at Journal of Hypertension 1999. Vol 17, No.2.

The proposed electronic blood pressure monitor has six models, including PG-800B18, PG-800B19, PG-800B19L, PG-800B28, PG-800B29, PG-800B51. All models follow the same software, measurement principle and NIBP algorithm.

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

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

5. Identification of Predicate Device

510(k) Number: K170151
Product Name: Electronic Blood Pressure Monitor
Model: PG-800B22, PG-800B23, PG-800B26, PG-800B27, PG-800B31, PG-800B32, PG-800B33, PG-800B35, PG-800B36, PG-800B37, PG-800B43 and PG-800B42
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+CORR.1:2006+CORR.2:2007+AM1:2012, Medical electrical equipment – Part 1: General requirements for basic safety, and essential performance
- 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
- 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
- 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.

7. Clinical Test Conclusion

No Clinical study is included in this submission, because the blood pressure measurement function including the measurement principle and NIBP algorithm of the proposed device is identical with that of the legally marketed Electronic Blood Pressure Monitor (predicat device, K170151), which is also manufactured by the sponsor. In addition, the cuff size of the proposed device is also same as that of the legally marketed Electronic Blood Pressure Monitor (predicat device, K170151).

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	**Proposed Device, Electronic Blood Pressure Monitor**	**Predicate Device, K170151 Electronic Blood Pressure Monitor**
Product Code	DXN	DXN
Regulation Number	21 CFR 870.1130	21 CFR 870.1130
Class	II	II
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 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.	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.
Measurement Site	Upper arm	Upper arm
Patient Population	Adult	Adult
Measurement Item	Systolic Pressure, Diastolic Pressure, Pulse Rate	Systolic Pressure, Diastolic Pressure, Pulse Rate
Measurement Method	Oscillometric	Oscillometric
Component	LCD / Key / Cuff / MCU / Pump / Batteries	LCD / Key / Cuff / MCU / Pump / Batteries
Blood Pressure Range	30~280mmHg/	30 ~ 280 mmHg
Blood Pressure Accuracy	3mmHg	3 mmHg
Pulse Rate Range	40 ~ 199 bpm	40 ~ 199 bpm
Data storage	SYS, DIA, Pulse Rate, Measurement Time, Memory Number.	SYS, DIA, Pulse Rate, Measurement Time, Memory Number.
WHO BP Classification	Model PG-800B18, PG-800B19, PG-800B19L, PG-800B28, PG 800B29 has WHO BP Classification Per WHO Classification Model PG-800B51 has not WHO BP Classification	All models provide WHO Classification
Power Supply	4 x 1.5V Batteries (LR03 or AAA) for models PG-800B18, PG-800B19, PG-800B19L ,PG-800B28, PG-800B29 Rechargeable Li-ion Battery PL 652035HC for model: PG-800B51	4x 1.5V Battery (AA or LR6 batteries)
Records Quantity	Single patient records quantity:90 for E)for models PG-800B18, PG-800B19, PG-800B28, PG-800B29, PG-800B51	Single patient records quantity:90 for Electronic Blood Pressure Monitor (PG-800B42)

	Doulbe patient records quantity: 90/90 for r for model :PG PG-800B19L	Doulbe patient records quantity:60/60 for Electronic Blood Pressure Monitor (PG-800B22, PG-800B23, PG-800B26, PG-800B27, PG-800B31, PG-800B32, PG-800B33, PG-800B35, PG-800B36, PG-800B37, PG-800B43)
Arm circumference	22~32cm and 32~42cm	22~32cm and 32~42cm
Electrical Safety	Comply with IEC 60601-1	Comply with IEC 60601-1
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2
Particular Performance	Comply with IEC 80601-2-30:2009	Comply with IEC 80601-2-30:2009
Clinical study	Not conducted	Conducted according to ISO 81060-2
Patient Contact Material	Cuff – Nylon Brush Tricot Enclosure – ABS Key - ABS	Cuff – Nylon Enclosure – ABS Key - ABS
Software Level Concern	Moderate	Moderate

By comparisons, there are mainly four differences between proposed device and predicated device, which are power supply, voltage, record quantities and clincial study.

SE Analysis 1-WHO BP classification

Majority models of proposed device have WHO BP classification which is identical to predicated device except model PG-800B51. Yet the WHO BP classification indicating is only for reference, it cannot be used as diagnosis criteria. This difference will not affect the safety and effectiveness, therefore this item is considered as substantial equivalence.

SE Analysis 2- Power supply

The difference between proposed device and predicated device (K170151) is the batteries , the proposed device use 4 x 1.5V Batteries (for models: PG-800B18, PG-800B19, PG-800B19L ,PG-800B28, PG-800B29) and Rechargeable Li-ion Battery PL 652035HC for model: PG-800B51 while the predicate device use four AA or LR6 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.

SE Analysis 3 –Record quantities

For single patient model, the proposed device has the same record quantities as predicate device. For double patient model, the records quantities of proposed device is 90/90 while for predicated device is 60/60 , yet the proposed device adopt 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.

SE Analysis 4- Clinical study

No Clinical study is included in this submission, because the blood pressure measurement function including the measurement principle and NIBP algorithm of the proposed device is identical with that of the legally marketed Electronic Blood Pressure Monitor (predicat device, K170151), which is also manufactured by the sponsor. In addition, the cuff size of the proposed device is also same as that of the legally marketed Electronic Blood Pressure Monitor (predicat device, K170151).

9. 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.