June 14, 2024

Shenzhen Pango Medical Electronics Co., Ltd.
% Cassie Lee
Official Correspondent
Guangzhou GLOMED Biological Technology Co., Ltd.
2231, Building 1, Rui Feng Center, Kaichuang Road
Huangpu District
Guangzhou, Guangdong 510700
China

Re: K240729
Trade/Device Name: Electronic Blood Pressure Monitor (Model: PG-800B30, PG-800B38, PG-800B39, PG-800B45, PG-800B46, PG-800B47, PG-800B48, PG-800B53, PG-800B55, PG-800B56, PG-800B57, PG-800B58, PG-800B61)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: March 15, 2024
Received: March 18, 2024

Dear Cassie Lee:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240729

Device Name

Electronic Blood Pressure Monitor (Model: PG-800B30, PG-800B38, PG-800B39, PG-800B45, PG-800B46, PG-800B47, PG-800B48, PG-800B53, PG-800B55, PG-800B56, PG-800B57, PG-800B58, PG-800B61)

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.
The intended arm circumference includes 22 cm~32 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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510(k) Summary of K240729

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Date of the summary prepared: June 10, 2024

2. Submitter's Information

Company Name: Shenzhen Pango Medical Electronics Co., Ltd.
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Application Correspondent
Contact Person: Ms. Cassie Lee
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Title: Manager
Tel: +86 20 8266 2446
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3. Subject Device Information

Company Name: Shenzhen Pango Medical Electronics Co., Ltd.
Trade Name: Electronic Blood Pressure Monitor
Model: PG-800B30, PG-800B38, PG-800B39, PG-800B45, PG-800B46, PG-800B47, PG-800B48, PG-800B53, PG-800B55, PG-800B56, PG-800B57, PG-800B58, PG-800B61
Medical Specialty: Cardiovascular
Common Name: Noninvasive blood pressure measurement system
Classification Name: System, Measurement, Blood-Pressure, Non-Invasive
Regulation Number: 21 CFR 870.1130
Product Code: DXN
Regulation Class: Class II

4. Predicate Device Information

510(k) Number: K170151
Company Name: Shenzhen Pango Medical Electronics Co., Ltd.
Trade 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-800B42 and PG-800B43
Medical Specialty: Cardiovascular
Common Name: Noninvasive blood pressure measurement system
Classification Name: System, Measurement, Blood-Pressure, Non-Invasive
Regulation Number: 21 CFR 870.1130
Product Code: DXN
Regulation Class: Class II

5. Device Description

The proposed device, Electronic Blood Pressure Monitor, is a battery driven non-invasive blood pressure monitor. It can 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 WHO (World Health Organization) 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 13 models, including PG-800B30, PG-800B38, PG-800B39, PG-800B45, PG-800B46, PG-800B47, PG-800B48, PG-800B53, PG-800B55, PG-800B56, PG-800B57, PG-800B58, PG-800B61. All models follow the same software, measurement principle and NIBP algorithm. The main differences are product appearance and key numbers.
The product is provided non-sterile, and not to be sterilized by the user prior to use.

6. Intended Use / 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.
The intended arm circumference includes 22 cm~32 cm.

7. Comparison to predicate devices

Compare with the predicate devices, the subject device is very similar in technical design, intended use/indications for use, functions, etc. And the differences between the subject device and predicate devices do not raise new questions of safety or effectiveness. Please refer to the detailed Substantial Equivalence Comparison of the subject device and predicate devices in the following table.

Elements of Comparison	Subject Device	Predicate Device	Verdict
Company	Shenzhen Pango Electronic Co.,Ltd.	Shenzhen Pango Electronic Co.,Ltd.	--
Trade Name	Electronic Blood Pressure Monitor	Electronic Blood Pressure Monitor	--
Model	PG-800B30, PG-800B38, PG-800B39, PG-800B45, PG-800B46, PG-800B47, PG-800B48, PG-	PG-800B22, PG-800B23, PG-800B26, PG-800B27, PG-800B31, PG-800B32, PG-800B33, PG-800B35, PG-800B36,	--

Elements of Comparison	Subject Device	Predicate Device	Verdict
	800B53, PG-800B55, PG-800B56, PG-800B57, PG-800B58, PG-800B61	PG-800B37, PG-800B42 and PG-800B43	
510(k) Number	K240729	K170151	--
Medical Specialty	Cardiovascular	Cardiovascular	Same
Regulation	Noninvasive blood pressure measurement system	Noninvasive blood pressure measurement system	Same
Product Code	DXN	DXN	Same
Regulation Class	Class II	Class II	Same
Intended Use / 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. The intended arm circumference includes 22 cm~32 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.	Similar Note 1
Type for use	OTC	OTC	Same
Measurement Site	Upper arm	Upper arm	Same
Patient Population	Adult	Adult	Same
Measurement Item	Systolic Pressure, Diastolic Pressure, Pulse Rate	Systolic Pressure, Diastolic Pressure, Pulse Rate	Same
Measurement Method	Oscillometric	Oscillometric	Same
Component	LCD / Key / Cuff / MCU / Pump / Batteries	LCD / Key / Cuff / MCU / Pump / Batteries	Same
Power Source	PG-800B30, PG-800B38, PG-800B39, PG-800B45, PG-800B46, PG-800B47, PG-800B48, PG-800B53, PG-800B55, PG-800B56, PG-800B57, PG-800B58: 4x1.5V AAA or LR03 batteries PG-800B61: 4x1.5V AA or LR06 batteries	4x 1.5V Battery (AA or LR6 batteries)	Same
Blood Pressure Range	30~280 mmHg	30~280 mmHg	Same
Blood Pressure	3mmHg	3mmHg	Same

Elements of Comparison	Subject Device	Predicate Device	Verdict
Accuracy			
Pulse Rate Range	40-199bpm	40-199bpm	Same
Cuff Circumference	22-32cm	22-32cm and 32-42cm	Similar Note1
Patient Contact Material	Cuff –Silk Cloth Enclosure – ABS Key - ABS	Cuff – Nylon Enclosure – ABS Key - ABS	Similar Note 2
Electrical Safety	Comply with IEC 60601-1	Comply with IEC 60601-1	Same
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Same
Particular Performance	Comply with IEC 80601-2-30	Comply with IEC 80601-2-30	Same
Clinical measurement performance	Comply with ISO 80601-2	Comply with ISO 80601-2	Same Note 3
Software Level Concern	Moderate	Moderate	Same

Comparison in Detail(s):

Note 1:

Though the cuff circumference in “Intended Use / Indications for Use” and “Cuff Circumference” of the subject device is only one cuff type with a circumference of 22-32cm, and the predicate device has 2 cuff types with a circumference of 22-32cm or 32-42cm. The cuff type with a 22-32cm circumference is the same as the predicate device’s 22-32cm cuff type. So the difference between the subject device and the predicate device will not raise any safety or effectiveness issues.

Note 2:

Although the cuff material of the subject device is different from the predicate device, we conducted the biocompatibility tests according to ISO 10993-5 and ISO 10993-10 on the cuff of subject device, and all test results are in compliance with standards’ requirements. So the difference between the subject device and the predicate device will not raise any safety or effectiveness issues.

Note 3:

No Clinical measurement performance test 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 (predicate 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 (predicate device, K170151). So, there is no necessary to conduct the additional clinical measurement performance on our subject device.

8. Test Summary

8.1 Summary of Non-clinical tests

Non-clinical tests were performed on the subject device in order to validate the design and to assure

conformance with the following voluntary design standards in connection with medical device electrical safety, and electromagnetic compatibility:

- Electrical safety and electromagnetic compatibility (EMC)
  Electrical safety and EMC testing were conducted on the Electronic Blood Pressure Monitor. The subject device complies with the IEC 60601-1, IEC 60601-1-11 and IEC 80601-2-30 standards for safety and the IEC 60601-1-2 standard for EMC.
- Software Verification and Validation Testing
  Software verification and validation testing were conducted and documented which 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 "Moderate" level of concern, since a failure in the software could result in minor injury to the patient or operator.
- Human Factor and Usability Testing
  Usability test were conducted and documented according to the recognized consensus standards of IEC 62366-1. The result of the usability demonstrated all the users in testing did not show any critical errors and represented the performance of using can be smoother by extra practices without specific usability problems. The Electronic Blood Pressure Monitor has been found to be reasonably safe and effective for the intended users, uses and use environments.

8.2 Summary of Clinical Testing

No Clinical measurement performance test 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 (predicate 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 (predicate device, K170151). So, there is no necessary to conduct the additional clinical measurement performance on our subject device.

9. Final conclusion

The subject device is as safe, as effective, and performs as well as the legally marketed predicated devices K170151.