October 16, 2024

Shenzhen HBcare Technology Co.,Ltd
Xuyu Lee
Quality Manager
A208, Block A and B, No.1 ChuangJin, District 28,
Dalang community, Xin'an street, Baoan
Shenzhen, 516000
China

Re: K241613
Trade/Device Name: Elecrtronic Blood Pressure Monitor, Models: BP-201, BP-202, BP-203, BP-204, BP-205, BP-206
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: June 5, 2024
Received: June 5, 2024

Dear Xuyu 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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Stephen C. Browning -S

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)*
K241613

Device Name
Electronic Blood Pressure Monitor, Models: BP-201, BP-202, BP-203, BP-204, BP-205 and BP-206

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 adults 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 ~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.

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K241613

510(k) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

1. Applicant	shenzhen HBcare Technologies co., Ltd A208, Block A and B, No.1 ChuangJin, District 28, Dalang community, Xin'an street, Baoan, Shenzhen, P.R.China.
Contact Person	KAI WANG
Prepare date	2024-02-01
2. Device name and classification	Device Name: Electronic Blood Pressure Monitor Models: BP-201, BP-202, BP-203, BP-204, BP-205 and BP-206 Classification Name: 21 CFR 870.1130 Noninvasive Blood Pressure Measurement System Product code: DXN Regulatory Class: Class II
3. Predicate Device(s)	Shenzhen Pango Electronic Co., Ltd., PG-800B36 Electronic Blood Pressure Monitor cleared under K170151.
4. Device Description	The electronic blood pressure monitor uses fuzzy logic intelligence to detect both upper and lower pressure value simultaneously. The personalized optimal inflation level determines the result of each measurement. It is effective to reduce the discomfort by wrongly inflating the CUFF and also to reduce the wrong measurement value, thus, it improves the accuracy of the measurement. The device would store 99 groups of measurement values for 2 users and display the average reading of the latest 3 groups of measurement results. The device is composed of a main body and a cuff. The main body is composed of a central processing unit, a pressure sensor, an air pump, a solenoid valve, a uniform speed vent valve, a PCB board, and a LCD liquid crystal display.
5. 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 adults 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 ~32 cm.

6. 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.

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

ITEM	**Proposed Device BP-201, BP-202, BP-203, BP-204, BP-205 and BP-206**	**Predicate Device PG-800B36 Electronic Blood Pressure Monitor cleared under K170151.**	**Comparison Result**
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 adults 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 22~32 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.	Different[1]
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 Dry Battery	4x1.5V AAA Alkaline Battery	Different[2]
Physical Dimensions(mm)(Length*Width*Height)	Approx:147*100*60mm	Approx: 140 x100 x50mm	Different[3]
Weight	About 270 g (not including battery and cuff)	Approx: 420 g, excluding battery	

Measurement Range	Blood Pressure	0 ~ 299 mmHg	Blood Pressure	30 ~ 280 mmHg	Different[4]
	Pulse Rate	40 -199bpm	Pulse Rate	40-199 bpm	
Accuracy	Static Pressure	±3 mmHg	Static Pressure	±3 mmHg	Same
	Pulse rate	±5%	Pulse	±5%	
Arm Circumference	22 cm~32 cm		22 cm~42 cm		Different[4]
Patient Contact Material	Cuff – Polyester, Nylon, PVC, Iron		Cuff –Nylon		Different[5]
Applied Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 ISO 80601-2-30 ISO 81060-2		IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 ISO 80601-2-30 ISO 81060-2		Same
Operation Environments	+5℃~+40℃, 15%RH~85%RH Atmospheric Pressure: 70 kPa~105 kPa		+5℃~+40℃, 15%RH~93%RH Atmospheric Pressure: 50 kPa~106 kPa		Different[6]
Storage Environments	-20℃~+50℃, 15%RH~85%RH Atmospheric Pressure: 70 kPa~106 kPa		-20℃~+55℃, 0%RH~93%RH Atmospheric Pressure: 50 kPa~106 kPa		

Justification for the differences:

1) Different Indications for Use

As indicated in the comparison table, the application scenario of the subject device and the predicate device can be used both in hospital and home on the adults' upper arm, they have same indications for use, they are just some language description difference and different circumference range.

2) Different Power Source

BP-201, BP-202, BP-203, BP-204, BP-205 and BP-206 are powered by 4x1.5V Dry Battery, which is different from the predicate. Such difference is verified per the international standard ISO 60601-1, and results show PASS, so no safety problems will be raised.

3) Different Physical Specifications

The subject and the predicate are of different size but proximity. Moreover, such engineering design has been verified during the international standards, so such minor different will not raise any safety and effectiveness questions.

4) Different Measurement Range& Arm Circumference

Different systems show different measurement range, both the predicate and the subject are verified to meet the internal standard's requirements in Clause 201.12.1.103 of ISO 80601-2-30, which is indicated that the Automated Sphygmomanometer shall be capable of indicating systolic blood pressure over at least the range of 60 mmHg (8,0 kPa) to 230 mmHg (30,7 kPa) in Non-neonate mode.

As for the different Arm Circumference, it depends on the cuff equipped with the system, which were taken into consideration during the systematic verification. So, such difference will not raise any safety and effectiveness questions.

5) Different Patient Contact Material

The standards ISO 10993-5, ISO 10993-10 and ISO 10993-23 are quoted to evaluate the biocompatibility of the applied parts of the system, and the results indicated in the corresponding reports show no cytotoxicity, no skin irritation and sensitization, so different patient contact materials will not raise new questions on safety and effectiveness.

6) Different Operation & Storage Environments

Existing difference on the operation and storage environments (including Temperature and Relative Humidity) between the subject device and the predicate, but the system has been proved to be safe and effective since the safety testing was conducted under the suggested environment; Moreover, environment testing data shows the device can work as declared under the suggested conditions. So those changes will not cause any safety and effectiveness problem.

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, 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.

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 Arm-type 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 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 Arm-type 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 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers.

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 proposed devices were found to have a safety and effectiveness profile that the same to the predicate device.

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 proposed Electronic Blood Pressure Monitor is substantially equivalent to the predicate device.