May 12, 2021

Shenzhen LEPU Intelligent Medical Equipment Co., Ltd.
℅ Arthur Goddard
President
FDA Regulatory and Quality Systems Consultant
31853 Cedar Road
Mayfield Heights, Ohio 44124-4445

Re: K210435
Trade/Device Name: Automatic Arm 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: February 8, 2021
Received: February 12, 2021

Dear Arthur Goddard:

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)*

K210435

Device Name
Automatic Arm Electronic Blood Pressure Monitor

Indications for Use *(Describe)*
The device is a digital monitor intended to measure the diastolic, systolic blood pressures and pulse rate in adult patient population by using a non-invasive oscillometric technique in which an inflatable CUFF is wrapped around the upper arm of which the circumference includes 22 cm to 32 cm (8.7 inches to 12.6 inches) or 22 cm to 42 cm (8.7 inches to 16.5 inches). It can be used in hospital environment or at home.

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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Section 5: 510(K) Summary

This summary of 510(K) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1900 and 21 CFR 807.92.

The assigned 510(K) Number: K210435

5. 510(K) Summary

5.1. Date of Preparation: February 8th, 2021

5.2. Sponsor

Shenzhen Lepu Intelligent Medical Equipment Co., Ltd.
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5.3. Official Correspondent

Mr. Arthur Goddard
31853 Cedar Road, Cleveland, Ohio, 44124-4445, U.S.A.
Tel: (216) 233-5722
Email: asjgoddard@aol.com

5.4. Subject Device Identification

Subject Device Name: Automatic Arm Electronic Blood Pressure Monitor
Model: LBP70C, LBP70D
Common name: Noninvasive Blood Pressure Measurement System
Classification Name(s): Noninvasive Blood Pressure Measurement System
Product Code: DXN
Regulation Number: 21 CFR 870.1130
Review Panel: Cardiovascular
Classification: II

5.5. Predicate Device

510(k) Number: K183058
Device Name: Arm-type Electronic Blood Pressure Monitor
Manufacturer: Shenzhen BSX Technology Electronics Co., Ltd.

5.6. Indications for use

The device is a digital monitor intended to measure the diastolic, systolic blood pressures and pulse rate in adult patient population by using a non-invasive oscillometric technique in which an inflatable CUFF is wrapped around the upper arm of which the circumference includes 22 cm to 32 cm (8.7 inches to 12.6 inches) or 22 cm to 42 cm (8.7 inches to 16.5 inches). It can be used in hospital environment or at home.

5.7. Device Description

The Automatic Arm Electronic Blood Pressure Monitor, including LBP70C and LBP70D, can automatically complete the inflation, deflation and measurement, which can measure systolic and diastolic blood pressure as well as the pulse rate of adult patient with arm circumference ranging from 22 cm to 32 cm (8.7 inches to 12.6 inches) or 22 cm to 42 cm (8.7 inches to 16.5 inches) by the oscillometric technique. User can select the blood pressure unit mmHg or KPa.

The device has irregular heart beat (IHB) indicator which can indicate a rhythm 25% less or 25% more than the average rhythm detected while measuring the systolic and diastolic blood pressure.

The subject device consists of the PCBA, pressure sensor, operation keys, pump, control valve, LCD screen, cuff, batteries and optional accessory AC adapter. The two models have same intended use, working principle, measuring range, accuracy, cuff, component and appearance. They are only different in power supply. Model LBP70C is powered by 4 AA alkaline batteries or AC adapter, while model LBP70D is powered by rechargeable lithium-polymer battery or AC adapter.

The device has a memory function that can automatically store up to 90 sets of data for each user. It can also display the latest measurement result.

5.8. Predicate Devices and Subject Device Comparison

Table 5-1 Feature Comparison with Predicate Devices

Item	Subject Device	Predicate Device K183058	Remark
Product Name	Automatic Arm Electronic Blood Pressure Monitor	Arm-type Electronic Blood Pressure Monitor	SE
Product Code	DXN	DXN	
Regulation Number	21 CFR 870.1130	21 CFR 870.1130	
Classification Name(s)	Noninvasive Blood Pressure Measurement System	Noninvasive Blood Pressure Measurement System	
Classification	II	II	
Indications for	The device is a digital monitor	The blood pressure monitor	Discussion 1

Item	Subject Device	Predicate Device K183058	Remark
use	intended to measure the diastolic, systolic blood pressures and pulse rate in adult patient population by using a non-invasive oscillometric technique in which an inflatable cuff is wrapped around the upper arm of which the circumference includes 22 cm to 32 cm (8.7 inches to 12.6 inches) or 22 cm to 42 cm (8.7 inches to 16.5 inches). It can be used in hospital environment or at home.	is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable CUFF is wrapped around the arm of which the circumference includes 22 cm~32 cm. It is intended to be used in hospital environment or at home.	

Discussion 1:

The indications for use of the subject device and predicate device are compared from the following aspects:

Item	Subject Device	K183058	Discussion
Intended patient population	Adult	Adult	SE
Intended application site	Upper arm	Upper arm	SE
Intended use environment	hospital or home	hospital or home	SE
Measurement Principle	non-invasive oscillometric	non-invasive oscillometric	SE
Arm Circumference	22 cm~32 cm or 22 cm~42 cm	22 cm~32 cm	A
Basic functions	Measure the diastolic, systolic blood pressures and pulse rate	Measures the diastolic and systolic blood pressures and pulse rate	SE

A. The subject device and the predicate device are different in arm circumference. The 22-32cm of the arm circumference of subject device is substantially equivalent to the predicate device, and the 22-42cm of the arm circumference of subject device is substantially equivalent to the reference device (K192609, produced by Globalcare Medical

Item	Subject Device	Predicate Device K183058	Remark
Technology Co., Ltd). Additionally, LEPU Intelligent Medical has verified the accuracy of the measurement within 22-32cm and 22-42cm of the arm circumference accordance to the requirements of ISO 81060-2, and the results meet the requirements. Please refer to Section 20 for details. So, the difference does not raise any new issues of safety or efficacy. Per the comparison and discussion above, the subject device and predicate device have same intended patient population, intended application site, intended use environment, measurement principle and basic functions. Arm circumference of the subject and the predicate device are substantially the same. Therefore, the noted difference in indications for use does not raise any new issues of safety or efficacy. The subject device can be considered to be substantially equivalent to that of the predicate device.			
Contacting Material	Enclosure-ABS+PMMA Cuff- Polyester Air tube-PVC	Cuff - Polyester	Discussion 2
Discussion 2: The cuff of the two devices are made of same materials. The materials of the enclosure of the predicate device are not mentioned. The materials used in subject device have excellent performance and safety, and can meet the requirements of the device for the material. The biological safety of all the materials has been verified, including cytotoxicity, sensitization and irritation tests. The test results meet the requirements of the ISO10993 series of standards. Please refer to Section 15 for detail. So, the difference does not raise any new issues of safety or efficacy. The subject device can be considered to be substantially equivalent to that of the predicate device.			
Power Source	4x1.5V AA alkaline batteries or AC adapter (LBP70C) 3.7V 2200mAh Rechargeable lithium battery or AC adapter (LBP70D)	4x1.5V AAA Alkaline Battery (BSX516, BSX525, BSX583, BSX593 and BSX595) 3.7V 400mAh Li-ion Battery (BSX523)	Discussion 3
Discussion 3: The subject device and the predicate device are different in power source. For the alkaline battery power supply method, although the power supply battery model is different, the voltage of the two devices is both 6V. For the lithium battery power supply method, the voltage of the two devices is both 3.7V. The battery capacity of the subject device is 2200mAh, which is better than the 400mAh of the predicate device. Regardless of the power supply method, the voltage of the two devices is the same, so the difference does not raise any new issues of safety. Additionally, LEPU Intelligent Medical has verified the power source requirements of the device in accordance with the requirements in IEC 80601-2-30 and IEC 60601-1, and the results meet the requirements. So, the difference does not raise any new issues of safety or efficacy. The subject device can be considered to be substantially equivalent to that of the predicate			

Item	Subject Device	Predicate Device K183058	Remark
device.			

Table 5-2 Specification Comparison

Item	Subject Device		Predicate Device K183058		Remark
Measurement Range	Blood Pressure	Static pressure: 0~280 mmHg/ 0~37.3 kPa; SYS:(60~255) mmHg/ (8.0~34.0) kPa DIA: (30~195) mmHg/ (4.0~26.0) kPa	Blood Pressure	0-299mmHg	Discussion 4
	Pulse rate	40 to 199 bpm	Pulse rate	40 to 180 bpm	

Discussion 4:

The subject device and predicate device are different in measurement range.

The blood pressure measurement range (0~280mmHg) of subject device is within that of predicate device (0~299mmHg). According to the table below, the systolic and diastolic blood pressure measurement range can meet the requirement of IEC 80601-2-30.

Item	IEC 80601-2-30 Requirement	Subject Device	Conclusion
Systolic blood pressure	At least 60~230mmHg	60~255mmHg	Meet the requirement
Diastolic blood pressure	At least 40~130mmHg	30~195mmHg	Meet the requirement

The PR measurement range of the subject device is 40~199bpm, which is greater than the 40~180bpm of the predicate device. For this reason, LEPU Intelligent Medical has verified the accuracy of the measurement within the measurement range, and the results meet the requirements, please refer to Section 18 for details. So, the difference does not raise any new issues of safety or efficacy. The subject device can be considered to be substantially equivalent to that of the predicate device.

Accuracy	Blood Pressure	±3 mmHg/ ±0.4 kPa	Blood Pressure	±3 mmHg	SE
	Pulse rate	±5%	Pulse rate	± 5%	
Operating Temperature	5℃~40℃		5℃~40℃		Discussion 5
Operating	15%RH~85%RH		15%RH~85%RH		

Item	Subject Device	Predicate Device K183058	Remark
humidity			
Operating atmospheric pressure	70 kPa ~106 kPa	80 kPa~106kPa	
Storage temperature	-20℃~55℃	-20℃~55℃	
Storage humidity	≤93%RH	10%RH~93%RH	
Storage atmosphere pressure	50 kPa ~106kPa	70 kPa~106kPa	

Discussion 5:

The subject device and the predicate device are different in operating/storage atmospheric pressure and storage humidity. LEPU Intelligent Medical has verified the environmental requirements of the device in accordance with the requirements in IEC 80601-2-30, and the results meet the requirements. So, the difference does not raise any new issues of safety or efficacy. The subject device can be considered to be substantially equivalent to that of the predicate device.

Table 5-3 Performance and Safety Comparison

Item	Subject Device Finger pulse oximeter	Predicate Device K161560 Fingertip Pulse Oximeter	Remark
Particular requirements for basic safety and essential performance	Meeting the requirements of IEC 80601-2-30	Meeting the requirements of IEC 80601-2-30	SE
Electrical Safety	Meeting the requirements of IEC 60601-1 and IEC 60601-1-11	Meeting the requirements of IEC 60601-1 and IEC 60601-1-11	SE
Electromagnetic Compatibility	Meeting the requirements of IEC 60601-1-2	Meeting the requirements of IEC 60601-1-2	SE
Biocompatibility	Meeting the requirements of ISO 10993-1, ISO 10993-5, ISO 10993-10	Meeting the requirements of ISO 10993-1, ISO 10993-5, ISO 10993-10	SE
Clinical study	Meeting the requirements of ISO 81060-2	Meeting the requirements of ISO 81060-2	SE

5.9. Performance Tests Summary

Bench test were conducted to verify that the subject device met all design specifications, as was Substantially Equivalent (SE) to the predicate device.

- **Biocompatibility Testing**

  The Automatic Arm Electronic Blood Pressure Monitor was assessed against the International Standard ISO 10993-1, "Biological evaluation of medical devices. Part 1. Guidance on selection of tests." The subject device would be classified as a Surface Medical Device in contact with the intact skin for a Limited Duration (<24 hours). The following test were performed for any user contacting material:

Test	Standard	Results
Cytotoxicity Study using MTT Method	ISO 10993-5	Under the conditions of this study, the MEM extracts of test article would be considered no cytotoxicity potential. The negative controls, blank controls, and the positive controls performed as anticipated.
Skin Sensitization Study Guinea Pig Maximization Test	ISO 10993-10	Under the condition of this study, the test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig. The test article was not considered a sensitizer in the guinea pig maximization test.
Skin Irritation Study	ISO 10993-10	Under the conditions of this study, the irritation response category of the test article is classified as Negligible for polar extract and Negligible for non-polar extract.

- **Non-clinical Tests**

  The Automatic Arm Electronic Blood Pressure Monitor is tested per the following standard, to evaluate its performance. The test results demonstrated that the proposed device comply with the standard requirements.

  IEC 60601-1: 2005+AMD1:2012 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 60601-1-11 Edition 2.0:2015-01 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 80601-2-30: Edition 2.0 2018-03 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated

non-invasive sphygmomanometers.

- **Clinical data**

  A clinical study was conducted per the requirement of *ISO 81060-2: 2018 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type* to validate the accuracy of blood pressure measurements by subject device based on an oscillometric method. In this clinical study, 85 patients (46 males and 39 females) participated in the clinical study. Same arm sequential method was adopted during the clinical study. The manual Mercury Sphygmomanometer was used as a reference sphygmomanometer. All the subjects were volunteer to take part in the clinical study, all the subjects completed the clinical study without any AE or side-effect. The results showed the accuracy of the subject device is within acceptable scope specified in ISO 81060-2.

- **Software**

  The software embedded in Automatic Arm Electronic Blood Pressure Monitor has been developed, documented, and validated in accordance with industry standards (IEC 62304 – Medical device software – Software life cycle processes) and FDA guidance (GUIDANCE FOR THE CONTENT OF PRE-MARKET SUBMISSIONS FOR SOFTWARE CONTAINED IN DEVICES).

5.10. Substantially Equivalent Conclusion

The subject device, Automatic Arm Electronic Blood Pressure Monitor, is determined to be Substantially Equivalent (SE) to the predicate device, in respect of safety and efficacy.