DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 10, 2017

Beijing Choice Electronic Technology Co., Ltd.
Lei Chen
Quality Director
No.9 Shuangyuan Road, Badachu Hi-tech Zone,
Shijingshan District
Beijing, 100041 CN

Re: K162089
Trade/Device Name: Blood Pressure Monitor CBP111/CBP112
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: January 3, 2017
Received: January 6, 2017

Dear Lei Chen:

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. 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.

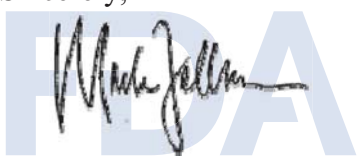
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K162089

Device Name
Blood Pressure Monitor CBP111/CBP112

Indications for Use *(Describe)*
The Blood Pressure Monitor CBP111/CBP112 is intended for non-invasive measuring of an adult individual's systolic, diastolic blood pressure and heart rate in hospital, at home or clinical use. Blood pressure readings should be taken on the upper arm of an adult only, and the suitable cuff size is from 22cm to 32cm.

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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# Section III 510(k) Summary

This summary of 510(k) is being submitted in accordance with the requirements of 21 CFR 807.92.

**There is no prior submission for the device.**

## 3.1 Submitter Information

**Manufacturer Name:**

Establishment Registration Number: 3005569927
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**Date prepared：July 22, 2016**

## 3.2 Proposed Device Information

**Device Common Name:** Non-invasive Blood Pressure Measurement System
**Device Trade/Proprietary Name:** Blood Pressure Monitor
**Model:** CBP111, CBP112
**Classification Name:** Non-invasive Blood Pressure Measurement System
**Regulation Number:** 870.1130
**Product Code:** DXN
**Class:** II
**Panel:** Cardiovascular

## 3.3 Predicate Device

**510(k) Number:** K143735
**Common Name:** Noninvasive Blood Pressure Measurement System

Premarket Notification 510(k) Submission-Section III 510(k) Summary

**Device Trade/Proprietary Name:** Digital Automatic Blood Pressure Monitor
**Model:** MD2300
**Classification Name:** Non-invasive Blood Pressure Measurement System
**Regulation Number:** 870.1130
**Product Code:** DXN
**Class:** II
**Manufacturer:** GRANDWAY TECHNOLOGY (SHENZHEN) LIMITED
**Intended Use:** The upper arm blood pressure monitor is used for non-invasive measurement and monitoring for adults arterial blood pressure. You can use it to measure your systolic and diastolic pressure, and pulse rate through an inflatable cuff wrapped around the upper arm. Quickly and easily, storing the results and displaying the progression of readings together with the average.

## 3.4 Device Description

Blood Pressure Monitor CBP111/CBP112 is a non-invasive blood pressure measurement system for use in hospital, at home or clinical use. It is designed to measure the systolic and diastolic blood pressure, and pulse rate of an individual in each measurement and then display the digital readings on LED screen. Blood pressure readings should be taken on the upper arm of an adult only.

The device utilizes the oscillometric methodology, in which an inflatable cuff is wrapped around the upper arm of an individual, for blood pressure measurement. This means the monitor detects your blood's movement through your brachial artery and converts the movement into a digital reading on LED screen.

The proposed device CBP111/CBP112 has the following components: power supply management module, blood pressure data acquisition module, MCU and peripheral, data communication module, data storage module, pump value plate controlling module and program debugging and burning module.

The Blood Pressure Monitor CBP111 and CBP112 have the same electrical circuit and structure design. They have the same accessories. They also have the same display type, control module and communication module. The difference between them is the measurement type. The CBP111 is reading the data while it is deflating. The CBP112 is reading the data while it is inflating.

The proposed device is not for life-supporting or life-sustaining, not for implant.

The device is not sterile and the transducers are reusable and do not need sterilization and re-sterilization.

The device is for over the counter use.

The device does not contain drug or biological products.

The device is software-driven and software validation is provided in ***software***.

## 3.5 Indications for use

The Blood Pressure Monitor CBP111/CBP112 is intended for non-invasive measuring of an adult individual's systolic, diastolic blood pressure and heart rate in hospital, at home or clinical use. Blood pressure readings should be taken on the upper arm of an adult only, and the suitable cuff size is from 22cm to 32cm.

## 3.6 Comparison of Technology Characteristics with the Predicate Device

Blood Pressure Monitor CBP111 is compared to the predicate device, Digital Automatic Blood Pressure MD2300 (K143735) in the device comparison table below

| Comparison between Blood Pressure Monitor CBP111 and Predicate Device | | | |
|---|---|---|---|
| Item | Predicate Device | Proposed Device(CBP111) | Proposed Device(CBP112) |
| Indication for use | The upper arm blood pressure monitor is used for non-invasive measurement and monitoring for adults arterial blood pressure. You can use it to measure your systolic and diastolic pressure, and pulse rate through an inflatable cuff wrapped around the upper arm. Quickly and easily, storing the results and displaying the progression of readings together with the average. | The Blood Pressure Monitor CBP111 is intended for non-invasive measuring of an adult individual's systolic, diastolic blood pressure and heart rate in hospital, at home or clinical use. Blood pressure readings should be taken on the upper arm of an adult only. | The Blood Pressure Monitor CBP112 is intended for non-invasive measuring of an adult individual's systolic, diastolic blood pressure and heart rate in hospital, at home or clinical use. Blood pressure readings should be taken on the upper arm of an adult only. |
| Measurement method | Non-invasive, Oscillometric | Non-invasive, Oscillometric | Non-invasive, Oscillometric |
| IHB Detection | Yes | No | No |
| Patient population | Adult | Adult | Adult |
| BP measurement range | Cuff pressure: 0~300 mmHg | Cuff pressure: 0~280 mmHg | Cuff pressure: 0~280 mmHg |

Premarket Notification 510(k) Submission-Section III 510(k) Summary

| | | | |
|---|---|---|---|
| Number of user | 2 independent users | Record the last results and do not distinguish the people | Record the last results and do not distinguish the people |
| Memory space | 2 users x 60 memory space | 2k byte (24C16) | 2k byte (24C16) |
| Resolution of measurement | Blood pressure: 1mmHg<br>Pulse rate: 1beat/min | Blood pressure: 1mmHg<br>Pulse rate: 1beat/min | Blood pressure: 1mmHg<br>Pulse rate: 1beat/min |
| Blood pressure measurement accuracy | ±3mmHg | ±3mmHg | ±3mmHg |
| Pulse rate measurement range | 40-180 beats/min | 40-180bpm | 40-180bpm |
| Pulse rate measurement accuracy | ±5% of reading | >60bpm ± 5%, ⩽ 60bpm, ± 3bpm | >60bpm ± 5%, ⩽ 60bpm, ± 3bpm |
| Display type | LCD | LED | LED |
| Power source | 4 x1.5V AA-batteries and/or AC adapter | 4 AA alkaline batteries | 4 AA alkaline batteries |
| Pressurization mode | Automatic inflation | Automatic inflation | Automatic inflation |
| Deflation mode | Automatic exhaust/Deflation | Automatic exhaust/Deflation | Automatic exhaust/Deflation |
| Operating condition | Temperature: +5℃ to 40℃<br>Humidity: 15% to 93% R.H. max<br>Atmosphere pressure: 700-1060hPa | Temperature: +5℃ to 40℃<br>Humidity: 15% to 93% R.H. max<br>Atmosphere pressure: 700-1060hPa | Temperature: +5℃ to 40℃<br>Humidity: 15% to 93% R.H. max<br>Atmosphere pressure: 700-1060hPa |

Premarket Notification 510(k) Submission-Section III 510(k) Summary

| | | | |
|---|---|---|---|
| Storage and transportation condition | Temperature: -25℃ to 70℃<br>Humidity: up to 93% R.H. max<br>Atmosphere pressure: 700-1060hPa | Temperature: -25℃ to 70℃<br>Humidity: up to 93% R.H. max<br>Atmosphere pressure: 700-1060hPa | Temperature: -25℃ to 70℃<br>Humidity: up to 93% R.H. max<br>Atmosphere pressure: 700-1060hPa |
| Material | Resistances, capacitances, transistors, Amplifiers, pressure sensor, CPU,PCB, cuff, ABS button, ABS cabinet, batteries and packaging | Resistances, capacitances, transistors, Amplifiers, pressure sensor, CPU, PCB, cuff, ABS button, ABS cabinet, batteries and packaging | Resistances, capacitances, transistors, Amplifiers, pressure sensor, CPU, PCB, cuff, ABS button, ABS cabinet, batteries and packaging |
| Compatibility with environment and other devices | No influence with environment and other device | No influence with environment and other device | No influence with environment and other device |
| Applicable standard | -EN 1060-1:1995+A2:2009<br>-EN 1060-3:1997+A2:2009<br>-IEC 60601-1: 2012<br>-IEC 60601-1-2:2007<br>-FCC Part 15 Subpart B<br>-ISO 10993-5:2009<br>-ISO 10993-10:2010<br>-IEC 62304:2006 | -IEC 60601-1: 2012<br>-IEC 60601-1-2:2007<br>-IEC 60601-1-11:2010<br>-FCC Part 15 Subpart B<br>-ISO 10993-5:2009<br>-ISO 10993-10:2010<br>-IEC 62304:2006<br>-ISO 81060-2:2013 | -IEC 60601-1: 2012<br>-IEC 60601-1-2:2007<br>-IEC 60601-1-11:2010<br>-FCC Part 15 Subpart B<br>-ISO 10993-5:2009<br>-ISO 10993-10:2010<br>-IEC 62304:2006<br>-ISO 81060-2:2013 |

| | | | |
|---|---|---|---|
| | -IEC 81060-2:2013 | -IEC 80601-2-30: 2013 | -IEC 80601-2-30: 2013 |

Blood Pressure Monitor CBP111/CBP112 is a non-invasive measuring device and utilizes the oscillometric methodology to measure the blood pressure reading. The key components of the device are: blood pressure data acquisition module, MCU and peripheral, data communication module, data storage module, pump valve plate controlling module. The predicate device adopts exactly same methodology and key components for measuring blood pressure.

## 3.7 Clinical and Non-clinical Tests

Clinical Test Summary

Testing to insure clinical accuracy of proposed devices in accordance with ISO 81060-2:2013 Non-invasive sphygmomanometers-Part 2: Clinical validation of automated measurement type as documented in Clinical Study Report.

85 patients (42 females and 43 males) were invited for the study. Standard auscultation method was used as the reference blood pressure monitor measuring in the left arm. Blood pressure measurements were repeated alternatively with the device and auscultation in the same arm according to the sequence in ISO81060-2:2013.

Non-Clinical Test Summary

The subject device CBP111 was tested to evaluate its safety and effectiveness, including the following:

a. EMC Test: IEC 60601-1-2:2007 Medical Electrical Equipment- Part 1-2: General requirements for safety- collateral standard: Electromagnetic compatibility-Requirements and tests.

b. Safety Test:

-IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

-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 systems used in the home healthcare environment.

c. FCC Test:

FCC 47 CFR Part 15, Subpart B

d. Biocompatibility Test:

The proposed blood pressure cuff selects the materials of the blood pressure cuff which has been cleared by FDA with the premarket notification number K151810. The materials of cuff meet the requirements of the following standards:

-ISO 10993-1:2009, Biological evaluation of medical devices –Part 1: Evaluation and testing within a risk management process.

-ISO 10993-5:2009 Biological evaluation of medial devices –Part 5: Test for In Vitro cytotoxicity.

-ISO 10993-10:2010 Third Edition Biological evaluation of medial devices –Part 10: Tests for irritation and skin sensitization.

e. Reliability Test:

IEC 80601-2-30:2013 Medical electrical equipment-Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers.

f. Software Verification and Validation

IEC 62304: 2006 Medical device software – Software life cycle processes.

The Blood Pressure Monitor CBP112 and CBP111 have the same electrical circuit and structure design. They have the same accessories. They also have the same display type, control module and communication module. The difference between them is the measurement type. The CBP111 is reading the data while it is deflating. The CBP112 is reading the data while it is inflating. So we think CBP111 laboratory test results can be used to support clearance of proposed device CBP112.

The subject device was tested and fulfilled the requirements of those standards mentioned above. The test results indicated that the safety and effectiveness of the proposed device is identical to that of the predicate device.

## 3.8 Conclusion

The proposed device Blood Pressure Monitor CBP111/CBP112 and predicate device have the same classification information, similar intended use, same design method, similar product design and specifications, and the similar performance as the predicated device. The main difference is that the predicated device has function of IHB detection while the proposed device does not. The difference does not influence the effectiveness and safety of the proposed device. According to the test results, the proposed device is as safe and as effective as the predicate device. So the proposed device is Substantially Equivalent (SE) to the predicate device which is US legally market device.