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

July 7, 2017

GRANDWAY TECHNOLOGY (SHENZEN) LIMITED
Mr. Patrick Chow
General Manager
Block 7, Zhu Keng Industrial Zone,
Ping Shan, Long Gang District,
Shenzhen, 518118
China

Re: K163648
Trade/Device Name: Digital Automatic Blood Pressure Monitor BPM41 Series, Digital Automatic Blood Pressure Monitor BPM45 Series
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: June 7, 2017
Received: June 8, 2017

Dear Mr. Patrick Chow:

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,

for

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)*

K163648

Device Name

Digital Automatic Blood Pressure Monitor BPM41 Series;
Digital Automatic Blood Pressure Monitor BPM45 Series

Indications for Use *(Describe)*

This device is for use by medical professional or home users. It is intended to measure the systolic and diastolic blood pressure of an adult individual by using a non-invasive technique, in which an inflatable cuff is wrapped around the upper arm.

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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1. Submitter identification

510(k) Submitter	GRANDWAY TECHNOLOGY (SHENZHEN) LIMITED
Address	Block 7, Zhu Keng Industrial Zone, Ping Shan, Long Gang District, 518118, Shenzhen, People's Republic of China
Phone Number	(00852)-2851-6789
Fax Number	(00852)-2851-6278
Contact Person	Mr. Patrick Chow
Date of Submission	22-Dec-2016

2. Device identification

Trade Name	Digital Automatic Blood Pressure Monitor BPM41 Series [Model No.: MD41X0] x --- The character (0, 1, 2, 3, 4, 5, 6, 7, 8, 9, A & B) is for the minor change revision of device. The mentioned "minor change" refers to those device changes not to be affecting the conformity test results of EMC & safety as well as device performance, i.e. IEC 60601-1 and IEC 60601-1-2. Digital Automatic Blood Pressure Monitor BPM45 Series [Model No.: MD45X0] x --- The character (0, 1, 2, 3, 4, 5, 6, 7, 8, 9, A & B) is for the minor change revision of device. The mentioned "minor change" refers to those device changes not to be affecting the conformity test results of EMC & safety as well as device performance, i.e. IEC 60601-1 and IEC 60601-1-2.
Common Name	Non-invasive Blood Pressure Measurement System
Classification Name	Non-invasive Blood Pressure Measurement System (CFR 870.1130, Class II, Product Code DXN)

3. Predicate device

Predicate Device	Digital Automatic Blood Pressure Monitor BPM25 & BPM 26 Series
Manufacturer	GRANDWAY TECHNOLOGY (SHENZHEN) LIMITED
510(k) Number	K150373

4. Device Description

Digital Automatic Blood Pressure Monitor BPM41 Series and Digital Automatic Blood Pressure Monitor BPM45 Series (Subject Device) are non-invasive blood pressure measurement systems for use by medical professional or at home. It is designed to measure the systolic and diastolic blood pressure, and pulse rate of an individual in each measurement and then display the readings on a digital panel.

The Subject Device utilize 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.

The table below illustrate the feature presence in the Subject Device:

Series	Model	LCD type	Backlight	Sound	DC jack
MD41 Series	MD4100	Positive Reflective	No	Buzzer	No
	MD4110	Positive Reflective	No	Voice	Yes
	MD4120	Positive Reflective	No	Buzzer	Yes
	MD4130	Positive Reflective	No	Voice	No
	MD4140	Negative transimissive	Yes	Buzzer	Yes
	MD4150	Negative transimissive	Yes	Buzzer	No
	MD4160	Negative transimissive	Yes	Voice	Yes
	MD4170	Negative transimissive	Yes	Voice	No
	MD4180	Positive transimissive	Yes	Buzzer	Yes
	MD4190	Positive transimissive	Yes	Buzzer	No
	MD41A0	Positive transimissive	Yes	Voice	Yes
	MD41B0	Positive transimissive	Yes	Voice	No
MD45 Series	MD4500	Positive Reflective	No	Buzzer	No
	MD4510	Positive Reflective	No	Voice	Yes
	MD4520	Positive Reflective	No	Buzzer	Yes
	MD4530	Positive Reflective	No	Voice	No
	MD4540	Negative transimissive	Yes	Buzzer	Yes
	MD4550	Negative transimissive	Yes	Buzzer	No
	MD4560	Negative transimissive	Yes	Voice	Yes
	MD4570	Negative transimissive	Yes	Voice	No
	MD4580	Positive transimissive	Yes	Buzzer	Yes
	MD4590	Positive transimissive	Yes	Buzzer	No
	MD45A0	Positive transimissive	Yes	Voice	Yes
	MD45B0	Positive transimissive	Yes	Voice	No

5. Indication for use

This device is for use by medical professional or home users. It is intended to measure the systolic and diastolic blood pressure on an adult individual by using a non-invasive technique, in which an inflatable cuff is wrapped around the upper arm.

6. Comparison of technological characteristics between the Subject Device and the Predicate Devices

The Subject Device are compared to the Predicate device in the device comparison table below:

Item	Predicate Device (K150373)	Subject Device (BPM41 Series)	Subject Device (BPM45 Series)	Comment
Indication for Use	This device is for use by medical professional or home users. It is intended to measure the systolic and diastolic blood pressure of an adult individual by using a non-invasive technique, in which an inflatable cuff is wrapped around the upper arm.	This device is for use by medical professional or home users. It is intended to measure the systolic and diastolic blood pressure on an adult individual by using a non-invasive technique, in which an inflatable cuff is wrapped around the upper arm.	This device is for use by medical professional or home users. It is intended to measure the systolic and diastolic blood pressure on an adult individual by using a non-invasive technique, in which an inflatable cuff is wrapped around the upper arm.	Identical
Patient Population	Adult	Adult	Adult	Identical
Measurement Method	Non-invasive, Oscillometric	Non-invasive, Oscillometric	Non-invasive, Oscillometric	Identical
BP Measurement Range	Cuff Pressure: 0 - 300 mmHg Systolic Pressure: 50 - 250 mmHg Diastolic Pressure: 30 - 200 mmHg	Cuff Pressure: 0 - 300 mmHg Systolic Pressure: 50 - 250 mmHg Diastolic Pressure: 30 - 200 mmHg	Cuff Pressure: 0 - 300 mmHg Systolic Pressure: 50 - 250 mmHg Diastolic Pressure: 30 - 200 mmHg	Identical
Resolution of Measurement	Blood Pressure: 1 mmHg or 0.1kPa Pulse Rate: 1 beat/ min	Blood Pressure: 1 mmHg or 0.1kPa Pulse Rate: 1 beat/ min	Blood Pressure: 1 mmHg or 0.1kPa Pulse Rate: 1 beat/ min	Identical
Blood Pressure Measurement Accuracy	± 3 mmHg	± 3 mmHg	± 3 mmHg	Identical
Pulse Rate Measurement Range	40 - 180 beats/min	40 - 180 beats/min	40 - 180 beats/min	Identical
Pulse Rate Measurement Accuracy	± 5 % of the reading	± 5 % of the reading	± 5 % of the reading	Identical
IHB Detection	Yes	Yes	Yes	Identical
Number of User	2 independent users	4 independent users	2 independent users	Different (BPM41 Series)[1] Identical (BPM45 Series)
Memory Space	2 users × 120 memory space (Total 240 memory space)	4 users × 120 memory space (Total 480 memory space)	2 users x 240 memory space (Total 480 memory space)	Different[2]
Voice function	Present (depends on model)	Present (depends on model)	Present (depends on model)	Identical
Alarm clock function	Absent	Present	Present	Different[3]
Backlight	Present (depends on model)	Present (depends on model)	Present (depends on model)	Identical
Display Type	LCD	LCD	LCD	Identical
Power Source	4 × 1.5 V AA-batteries; and/or AC adaptor (6V/600mA)	4 × 1.5 V AAA-batteries; and/or AC adaptor (6V/600mA)	4 x 1.5 V AA-batteries; and/or AC adaptor (6V/600mA)	Different (BPM41 Series)[4] Identical (BPM45 Series)
Pressurization Mode	Automatic Inflation	Automatic Inflation	Automatic Inflation	Identical
Deflation Mode	Automatic Exhaust/ Deflation	Automatic Exhaust/ Deflation	Automatic Exhaust/ Deflation	Identical

Item	Predicate Device (K150373)	Subject Device (BPM41 Series)	Subject Device (BPM45 Series)	Comment
Operating Condition	Temperature: +5 to +40 °C Humidity: 15 to 93 % R.H. max Atmospheric Pressure: 700-1060 hPa	Temperature: +5 to +40 °C Humidity: 15 to 93 % R.H. max Atmospheric Pressure: 700-1060 hPa	Temperature: +5 to +40 °C Humidity: 15 to 93 % R.H. max Atmospheric Pressure: 700-1060 hPa	Identical
Storage and Transportation Condition	Temperature: -25 to +70 °C Humidity: up to 93% R.H. max Atmospheric Pressure: 700-1060 hPa	Temperature: -25 to +70 °C Humidity: up to 93% R.H. max Atmospheric Pressure: 700-1060 hPa	Temperature: -25 to +70 °C Humidity: up to 93% R.H. max Atmospheric Pressure: 700-1060 hPa	Identical
Material	Resistances, capacitance, transistors, amplifiers, pressure sensor, CPU, PCB, cuff ABS button, ABS cabinet, batteries and packaging	Resistances, capacitance, transistors, amplifiers, pressure sensor, CPU, PCB, cuff ABS button, ABS cabinet, batteries and packaging	Resistances, capacitance, transistors, amplifiers, pressure sensor, CPU, PCB, cuff ABS button, ABS cabinet, batteries and packaging	Identical
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	Identical
Applicable Standard	- EN 1060-1:1995+A2:2009 - EN 1060-3:1997+A2:2009 - IEC 60601-1:2012 - EN 60601-1-2:2007 - FCC Part 15 Subpart B - IEC 81060-2:2009 - IEC 80601-2-30:2009+A1:2013	- ISO 81060-1:2007 - EN 1060-3:1997+A2:2009 - IEC 60601-1:2012 - IEC 60601-1-2:2014 - IEC 60601-1-11:2015 - FCC Part 15 Subpart B - IEC 81060-2:2013 - IEC 80601-2-30:2009+A1:2013	- ISO 81060-1:2007 - EN 1060-3:1997+A2:2009 - IEC 60601-1:2012 - IEC 60601-1-2:2014 - IEC 60601-1-11:2015 - FCC Part 15 Subpart B - IEC 81060-2:2013 - IEC 80601-2-30:2009+A1:2013	Equivalent[5]

[1] The number of user between the Subject Device (BPM45 Series) and the Predicate Device is different but this will neither raise any safety issues nor affect the essential performance of the subject device.

[2] The total memory space between the Subject Device and the Predicate Device is different but this will neither raise any safety issues nor affect the essential performance of the subject device.

[3] The Subject Device has a new alarm clock function but this new function will neither raise any safety issues nor affect the essential performance of the subject device.

[4] The battery type used in Subject Device (BPM41 Series) and the Predicate Device is different but this will neither raise any safety issues nor affect the essential performance of the subject device.

[5] The standards used in Subject Device are updated and they are equivalent to the standards used in the Predicate Device.

7. Clinical and Non-clinical Tests

Clinical Test Summary

Testing to insure clinical accuracy of the device in accordance with ISO 81060-2 as documented in Clinical Test report.

For the Subject Device (BPM 41 Series), one hundred patients (50 males and 50 females) 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 ISO 81060-2.

For the Subject Device (BPM 45 Series), one hundred patients (51 males and 49 females) 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 ISO 81060-2.

Non-Clinical Test Summary

The Subject Device has performed several non-clinical tests to show that all requirement specifications and standard requirements are met. The tests includes the follows:

- ISO 81060-1:2007
- EN 1060-3:1997+A2:2009
- IEC 60601-1:2012
- IEC 60601-1-2:2007 (for BPM45 Series only)
- IEC 60601-1-2:2014 (for BPM41 Series only)
- IEC 60601-1-11:2015
- IEC 80601-2-30:2009+A1:2013

All of the clinical and non-clinical testing performed on the Subject Device are same as the Predicate Device. Therefore, no bench test is conducted to show the performance of the Subject Device are equivalent to the Predicate Device.

8. Conclusion

The Subject Device has the same intended use and same technological characteristics as the Predicate Device. Moreover both clinical and non-clinical testing has demonstrated that no differences in the technological characteristics and questioning on safety or effectiveness to be raised. Thus, the Subject Device are substantially equivalent to the Predicate Device.