DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 19, 2017

Grandway Technology (Shenzhen) Limited
Patrick Chow
General Manager
Block 7, Zhu Keng Industrial Zone, Ping Shan District,
Shenzhen, 518118
CHINA

Re: K163113
Trade/Device Name: Digital Automatic Wrist Blood Pressure Monitor SWBPM22 Series, Models MD2200 and MD2210
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: December 16, 2016
Received: December 23, 2016

Dear 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)*

K163113

Device Name

Digital Automatic Wrist Blood Pressure Monitor SWBPM22 Series, models MD2200 and MD2210

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 wrist.

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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GRANDWAY TECHNOLOGY (SHENZHEN) LIMITED 510(k) Summary

Re: K_____

CHECK ONLY ONE

☒ 510(k) Summary. Attached is a summary of safety and effectiveness information upon which an equivalence determination could be based.

☐ 510(k) Statement. I certify that, in my capacity as (*the position held in company by person required to submit the premarket notification, preferably the official correspondent)* of *(company name)*, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

Patrick Chow, General Manager
(00852)-2851-6789
02-Nov-2016

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
01	02-Nov-2016

2. Device identification

Trade Name	Digital Automatic Wrist Blood Pressure Monitor SWBPM22 Series [Model No.: MD2200 and MD2210]
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 Wrist Blood Pressure Monitor SWBPM22 Series
Manufacturer	GRANDWAY TECHNOLOGY (SHENZHEN) LIMITED
510(k) Number	K142088

4. Device Description

Digital Automatic Wrist Blood Pressure Monitor SWBPM22 Series is a non-invasive blood pressure measurement system 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 device utilizes the oscillometric methodology, in which an inflatable cuff is wrapped around the wrist 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 Digital Automatic Wrist Blood Pressure Monitor SWBPM22 Series.

Model	BP Measurement	Pulse Rate Measurement	WHO Classification	IHB	LCD Type	LCD Size (mm)	User x Memory
MD2200	✔	✔	✔	✔	Positive reflective	42 x 48	2 x 120
MD2210	✔	✔	✔	✔	Positive reflective	62 x 59	2 x 120

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 wrist.

6. Comparison of technological characteristics between new Device and predicate Devices

Digital Automatic Wrist Blood Pressure Monitor SWBPM22 Series is compared to the predicate device, Digital Automatic Wrist Blood Pressure Monitor SWBPM22 Series (K142088) in the device comparison table below.

Item	Predicate Device	New device	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 on an adult individual by using a non-invasive technique, in which an inflatable cuff is wrapped around the wrist.	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 wrist.	Identical
Measurement Method	Non-invasive, Oscillometric	Non-invasive, Oscillometric	Identical
IHB Detection	Yes	Yes	Identical
Patient Population	Adult	Adult	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	Identical
Number of User	2 independent users	2 independent users	Identical
Memory Space	2 users × 120 memory space	2 users × 120 memory space	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	Identical
Blood Pressure Measurement Accuracy	± 3 mmHg	± 3 mmHg	Identical
Pulse Rate Measurement Range	30 - 180 beats/min	40 - 180 beats/min	Similar
Pulse Rate Measurement Accuracy	± 5 % of the reading	± 5 % of the reading	Identical
Display Type	LCD	LCD	Identical
Power Source	2 × 1.5 V AAA-batteries	2 × 1.5 V AAA-batteries	Identical
Pressurization Mode	Automatic Inflation	Automatic Inflation	Identical
Deflation Mode	Automatic Exhaust/ Deflation	Automatic Exhaust/ Deflation	Identical
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	Identical

Item	Predicate Device	New device	Comment
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	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	Identical
Compatibility with Environment and Other Devices	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	- ISO 81060-1:2007 - EN 1060-3:1997+A2:2009 - IEC 60601-1:2012 - IEC 60601-1-2:2014 - FCC Part 15 Subpart B - IEC 81060-2:2013	Equivalent

Digital Automatic Wrist Blood Pressure Monitor SWBPM22 Series is a non-invasive measuring device and utilizes the oscillometric methodology to measure the blood pressure reading. The key components of device are: a pressure sensor, an electric valve and an electronic control module together with an electric pump. The electric pump inflate (and deflate) the inflatable cuff automatically according to our designed architecture. The predicate device adopts exactly same methodology and key components for measuring blood pressure.

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.

One hundred patients (49 males and 51 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

Digital Automatic Wrist Blood Pressure Monitor SWBPM22 Series 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 60601-1-2:2014

- FCC Part 15 Subpart B

All of the clinical and non-clinical testing performed on Digital Automatic Wrist Blood Pressure Monitor SWBPM22 Series are same as the predicate device. Therefore, no bench test is conducted to show the performance of Digital Automatic Wrist Blood Pressure Monitor SWBPM22 Series is equivalent to the predicate device.

8. Conclusion

Digital Automatic Wrist Blood Pressure Monitor SWBPM22 Series has the same intended use and same technological characteristics as the predicate device, Digital Automatic Wrist Blood Pressure Monitor SWBPM22 Series (K142088). 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, Digital Automatic Wrist Blood Pressure Monitor SWBPM22 Series is substantially equivalent to the predicate device.