April 10, 2018

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

Re: K171379
Trade/Device Name: Digital Automatic Wrist Blood Pressure Monitor MD4300
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: March 1, 2018
Received: March 1, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171379

Device Name
Digital Automatic Wrist Blood Pressure Monitor MD4300

Indications for Use *(Describe)*
The wrist blood pressure monitor is used to carry out non-invasive measurement and monitoring of the arterial blood pressure values in adults. This allows you to quickly and easily measure your blood pressure, save the measured values and display the development and average values of the measured values taken. You are also warned of possible existing irregular heartbeat.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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	05-May-2017

2. Device identification

Trade Name	Digital Automatic Wrist Blood Pressure Monitor MD4300 [Model No.: MD4300]
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 MD2400
Manufacturer	GRANDWAY TECHNOLOGY (SHENZHEN) LIMITED
510(k) Number	K143733

4. Device Description

Digital Automatic Wrist Blood Pressure Monitor MD4300 (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 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 Subject Device equipped with Bluetooth transmission function, which enable user to transfer the measurement record from the device to a mobile platform through Bluetooth. User can manage the measurement record by using the mobile application.

5. Indication for use

The wrist blood pressure monitor is used to carry out non-invasive measurement and monitoring of the arterial blood pressure values in adults. This allows you to quickly and easily measure your blood pressure, save the measured values and display the development and average values of the measured values taken. You are also warned of possible existing irregular heartbeat.

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 (K143733)	Subject Device	Comment
Indication for Use	The wrist blood pressure monitor is used to carry out non-invasive measurement and monitoring of arterial blood pressure values in human adults. This allows you quickly and easily measure your blood pressure, save the measurements and display the development of the measurements. You are also warned of possible existing cardiac arrhythmia.	The wrist blood pressure monitor is used to carry out non-invasive measurement and monitoring of the arterial blood pressure values in adults. This allows you to quickly and easily measure your blood pressure, save the measured values and display the development and average values of the measured values taken. You are also warned of possible existing irregular heartbeat.	Equivalent
Patient Population	Adult	Adult	Identical
Measurement Method	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	Identical
Resolution of Measurement	Blood Pressure: 1 mmHg Pulse Rate: 1 beat/ min	Blood Pressure: 1 mmHg Pulse Rate: 1 beat/ min	Identical
Blood Pressure Measurement Accuracy	± 3 mmHg	± 3 mmHg	Identical
Pulse Rate Measurement Range	40 - 180 beats/min	40 - 180 beats/min	Identical
Pulse Rate Measurement Accuracy	± 5 % of the reading	± 5 % of the reading	Identical
IHB Detection	Yes	Yes	Identical
Number of User	2 independent users	2 independent users	Identical
Memory Space	2 users × 60 memory space (Total 120 memory space)	2 users × 60 memory space (Total 120 memory space)	Identical
Number of button	4 (Memory, Clock, User, Start/Stop)	3 (M1, M2 and Start/Stop)	Different[1]
Bluetooth data transmission	Absent	Present	Different[2]
Backlight	Absent	Present	Different[3]
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
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

Item	Predicate Device (K143733)	Subject Device	Comment
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 - IEC 80601-2-30:2009+A1:2013	- ISO 81060-1:2007 - EN 1060-3:1997+A2:2009 - IEC 60601-1:2012 - IEC 60601-1-2:2007 - IEC 60601-1-11:2015 - FCC Part 15 Subpart B - FCC Part 15 Subpart C - IEC 81060-2:2013 - IEC 80601-2-30:2009+A1:2013 - EN 300 328 V1.8.1 & EN 62479:2010 - EN 301 489-1 V1.9.2 & EN 301 489-17 V2.2.1	Equivalent/ Different[4]

[1] The number of button 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.

[2] A new Bluetooth data transmission function is added to the Subject Device. This additional feature will not affect the essential performance of the Subject device.

[3] A new backlight illumination function is added to the Subject Device. This additional feature will not affect the essential performance of the Subject device.

[4] The some of 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. One hundred patients (60 males and 40 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

- ✧ IEC 60601-1-11:2015
- ✧ IEC 80601-2-30:2009+A1:2013
- ✧ FCC Part 15 Subpart B
- ✧ FCC Part 15 Subpart C
- ✧ EN 300 328 V1.8.1 & EN 62479:2010
- ✧ EN 301 489-1 V1.9.2 & EN 301 489-17 V2.2.1

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.