September 7, 2023

Weony (Shenzhen) Technology Co., Ltd.
Lucy Yan
Consultant
401, the 6th building, Changfeng Industrial Zone
Dongkeng Community, Fenghuang Street, Guangmi
Shenzhen, GuangDong 518132
China

Re: K231542
Trade/Device Name: Digital Blood Pressure Monitor WBP Series
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: May 18, 2023
Received: May 30, 2023

Dear Lucy Yan:

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,

Stephen C. Browning -S

LCDR 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)*
K231542

Device Name
Digital Blood Pressure Monitor WBP Series

Indications for Use *(Describe)*
The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 13.5cm to 21.5cm in home and hospital facilities by using a non-invasive oscillometric technique. The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.

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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510(k) Summary

K231542

This summary of 510(k) information is submitted as required by requirements of SMDA and 21 CFR §807.92.

1 Administrative Information

Submission Date	May. 18, 2023
Manufacturer information	Submitter's Name: WEONY (SHENZHEN) TECHNOLOGY CO., LTD. Address: 401, the 6th building, Changfeng Industrial Zone, Dongkeng Community, Fenghuang Street, Guangming District, Shenzhen, 518132, PR. China. Contact person: Autumn Liu TEL: 86-755-86057437 E-Mail: autumn.liu@weony-sz.com
Submission Correspondent	Contact person: Ms Lucy.Yan E-Mail: Lucy.yan@aivikon.com Address: 401, the 6th building, Changfeng Industrial Zone, Dongkeng Community, Fenghuang Street, Guangming District, Shenzhen, 518132, PR. China.
Establishment registration number	NA

2 Device Information

Common name of the device	System, Measurement, Blood-Pressure, Non-Invasive
Trade name of the device	Digital Blood Pressure Monitor WBP Series
Type/Model of the device	WBP203, WBP204, WBP205, WBP206
Classification information	Classification panel: Cardiovascular Classification name: System, Measurement, Blood-Pressure, Non-Invasive Regulation Number: 870.1130 Device Class: II

type of 510(k) submission	Product Code: DXN Traditional

3 Predicate Device Information

Primary predicate device:

Sponsor:	Omron Healthcare, Inc.
Device:	Model HEM-6131
510(K) Number:	K131742

Reference predicated device :

Sponsor:	WEONY (SHENZHEN) TECHNOLOGY CO., LTD.
Device:	WBP101, WBP102, WBP103, WBP104, WBP105, WBP106, WBP107.
510(K) Number:	K210671

4 Device Descriptions

Weony Digital Blood Pressure Monitor WBP Series are designed to measure the systolic and diastolic blood pressure and pulse rate of an individual (at least 12 or above) by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist. Our method to define systolic and diastolic pressure is similar to the auscultatory method but uses an electronic pressure sensor rather than a stethoscope and mercury manometer. The sensor converts tiny alterations in cuff pressure to electrical signals, by analyzing those signals to define the systolic and diastolic blood pressure and calculating pulse rate, which is a well-known technique in the market called the "oscillometric method".

The main components of the Blood Pressure Monitor are the main unit and cuff unit. ABS is used to outer housing of the main unit. The preformed cuff unit, which is applicable to wrist circumference approximately between 135 and 215 mm, includes the inflatable bladder and PU shell. All models of the wrist blood pressure monitor use a single size of cuff. The device consists of the microprocessor, the pressure sensor, the operation keys, the pump, the electromagnetic deflation control valve, and the LCD. The subject devices are powered by two AAA alkaline batteries or adatpter.

The device has irregular heart beat (IHB) indicator which compares the longest and the shortest time intervals of detected pulse waves to mean time interval and displays a warning signal with the reading to indicate the detection of irregular pulse rhythm when the difference of the time intervals is over a specified range.

5 Intended Use/ Indications for Use

The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 13.5cm to 21.5cm in home and hospital facilities by using a non-invasive oscillometric technique. The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.

6 SE Comparison

Table 1. Substantial Equivalence Comparison

Characteristics	Subject device	Primary Predicate device (K131742)	Reference Predicate device (K210671)	Remark
Device Name	Digital Blood Pressure Monitor WBP Series	Model HEM-6131	Digital Blood Pressure Monitor	NA
Device Model	WBP203, WBP204, WBP205, WBP206,	HEM-6131	WBP101, WBP102, WBP103, WBP104, WBP105, WBP106, WBP107.	NA
Manufacturer	WEONY (SHENZHEN) TECHNOLOGY CO., LTD.	Omron Healthcare, Inc.	WEONY (SHENZHEN) TECHNOLOGY CO., LTD.	NA
Intended Use/ Indication for Use	The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 13.5cm to 21.5cm in home and hospital facilities by using a non-invasive oscillometric technique. The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.	The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 5 1/4 inches to 8 1/2 inches (13.5 cm to 21.5 cm). The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.	The subject device intended to measure the diastolic, systolic blood pressures and pulse rate of an adult individual in hospitals and home environments by using a non-invasive oscillometric technique with a single upper arm cuff (22-36 cm). The device detects the appearance of irregular heart beats during measurement and gives a warning signal with readings.	SE
Intended Population	adult	adult	adult	Same
Environment of USE	Home	Home	Home	Same
Intended Anatomical site	Wrist	Wrist	upper arm	Same as K131742
Prescription & OTC	OTC	OTC	OTC	Same
Patient Connection	Yes via Cuff	Yes via Cuff	Yes via Cuff	Same
Working Principle	Oscillometric method	Oscillometric method	Oscillometric method	Same
Pressure sensor	Piezo resistance sensor	Piezo resistance sensor	Piezo resistance sensor	Same
Pressurization Source	Automatic internal pump	Automatic internal pump for inflation Automatic internal valve for deflation	Automatic internal pump	Same
Internal Power supply	2pcs “AAA” alkaline Batteries	2 pcs “AAA” alkaline Batteries	4pcs “AA” alkaline Batteries	Same as K131742
Memory Function	2 × 90 memories (SYS, DIA, Pulse)	60 measurements	2 × 90 memories (SYS, DIA, Pulse)	Same as K231288
Cuff Size	13.5 cm to 21.5 cm	13.5 cm to 21.5 cm	220mm~360mm	Same as K131742

Measuring range	Pressure: 0 to 299 mmHg (in 1 mmHg increment);	Pressure: 0 to 299 mmHg (in 1 mmHg increment);	Pressure: 0 to 299 mmHg (in 1 mmHg increment);	Same
	Pulse: 40 to 180 beat/minute	Pulse: 40 to 180 beat/minute	Pulse: 40 to 180 beat/minute	
Measuring resolution	1 mmHg	1 mmHg	1 mmHg	Same
Accuracy	Pressure: ±3mmHg; Pulse: ±5%	Pressure: ±3mmHg or 2% of reading; Pulse ±5%.	Pressure: ±3mmHg; Pulse: ±5%	Same
Display Type	LCD digital display	LCD digital display	LCD digital display	Same
Irregular Heartbeat Detection	Yes	Yes	Yes	same
Operating Condition	10~40℃,	10~40℃,	10~40℃,	Different Note01; Same as K231288
	15%~85%RH	15%~85%RH	15%~90%RH	
Storage Condition	-20~55℃,	-20~60℃,	-20~55℃,	Different Note02; Same as K231288
	10%~95%RH	10%~95%RH	10%~95%RH	
Dimension	L78mm*W65mm*H66mm	78(W)*60(D)*21(H)mm	L140mm*W116mm*H55mm	SE
Weight	Approx. 81.5g(batteries not included)	Approximately 101g	Approx. 265.5g(batteries not included)	SE
Materials	Patient contact materials of the cuff have been tested in accordance with ISO 10993 tested in accordance with accordance with ISO 10993 and FDA guidance	Patient contact materials of the cuff have been tested in accordance with ISO 10993 tested in accordance with accordance with ISO 10993 and FDA guidance	Patient contact materials of the cuff have been tested in accordance with ISO 10993 tested in accordance with accordance with ISO 10993 and FDA guidance	Same

Note01 &02: The subject devices have different environment conditions of operation and storage from predicate device, but the subject devices have been tested by IEC 60601-1-2, IEC 60601-1-11, IEC 80601-2-30 and ISO81060-2.
The subject device is as same as predicate device in Working Principle, intended patient population, intended application site, measuring accuracy. Only their environment conditions are a little bit different (refer to Note01 to Note 02) which had been validated. Als, the differences would not raise any safety or effectiveness issue based on tests in this submission.
Thus, the subject device is Substantially Equivalent (SE) to the predicate device which is legally marketed in US.

7 Brief discussions of the non-clinical tests [807.92(b)(1)]:

The subject device conforms to the following guidances and standards:

- ✧ Non-Invasive Blood Pressure (NIBP) Monitor Guidance
- ✧ IEC 60601-1:2005+A1:2012+A2:2020: 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: 2015 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;
- ✧ ISO 10993-5: 2009 /(R)2014 Biological evaluation of medical devices – Part 5: Tests for In Vitro cytotoxicity;
- ✧ ISO 10993-10: 2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization;
- ✧ IEC 80601-2-30: 2018 Medical electrical equipment - Part 2-30: Particular Requirements for the Basic Safety and Essential Performance of Automated Non-invasive Sphygmomanometers

The nonclinical, bench testing included:

• Performance verification testing including Static Pressure accuracy, Static Leakage and Dynamic Pressure accuracy to confirm acceptable performance of device features and functions

• Cleaning verification testing to confirm device retains its performance when cuff is cleaned with household detergents (70% alcohol) as may be required in home use environment

• Product life verification testing to confirm device retains its performance when the device was used to measure blood pressure for at least 2 years as may be required in home use environment

• Irregular heart beat testing against the reference predicate WBP101 device (K210671)

Other nonclinical safety testing included:

• Biocompatibility of patient-contacting materials per ISO 10993-1 requirements

• Evaluation of relevant electrical safety, electromagnetic compatibility and electrostatic discharge requirements per IEC60601 and 80601 requirements

• Software verification and validation

The collective results of the nonclinical testing demonstrate that the materials chosen, the manufacturing processes, and design of WBP203 SERIES meet the established specifications necessary for consistent performance during its

intended use. In addition, the collective bench testing demonstrates that WBP203 SERIES does not raise different questions of safety or effectiveness for measurement of blood pressure and pulse in a home use environment when compared to the predicates.

8 Brief discussions of clinical tests [807.92(b)(2)]:

✧ ISO 81060-2:2018 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type;

In this clinical investigation, 85 patients (41 males and 44 females) participated in the clinical study. Same arm sequential method was adopted during the clinical testing. The manual Mercury Sphygmomanometer was used as a reference device. 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 blood pressure monitor is within acceptable scope specified in ISO 81060-2.

9 Other information (such as required by FDA guidance)

No other information.

11 Conclusions

The subject device:

Digital Blood Pressure monitor manufactured by WEONY (SHENZHEN) TECHNOLOGY CO., LTD. is respectively substantially equivalent to the primary predicate device Blood Pressure Monitor manufactured by Omron Healthcare, Inc. (K131742) and the reference predicate device Digital Blood Pressure Monitor manufactured by WEONY (SHENZHEN) TECHNOLOGY CO., LTD. (K210671).