

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
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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 panel: Cardiovascular
Classification information	Classification name: System, Measurement, Blood-Pressure, Non-Invasive Regulation Number: 870.1130 Device Class: II

type of submission	510(k)	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 adapter.

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: ± 3 mmHg; Pulse: $\pm 5\%$	Pressure: ± 3 mmHg or 2% of reading; Pulse $\pm 5\%$.	Pressure: ± 3 mmHg; Pulse: $\pm 5\%$	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).