February 13, 2026

Shenzhen IMDK Medical Technology Co., Ltd.
Yijie You
Manager
Qimmiq Medical Consulting Service Co., Ltd.
RM.406, Building C, Run Science Park
Guangzhou, Guangdong 510663
China

Re: K253133
Trade/Device Name: Wrist Blood Pressure Monitor (BPM-W1VL)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: September 25, 2025
Received: January 13, 2026

Dear Yijie You:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253133

Please provide the device trade name(s).

Wrist Blood Pressure Monitor (BPM-W1VL)

Please provide your Indications for Use below.

The Wrist Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of person older than twelve (12) years via non-invasive oscillometric technique in medical facilities or at home. The intended wrist circumference is 13.5-21.5 cm.

Contraindications:
1). Patients with severe heart (including significantly irregular heart rhythm, Bigeminy, trigeminy, isolated ventricular premature beat (VPB), atrial fibrillation), liver or kidney disease or blood circulation disorders.
2). Newborns, infants, children, people with mental disorders and people who cannot explain their thoughts;
3). The one who with upper limb trauma don't use this device;
4). The one who with artificial heart and skin ulcers is prohibited to use this device.
5). Patients are Pregnant;
6). Patients has been diagnosed with preeclampsia.
7). Patients with diabetes.
8). Patients who are undergoing vasoactive treatment.
9). Patients with (such as atrial fibrillation).
10). Patients with peripheral artery disease or other conditions that affect arterial compliance.

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (Part 21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

[As required by section 807.92(c)]

1. 510(k) owner (Applicant)

Establishment Registration number:		3015007456
Name:		Shenzhen IMDK Medical Technology Co., Ltd.
Address:		904, 9F, Guangming Tianan Cloud Park Building, 255 Zhenmei Road, Zhenmei Community, Xinhu Street, Guangming District, Shenzhen, 518107, PEOPLE'S REPUBLIC OF CHINA
Contact Person	**Name:**	Xia yuan
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	TEL:	+86-13662694320
	Email:	vicky-xia@imdker.com

2. Submission Correspondent (Authorized representative)

Name:	You Yijie
Company Name	Qimmiq Medical Consulting Service Co., Ltd
Address:	RM.406, Building C, Run Science Park, No.18 Shenzhou Road, Huangpu, Guangzhou, Guangdong 510663 P.R. China
TEL:	(+86)020-82245821
FAX:	(+86)020-82245821
Email:	jet.you@qimmiq-med.com

3. Device Information

Purpose of the application: 510(K) submission
Submission Type: Traditional 510(K)
The reason for the 510(k): It is a new device

Trade Name: Wrist Blood Pressure Monitor
Model: BPM-W1VL
Common name of the device: Wrist Blood Pressure Monitor

Classification name: System, Measurement, Blood-Pressure, Non-Invasive
Regulation name: Noninvasive blood pressure measurement system
Review panel: Cardiovascular
Product code: DXN
Regulation Class: II

Regulation Number: 21 CFR 870.1130

4. Predicate Device Information

510(k) submitter/holder:	Shenzhen Jumper Medical Equipment Co., Ltd
510(K) Number:	K231310
Trade name:	Electronic Blood Pressure Monitor
Model:	HWA10
Review Panel:	Cardiovascular
Product Code:	DXN
Regulation Class:	II
Regulation Number:	21 CFR 870.1130

5. Reference Device Information

510(k) submitter/holder:	Jiangsu Yuyue Medical Equipment& Supply Co., Ltd.
510(K) Number:	K221372
Trade name:	Electronic Blood Pressure Monitor
Model:	YE8800AR
Review Panel:	Cardiovascular
Product Code:	DXN
Regulation Class:	II
Regulation Number:	21 CFR 870.1130

6. Device description

Wrist Blood Pressure Monitor, model: BPM-W1VL is a Noninvasive Blood Pressure Measurement System that is intended to measuring blood pressure through oscillation mensuration. The subject device will automatically start to take measurements after the inflation of the cuff is finished, the results will show the systolic pressure and diastolic pressure with pulse rate. The blood pressure monitor will store the measurements automatically; The record maybe revisited.

It measures blood pressure and pulse rate through inflating cuff which rounding the wrist of patients. The BPM-W1VL is small, portable and used at home or in medical facilities environment. The Wrist Blood Pressure Monitor consists of two parts: main unit and cuffs. The BPM-W1VL is composed of PCBA, crystal oscillator, pump, valve, enclose, and LCD.

Principle of operation:

This product uses the Oscillometric Measuring method to detect blood pressure. When the cuff is fully inflated to reach a pressure above systolic pressure, no blood flow occurs through the artery. As the cuff is deflated below the systolic pressure, the reducing pressure exerted on the artery allows blood to flow through it and sets up a detectable vibration in the arterial wall. When the cuff pressure falls below the patient's diastolic pressure, blood flows smoothly through the artery in the usual pulses, without any vibration being set up in the wall. Vibrations occur at any point where the cuff pressure is sufficiently high that the blood has to push the arterial wall open in order to flow through the artery. The vibrations are transferred from the arterial wall, through the air inside the

cuff, into a transducer in the monitor that converts the measurements into electrical signals. Hence when it starts inflating the cuff, meanwhile, the unit detects pressure oscillations generated by beat-to-beat pulsatile, which is used to determine the systolic and diastolic pressure, and pulse rate. And Wrist circumference is 13.5-21.5 cm.

7. Indications for Use

The Wrist Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of person older than twelve (12) years via non-invasive oscillometric technique in medical facilities or at home. The intended wrist circumference is 13.5-21.5 cm.

8. Contraindication

1). Patients with severe heart (including significantly irregular heart rhythm, Bigeminy, trigeminy, isolated ventricular premature beat (VPB), atrial fibrillation), liver or kidney disease or blood circulation disorders.
2). Newborns, infants, children, people with mental disorders and people who cannot explain their thoughts;
3). The one who with upper limb trauma don't use this device;
4). The one who with artificial heart and skin ulcers is prohibited to use this device.
5). Patients are Pregnant;
6). Patients has been diagnosed with preeclampsia.
7). Patients with diabetes.
8). Patients who are undergoing vasoactive treatment.
9). Patients with (such as atrial fibrillation).
10). Patients with peripheral artery disease or other conditions that affect arterial compliance.

9. Summary of technological characteristics of device compared to the predicate devices (K231310)

SE Comparisons	**Subject device** (Wrist Blood Pressure Monitor, model: BPM-W1VL)	**Predicate device** (Electronic Blood Pressure Monitor, Model: HWA10)	**Reference device** (YUWELL® Electronic Blood Pressure Monitor, Model: YE8800AR)	**Discussion of difference**
510K Number	/	**K231310**	**K221372**	**/**
Model	BPM-W1VL	HWA10	YE8800AR	**/**
Classification	21CFR 870.1130	21CFR 870.1130	21CFR 870.1130	**Same**
Product Code	DXN	DXN	DXN	**Same**
FDA Class	II	II	II	**Same**
Indications for Use	The Wrist Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of person older than twelve (12) years via non-	The Electronic Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person via non-invasive oscillometric	This product is intended to measure the blood pressure and pulse rate of adult more than 12 years old and with wrist circumference ranging from 13.5 cm to 19.5 cm at	**Different** (Discussion is indicated in D1)

	invasive oscillometric technique in medical facilities or at home. The intended wrist circumference is 13.5-21.5 cm.	technique at medical facilities or at home. The intended wrist circumference is 13.5-21.5 cm.	household or medical center (not suitable for neonate, pregnancy or pre-eclampsia.)	
Patient Population	Person older than twelve (12) years	Adults	Adult whom more than 12 years old	**Different** (Discussion is indicated in D1)
Design Method	Cuff oscillometric method	Cuff oscillometric method	Oscillation mensuration	**Same**
Measurement Site	Wrist	Wrist	Wrist	**Same**
Cuff Circumference	13.5-21.5 cm.	13.5-21.5 cm.	13.5-19 cm.	**Same with predicate device**
Memory Size	Double 99 groups	Not public	Up to 74 sets of data	**Different** (Discussion is indicated in D2)
Blood Pressure Measurement Range	Cuff pressure range 0 to 295mmHg; SYS:60mmHg~230mmHg; DIA: 40mmHg~130mmHg	Cuff pressure range 0 to 295mmHg	Pressure range: 0~300 mmHg; Diastolic: 40-210 mmHg; Systolic: 60~260 mmHg.	**Different** (Discussion is indicated in D3)
Blood Pressure Measurement Accuracy	±3 mmHg	±3 mmHg	Within ±3 mmHg	**Same**
Pulse Measurement Range	40~200 beats/min	40 ~ 199 beats/min	Pulse rate: 40~200 beats/min;	**Different** (Discussion is indicated in D4)
Pulse Rate Accuracy	Within ±5 % of reading	Within ±5 % of reading	Within ±5 % of reading	**Same**
Pressure Sensor	Piezo resistance sensor	Piezo resistance sensor	Semiconductor pressure sensor	**Same with predicate device**
Inflation Method	Automatic inflation with electric pump	Automatic inflation with electric pump	Automatic inflation with piezoelectric pump	**Same with predicate device**
Deflation Method	Automatic rapid deflation valve	Automatic rapid deflation valve	Automatic rapid deflation valve	**Same**
Operating Environment	Ambient temperature: +5℃~ +40℃; Relative humidity (RH): 15%~85%;	Ambient temperature: 5 to 40℃ (41 to 104 °F); Relative humidity (RH): 15 to 85 %RH (non-condensing);	Ambient temperature: +5 ℃~+40 ℃; Relative humidity (RH): 15% ~90% RH (no condensation); Atmospheric pressure:	**Different** (Discussion is indicated in D5)

	Atmospheric pressure: 80 kPa~106kPa	Atmospheric pressure: 700 to 1060 hPa	80 kPa~106kPa	
Storage Environment	Ambient temperature: -20℃ ~+50℃ Relative humidity (RH): 15%~85% Atmospheric pressure: 80 kPa~106kPa	Ambient temperature: -20 to 55 °C (-4 to 131 °F); Relative humidity (RH): 10 to 93 %RH (non-condensing); Atmospheric pressure:700 to 1060 hPa	Ambient temperature: -20 ℃~+55 ℃ Relative humidity (RH): 15%~90% RH (no condensation) Atmospheric pressure: 70 kPa~106 kPa	**Different** (Discussion is indicated in D6)
Dimensions	72mm(W) × 83mm (D) × 77.5 mm(H)	61 (W) × 24.1(D) × 87 (H)mm	Approx.L89 mm x W62 mm x H21 mm	**Different** (Discussion is indicated in D7)
Weight	Approximate 125 g. (Without battery)	Approx. 111 ± 5g (without batteries)	About 109g	**Different** (Discussion is indicated in D8)
Display	LCD digital display	LCD digital display	LCD digital display	**Same**
Power Source	2 X AAA batteries	2 X AAA batteries	AC adapter: input 100-240V~ 50/60Hz, 0.35A MAX, output 5V 1000mA; Battery: DC 3.7V	**Same with predicate device**
Measurement Item	SYS, DYS, Pulse Rate	SYS, DYS, Pulse Rate	SYS, DYS, Pulse Rate	**Same**
Performance	ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01	ISO 81060-2:2020	Comply ANSI/AAMI/ISO 81060-2	**Same**
Performance	IEC 80601-2-30: Edition 2.0 2018-03	IEC 80601-2-30	IEC 80601-2-30	**Same**
Biocompatibility	Comply FDA Guidance “Use of International Standard ISO 10993-1”.	ISO 10993-1, FDA Guidance, Tests included Cytotoxicity, Sensitization and Intracutaneous Reactivity	Comply ISO 10993 and FDA Guidance (Tested items including Cytotoxicity, Sensitization and Intracutaneous Reactivity)	**Same**
Electrical Safety	ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]	IEC60601-1	IEC60601-1	**Same**
EMC	IEC 60601-1-2: 2014+AMD1:2020	IEC 60601-1-2	IEC 60601-1-2	**Same**
Home Use	IEC 60601-1-11:2015/2020	IEC 60601-1-11	Not public	**Same**
Patient Interface	Cuff, button	Cuff, button	Cuff, button	**Same**
Principle of operation	Oscillometric Measuring method	Oscillometric Measuring method	Oscillometric Measuring method	**Same**

User Interface	Cuff, button	Cuff, button	Cuff, button	**Same**
Software	Embedded	Embedded	Embedded	**Same**

The discussion of differences exist between the subject and predicate devices is listed in following:

D1: The difference of Patient Population between subject device and predicate device is that the Patient Population of **subject device** is "**Person older than twelve (12) years**" and **predicate device** is "**Adults**"; the **reference device** has a same Patient Population of "**Person older than twelve (12) years**", and this difference is also addressed through clinical trial conducted with subject device according to ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01, the results of clinical trial meet the requirements of ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01, therefore, the difference of subject device with predicate device HWA10 (K231310) will not affect the safety and effectiveness.

D2: The Memory Size of subject device is different with predicate device predicate device HWA10 (K231310) which will not affect the safety and effectiveness.

D3: The difference of Blood Pressure Measurement Range between subject device and predicate device is that the Blood Pressure Indication Range of subject device is **"Cuff pressure range 0 to 295mmHg, DIA: 40 mmHg~130mmHg & SYS: 60 mmHg ~ 230mmHg"** and predicate device is **"Cuff pressure range 0 to 295mmHg"**, the Blood Pressure Indication Range of subject device is in the range of predicate device and meets the requirements of IEC 80601-2-30: Edition 2.0 2018-03, and this difference is also addressed through clinical trial conducted with subject device according to ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01, the results of clinical trial meet the requirements of ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01, therefore, the difference of subject device with predicate device HWA10 (K231310) will not affect the safety and effectiveness.

D4: The Measurement Pulse Range of subject device is tiny different with predicate device and same with reference device, and this difference is also addressed through clinical trial conducted with subject device according to ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01, therefore, the difference of subject device with predicate device HWA10 (K231310) will not affect the safety and effectiveness.

D5: The operating Environment of subject device are different with predicate device HWA10 (K231310), the difference introduces risks mitigated by testing in accordance with IEC 60601-1-11 and ANSI AAMI ES60601-1 provided in this submission, therefore the difference does not raise new questions of safety and effectiveness.

D6: The Storage Environment of subject device is different with predicate device HWA10 (K231310), the difference introduces risks mitigated by testing in accordance with IEC 60601-1-11 and ANSI AAMI ES60601-1 provided in this submission, therefore the difference does not raise new questions of safety and effectiveness.

D7: The Dimensions of subject device is different with predicate device predicate device HWA10 (K231310) will not affect the safety and effectiveness.

D8: The Weight of subject device is tiny different with predicate device predicate device HWA10 (K231310) will not affect the safety and effectiveness.

10. Discussion of Non-Clinical Tests Performed for Safety and

effectiveness are as follows

The recognized consensus standards for safety of medical electrical equipment: ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021], IEC 60601-1-11:2015/2020, IEC 60601-1-2: 2014+AMD1:2020 for electromagnetic compatibility, IEC 80601-2-30: Edition 2.0 2018-03, ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01 for performance, IEC 62304 Edition 1.1 2015-06 for software verification are complied. See below table for details:

Standards	Standards Name
ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
IEC 60601-1-2: 2014+AMD1:2020	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances - Requirements And Tests
IEC 60601-1-11:2015/2020	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
IEC 80601-2-30: Edition 2.0 2018-03	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01	Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type
IEC 62304 Edition 1.1 2015-06	Medical device software - Software life cycle processes

- **Electrical safety and electromagnetic compatibility (EMC)**
  Electrical safety and EMC testing were conducted on the subject device BPM-W1VL. The system complies with the AAMI ANSI ES60601-1, IEC 60601-1-11 for electrical safety, the IEC 60601-1-2 standard for EMC, IEC 80601-2-30 and ISO 81060-2 for performance.

- **Software Verification and Validation Testing**
  Software verification and validation was performed for the subject device in accordance with Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff, May 2005.

  Software Description:
  The software for this device was considered as a “moderate” level of concern, since a failure or latent flaw in the software could result in Minor Injury, either to a patient or to a user of the device. The software of the system, on the whole, is accountable for the system scheduler of the device, including Pressure and pulse signal acquisition, calculation and display, the button presses of end user, display the result of the measurement, measurement data storage and average calculation, memory data query, prompt of error message, low battery voltage detection and

prompt, measurement Unit conversion.

11. Discussion of Clinical Accuracy Testing Performed

The clinical accuracy test report and data analysis followed the requirements of the ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01.

The clinical accuracy testing evaluated 85 of subjects, division of all subjects:

Subjects requirement		**Number specified in ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01**	**Actual number**	
Total		A minimum of 85 people	85	
Male		At least 26 people	43	
Female		At least 26 people	42	
Age > 12		100%	100%	
Wrist circumference range (of total 85 people)	13.5 ≤ x <15.5 cm	≥ 20%	25	29.41%
	15.5 ≤ x <17.5 cm	≥ 20%	22	25.88%
	17.5 ≤ x < 19.5 cm	≥ 20%	18	21.18%
	19.5 ≤ x ≤ 21.5 cm	≥ 20%	20	23.53%
	13.5 ≤ x ≤ 14.5 cm	≥10%	15	17.65%
	20.5 ≤ x ≤ 21.5 cm	≥10%	14	16.47%
Systolic BP (A total of 680 blood pressure measurements)	Systolic BP ≤ 100mmHg	≥5%	56	8.24%
	Systolic BP ≥ 160mmHg	≥5%	48	7.06%
	Systolic BP ≥140mmHg	≥20%	160	23.53%
Diastolic BP (A total of 680 blood pressure measurements)	Diastolic BP ≤ 60mmHg	≥5%	38	5.53%
	Diastolic BP ≥ 100mmHg	≥5%	129	18.97%
	Diastolic BP ≥ 85mmHg	≥20%	246	36.18%

The test data showed the clinical accuracy of the subject device complied with the requirements of ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01.

Reference equipment used for measurements:

Name	Aneroid sphygmomanometer
Model	CM-BPM-D
Manufacturer	Shanghai Caremate Medical Device Co. Ltd
Measuring Method	Aneroid/auscultation method
K number	K211084

12. Conclusions

The Wrist Blood Pressure Monitor, model: BPM-W1VL, have the same intended use and similar characteristics as the cleared predicate device Electronic Blood Pressure Monitor, Model: HWA10. Moreover, bench testing contained in this submission supplied demonstrate that the differences existed between BPM-W1VL and HWA10 do not raise any new questions of safety or effectiveness.

The non-clinical tests support the safety of the device and the hardware and software verification and validation demonstrate that the Wrist Blood Pressure Monitor, model: BPM-W1VL performs as intended in the specified use conditions are same with predicate device. The clinical performance tests demonstrate that the Wrist Blood Pressure Monitor, model: BPM-W1VL performs comparably to the predicate device that is currently marketed for the same intended use. Thus, the Wrist Blood Pressure Monitor, model: BPM-W1VL is Substantially Equivalent (SE) to the predicate device.