February 13, 2026

Shenzhen Hingmed Medical Instrument Co., Ltd.
Dien Wang
Register Engineer
4th Floor, Zhonghangfeixiang Building, NO. 371, Guangshen Rd
Baoan District
Shenzhen, Guangdong 518103
China

Re: K251581
Trade/Device Name: Wearable Ambulatory Blood Pressure Monitor (WBP-02A)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: January 16, 2026
Received: January 16, 2026

Dear Dien Wang:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251581

Device Name
Wearable Ambulatory Blood Pressure Monitor (WBP-02A)

Indications for Use *(Describe)*
The Wearable Ambulatory Blood Pressure Monitor, model WBP-02A is a non-invasive oscillometric ambulatory blood pressure monitor that is intended to measure systolic and diastolic pressure in individuals aged 12 years and older. The collected data can be transmitted to a PC via USB for healthcare professionals to review and analyze. This device is not intended for diabetic patients, pregnant women, or patients with arrhythmia. It is intended for prescription use only.

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.

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510(k) Summary

K251581

Prepared in accordance with the requirements of 21 CFR Part 807.92

(1) Submitter Information

Submitter's Name :	Shenzhen Hingmed Medical Instrument Co., Ltd.
Address :	4th Floor, Zhonghangfeixiang Building, NO. 371, Guangshen Road, Baoan District, Shenzhen, China
Telephone Number :	+86-0755-232069446
Contact Person :	Dien Wang
	E-mail: dien.wang@hingmed.com
Date Prepared :	12.Dec.2024

(2) Name of Device

Proprietary Name :	Wearable Ambulatory Blood Pressure Monitor
Model :	WBP-02A
Common Name :	System, Measurement, Blood-Pressure, Non-Invasive
Classification Name :	Noninvasive Blood Pressure Measurement System
Review Panel :	Cardiovascular
Product Code :	DXN
Regulation Number :	21 CFR 870.1130
Regulatory Class :	Class II

(3) Legally-Marketed Predicate Device

Manufacture :	SunTech Medical, Inc
Device Name :	Oscar 2
Model :	250
510(k) Number :	K151520
Product Code :	DXN
Regulation Number :	21 CFR 870.1130
Regulation Class :	Class II

(4) Device Description

The WBP-02A Ambulatory Blood Pressure Monitor from Hingmed Medical comprises a main unit, a cuff, a USB data cable, and PC analysis software. This compact and portable device is worn comfortably on the patient's upper arm. The cuff inflates to occlude the brachial artery and then gradually deflates. The device employs the oscillometric method to measure blood pressure and pulse parameters during the deflation phase, capturing the transition from blood flow occlusion to restoration. The main unit's internal memory can store up to 300 measurement records. Upon completion of the monitoring period, the data is transferred via the USB cable to a computer for comprehensive statistical analysis using the dedicated software.

The ambulatory blood pressure monitor software has two components: embedded software and PC software.
The embedded software runs on the main control unit, directing the monitor to take measurements and collect blood pressure data, which it sends to the PC software via USB. The PC software analyzes the data, generates charts for medical review, and can also configure the device—such as setting measurement intervals—and initiate readings.
The PC software operates offline and does not replace any tasks performed by healthcare professionals.
The device firmware does not include the calculation function for Mean Arterial Pressure (MAP), and the OLED screen on the host device does not display MAP values. The accompanying PC software can display the hourly average MAP value and its trend graph.
MAP is calculated using the standard equivalent formula, as follows:
Calculation Formula: MAP = (SBP + 2 × DBP) / 3
Alternative expression: MAP = DBP + (1/3) × PP

Where:
SBP = Systolic Blood Pressure
DBP = Diastolic Blood Pressure
PP = Pulse Pressure (SBP – DBP)
Note on the Formula:
The expression "MAP = (SBP + 2 × DBP) / 3" is mathematically equivalent to the standard MAP formula "DBP + 1/3 × (SBP – DBP)".

(5) Intended Use

The Wearable Ambulatory Blood Pressure Monitor, model WBP-02A is a non-invasive oscillometric ambulatory blood pressure monitor that is intended to measure systolic and diastolic pressure in individuals aged 12 years and older. The collected data can be transmitted to a PC via USB for healthcare professionals to review and analyze. This device is not intended for diabetic patients, pregnant women, or patients with arrhythmia. It is intended for prescription use only.

(6) Intended users

Health care professionals.

(7) Target population

Individuals aged 12 years and older.

(8) Prescription Status

Prescription use only (Rx only).

(9) Contraindication

a. Cardiac and High-Risk Physiological Conditions: Not intended for special populations, such as diabetic patients, pregnant women, or patients with arrhythmia who may require specific evaluation due to physiological factors that could affect the accuracy of cuff-based blood pressure measurements.

b. Vascular Conditions: Not intended for patients with carotid or aortic valve stenosis, or those exhibiting systemic contraction or localized spasms of muscular conduction arteries (e.g., after hypothermic

cardiopulmonary bypass surgery, Raynaud's phenomenon, or extreme cold exposure).

c. Prior Surgical History: Not intended for patients who have undergone bilateral mastectomy.

d. Limb Condition Restrictions: Do not use on arms with peripherally inserted central catheters (PICC), intravenous (IV) lines, or arterial lines.

(10) Comparison to Predicate Device

Substantial Equivalence Comparison Table

Items		Subject Device	Predicate Device	Verdict
		Hingmed ABPM	**Oscar 2 ABPM**	
Basic information	Model	WBP-02A	Oscar 2	--
	Manufacturer	Shenzhen Hingmed Medical Instrument Co., Ltd.	SunTech Medical Inc.	--
	510(k) Number	Applying	K151520	--
	Picture			--
Clinical application	Product Code	DXN	DXN	Same
	Indications for use	The Wearable Ambulatory Blood Pressure Monitor, model WBP-02A is a non-invasive oscillometric ambulatory blood pressure monitor	The Oscar 2, Model 250 system is a non-invasive oscillometric ambulatory blood pressure monitor that is intended to be used with AccuWin Pro, a	Different (Note 1)

		that is intended to measure systolic and diastolic pressure in individuals aged 12 years and older. The collected data can be transmitted to a PC via USB for healthcare professionals to review and analyze. This device is not intended for diabetic patients, pregnant women, or patients with arrhythmia. It is intended for prescription use only.	PC-based computer program for the recording and displaying of up to 250 measurements of systolic and diastolic blood pressure and heart rate. It is intended for use as an aid or adjunct to diagnosis and treatment when it is necessary to measure an adult and pediatric (> 3yrs.) patient's systolic and diastolic blood pressures over an extended period of time. The system is only for measurement, recording, and display. It makes no diagnoses. Optionally, The Model 250 will provide a derived ascending aortic blood pressure waveform and a range of central	

			arterial indices. These measurements are provided non invasively through the use of a brachial cuff. It is to be used on those patients where information related to ascending aortic blood pressure is desired but the risks of cardiac catheterization procedure or other invasive monitoring may outweigh the benefits (excludes pediatric subjects). BlueTooth, wireless connectivity will be offered as an option.	
	Contraindication	a. Cardiac and High-Risk Physiological Conditions: Not intended for special populations, such as diabetic patients, pregnant women, or patients with	a. CONTRAINDICATION: Do not use on patients with erratic, accelerated or mechanically controlled irregular heart rhythms, including patients with	Different (Note 2)

		arrhythmia who may require specific evaluation due to physiological factors that could affect the accuracy of cuff-based blood pressure measurements. b. Vascular Conditions: Not intended for patients with carotid or aortic valve stenosis, or those exhibiting systemic contraction or localized spasms of muscular conduction arteries (e.g., after hypothermic cardiopulmonary bypass surgery, Raynaud's phenomenon, or extreme cold exposure). c. Prior Surgical History: Not intended for patients who have undergone bilateral mastectomy. d. Limb Condition Restrictions: Do not use on arms with peripherally inserted central catheters (PICC),	arrhythmias. b. CONTRAINDICATION: Do not use on patients with carotid or aortic valve stenosis. c. CONTRAINDICATION: The system is not applicable in generalized constriction or localized spasm of muscular conduit arteries such as seen immediately after hypothermic cardiopulmonary bypass surgery or accompanying Raynaud's phenomenon or intense cold. d. CONTRAINDICATION: Do not use system on patients who have had a double mastectomy e. CONTRAINDICATION: Do not use on the same arm of patients with a peripherally inserted central catheter (PICC) line, Intraveneous	

		intravenous (IV) lines, or arterial lines.	(IV) or arterial line.	
	Target population	Individuals aged 12 years and older	People aged 3 years and over	Different (Note 3)
	Anatomical site	upper arm	upper arm	Same
	Location of use (primary)	Physician's office, clinic, research center (under supervision of physician) and patient home environment	Physician's office, clinic, research center (under supervision of physician) and patient home environment	Same
	Working environment	Temperature：10-40℃，Humidity: 15%-85%	Temperature：10-50℃，Humidity: 20%-90%	Different (Note 4)
Structure and material	Composition	Main unit, cuff, PC software	Main unit, cuff, PC software	Same
	Material (contact with human)	Cuff: encrypted canvas	Cuff: nylon	Different (Note 5)
	Combined equipment	PC	PC	Same

	Hose	No hose	About 1-1.5 meters	Different (Note 6)
	Shape	Small, lightweight, portable	Small, lightweight, portable	same
	Power supply	Internal battery-DC 3.7V (one piece of Li-battery)	3 Volt Two “AA” alkaline or rechargeable batteries	Different (Note 7)
Main function and specifications	Measuring method	Step deflation, Oscillometric method	Step deflation, Oscillometric method	Same
	Over-pressure protection	Deflate automatically if cuff pressure is over than 290 mmHg	Deflate automatically if cuff pressure is over than 300 mmHg	Different (Note 8)
	Power-off protection	Stop measuring if power fails	Stop measuring if power fails	Same
	Measuring period protection	Stop measuring if single measuring period is over than 150s, and deflate the cuff	Stop measuring if single measuring period is over than 140s, and deflate the cuff	Different (Note 9)
	Measuring range	Systolic: 40-260 mmHg Diastolic: 20-210 mmHg	Systolic: 40-260 mmHg Diastolic: 25-200 mmHg	Different (Note 10)
	System error	±5 mmHg mean error & 8 mmHg standard deviation.	±5 mmHg mean error & 8 mmHg standard deviation.	Same

	Pressure accuracy	⩽ ±3 mmHg	⩽ ±3 mmHg	Same
	Data storage	300 readings	250 readings	Different (Note 11)
	Data statistic	PC software possesses statistical functions by means of graphs and texts	PC software possesses statistical functions by means of graphs and texts	Same
	Data inquiry	PC software claims historical data inquiring function	PC software claims historical data inquiring function	Same
	Data transmission	USB data transmission cable	USB data transmission cable, BlueTooth, wireless connectivity will be offered as an option.	Different (Note 12)
	Alarming	Upper limit and lower limit setting, alarm when measuring value is beyond settings	Upper limit and lower limit setting, alarm when measuring value is beyond settings	Same
	Power notice	Yes	Yes	Same
	Body position judgment	Yes	Yes	Same
	Programming	Yes	Yes	Same

	biological compatibility	Yes	Yes	Same
Standards Compliance	AAMI/IEC 60601-1 Electrical Safety & Applicable Collateral Standards	60601-1 & 60601-1-6 60601-1-8 60601-1-11	60601-1 & 60601-1-6 60601-1-11	Different (Note 13)
	IEC 60601-1-2 EMC	60601-1-2	60601-1-2	Same
	AAMI/IEC 80601-2-30	80601-2-30	80601-2-30	Same
	ISO 81060-2	81060-2	81060-2	Same

Note 1 : The indications for use of the subject device and the predicate device are substantially equivalent. Both of them are used for 24-hour ambulatory blood pressure monitoring for patients, and both of them are non-invasive. The differences are that the subject device omits the pulse rate(heart rate) measurement function available in the predicate device, and the subject device is indicated for use in patients aged 12 years and older, whereas the predicate device is indicated for patients aged 3 years and older. The measurement functions and intended population of the subject device are validated according to ISO 80601-2-30 and ISO 81060-2. The subject device is as safe and effective as the predicate device.

Note 2: The contraindications of the subject device differ slightly from those of the predicate device. The subject device excludes pregnant women and diabetic patients. Corresponding clarifications have been added to the instructions for use to prevent inappropriate use of the device. This difference does not raise new safety or effectiveness concerns.

Note 3: The subject device is intended for use in patients aged 12 years and older, while the predicate device is intended for patients aged 3 years and older. The intended population of the subject device has been clinically validated according to ISO 80601-2. The subject device is as safe and effective as the predicate device.

Note 4: The working environment of the subject device is different from that of the predicate device the predicate device. The working environment of the subject device has been validated according to IEC 80601-2-30. The subject device is as safe and effective as the predicate device.

Note 5: The subject device’s cuff is made of encrypted canvas, while the the cuff of the predicate device is made of nylon. The subject device’s cuff has passed biocompatibility tests in accordance with ISO 10993-5 and ISO 10993-23. The subject device is as safe and effective as the predicate device.

Note 6: The subject device is tubeless. Compared with the predicate device, it reduces the influence of airflow and avoids the risk of suffocation caused by tube entanglement. In addition, the absence of tubes makes the product more convenient to wear and disassemble. The differences between the subject device and the predicate device do not affect the safety or effectiveness of the subject device.

Note 7: The subject device uses a rechargeable lithium battery as its power source. Compared with the alkaline batteries used in the predicate device, the rechargeable battery offers higher reusability and reduces environmental impact. The lithium

battery used in the subject device has been validated according to IEC 62133-2. The subject device is as safe and effective as the predicate device.

Note 8 & Note 9 & Note 10: There are minor differences between them. The subject device has been validated according to IEC 80601-2-30. These differences do not raise new safety or effectiveness concerns. The subject device is as safe and effective as the predicate device.

Note 11: The subject device can store 300 pieces of data, while the predicate device can store 250 pieces of data. The differences between the subject device and the predicate device do not affect the safety or effectiveness of the subject device.

Note 12: The predicate device transmits data via Bluetooth, whereas the subject device uses USB for data transmission. The data transmission security and effectiveness of the subject device have been verified through cybersecurity testing. The subject device is as safe and effective as the predicate device.

Note 13: The subject device is equipped with an alarm function, while the predicate device is not. The subject device has been verified according to IEC 60601-1-8. This difference does not raise new safety or effectiveness concerns. The subject device is as safe and effective as the predicate device.

(11) Performance Data

Non-clinical test:

Testing information demonstrating safety and effectiveness of the device in the intended environment of use is supported by testing that was conducted.
The following testing was conducted to prove safety and effectiveness as well as substantial equivalence to the predicate devices.

Electrical Safety and performance requirements:

- IEC 60601-1:2005+AMD1:2012+AMD2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-8:2006+AMD1:2012+AMD2:2020 Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- 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

- IEC 62133-2:2017+AMD1:2021 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

Electromagnetic compatibility requirements:

- IEC 60601-1-2:2014+AMD1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC TS 60601-4-2:2024 Medical electrical equipmentPart 4-2: Guidance and interpretation- Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

Home-used medical equipment requirements and environmental test:

- IEC 60601-1-11:2015+AMD1:2020 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

Bio-compatibility Evaluation for patient contacting components:

- ISO 10993-5: 2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2021 Biological evaluation of medical devices Part 10: Tests for skin sensitization
- ISO 10993-23:2021 Biological evaluation of medical devices Part 23: Tests for irritation

Mean Arterial Pressure (MAP)

- The device firmware does not include the calculation function for Mean Arterial Pressure (MAP), and the OLED screen on the host device does not display MAP values. The accompanying PC software can display the hourly average MAP value and its trend graph. MAP is calculated using the standard equivalent formula. The MAP calculation formula was validated through code review and integrated system testing as part of the PC software verification process. Code review confirmed its correct implementation, while system testing verified that the resulting charts accurately reflected the expected physiological trends based on test data with known blood pressure values, thereby confirming the calculation's correctness in the software's graphical output.
- According to the calculation formula of MAP, the measurement error of MAP is determined by the measurement error of blood pressure. The measurement error of blood pressure has been validated according to ISO 81060-2 and ISO 80601-2-30, and the validation results meet the requirements. Thus, it can be

concluded that the measurement error of MAP also complies with the requirements.

Clinical test:

- ISO81060-2:2018+AMD2020 Non-invasive sphygmomanometers - Part2: Clinical investigation of intermittent automated measurement type.

These test devices have undergone clinical validation in accordance with the ISO 81060-2:2018+A1:2020 standard to verify their clinical accuracy for the intended use. The clinical trial consisted of two main parts: a general study and an ambulatory supplementary study, both conducted in strict compliance with the standard requirements. The general study included 95 subjects, while the ambulatory study involved 36 subjects.
In the general population, the mean difference between the device and observer measurements was 3.98 ± 3.77 mmHg for systolic blood pressure and 3.53 ± 3.37 mmHg for diastolic blood pressure. Both the mean and standard deviation values were below the maximum limits defined in the trial protocol, fulfilling the requirements of Criterion 1 and Criterion 2. During the ergometric test, the mean device-observer difference was 3.84 ± 2.97 mmHg for systolic blood pressure and 3.30 ± 3.06 mmHg for diastolic blood pressure.

(12) Conclusion

Based on the information provided in this premarket notification submission and the testing conducted, it is concluded that the subject device is substantially equivalent to the legally marketed predicate device described herein.