April 1, 2026

Shenzhen HanHan Technology Co., Ltd.
Yong Zhang
General Manager
Bldg. B1,B301,Yingzhan Technology Park,#8 Longtian Tong
Fuyu Rd., Longtian Community, Longtian St., Pingshan Dis
Shenzhen, 518118
China

Re: K254225
Trade/Device Name: Arm Blood Pressure Monitor (HH-802CB, HH-802EB, HH-805CB, HH-812CB, HH-808CL, HH-808EL)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: December 25, 2025
Received: December 29, 2025

Dear Yong Zhang:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K254225

Device Name
Arm Blood Pressure Monitor (HH-802CB, HH-802EB, HH-805CB, HH-812CB, HH-808CL, HH-808EL)

Indications for Use *(Describe)*
The Arm Blood Pressure Monitor is intended to measure the systolic pressure and diastolic pressure, as well as the pulse rate of adult person via non-invasive oscillometric technique at medical facilities or at home.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

1. Submitter:	Shenzhen HanHan Technology Co., Ltd Building B1, b301, Yingzhan Technology Park,No.8 Longtian Tongfuyu Road, Longtian Community, Longtian Street, Pingshan District, Shenzhen, 518118, China TEL: 86-755-8464413
Contact Person:	Yong Zhang
Prepare date:	2025-12-25
2. Device name and classification	**Device Name:** Arm Blood Pressure Monitor **Models:** HH-802CB, HH-802EB, HH-805CB, HH-812CB, HH-808CL, HH-808EL **Classification Name:** 21 CFR 870.1130 Cardiovascular Diagnostic Devices **Product code:** DXN **Regulatory Class:** Class II
3. Reason for Submission	Submission for the 510(k) clearance.
4. Predicate Device(s)	**Manufacturer:** Shenzhen Ruiankang Technology Co.,Ltd., **Trade/Device name:** Blood Pressure Monitor, RAK260, RAK262, RAK263, RAK266, RAK268, RAK269, RAK282, RAK283, RAK286, RAK288, RAK289, RAK291, RAK292, RAK293, RAK295, RAK296, RAK297, RAK298 **510(k) number:** K242528
5. Device Description	The Arm Blood Pressure Monitor is designed as an automatic non-invasive arm blood pressure monitor driven by battery or AC power. It can automatically complete the inflation, deflation and measurement, which can measure systolic and diastolic blood pressure as well as the pulse rate of adult person at upper arm within its claimed range and accuracy via the oscillometric technique. The result will be displayed in the international unit mmHg or Kpa. The device has the data storage function in order for data reviewing, including the systolic pressure, diastolic pressure, pulse rate and measurement time. The device also has low voltage indication, which will be triggered when the battery is low. The proposed device is intended to be used in medical facilities or at home. And the effectiveness of this sphygmomanometer has not been established in pregnant (including pre-eclamptic) patients. The product is provided non-sterile, and not to be sterilized by the user prior to use.
6. Indications for Use	The Arm Blood Pressure Monitor is intended to measure the systolic pressure and diastolic pressure, as well as the pulse rate of adult person via non-invasive oscillometric technique at medical facilities or at home.

7. Predicate Device Comparison

Please refer to following table to find differences between the subject device and predicate device.

Table 1 Comparison between the predicate and the subject device

ITEM	Proposed Device	Predicate Device	Comparison Result
Manufacture	Shenzhen HanHan Technology Co., Ltd	Shenzhen Ruiankang Technology Co.,Ltd.	/
Indications for Use	The Arm Blood Pressure Monitor is intended to measure the systolic pressure and diastolic pressure, as well as the pulse rate of adult person via non-invasive oscillometric technique at medical facilities or at home.	The Blood Pressure Monitor is intended to measure the systolic pressure and diastolic pressure, as well as the pulse rate of adult person via non-invasive oscillometric technique at medical facilities or at home.	Same
Contraindications	Not Known	Not Known	Same
Application scenario	Medical Facilities and Home Use	Medical Facilities and Home Use	Same
Operational Specifications			
Principle	Oscillometric	Oscillometric	Same
Measurement Item	SYS, DYS, Pulse Rate	SYS, DYS, Pulse Rate	Same
Intended patient population	Adult	Adult	Same
Intended application site	Upper arm	Upper arm	Same
Blood pressure measurement range	0~260 mmHg SYS: 60~260mmHg(8kPa~34.7kPa) DID: 30~195mmHg(4kPa~26.6kPa)	25~255 mmHg	Different[1]
Accuracy	± 3 mmHg	± 3 mmHg	Same
Heart rate measurement range	40-199 bpm	40-199 bpm	Same
Accuracy	± 5%	± 5%	Same
Cuff circumference	22 ~36 cm	22 ~32 cm	Different[2]
Components	LCD/Key/Cuff/MCU/Pump/Batteries	LCD/Key/Cuff/MCU/Pump/Batteries	Same
Auto shutdown	YES	YES	Same
Operating environment	Temperature: 5°C~ 40°C Humidity: 15%–90% RH, Atmospheric pressure: 80 kPa - 106 kPa	Temperature: 5°C~ 40°C Humidity: 15%–80% RH, Atmospheric pressure: 70 kPa - 106 kPa	Different[3]
Storage/transport environment	Ambient Temperature: - 20°C to 55°C Relative Humidity: 10-93% RH,	Ambient Temperature: - 20°C to 55°C Relative Humidity: 10-93% RH,	

	Atmospheric pressure: 80 kPa - 106 kPa	Atmospheric pressure: 70 kPa - 106 kPa	
Power supply	HH-802CB, HH-802EB,HH-805CB, HH-812CB: 4 pcs AAA batteries or power by 5Vdc,2A AC adaptor HH-808CL, HH-808EL: 3.7V Lithium battery, Charged by 5V 1A AC adapter	6Vdc (4 *1.5V AAA batteries)	Different[4]
Memory	2*99	2*99	Same
Compliance Standards			
Bio-compatibility	ISO 10993-1 ISO 109903-5 ISO 10993-10 ISO 10993-23	ISO 10993-1 ISO 109903-5 ISO 10993-10	Different[5]
Electrical Safety	IEC 60601-1 IEC 60601-1-11	IEC 60601-1 IEC 60601-1-11	
EMC	IEC 60601-1-2	IEC 60601-1-2	
Performance	IEC 80601-2-30	IEC 80601-2-30	

Justification for the differences:

1) Different Blood pressure measurement range

   The Blood pressure measurement range of the subject device is minor different form that of the predicate device, but the measurement range of the subject device has been verified by IEC 60601-1 and IEC 80601-2-30, so the different range will be acceptable for the subject device.

2) Different Cuff circumference

   The range of pressure is wider than the predicate device while the cuff circumference is narrower than predicate device. They have the same accuracy. The differences are very slightly and they both contain the blood pressure range of most people, and the measurement range of proposed device is fully verified according to IEC 80601-2-30, so the different range and accuracy will be acceptable for the subject device.

3) Different Operating environment and Storage/transport environment

   Minor difference to operation, storage/transport environment for the subject device, but the monitor has been proved to be safe and effective since the safety testing was conducted under the suggested environment; Moreover, environment testing data shows the device can work as declared under the suggested conditions. So those changes will not cause any safety and effectiveness problem.

4) Different power supply

   The Power Source is slightly different. The subject device meets the requirements of IEC60601-1. Thus, the difference does not raise different questions of safety and effectiveness

5) Different Bio-compatibility standard

   The subject device has been tested ISO 10993-5, ISO10993-10 and ISO 10993-23 according to the updated of the standard.

As seen in the comparison tables, the subject and predicate devices have same intended use, design principle, similar design features and performance specifications. The different technological characteristics between the subject and predicate devices will not raise different questions of safety or effectiveness as demonstrated in the non-clinical and clinical evidence.

8. Performance Testing

Performance data includes "Non-Clinical Data" and "Clinical Data", brief description of which are shown as below.

Non-Clinical Testing:

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the Blood pressure monitor was conducted in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The worst case of the whole system is considered tissue contacting for duration of More than 30 days. And the testing included the following tests, results of which demonstrate the biocompatibility of the subject device:

- Cytotoxicity
- Skin Sensitization
- Skin Irritation

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted, and the results show that the subject device complies with the IEC 60601-1: 2005+AMD1 (2012) +AMD2 (2020) *Medical electrical equipment Part 1: General requirements for basic safety and essential performance* for safety and the 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* standard for EMC.

Bench Testing

Bench testing was conducted and the results show that the subject device complies with the IEC 80601-2-30: *Medical electrical equipment – Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers. And blood pressure Accuracy meets the requirements defined in IEC 80601-2-30.*

Home-used medical equipment requirements and environmental test:

Environmental testing was conducted and the test results show that the subject device complies with the IEC 60601-1-11:2015 +A1:2020 *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.*

Software Verification and Validation Testing

Software documentation including verification & validation was provided in accordance with FDA Guidance: *Guidance for the* Content *of Premarket Submissions for Software Contained in Medical Devices* for software with a moderate level of concern.

Clinical data:

Clinical test has been performed in accordance with ISO 81060-2:2018 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type. The clinical test included 85 adult subjects. All data's mean error and standard deviation of differences for systolic, diastolic pressure is not over the limits of ISO 81060-2: 2018. No adverse effect and/or complication is found in the study.

9. Conclusion

Verification and validation testing was conducted on the subject device Blood pressure monitor and all testing passed pre-specified criteria. The subject device and the predicate device have very similar intended use and the differences in technological features do not raise different questions of safety and effectiveness. This premarket notification submission demonstrates that the subject device is substantially equivalent to the predicate device.