April 21, 2026

Beijing Hanvon Health Technology Co., Ltd.
Qingjun Yi
Regulatory Responsible
Rm. 162, 1st Floor And Rm. 256, 2nd Floor,
Hanwang Bldg. 5, #8 Dongbeiwangxi Rd.,Haidian District
Beijing, Beijing 100193
China

Re: K253982
Trade/Device Name: Korotkoff Sound Blood Pressure Monitor (KSY6600A, KSY6620B, KSY6600, KSY3500A, KSY3500B, KSY3500, KSY3200A, KSY3200B, KSY3200, KSY3160B, KSY3150B, KSY3150, KSY3100A, KSY3110, KSY3110B, KSY3118B, KSY3128B, KSY3120B, KSY3120, KSY3100B, KSY3100, KSY3050A, KSY3080B, KSY3080, KSY3060B, KSY3050B, KSY3050 and KSY3160)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: December 10, 2025
Received: December 12, 2025

Dear Qingjun Yi:

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

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.	K253982

Please provide the device trade name(s).

Korotkoff Sound Blood Pressure Monitor (KSY6600A, KSY6620B, KSY6600, KSY3500A, KSY3500B, KSY3500, KSY3200A, KSY3200B, KSY3200, KH3160B, KSY3150B, KSY3150, KSY3100A, KSY3110, KSY3110B, KSY3118B, KSY3128B, KSY3120B, KSY3120, KSY3100B, KSY3100, KSY3050A, KSY3080B, KSY3080, KSY3060B, KSY3050B, KSY3050 and KH3160)

Please provide your Indications for Use below.

The device is a digital monitor intended for use in measuring the systolic pressure and diastolic pressure, as well as the pulse rate of adults and adolescents via a non-invasive auscultatory method in medical facilities or at home, with an inflatable cuff wrapped around the upper arm for arm circumferences ranging from 22 to 42 cm. The measurement ranges of the device are systolic pressure 40 ~ 280 mmHg (supported by automatic mode for 40 to 210 mmHg and manual mode for 210 to 280 mmHg), diastolic pressure 20 ~ 220 mmHg, and pulse rate 40 ~ 240 beats/min.
The device can detect Irregular Heart Beat (IHB), Atrial Fibrillation, Tachycardia, and evaluate Blood Pressure Variability (BPV) and Time in Target Range (TTR) according to the measured blood pressure values.

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) #: K253982

510(k) Summary

Prepared on: 2026-04-21

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Beijing Hanvon Health Technology Co., Ltd.
Applicant Address	Room 162, 1st Floor and Room 256, 2nd Floor, Hanwang Building, Building 5, No.8 Dongbeiwangxi Road, Haidian District Beijing 100193 China
Applicant Contact Telephone	(010) 82786525
Applicant Contact	Mr. Qingjun Yi
Applicant Contact Email	yiqingjun@hanwang.com.cn

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Korotkoff Sound Blood Pressure Monitor (KSY6600A, KSY6620B, KSY6600, KSY3500A, KSY3500B, KSY3500, KSY3200A, KSY3200B, KSY3200, KH3160B, KSY3150B, KSY3150, KSY3100A, KSY3110, KSY3110B, KSY3118B, KSY3128B, KSY3120B, KSY3120, KSY3100B, KSY3100, KSY3050A, KSY3080B, KSY3080, KSY3060B, KSY3050B, KSY3050 and KH3160)
Common Name	Noninvasive blood pressure measurement system
Classification Name	System, Measurement, Blood-Pressure, Non-Invasive
Regulation Number	870.1130
Product Code(s)	DXN, DXN

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K251120	Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP Progress (BP3T01-1B)	DXN

Device Description Summary

21 CFR 807.92(a)(4)

The Korotkoff Sound Blood Pressure Monitor is designed as an automatic non-invasive blood pressure monitor. 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 Korotkoff sound method. And the monitor will indicate possibility of AFib if an irregularity from pulse to pulse intervals is detected during a measurement. Also Blood Pressure Variability (BPV) and Time in Target Range (TTR) can be indicated on the screen after the measurement.
The device has the data storage function in order for data reviewing, 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.
The monitor is composed of main unit (including control circuit, LCD display, battery and keys) , cuff and AC Adapter (optional).

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The device is a digital monitor intended for use in measuring the systolic pressure and diastolic pressure, as well as the pulse rate of adults and adolescents via a non-invasive auscultatory method in medical facilities or at home, with an inflatable cuff wrapped around the upper arm for arm circumferences ranging from 22 to 42 cm. The measurement ranges of the device are systolic pressure 40 ~ 280 mmHg (supported by automatic mode for 40 to 210 mmHg and manual mode for 210 to 280 mmHg), diastolic pressure 20 ~ 220 mmHg, and pulse rate 40 ~ 240 beats/min.

The device can detect Irregular Heart Beat (IHB), Atrial Fibrillation, Tachycardia, and evaluate Blood Pressure Variability (BPV) and Time in Target Range (TTR) according to the measured blood pressure values.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject device and predicate share the same primary intended use and target population, well-established, non-invasive, upper-arm BP measurement technologies with comparable accuracy and safety. All differences are secondary features, not changes to indication or patient group.
The subject device extends the range by 2 cm (upper limit only), covering a standard adult arm size subset already addressed by cleared upper arm cuffs. No new mechanical, biocompatibility, or measurement risks are introduced. Performance is validated over the full range to meet accuracy requirements.
Ranges of both devices are clinically appropriate for adult BP/PR monitoring and consistent with cleared electronic sphygmomanometers. Accuracy and reliability are verified per applicable standards (e.g., ISO 81060-1).
Both devices can detect the appearance of irregular heartbeat during measurement and gives a warning signal with the reading once the irregular heartbeat is detected. While the subject device can also evaluate the atrial fibrillation, tachycardia detection; BPV and TTR evaluation based on measured BP, which are provide as informational alerts/metrics only; they do not modify measurement, diagnosis, or therapy. No new safety hazards are introduced; performance is validated to minimize false alerts without compromising core measurement.
All the verification evidence (e.g., product specification comparison table, software function test report, clinical validation data) confirm that all differences are minor, well-characterized, and do not affect the safe and effective use of the device for its intended purpose.

Technological Comparison

21 CFR 807.92(a)(6)

1) Different Application scenarios
The subject device is intended to be used in both home and clinical environment while only home healthcare environment is claimed for the predicate. The application of such product in the clinical environments decrease the application risks since it will be operated by healthcare person. Therefore, the difference does not raise any issues concerning safety and effective.
2) Displayed info.
The suggestive Atrial Fibrillation(AFib), Blood Pressure Variability (BPV) and Time in Target Range (TTR) is not avaialble for the predicate device, these displayed information are results from software analysis base on the DIA, SYS and the pulse rate information, and these function has been well demonstration by the software verification and validation, so this difference will not the difference does not raise any issues concerning safety and effective.
3) Different Blood pressure measurement&Heart rate range and accuracy
The Blood pressure measurement&Heart rate ranges 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.
Regarding the accuracy, both are also well evaluated per the international standards IEC 80601-2-30 and ISO 81060-2, and the results show compliance with the requirements defined, no safety or effectiveness will be affected by this difference.
4) Different Cuff circumference
The range of cuff circumference is minor differently from that of the predicate device with different blood pressure measurement 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 and the system clinical accuracy validation per ISO 81060-2, so the different range and accuracy will be acceptable for the subject device.
5) Operating and storage environment
The operation and storage conditions of subject device is different from that of predicate devices, but they all complied with the IEC 60601-1-11 and IEC 60601-1, so the difference will not raise any new safety and effectiveness issues.
6) Different Power supply and IP rating
The power supply and IP rating between the subject device and the predicate device are different, the battery of the subject device has been tested to the IEC 62133-2. In addition, the subject device has been tested to IEC 60601-1, IEC 60601-1-11 and IEC 60601-1-2 to evaluate the electrical safety including the IP rating. Therefore, the difference does not raise any new safety and effectiveness issues.

The subject and predicate devices have same 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.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The following performance data were provided in support of the substantial equivalence determination.
1) Non-Clinical Testing:
The following performance data were provided in support of the substantial equivalence determination.
Biocompatibility testing
The biocompatibility evaluation for the Korotkoff Sound Bood 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 less than 24 hours. And the battery of 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.

Usability Evaluation
The monitor is evaluated per IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.
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.

Software Verification and Validation Testing
Software verification and validation testing were conducted and Basic Documentation Level was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." since a failure or latent flaw of the device software function(s) (e.g., software fails to properly measure the blood pressure or fail to display any prompt) would not present a hazardous situation with a probable risk of death or serious injury to either a patient, user of the device, or others in the environment of use prior to the implementation of risk control measures..

Clinical data:
Substantial equivalence was based in part on the clinical study.
Blood pressure measurement accuracy has been performed on KSY 3050A and KSY 6600A respectively to cover all the models involved in this submission in accordance with ISO 81060-2:2018 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type. All data's mean error and standard deviation of differences for systolic, diastolic pressure is not over the limits of ISO 81060-2: 2018.
For the clinical study on KSY 3050A, a total of 90 people aged 20 to 90 years old volunteered to participate in the clinical verification trial of the Korotkoff Sound Blood Pressure Monitor. All completed the trial and successfully withdrew from the group. The data of 88 people met the clinical evaluation requirements, generating 264 sets of evaluation data. There are 47 males, accounting for 53.4%, and 41 females, accounting for 46.6%. The systolic blood pressure range is 89.0-200.0mmHg, and the diastolic blood pressure range is 50.0 117.0 mmHg.
For the clinical study on KSY 6600A, a total of 90 people aged 20 to 84 years old volunteered to participate in the clinical verification trial of the Korotkoff Sound Blood Pressure Monitor. All completed the trial and successfully withdrew from the group. The data of 87 people met the clinical evaluation requirements, generating 261 sets of evaluation data. There are 36 males, accounting for 41.4%, and 51 females, accounting for 58.6%. The systolic blood pressure range is 86.0-179.0mmHg, and the diastolic blood pressure range is 46.0 116.0 mmHg.

And clinical verification regarding the Atrial Fibrillation notification is also conducted with a 97.3% sensitivity and 100% specificity. A

total of 74 volunteers participated in the clinical verification test of the AFib function of the Korotkoff Sound Blood Pressure Monitor. They all completed the trial and successfully withdrew from the group, generating 74 sets of evaluation data. Aged 31 to 93, 27 males accounting for 36.5%, and 47 females, accounting for 63.5%. Systolic blood pressure range is 88-180mmHg, diastolic blood pressure range is 53-112mmHg, pulse range is 43-140 beats/min.

No adverse effect and/or complication is found in the clinical study.

Summary
Based on the clinical performance as documented in the clinical study, the monitor was found to have a safety and effectiveness profile that is similar to the predicate device.