October 9, 2025

HONSUN (Nantong) Co.,Ltd.
Sara Xu
No.8, Tongxing Road
Nantong Economic & Technological Development Area
Nantong, Jiangsu 226009
China

Re: K251795
Trade/Device Name: Wrist automatic blood pressure monitor (LD-735, LD-752, LD-753)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: September 12, 2025
Received: September 16, 2025

Dear Sara Xu:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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,

Hetal B. Odobasic -S

for

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
OHT2: 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.	K251795

Please provide the device trade name(s).

Wrist automatic blood pressure monitor (LD-735, LD-752, LD-753)

Please provide your Indications for Use below.

The wrist automatic blood pressure monitor LD-735,LD-752,LD-753 is intended for the non-invasive measurement of systolic and diastolic arterial blood pressure and pulse rate in adults (aged 15 and above).

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)

Summary of special 510(K)

Date prepared: 12-May-2025

1. Submitter

Company:	HONSUN(Nantong)Co.,Ltd.
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Phone:	+86-513-80580116
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Contact Person:	Sara Xu
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2. Modified Device information

Name of Device:	Wrist Automatic Blood Pressure monitor
Model:	LD-735,LD-752,LD-753
Common Name:	Non-invasive blood pressure measurement system
Classification Name:	System, Measurement, Blood-Pressure, Non-Invasive
Regulation number:	21 CFR 870.1130
Regulatory Class:	II
Product Code:	DXN
Review Panel:	Cardiovascular

3. Cleared Device information

Name of Device:	Wrist Automatic Blood Pressure monitor
Model:	LD-737
510k number:	K131463
Common Name:	Non-invasive blood pressure measurement system
Regulation number:	21 CFR 870.1130
Regulatory Class:	II
Product Code:	DXN
Review Panel:	Cardiovascular

4. Device description

The Wrist Automatic Blood Pressure Monitor is an automatic, non-invasive, blood pressure measurement device that is intended to measure the systolic and diastolic arterial blood pressure and pulse rate. The systolic and diastolic pressure are determined using the oscillometric method, where the cuff is inflated with a pump and deflates via an automatic electronic valve. During the inflation measurements, an electric pump within the main unit slowly inflates the wrist cuff, generating cuff pressure which is monitored and from which pulse waveform data is extracted. This waveform data is analyzed by software algorithms

within the sensor to determine systolic pressure and diastolic pressure.
The Wrist Automatic Blood Pressure Monitor consists of two parts: main unit and the wrist cuff. The main unit is mainly composed of pump, valve, PCB, enclosure and LCD. The cuff, which is applicable to wrist circumference approximately between 12.5 and 20.5cm, includes the inflatable bladder and the nylon shell.

5. Intended use and indications for use

The wrist automatic blood pressure monitor LD-735,LD-752,LD-753 is intended for the non-invasive measurement of systolic and diastolic arterial blood pressure and pulse rate in adults (aged 15 and above).

6. Operation principle

This device adopts the oscillometric technology with Fuzzy Algorithm to measure the arterial blood pressure and pulse rate. The cuff is wrapped around the arm and automatically inflated by the air pump. The sensor of the device catches weak fluctuation of the pressure in the cuff produced by extension and contraction of the artery of the arm in response to each heartbeat. The amplitude of the pressure waves is measured, converted in millimeters of the mercury column, and is displayed by digital value.

7. Comparisons of technological characteristic with the predicate device

Items	Subject Device LD-735	Subject Device LD-752	Subject Device LD-753	Predicate Device LD-737(K131463)	Remark
Device name	Wrist Automatic Blood Pressure Monitor	Wrist Automatic Blood Pressure Monitor	Wrist Automatic Blood Pressure Monitor	Wrist Automatic Blood Pressure Monitor	Same
Classification	II	II	II	II	Same
Product code	DXN	DXN	DXN	DXN	Same
Regulation number	870.1130	870.1130	870.1130	870.1130	Same
Indications for use	The wrist automatic blood pressure monitor is intended for the non-invasive measurement of systolic and diastolic arterial	The wrist automatic blood pressure monitor is intended for the non-invasive measurement of systolic and diastolic arterial	The wrist automatic blood pressure monitor is intended for the non-invasive measurement of systolic and	The Wrist Automatic Blood Pressure Monitor LD-737 is device intended to measure the systolic and diastolic blood	Same

	blood pressure and pulse rate in adults (aged 15 and above).	blood pressure and pulse rate in adults (aged 15 and above).	diastolic arterial blood pressure and pulse rate in adults (aged 15 and above).	pressure and pulse rate of an adult individual by using non-invasive technique in which an inflatable cuff is wrapped around the wrist.	
Measuring method	Oscillometric Method	Oscillometric Method	Oscillometric Method	Oscillometric Method	Same
Cuff location	Wrist	Wrist	Wrist	Wrist	Same
Specification					
Measuring range	40 to 180mmHg (DIA, diastolic pressure) 60 to 260mmHg (SYS, systolic pressure) 40 to 160 beats/minute (PUL, pulse rate)	40 to 180mmHg (DIA, diastolic pressure) 60 to 260mmHg (SYS, systolic pressure) 40 to 160 beats/minute (PUL, pulse rate)	40 to 180mmHg (DIA, diastolic pressure) 60 to 260mmHg (SYS, systolic pressure) 40 to 160 beats/minute (PUL, pulse rate)	40 to 180mmHg (DIA, diastolic pressure) 60 to 260mmHg (SYS, systolic pressure) 40 to 160 beats/minute (PUL, pulse rate)	Same
Measuring accuracy	±3mmHg for static pressure ±5% of the reading for the pulse rate	±3mmHg for static pressure ±5% of the reading for the pulse rate	±3mmHg for static pressure ±5% of the reading for the pulse rate	±3mmHg for static pressure ±5% of the reading for the pulse rate	Same
Inflation	Automatic by the pump	Automatic by the pump	Automatic by the pump	Automatic by the pump	Same
Rapid deflation	Automatic electronic valve	Automatic electronic valve	Automatic electronic valve	Automatic electronic valve	Same
Batteries	2*AAA batteries	2*AAA batteries	2*AAA batteries	2*AAA batteries	Same
Operation condition	5℃ to 40℃, 15% to 90%RH, 700hPa to 1060hPa	5℃ to 40℃, 15% to 90%RH, 700hPa to 1060hPa	5℃ to 40℃, 15% to 90%RH, 700hPa to	10℃ to 40℃,90% and below(non-condensing)	Similar Note 1

			1060hPa		
Transport and storage condition	-25℃ to 70℃, 15% to 90%RH, 700hPa to 1060hPa	-25℃ to 70℃, 15% to 90%RH, 700hPa to 1060hPa	-25℃ to 70℃, 15% to 90%RH, 700hPa to 1060hPa	-20℃ to 55℃,90% and below(non-condensing)	Similar Note 2
Cuff size	Applicable for wrist circumstance 12.5~20.5cm	Applicable for wrist circumstance 12.5~20.5cm	Applicable for wrist circumstance 12.5~20.5cm	Applicable for wrist circumstance 12.5~20.5cm	Same
Main body dimension	62(L)*61(W)*25(H)mm	66(L)*70(W)*30(H)mm	66(L)*70(W)*30(H)mm	66(L)*70(W)*30(H)mm	Similar Note 3
Weight	Approximately 98g without batteries	Approximately 110g without batteries	Approximately 110g without batteries	Approximately 123g without batteries	Similar Note 4
Function					
Memory	Yes (90 memories)	Yes (2*90 memories in two group)	Yes (2*90 memories in two group)	Yes (2*90 memories in two group)	Similar Note 5
Automatic power-off	Yes	Yes	Yes	Yes	Same
Date and time	/	Yes	Yes	Yes	Similar Note6
WHO	/	Yes	Yes	Yes	Similar Note 7
Irregular heartbeat detector	/	Yes	Yes	Yes	Similar Note 8
Low battery detection	Yes	Yes	Yes	Yes	Same
Applicable for standards					
Biocompatibility	All user directly contacting materials are compliance with ISO 10993-5 and ISO10993-10 requirements	All user directly contacting materials are compliance with ISO 10993-5 and ISO10993-10 requirements	All user directly contacting materials are compliance with ISO 10993-5 and ISO10993-10 requirements	All user directly contacting materials are compliance with ISO 10993-5 and ISO10993-10 requirements	Same
Electrical Safety	Comply with ANSI AAMI ES 60601-1	Comply with ANSI AAMI ES 60601-1	Comply with ANSI AAMI ES 60601-1	Comply with ANSI AAMI ES 60601-1	Same

	requirements				
EMC	Comply with IEC 60601-1-2 requirements	Comply with IEC 60601-1-2 requirements	Comply with IEC 60601-1-2 requirements	Comply with IEC 60601-1-2 requirements	Same
Others	Comply with IEC 60601-1-11 requirements	Comply with IEC 60601-1-11 requirements	Comply with IEC60601-1-11 requirements	Comply with IEC60601-1-11 requirements	Same

Discussion：

Note 1：Operation condition

The operation condition of the subject device are different with predicate device LD-737 (K131463), the difference introduces risks mitigated by testing in accordance with IEC 60601-1-11 and ANSI AAMI ES 60601-1 provided in this submission, therefore the difference does not raise new risk of safety and effectiveness.

Note 2: Transport and storage condition

The transport and storage condition of the subject device are different with predicate device LD-737 (K131463), the difference introduces risks mitigated by testing in accordance with IEC 60601-1-11 and ANSI AAMI ES 60601-1 provided in this submission, therefore the difference does not raise new risk of safety and effectiveness.

Note 3: Main body dimension

As for LD-735, its dimension is different with predicate device LD-737 (K131463) will not affect the safety and effectiveness.

Note 4: Weight

The weight of subject device is different with predicate device LD-737 (K131463) will not affect the safety and effectiveness.

Note 5/6/7/8: Memory, Date & Time, WHO,Irregular heartbeat detector

As for LD-735, it deletes the function of Date & Time, WHO,Irregular heartbeat detector, and only owns the one group with 90 sets of memories compared with predicate device LD-737 (K131463). These functions are additional functions, which will not influence the use of blood pressure monitor. Therefore it will not affect the effectiveness or raise any safety issues.

Conclusion

Based on above comparative analysis, compared with the predicate device LD-737 (K131463), the subject device does not raise new issues of safety and effectiveness.
Thus, the subject device is as safe, as effective and substantially equivalent to the predicate device.

8. Assessment of Non-clinical testing

8.1 Electrical safety and Electromagnetic Compatibility Testing

The electrical safety and EMC testing were conducted on the subject device. The related standards are shown as follows:

Standard	Descriptions
ANSI AAMI ES 60601-1	Medical electrical equipment-Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2	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	Medical electrical equipment-Part 1-11: General requirements for basic safety and essential performance-Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
ISO 80601-2-30	Medical electrical equipment-Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanomaters

8.2 Biocompatibility Evaluation

The biocompatibility evaluations of the subject device were 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” and FDA biocompatibility guidance, the Cytotoxicity test, Sensitization test, Irritation test are needed. The subject devices use the same patient-contact materials(cuff) with the predicate device, so the biocompatibility is not affected and it will not affect the effectiveness or raise any safety issues.

8.3 Software Verification and Validation Evaluation

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.

9. Conclusion

The wrist automatic blood pressure monitor (LD-735, LD-752, LD-753) have same intended use and similar characteristics as the cleared predicate device, model LD-737. Moreover, bench testing contained in this submission supplied demonstrate that the differences between subject device LD-735, LD-752, LD-753 and predicate device will not raise any safety and effectiveness issue.

The nonclinical tests support the safety of the device and the hardware and software verification and validation demonstrate that the wrist automatic blood pressure monitor perform as intended in the specified use conditions are same with predicate device. The performance tests demonstrate that the wrist automatic blood pressure monitor performs comparably to the predicate device that is currently marketed for the same intended use. Thus, the wrist automatic blood pressure monitor, model LD-735, LD-752, LD-753 is substantially equivalent to the predicate device.