August 31, 2026

Honsun (Nantong) Co., Ltd.
Jian Shen
Regulatory Affairs Director
#8 Tongxing Rd., Economic & Technological, Development Area
Nantong, Jiangsu 226009
China

Re: K262658
Trade/Device Name: Automatic Digital Blood Pressure Monitor (LD-526)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: July 30, 2026
Received: July 30, 2026

Dear Jian Shen:

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

CDR 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.	

Please provide the device trade name(s).

Automatic Digital Blood Pressure monitor (LD-526)

Please provide your Indications for Use below.

The device is a non-invasive blood pressure monitoring instrument intended for the measurement of systolic and diastolic arterial blood pressure and pulse rate in adults.

Please select the types of uses (select one or both, as applicable).	☐ Prescription Use (21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

Summary of special 510(K)

Date: 8-May-2026

1. Submitter

Company:	HONSUN(NANTONG)Co., Ltd.
Establishment registration number:	3007740533
Address:	No.8, Tongxing Road, Nantong Economic &Technological development Area, Jiangsu, 226009, China
Phone:	+86-513-80580116
Fax:	+86-513-80580080
Contact Person:	Jian Shen
Email:	Jason@lordmed.com

2. Modified Device information

Name of Device:	Automatic Digital Blood Pressure Monitor
Model:	LD-526
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:	Automatic Digital Blood Pressure Monitor
Model:	LD-537
510k number:	K170466
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 Automatic Digital 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, a pump within the main unit slowly inflates the 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 Automatic Digital Blood Pressure Monitor consists of two parts: main unit and cuff. The main unit is mainly composed of pump, valve, PCB, enclosure and LCD. The cuff, which is applicable to arm circumference approximately between 22 and 42cm, includes the inflatable bladder and the shell.

5. Intended use and indications for use

The device is a non-invasive blood pressure monitoring instrument intended for the measurement of systolic and diastolic arterial blood pressure and pulse rate in adults.

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-526**	**Predicate Device LD-537**	**Remark**
Device name	Automatic Digital Blood Pressure Monitor	Automatic Blood Pressure Monitor	Same
Classification	II	II	Same
Product code	DXN	DXN	Same
Regulation number	870.1130	870.1130	Same
Indications for use	The device is a non-invasive blood pressure monitoring instrument intended for the measurement of systolic and diastolic arterial blood pressure and pulse rate in adults	The Scian Automatic Digital Blood Pressure Monitor LD-518&LD-537 are devices intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. Besides, they can detect the appearance of irregular heartbeat during measurement, and give a	Same

		warning signal once the irregular heartbeat is detected.	
Measuring method	Oscillometric Method	Oscillometric Method	Same
Cuff location	Upper arm	Upper arm	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 260 mmHg (blood pressure) 40 to 160 beats/minute (pulse rate)	Similar Note 1
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	Same
Inflation	Automatic by the pump	Automatic by the pump	Same
Rapid deflation	Automatic electronic valve	Automatic electronic valve	Same
Power source	Battery: 4 AAA*1.5V, AC Adapter (Type C)	Battery: 4 AA*1.5V, AC Adapter	Similar Note 2
Cuff range	22cm~32cm (Standard) 22cm~42cm(optional)	22cm~42cm (Standard) 22cm~32cm(optional)	Same
Operation condition	5℃ to 40℃, 15% to 90%RH, 700hPa to 1060hPa	10℃ to 40℃, 15%~85%RH, 700hPa~1060hPa	Similar Note 3
Transport and storage condition	-25℃ to 70℃, 15% to 90%RH, 700hPa to 1060hPa	-20℃ to 55℃, 85%RH and below, 500hPa to 1060hPa	Similar Note 4
Main body dimension	125(L)*96(W)*70(H)mm	105(L)*120(W)*55(H)mm	Similar Note 5
Weight	Approximately 220g without batteries	Approximately 310g without batteries	Similar Note 6
Function			
Memory	2*90 sets	2*90 sets	Same
Date and time	Yes	Yes	Same
WHO	Yes	Yes	Same
Irregular heartbeat detector	Yes	Yes	Same
Voice broadcast	Yes	Yes	Same

Applicable for standards			
Biocompatibility	All user directly contacting materials are compliance with ISO 10993-5 and ISO10993-10/ISO 10993-23 requirements	All user directly contacting materials are compliance with ISO 10993-5 and ISO10993-10/ISO 10993-23 requirements	Same
Electrical Safety	Comply with ANSI AAMI ES 60601-1 requirements	Comply with ANSI AAMI ES 60601-1 requirements	Same
EMC	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	Same

Difference Discussion：

Note 1：Measuring range

The blood pressure measurement range of the predicate device is 40 to 260mmHg, while the measurement range of the proposed device under review has been further subdivided into 40 to 180mmHg (DIA diastolic pressure) and 60 to 260mmHg (SYS, systolic pressure). The actual measurement ranges for both are identical. Therefore, the difference is considered not raise any issues in safety and effectiveness.

Note 2：Power source

The charging method of the subject device is same as predicate device. While the specification of batteries and adaptors are different. The charging interface of the proposed device has been changed to Type-C interface (Note: Type-C port is limited to power delivery only and has no actual communication functionality). And the battery of the target device has been changed to 4* AAA batteries. The test results in IEC 60601-1 demonstrated that the proposed device is safety and the performance satisfied the specification. The difference will not raise new issue of safety and effectiveness.

Note 3：Operation condition

The operation condition of the subject device is different with predicate device LD-537 (K170466), the difference introduces risks tested and evaluated by verifying test in accordance with IEC 60601-1-11 and ANSI AAMI ES 60601-1 provided in this submission, therefore the difference will not raise new issues of safety and effectiveness.

Note 4: Transport and storage condition

The transport and storage condition of the subject device are different with predicate device LD-537 (K170466), the difference introduces risks tested and evaluated by verifying test in accordance with IEC 60601-1-11 and ANSI AAMI ES 60601-1 provided in this submission, therefore the difference will not raise new issues of safety and effectiveness.

Note 5: Main body dimension

As for LD-526, its dimension is different with predicate device LD-537 (K170466) will not affect the safety and effectiveness.

Note 6: Weight

The weight of subject device is different with predicate device LD-537 (K170466) will not affect the safety and effectiveness.

Conclusion

Based on above comparative analysis, compared with the predicate device LD-537 (K170466), the subject device will not raise new issues of safety and effectiveness. Thus, the subject device is as safe & 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 sphygmomanometers

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 a new safety issue.

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. Assessment of clinical testing

The subject device leverages the clinical testing data from its predicate device, model LD-537 (K170466). As demonstrated in the comparison table (Section 7), the subject device shares the same intended patient population (adults), identical blood pressure and pulse rate measurement ranges, and identical accuracy specifications (±3 mmHg for static pressure, ±5% of reading for pulse rate) as the predicate device. Both devices utilize the same fundamental oscillometric measurement principle and are intended for use in the same environments.

Given these core equivalencies in design, intended use, and performance specifications, the clinical data supporting the safety and effectiveness of the predicate device LD-537 is directly applicable and sufficient to support the substantial equivalence of the subject device model LD-526. The minor modifications identified in Discussions 1 through 6 are not related to clinical performance and do not affect the validity of the leveraged clinical data. Therefore, no new clinical studies are required for the subject device.

10. Conclusion

The subject devices have same intended use and similar characteristics as per the cleared predicate device. Moreover, bench testing contained in this submission supplied demonstrate that the differences between subject device 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 subject device performs as intended in the specified use conditions are same with predicate device. The performance tests demonstrate that the subject device performs comparably to the predicate device that is currently marketed for the same intended use. Thus, the subject device is substantially equivalent to the predicate device.