April 28, 2026

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

Re: K260260
Trade/Device Name: Automatic Digital Blood Pressure Monitor (LD-587, LD-528, LD-562, LD-581, LD-521, LD-527, LD-572, LD-569)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: April 2, 2026
Received: April 2, 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

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
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Office of Cardiovascular Devices
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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)*
K260260

Device Name
Automatic Digital Blood Pressure Monitor (LD-587, LD-528, LD-562, LD-581, LD-521, LD-527, LD-572, LD-569)

Indications for Use *(Describe)*
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.

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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Summary of special 510(K)

510K number: K260260

Date prepared: 22-April-2026

1. Submitter

Company:	HONSUN(Nantong)Co.,Ltd.
Establishment registration number:	3007740533
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2. Modified Device information

Name of Device:	Automatic Digital Blood Pressure Monitor
Model:	LD-587, LD-528, LD-562, LD-581, LD-521, LD-527, LD-572, LD-569
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 display. The cuff, which is applicable to arm circumference approximately between 22 and 32cm, 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

The Automatic Digital Blood Pressure Monitor is designed to measure the systolic and diastolic blood pressure and pulse rate of an individual by using a non-invasive technique in which an inflatable cuff is wrapped around the arm. Our method to define systolic and diastolic pressure is similar to the auscultatory method but uses an electronic semiconductor sensor rather than stethoscope and aneroid or mercurial manometer. The sensor converts tiny alterations in cuff pressure to electrical signals, by analyzing those signals to define the systolic and diastolic blood pressure and calculating pulse rate, which is a well-known technique in the market called the “oscillometric method”.

7. Comparisons of technological characteristic with the predicate device

Features	Subject Device	Predicate Device	Remark
General Comparison			
Applicant	HONSUN (NANTONG) Co., Ltd.	HONSUN (NANTONG) Co., Ltd.	/
Device name	Non-invasive blood pressure measurement system	Non-invasive blood pressure	/
Model	LD-587, LD-528, LD-562, LD-581, LD-521, LD-527, LD-572, LD-569	LD-537	
Classification	21 CFR 870.1130	21 CFR 870.1130	Same

Regulation			
Classification and Code	Class II, DXN	Class II, DXN	Same
Intended 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 warning signal once the irregular heartbeat is detected.	Discussion 1
Patient Populations	Adults	Adults	Same
Performance Comparison			
Principle	Oscillometric method	Oscillometric method	Same
Anatomical sites	Upper Arm	Upper Arm	Same
Where used (hospital, home, ambulance, etc.)	Hospital, clinics, home	Hospital, clinics ,home	Same
Blood Pressure Measureme	40 to 180 mmHg (DIA diastolic pressure) 60 to 260 mmHg (SYS, systolic	40 to 260 mmHg (blood pressure) 40 to 160 beats/minute	Discussion 2

nt	pressure) 40 to 160 beats/minute (PUL, pulse rate)		(pulse rate)	
Pulse rate measurement	±3 mmHg for static pressure ± 5% of the reading for the pulse rate		±3 mmHg for static pressure ±5% of the reading for the pulse rate	Same
Cuff Deflation	Automatic deflation		Automatic deflation	Same
Energy used and/or delivered	4*AA/AAA batteries; Type-C/Micro USB AC adapter		4xAA batteries；AC adapter	Discussion 3
Human factors	Blood pressure		Blood pressure	Same
Performance	Measuring systolic and diastolic blood pressure and pulse rate of adult individual		Measuring systolic and diastolic blood pressure and pulse rate of adult individual	Same
Compatibility with environment and other devices	Temperature: 5℃~40℃, Relative humidity :15%~90%RH, Atmospheric: 70KPa~106KPa.		Temperature: 10℃~40℃, Relative humidity :15%~85%RH, Atmospheric: 700hPa~1060hPa.	Discussion 4
Cuff range	22cm~32cm		22cm~42cm (Standard) 22cm~32cm(optional)	Same
Function	Memory recall:2*100 sets	LD-587/LD-528	● Memory recall:2*90 sets; ● Voice broadcast ● WHO Blood Pressure Classification Indication ● Setting the Date and Time ● Irregular Heartbeat Detector	Discussion 5
	Memory recall:2*90 sets	LD-562/LD-581/LD-527/LD-569		Same
	Memory recall: 90 sets	LD-521/LD-572		

	WHO Blood Pressure Classification Indication	LD-587/LD-528/LD-562/LD-581/LD-521/LD-527/LD-569		
	Voice broadcast	LD-587/LD-528		
	Irregular Heartbeat Detector	LD-587/LD-528/LD-562/LD-581/LD-521/LD-572/LD-527/LD-569		
	Setting the Date and Time	LD-587/LD-528		
EMC, Electrical and biological Safety Comparison				
Biocompatibility	Cuff, according to ISO-10993		Cuff, according to ISO-10993	Same
Electrical safety	According to IEC 60601-1-2 According to IEC 60601-1 According to IEC 60601-1-11		According to IEC 60601-1-2 According to IEC 60601-1 According to IEC 60601-1-11	Same

Justification of difference:

Discussion 1：Intended use

The indication for use is same as the predicate devices. They are intended for the measurement of systolic and diastolic arterial blood pressure and pulse rate. The difference description of the intended use occurred is considered not raise any issues in safety and effectiveness and they can be considered substantially equivalent in safety and effectiveness.

Discussion 2：Blood Pressure Measurement

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

Discussion 3：Energy used and/or delivered

The charging method of the proposed device is same as predicate device. While the

specification of batteries and adapters are different. The charging interface of the proposed device has been changed to Type-C/Micro USB port. Note: the micro-USB/Type-C port is limited to power delivery only and has no actual communication functionality. The battery of the target device has been changed to 4 * AA or 4AAA batteries. The test results in IEC 60601-1 demonstrated that the proposed device is safety and the performance satisfied the specification. Therefore, the difference is considered would not raise any issues in safety and effectiveness and they can be considered substantially equivalent.

Discussion 4：Compatibility with environment and other devices

The operation condition of the proposed device is different from predicate device. The IEC 60601-1and IEC60601-1-2 can prove equivalent safety and performance. Therefore, the difference is considered would not raise any issues in safety and effectiveness and they can be considered substantially equivalent.

Discussion 5：Function

The memory recall times of the proposed device is more than predicate device. The ISO 81060-2-30 can prove equivalent safety and performance. Therefore, the difference is considered would not raise any issues in safety and effectiveness and they can be considered substantially equivalent.

Conclusion

Based on above comparative analysis, the subject device performs comparably to the predicate device LD-537 (K170466). Thus, the subject device is 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. Clinical Testing

Clinical Data Leveraging Statement:

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 (hospital, clinic, home).

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 models LD-587, LD-528, LD-562, LD-581, LD-521, LD-527, LD-572, LD-569. The minor modifications identified in Discussions 1 through 5 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 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 (hospital, clinic, home).

Base on the performance tests and associate with the non-clinical testing`s assessment, the subject device performs comparably to the predicate device.

Furthermore, the clinical data from the predicate device (K170466) is leveraged and remains

valid for the subject device due to the identical patient population, measurement ranges, and accuracy specifications. Thus, the subject device is substantially equivalent to the predicate device.