July 23, 2026

Guangzhou Daxin Health Technology Co., Ltd.
Yanjuan (Jane) Zhu
RA
Rm. 510, Bldg. A02, Guangzhou Knowledge City International Leading Talent Agglomeration Area, # 5 Suike St., Huangpu District, Guangzhou, Guangdong, China
Rm. 601, Bldg. 3, # 9, Jinshagang Rd. 1, Dalang Town, Dongguan City Guangdong
Guangzhou, Guangdong 510700
China

Re: K261136
Trade/Device Name: Blood Pressure Monitor (M501, M501A, M502, M502A, M502C, M502D)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: April 7, 2026
Received: April 7, 2026

Dear Yanjuan (Jane) Zhu:

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.	K261136

Please provide the device trade name(s).

Blood Pressure Monitor (M501,M501A,M502,M502A,M502C,M502D)

Please provide your Indications for Use below.

The Eletronic Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person via non-invasive oscillometric technique in which an inflatable CUFF is wrapped around the upper arm.It can be used at home or in medical facilities.

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)

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 801.92.

Prepared on: March 28, 2026

1. Submitter's Information

Sponsor Name: Guangzhou Daxin Health Technology Co., Ltd.
Establishment Registration Number:
Address:Room 510, Building A02,Guangzhou Knowledge City International Leading Talent Agglomeration Area,No. 5 Suike Street,Huangpu District,Guangzhou,Guangdong,China.
Post Code: 510700
Contact name: LuPeng Guo,Zhu Yanjuan(Jane)
Tel: +86 020-82662446,0769-89060018,17324378052
Fax: /
E-mail: zhuyj@daxinhealth.com,guolp@daxinhealth.com
Manufacturer Address: Room 601, Building 3, No. 9, Jinshagang Road 1, Dalang Town, Dongguan City Guangdong
D-U-N-S Number: 722481840

Application Correspondent:

Contact Person: Ms.Jane Zhu
Guangzhou Daxin Health Technology Co., Ltd.
Address: Room 510, Building A02,Guangzhou Knowledge City International Leading Talent Agglomeration Area,No. 5 Suike Street,Huangpu District,Guangzhou,Guangdong,China.
Tel: +86 020-82662446,0769-89060018
Email: zhuyj@daxinhealth.com

2. Subject Device Information:

Subject Device Information
Type of 510(k): Traditional
Device Name:Blood pressure Monitor
Models: M501,M501A, M502, M502A, M502C, M502D
Classification Name: Clinical electronic thermometer.
Review Panel: Cardiovascular
Product Code: DXN
Regulation Number:21 CFR 870.1130
Regulatory Class: II

3. Predicate Device Information

Predicate Device (K222125)

Sponsor: Shenzhen AOJ Medical Technology Co., Ltd
Trade Name:Arm Blood Pressure Monitor
Model: AOJ-30B
Device Classification Name: System, Measurement, Blood-Pressure, Non-Invasive
Common Name: Arm Blood Pressure Monitor
Review Panel: Cardiovascular
Product Code: DXN
Regulation Number: 870.1130
Regulation Class: II

4. Device Description

The Eletronic Blood Pressure Monitor is used to measure the systolic and diastolic blood pressure as well as the pulse rate. It designed based on MCU technology which IC is SN8F5909(Bare Die:BP0004).It uses an air pump to inflate and pressurize the cuff, and uses the inflatable cuff to compress the arteries and blood vessels, so that the arteries and blood vessels are in a state of complete occlusion.Then open the bleed valve to slowly drop the pressure in the cuff. As the pressure in the cuff drops, the arteries are completely blocked-gradually open-fully-open. The pressure sensor collects the pressure in the cuff that changes in size, converts it into a digital signal and sends it to the CPU, uses embedded software to identify the corresponding pressure point in the process of blocked arterial blood flow, and obtains the body's diastolic and systolic blood pressure according to the software algorithm.The result of measurement displayed on the LCD screen.

The series models(M501,M501A,M502,M502A,M502C,M502D) share identical same circuit design, components, and internal wiring, differing only in model name, buttons, backlight color, and Bluetooth functionality(which do not affect the basic function).The structural composition and electrical principles of these models are identical the same,(M501 and M501A have 2 buttons,M502,M502A,M502C and M502D have 4 buttons,M501 and M501A are No-backlight,M502 and M502A are single-backlight,M502C and M502D are tricolor-backlight,M501,M502,M502C have no bluetooth function,M501A,M502A and M502D have bluetooth function).This device is intended for use on adults only,It can be used at home or in medical facilities.

The device has the data storage function in order for data reviewing, including the systolic pressure, diastolic pressure, pulse rate and measurement time. The result will be displayed in the international unit mmHg or kPa. The device also has low voltage indication, which will be triggered when the battery is low.The proposed device is intended to be used at homein or medical facilities.

The product is provided non-sterile, and not to be sterilized by the user prior to use.

All the models included in this submission follow the similar software, samemeasurement principle and same specifications. The differences existed between different models included in this submission will not affect the safety and effectiveness of the device.

The device is composed of the main body ,the cuff, 4xAAA batteries. The main body is composed of CPU , a pressure sensor, an air pump, a solenoid valve, a uniform speed vent valve, a PCB board, and an LCD liquid crystal display,software component.

5. Intended Use / Indications for Use

The Eletronic Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person via non-invasive oscillometric technique in which an inflatable CUFF is wrapped around the upper arm.It can be used at home or in medical facilities.

6. Comparison to predicate devices

Comparison to the predicate device, the subject device has same intended use, similar product design, same performance effectiveness, performance safety as the predicate devices. Please refer to following table to find differences between the subject device and predicate device. All the differences do not affect the basic design principle, usage,effectiveness and safety of the subject device. And no question is raised regarding to effectiveness and safety.

Table 1 Comparison between the subject device and the predicate device

Elements of Comparison	Subject Device	Primary Predicate Device (K222125)	Comparison Result
Manufacturer	Guangzhou Daxin Health Technology Co., Ltd	Shenzhen AOJ Medical Technology Co., Ltd.	N/A
Name of the Device	Blood Pressure Monitor	Arm Blood Pressure Monitor	Similar
Subject Device	M501,M501A,M502,M502A, 502C,M502D	AOJ-30B(K222125)	N/A
Intended Use/Indications for Use	The Eletronic Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person via non-invasive oscillometric technique in which an inflatable CUFF is wrapped around the upper arm.It can be used at home or in medical	The Electronic Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person via non-invasive oscillometric technique in which an inflatable	Similar

	facilities.	CUFF is wrapped around the upper arm at medical facilities or at home.	
Contraindications	Not Known	Not Known	Same
Application scenario	Medical Facilities and Home Use	Medical Facilities and Home Use	Same
Principle	Oscillometric	Oscillometric	Same
Measurement Item	SYS, DYS, Pulse Rate	SYS, DYS, Pulse Rate	Same
Patient population	Adult	Adult	Same
Measurement site	Upper arm	Upper arm	Same
Blood pressure measurement range	30-235 mmHg	30 - 255 mmHg	Different
Accuracy	± 3 mmHg	± 3 mmHg	Same
Heart rate measurement range	40-199 bpm	40-199 bpm	Same
Accuracy	± 5% of reading	± 5% of reading	Same
Cuff size	22 ~ 44 cm	22~36 cm	Different
Display	Blood Pressure (Systolic and Diastolic), Pulse rate, Date,	Blood Pressure (Systolic and Diastolic), Pulse rate, Date,	Same
	Time, WHO BP Classification Indicating Bar, Low Battery Icon, Heart Icon, Memory Record Number	Time, WHO BP Classification Indicating Bar, Low Battery Icon, Heart Icon, Memory Record Number	Same
Auto shutdown	YES	YES	Same

Operating environment	Temperature: 5°C~ 40°C Humidity: 15%–80% RH, Atmospheric pressure: 80 kPa - 105 kPa	Temperature: 5°C~ 40°C Humidity: 15%–90% RH, Atmospheric pressure: 70 kPa - 106 kPa	Different
Storage environment	Ambient Temperature: -20°C to 55°C Relative Humidity: 15-93% RH, Atmospheric pressure: 80 kPa - 105 kPa	Ambient Temperature: -20°C to 55°C Relative Humidity: 10-93% RH, Atmospheric pressure: 70 kPa - 106 kPa	Different
Battery type	6Vdc (4 *1.5VAAA batteries)	6Vdc (4 *1.5VAAA batteries)	Same
Weight	About 260± 5g without battery	AOJ-30A/AOJ-30B/ AOJ-30G:(262±5) g without battery;AOJ-30C: (316±5) g without battery;AOJ-30D: (349±5) g without battery; AOJ-30E: About 220 g without battery; AOJ-30F: About 220 g without battery	Different
Dimensions	134.5 mm * 102.5 mm * 67.3 mm	127 mm * 93 mm * 73 mm	Different
Patient Contacting	Surface-contacting, Less than 24 h	Surface-contacting, Less than 24 h	Same
Biocompatibility evaluation	Cytotoxicity, skin sensitization and irritation	Cytotoxicity, skin sensitization and irritation	Same
Electrical safety	IEC 60601-1 IEC 60601-1-11 ISO 80601-2-30	IEC 60601-1 IEC 60601-1-11 ISO 80601-2-30	Same
EMC	IEC 60601-1-2	IEC 60601-1-2	Same

Biocompatibility	ISO 10993-1 ISO 10993-5 ISO 10993-10	ISO 10993-1 ISO 10993-5 ISO 10993-10	Same
Data transmission	Has wireless function with Bluetooth and available for M501A,M502A and M502D only	Has wireless function with Bluetooth	Different

As seen in the comparison tables, the subject and predicate devices have almost the similar design features and performance specifications. As demonstrated in the bench testing, the different technological characteristics do not affect the safety and effectiveness of the subject device.

Note：

Note 1:Intended Use/Indications for Use：As indicated in the comparison table, the application scenario of the subject device and the predicate device both can be used both in hospital and home on the adults' upper arm, they have same indications for use, they are just some language description difference and different arm circumference sizes range.

Note 2: Blood pressure measurement range:The measurement range of subject device is different from the predicate device but are all in the range of WHO. And the performance testing shows that the subject device complies with the performance standard IEC 80601-2-30. Therefore, this difference does not affect the performance and safety questions.

Note 3: Cuff ： As the cuff is not a major performance device and has passed the biocompatibility test. The differences in the cuff do not affect any application of the device.

Performance Testing:

Performance data includes "Non-Clinical Data" and "Bench testing of the Clinical Data"（Checking the correction of the monitor meansurement of the blood pressure）.The brief description of which are shown as below.

Non-Clinical Data:

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

Biocompatibility testing:

The biocompatibility evaluation for the 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”, as recognized by FDA.The worst case of the whole system is considered tissue contacting for duration of less than 24 hours.The evaluation of biological safety of the applicable biological effect including :

- Skin Sensitization
- Skin Irritation
- Cytotoxicity

Electrical safety and electromagnetic compatibility (EMC):

Electrical safety and EMC testing were conducted on the device. The device complies with IEC TR 60601-4-2(Medical electrical equipment - Part 4-2: Guidance and interpretation- Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems) ,and with the IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance for safety, 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, and the 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 standard for EMC.

Bench Testing:

Bench testing was conducted on the device, consisting of all the accessories in the system. The system complies with the IEC 80601-2-30 Medical electrical equipment — Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers for performance effectiveness.The clinical bench testing has been conducted per ISO 81060-2:2018 Non-invasive sphygmomanometers - Part 2, Clinical validation of automated measurement type on the Sample representative M501（M501A,M502,M502A,502C,M502D）to do the clinic testing,and the clinical validation data on the models can cover all the models included in this submission.95subjects were involved for each study.Detailed information about the Subject number,Gender distribution,Age distribution,Blood pressure distribution, Subject preparation,Observer preparation,Reference determina tion,Clinical investigation methods and Data analysis are referred to ISO 81060-2: 2018 without any deviation.Through the research to confirm the effectiveness, usability,stability and safety of the Blood plessure monitor.

Software Verification and Validation Testing:

Software verification and validation testing were conducted and documentation 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." The software for this device was considered as a "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Cybersecurity:

The Cybersecurity verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance,including Cyber security vulnerabilities, cyber penetration testing,Identity verification, Authorization, Cryptography,Code, data and execution integrity,Confidential,Event detection and log recording,Elasticity and recovery,Firmware and software updates,and the risk control management had documented.

Summary:

Regarding the validation required in Performance Testing,Biocompatibility testing,EMC,FCC,Bench Testing,Software Verification and Validation Testing,Cybersecurity, and the others aspects,The data were provided in support of the substantial equivalence determination.

Conclusion:

Verification and validation testing was conducted on the subject device and all testing passed pre-specified criteria.This premarket notification submission demonstrates that the M501,M501A,M502,M502A,502C,M502D series Arm Blood Pressure Monitor is substantially equivalent to the predicate devices.