April 22, 2024

Andon Health Co Ltd
Yi Liu
President
No. 3 Jin Ping Street,Ya An Road
Nankai District
Tianjin, Tianjin 300190
China

Re: K234041
Trade/Device Name: Fully Automatic Electronic Blood Pressure Monitor (KD-5811VA);
Fully Automatic Electronic Blood Pressure Monitor (KD-5811BT);
Fully Automatic Electronic Blood Pressure Monitor (KD-5810VA);
Fully Automatic Electronic Blood Pressure Monitor (KD-5810BT);
Fully Automatic Electronic Blood Pressure Monitor (KD-5920VA);
Fully Automatic Electronic Blood Pressure Monitor (KD-5920BT);
Fully Automatic Electronic Blood Pressure Monitor (KD-5923TS)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: April 1, 2024
Received: April 1, 2024

Dear Yi Liu:

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.

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

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.

Submission Number *(if known)*

K234041

Device Name

Fully Automatic Electronic Blood Pressure Monitor (KD-5811VA);
Fully Automatic Electronic Blood Pressure Monitor (KD-5811BT);
Fully Automatic Electronic Blood Pressure Monitor (KD-5810VA);
Fully Automatic Electronic Blood Pressure Monitor (KD-5810BT);
Fully Automatic Electronic Blood Pressure Monitor (KD-5920VA);
Fully Automatic Electronic Blood Pressure Monitor (KD-5920BT);
Fully Automatic Electronic Blood Pressure Monitor (KD-5923TS)

Indications for Use *(Describe)*

Fully Automatic Electronic Blood Pressure Monitor is for use by medical professionals or at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is limited to 17cm-48cm (approx. 6 11/16″- 18 29/32″).

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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510(k) Summary

(In accordance with 21 CFR 807.92)

1.0 Submitter's Information

Name:	Andon Health Co., Ltd.
Address:	No 3, Jinping Street, Ya An Road, Nankai District, Tianjin, 300190, P.R. China
Phone Number:	86-22-87611660
Fax Number:	86-22-87612379
Contact:	Mr. Liu Yi
Date of Preparation:	January 29, 2024

2.0 Device Information

Device Name:	Fully Automatic Electronic Blood Pressure Monitor
Common Name:	Non-Invasive Blood Pressure Measurement System
Classification Name:	Non-Invasive Blood Pressure Measurement System

3.0 Classification

Product Code:	DXN
Regulation Number:	21 CFR 870.1130
Classification:	II
Review Panel:	870 Cardiovascular

4.0 Predicate Device Information

Manufacturer:	Andon Health Co., Ltd.
Device:	Fully Automatic Electronic Blood Pressure Monitor
510(k) Number:	K210770
Classification	II
Product Code	DXN

5.0 Intended Use

Fully Automatic Electronic Blood Pressure Monitor is for use by medical professionals or at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff

circumference is limited to 17cm-48cm (approx. 6 11/16″- 18 29/32″).

6.0 Device Description

Fully Automatic Electronic Blood Pressure Monitor is designed and manufactured according to IEC 80601-2-30.

The operational principle is based on oscillometric and silicon integrates pressure sensor technology. It can calculate the systolic and diastolic blood pressure, the measurements results can also be classified. If any irregular heartbeat is detected, it can be shown to the user.

7.0 Comparison of Technological Characteristics with Predicate Device

The following table is the summary of the technological characteristics of the proposed subject device and predicate device.

Item	**Subject Device** (KD-5811VA, KD-5811BT, KD-5810VA, KD-5810BT, KD-5920VA, KD-5920BT, KD-5923TS)	**Predicate Device** (KD-5811 K210770)	**Comparison Result**
Name and mode	Fully Automatic Electronic Blood Pressure Monitor	Fully Automatic Electronic Blood Pressure Monitor	Same
Model	KD-5811VA, KD-5811BT, KD-5810VA, KD-5810BT, KD-5920VA, KD-5920BT, KD-5923TS	KD-5811	--
Intended use	Fully Automatic Electronic Blood Pressure Monitor is for use by medical professionals or at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is limited to 17cm-48cm (approx. 6 11/16″ - 18 29/32″).	Fully Automatic Electronic Blood Pressure Monitor is for use by medical professionals or at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is limited to 22cm-48cm.	Different [1] (Note 1)
Rx or OTC	OTC	OTC	Same
Population	Adult	Adult	Same
Cuff Location	Upper arm	Upper arm	Same
Physical Attributes			
Weight (exclude batteries and cuff)	KD-5811VA, KD-5811BT: Approx. 239g (8 7/16 oz.) KD-5810VA, KD-5810BT: Approx. 191g (6 3/4oz.)	About 239g	Different [2] (Note 2)

Item	**Subject Device** **(**KD-5811VA, KD-5811BT, KD-5810VA, KD-5810BT, KD-5920VA, KD-5920BT, KD-5923TS**)**	**Predicate Device** (KD-5811 K210770)	**Comparison Result**
	KD-5920VA, KD-5920BT: Approx. 235g (8 9/32oz.) KD-5923TS: Approx. 166g (5 27/32 oz.)		
Dimensions	KD-5811VA, KD-5811BT: Approx.139.4mm×93.8mm×43.4mm (5 1/2″ × 3 11/16″ × 1 23/32″) KD-5810VA, KD-5810BT: Approx.139.4mm×93.8mm×41.8mm (5 1/2″ × 3 11/16″ × 1 21/32″) KD-5920VA, KD-5920BT: Approx.150mm×95mm×41mm (5 29/32″ × 3 3/4″ × 1 5/8″) KD-5923TS: Approx.107mm×80mm×52mm (4 7/32″ × 3 5/32″ × 2 1/16″)	139.4mm×93.8mm×43.4mm	Different [3] (Note 3)
Memory	KD-5811VA, KD-5811BT, KD-5810VA, KD-5810BT, KD-5920VA, KD-5920BT: 2×120 times KD-5923TS: 4×30 times	2×120 times 2×60 times 2×30 times	Different [4] (Note 4)
Displayed Calculated Parameters	SYS DIA Pulse IHB	SYS DIA Pulse IHB	Same
Wireless Function	KD-5811BT, KD-5810BT, KD-5920BT: Bluetooth wireless transmission function KD-5811VA, KD-5810VA, KD-5920VA, KD-5923TS: None	None	Different [5] (Note 5)
Voice Function	KD-5811VA, KD-5810VA, KD-5920VA: Voice guidance test procedure function KD-5811BT, KD-5810BT, KD-5920BT, KD-5923TS: None	None	Different [6] (Note 6)
Body Movement Reminder	KD-5811VA, KD-5811BT, KD-5810VA, KD-5810BT, KD-5920VA, KD-5920BT and KD-5923TS:	None	Different [7] (Note 7)

Item	**Subject Device (**KD-5811VA, KD-5811BT, KD-5810VA, KD-5810BT, KD-5920VA, KD-5920BT, KD-5923TS**)**	**Predicate Device** (KD-5811 K210770)	**Comparison Result**
	Body movement reminder function		
Cuff Wrap Reminder	KD-5811VA, KD-5811BT, KD-5810VA, KD-5810BT, KD-5920VA, KD-5920BT and KD-5923TS: Cuff wrap reminder function	None	Different [8] (Note 8)
Electrical Power			
Battery	KD-5811VA, KD-5811BT, KD-5810VA, KD-5810BT: 4 ×1.5V SIZE AA KD-5920VA, KD-5920BT, KD-5923TS: 4 ×1.5V SIZE AAA	4 ×1.5V SIZE AA	Different [9] (Note 9)
Environmental Operation			
Temperature	5℃～40℃(41℉～104℉)	10~40℃	Different [10] (Note 10)
Humidity	≤85%RH	≤85%	Same
Environmental Storage			
Temperature	-20℃～55℃(-4℉～131℉)	-20~50℃	Different [11] (Note 11)
Humidity	≤90%RH	≤85%	Different [12] (Note 12)
Performance NIBP			
Pulse Rate Range	40-180 beats/minute	40 -180times/min	Same
Pulse Rate Accuracy	Less than 60: ±3bpm More than 60 (incl.): ±5%	Less than 60: ±3bpm More than 60 (incl.): ±5%	Same
Technique/ Method	Oscillometric	Oscillometric	Same
Pressure Accuracy	Within±3mmHg	Within ±3mmHg	Same
Cuff Pressure Range	0-300mmHg	0-300mmHg	Same
Over pressure Limit	300mmHg	300mmHg	Same

Note 1: The cuff range has changed, but the clinical report we submitted confirmed that the subjected devices are as safe and effective as the predicate.

Note 2: Some of the device weight has changed, but the electrical safety report and the EMC report we submitted confirmed that the subjected devices are as safe and effective as the predicate.

Note 3: Some of the device dimensions have changed, but the electrical safety report and the EMC report we submitted confirmed that the subjected devices are as safe and effective as the predicate.

Note 4: Some of the device memory times have changed, but the software validation we submitted confirmed that the subjected are as safe and effective as the predicate.

Note 5: Bluetooth wireless transmission function has been added to some models, but the software validation

we submitted confirmed that the subjected are as safe and effective as the predicate.

Note 6: Voice function has been added to some models, but the software validation we submitted confirmed that the subjected are as safe and effective as the predicate.

Note 7: The body movement reminder function has been added to all subject models, but the software validation we submitted confirmed that the subjected are as safe and effective as the predicate.

Note 8: The cuff wrap reminder function has been added to all subject models, but the software validation we submitted confirmed that the subjected are as safe and effective as the predicate.

Note 9: The battery volume of some new models has changed, but the electrical safety report we submitted confirmed that the subjected devices are as safe and effective as the predicate.

Note 10: The temperature range of all the new models are changed, but the performance report we submitted confirmed that the subjected devices are as safe and effective as the predicate.

Note 11: The temperature range of all the new models are changed, but the performance report we submitted confirmed that the subjected devices are as safe and effective as the predicate.

Note 12: The humidity range of all the new models are changed, but the performance report we submitted confirmed that the subjected devices are as safe and effective as the predicate.

There are no significant differences between the two products and are identical in terms of intended use, materials, design, manufacturing methods.

8.0 Discussion of Non-Clinical Testing

Non-clinical tests conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1: 2005+AMD1: 2012+AMD2:2020 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-2:2014+A1:2020Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests
- 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
- IEC 80601-2-30: Edition 2.0 2018-03 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

None of the test demonstrates that the new Blood Pressure Monitors bring new questions of safety and effectiveness.

9.0 Clinical Test

Clinical test has been performed in accordance with ISO 81060-2.
For the cuff size with 15-24 cm, 20-34 cm, 30-44 cm, 15-24 cm, 22-42 cm， and 42-48 cm, 231 patients (107 males and 124 females) were invited for the study, standard auscultation method was used as the reference blood pressure monitor measuring, and same sequential method was chosen. Accuracy of the blood pressure monitors was verified by meeting criteria 1 and criteria 2 of ISO 81060-2.

10.0 Conclusion

The conclusion drawn from the nonclinical tests and clinical test demonstrate that the subject device Fully Automatic Electronic Blood Pressure Monitor (KD-5811VA, KD-5811BT, KD-5810VA, KD-5810BT, KD-5920VA, KD-5920BT and KD-5923TS) is substantially equivalent to the Fully Automatic Electronic Blood Pressure Monitor KD-5811 (K210770).