



February 15, 2023

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

Re: K222869

Trade/Device Name: Fully Automatic Electronic Blood Pressure Monitor  
Regulation Number: 21 CFR 870.1130  
Regulation Name: Noninvasive Blood Pressure Measurement System  
Regulatory Class: Class II  
Product Code: DXN  
Dated: December 26, 2022  
Received: January 4, 2023

Dear Liu Yi:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Robert T. Kazmierski -S**

for

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

## Indications for Use

510(k) Number (if known)  
K222869

Device Name  
Fully Automatic Electronic Blood Pressure Monitor

### 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 22cm-48cm.

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.

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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: September 15, 2022

### **2.0 Device Information**

Device Name: Fully Automatic Electronic Blood Pressure Monitor  
Common Name: Arm Blood Pressure Monitor  
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 22cm-48cm.

## 6.0 Device Description

Fully Automatic Electronic Blood Pressure Monitor ( KD-5811A, KD-5811V and KD-5815) 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, and display the result on the LCD. The measurements results can also be classified by the function of blood pressure classification indicator. 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	Predicate Device (KD-5811 K210770)	Comparison Result
Name and mode	Fully Automatic Electronic Blood Pressure Monitor	Fully Automatic Electronic Blood Pressure Monitor	--
Model	KD-5811A, KD-5811V, KD-5815	KD-5811	--
Rx or OTC	OTC	OTC	Same
Population	Adult	Adult	Same
Cuff Location	Upper arm	Upper arm	Same
<b>Physical Attributes</b>			
Weight (exclude batteries and cuff)	KD-5811A: About 223g KD-5811V: About 239g KD-5815: About 189g	About 239g	KD-5811V is same with predicate. KD-5811A and KD-5815 are changed.
Dimensions	KD-5811A: 139.4mm×93.8mm×42mm KD-5811V: 139.4mm×93.8mm×43.4mm KD-5815: 138mm×98mm×48.9mm	139.4mm×93.8mm×43.4mm	KD-5811V is same with predicate. KD-5811A and KD-5815 are changed.
Memory	KD-5811A, KD-5811V: 2×120 times 2×60 times 2×30 times	2×120 times 2×60 times 2×30 times	KD-5811A and KD-5811V are same with predicate.

Item	Subject Device	Predicate Device (KD-5811 K210770)	Comparison Result
	KD-5815: 1×60 times		KD-5815 is less memory times than predicate..
Displayed Calculated Parameters	SYS DIA Pulse IHB	SYS DIA Pulse IHB	Same
Display component	KD-5811A, KD-5811V: LCD with backlight  KD-5815: LCD	LCD with backlight	KD-5811A and KD-5811V are same with predicate. KD-5815 is without backlight.
Average function	1.Average value of all results in the current user memory zone. 2.Average the value of the latest 3 times.	1.Average value of all results in the current user memory zone. 2.Average the value of the latest 3 times	Same
Other Displayed Information	KD-5811A: Date Time Memory Battery usage Blood pressure classification Bodymove  KD-5811V: Date Time Memory Battery usage Blood pressure classification  KD-5815 Memory Battery usage Blood pressure classification	Date Time Memory Battery usage Blood pressure classification	KD-5811A is more function than predicate.  KD-5811V is same with predicate.  KD-5815 is less function than predicate.
<b>Electrical Power</b>			
DC Mains	5V	6V	Changed
Battery	4 ×1.5V SIZE AA	4 ×1.5V SIZE AA	Same

Item	Subject Device	Predicate Device (KD-5811 K210770)	Comparison Result
<b>Environmental Operation</b>			
Temperature	10~40°C	10~40°C	Same
Humidity	≤85%	≤85%	Same
<b>Environmental Storage</b>			
Temperature	-20~50°C	-20~50°C	Same
Humidity	≤85%	≤85%	Same
<b>Performance NIBP</b>			
Pulse Rate Range	40 -180times/min	40 -180times/min	Same
Pulse Rate Accuracy	Within ±5%	Within ±5%	Same
Technique/ Method	Oscillometric	Oscillometric	Same
Measure process	Measure during deflating	Measure during deflating	Same
Pressure Accuracy	Within ±3mmHg	Within ±3mmHg	Same
Cuff Pressure Range	0-300mmHg	0-300mmHg	Same
Overpressure Limit	300mmHg	300mmHg	Same
Algorithm	Amplitude	Amplitude	Same

There are no significant differences between the two products and they 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/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-2:2014, 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 Edition 2.0 2015-01 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 demonstrate that the new Blood Pressure Monitors raises new questions of safety and effectiveness as compared to the predicate.

### **9.0 Clinical Test**

Comparison and evaluation are carried out between the subject device and cleared devices, and it is showed that:

The proposed devices KD-5811A, KD-5811V and KD-5815 has the same algorithm and design principle with cleared device KD-5961 (K083246), so the clinical test report of KD-5961 can be used as a reference when considering the clinical effect of KD-5811A, KD-5811V and KD-5815.

Accuracy of the blood pressure monitors for the clinical test report was verified by meeting criteria 1 and criteria 2 of ISO 81060-2.

### **10. Comparison to the Predicate Device and Conclusion**

The conclusion drawn from the nonclinical tests and clinical test demonstrate that the subject device Fully Automatic Electronic Blood Pressure Monitor (KD-5811A , KD-5811V, and KD-5815) is substantially equivalent to the Fully Automatic Electronic Blood Pressure Monitor KD-5811 (K210770).

The subject devices are very similar with its predicate device in the intended use, design principle, materials, performance and applicable standards. Their appearance, the memory capacity, displayed information, DC mains and MCU is different.

However, the tests in this submission demonstrates that these small differences do not raise any new questions of safety and effectiveness. And the subject device is as safe and effective as the legally marketed predicate K210770.