July 29, 2021

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

Re: K210770
Trade/Device Name: Arm Blood Pressure Monitor, Wireless Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: June 24, 2021
Received: July 1, 2021

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer Shih Kozen
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210770

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.

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:	March 1, 2021

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.	Andon Health Co., Ltd.
Device:	Fully Automatic Electronic Blood Pressure Monitor	Wireless Electronic Blood Pressure Monitor
510(k) Number:	K183534	K162668
Classification	II	II
Product Code	DXN	DXN

5.0 Indications for 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-5810, KD5810B, KD-5811, KD-5920TL and KD-552) 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-5031M** K183534**)**	**Predicate Device (KD-926) (**K162668**)**	**Comparison Result**
Name and mode	Fully Automatic Electronic Blood Pressure Monitor	Fully Automatic Electronic Blood Pressure Monitor	Wireless Electronic Blood Pressure Monitor	--
Model	KD-5810, KD5810B, KD-5811, KD-5920TL KD-552	KD-5031M	KD-926	--
Rx or OTC	OTC	OTC	OTC	Same
Population	Adult	Adult	Adult	Same
Cuff Location	Upper arm	Upper arm	Upper arm	Same
Physical Attributes				
Weight (exclude batteries and cuff)	KD-5810: About 191g KD-5810B: About 180g KD-5811: About 239g KD-5920TL:About 235g KD-552: About 270g	About 300g	About 234g	Changed
Dimensions	KD-5810: 139.4mm×93.8mm×41.8mm KD-5810B: 139.4mm×93.8mm×41.8mm	165mmx96mm x65mm	145mm×90mm ×51mm	Changed

Item	Subject Device	Predicate Device (KD-5031M K183534)	Predicate Device (KD-926) (K162668)	Comparison Result
	KD-5811: 139.4mm×93.8mm×43.4mm KD-5920TL: 150mm×95mm× 41mm KD-552: 158.5mm×92.3mm×76.7mm			
Memory	KD-5810, KD-5810B, KD-5920TL& KD-552: 2×120 times 4×60 times 2×60 times 4×30 times KD-5811: 2×120 times 2×60 times 2×30 times	1×120 times 1×60 times 2×60 times 4×30 times	2×60 times	More memory function on meter
Displayed Calculated Parameters	SYS DIA Pulse IHB	SYS DIA Pulse IHB	SYS DIA Pulse IHB	Same
Display component	KD-5810, KD-5811, KD-5920TL &KD-552: LCD with backlight KD-5810B: LCD	LCD	1. LCD 2. Display on Smart Phone	Similar
Average function	KD-5810, KD-5810B, KD-5920TL& KD-552: 1.Average value of all results in the current user memory zone. 2. Average the value of the latest 3 times 3. Average value of all the results in last 7 days AM 4. Average value of all the results in last 7 days PM KD-5811:	Average the value of the latest 3 times	Averaging of the last three times measurement	More functions are added

Item	Subject Device	Predicate Device (KD-5031M K183534)	Predicate Device (KD-926) (K162668)	Comparison Result
	1. Average value of all results in the current user memory zone. 2. Average the value of the latest 3 times			
Other Displayed Information	Date Time Memory Battery usage Blood pressure classification	Date Time Memory Battery usage Blood pressure classification	Date Time Memory Battery usage Blood pressure classification (Displayed on device)	Similar
Electrical Power				
DC Mains	6V	6V	6V	Same
Battery	KD-5810, KD-5810B, KD-5811, & KD-552: 4 ×1.5V SIZE AA KD-5920TL: 4 ×1.5V SIZE AAA	4 ×1.5V SIZE AAA	4 ×1.5V SIZE AAA	Same
Environmental Operation				
Temperature	10~40℃	10~40℃	10~40℃	Same
Humidity	≤85%	≤85%	≤85%	Same
Environmental Storage				
Temperature	-20~50℃	-20~50℃	-20~50℃	Same
Humidity	≤85%	≤85%	≤85%	Same
Performance NIBP				
Pulse Rate Range	40 -180times/min	40 -180times/min	40 -180times/min	Same
Pulse Rate Accuracy	Within ±5%	Within ±5%	Within ±5%	Same
Technique/ Method	Oscillometric	Oscillometric	Oscillometric	Same
Measure process	KD5810, KD-5810B, KD-5811, & KD-5920TL: Measure during deflating	Measure during deflating	Measure during inflating	KD-5810, KD-5810B, KD-5811 and KD-5920TL are same with

Item	Subject Device	Predicate Device (KD-5031M K183534)	Predicate Device (KD-926) (K162668)	Comparison Result
	KD-552: Measure during inflating			predicate KD-5031M, and KD-552 are same with predicate KD-926
Pressure Accuracy	Within ±3mmHg	Within ±3mmHg	Within ±3mmHg	Same
Cuff Pressure Range	0-300mmHg	0-300mmHg	0-300mmHg	Same
Overpressure Limit	300mmHg	300mmHg	300mmHg	Same
Algorithm	Amplitude	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 were 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 80601-2-30:2009 & A1:2013,Medical Electrical Equipment - Part 2-30: Particular Requirements For The Basic Safety And Essential Performance Of Automated Noninvasive Sphygmomanometers

None of the tests 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-5810, KD-5810B, KD-5811 and KD-5920TL has the same algorithm and design principle with cleared device KD-5961 (K083246), so the clinical test report of KD-5961can be used as a reference when considering the clinical effect of KD-5810, KD-5810B, KD-5811 and KD-5920TL.

The proposed devices KD-552 has the same algorithm and design principle with cleared device BP3 (K102939) and BP5 (K120672), so the clinical test report of BP3 (K102939) and BP5 (K120672) can be used as a reference when considering the clinical effect of KD-552.

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-5810, KD-5810B, KD-5811, KD-5920TL and KD-552), is substantially equivalent to the Fully Automatic Electronic Blood Pressure Monitor KD-5031M (K183534) and KD-926 (K162668).

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, the average function, 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, as effective and performs as well as or better than the legally marketed predicate K183534 and K162668.