July 30, 2021

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

Re: K210768
Trade/Device Name: Wrist 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)*
K210768

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 wrist. The cuff circumference is limited to 14cm-25cm.

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:	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.	Andon Health Co., Ltd.
Device:	Fully Automatic Electronic Blood Pressure Monitor	Wireless Blood Pressure Wrist Monitor
510(k) Number:	K183535	K163276
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 wrist. The cuff circumference is limited to 14cm-25cm.

6.0 Device Description

Fully Automatic Electronic Blood Pressure Monitor (KD-743V, KD-743B, KD-752) 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 (KD-743V, KD-743B, KD-752)**	**Predicate Device (KD-753** K183535**)**	**Predicate Device (KD-721)** (K163276**)**	**Comparison Result**
Name and mode	Fully Automatic Electronic Blood Pressure Monitor	Fully Automatic Electronic Blood Pressure Monitor	Fully Automatic Electronic Blood Pressure Monitor	Same
Model	KD-743V, KD-743B KD-752	KD-753	KD-721	--
Rx or OTC	OTC	OTC	OTC	Same
Population	Adult	Adult	Adult	Same
Cuff Location	Wrist	Wrist	Wrist	Same
Physical Attributes				
Weight (exclude batteries and cuff)	KD-743V: 80g KD-743B: 78g KD-752: 80g	71g	About 67g	Changed
Dimensions	KD-743V: 87mm×66.3mm×33.3mm KD-743B: 87mm×66.3mm×33.3mm KD-752: 100mm×70mm×23.5mm	83mm×74mm ×26mm	78mm×60mm ×28mm	Changed

Item	Subject Device (KD-743V, KD-743B, KD-752)	Predicate Device (KD-753 K183535)	Predicate Device (KD-721) (K163276)	Comparison Result
Memory	KD-743V& KD-743B: 1×120 times 1×60 times 2×60 times 4×30 times KD-752: 2×120 times 4×60 times 2×60 times 4×30 times	1×120 times 1×60 times 2×60 times 4×30 times	2×60 times	KD-743V& KD-743B are same with predicate device KD-753 KD-752 add more memory function on meter
Displayed Calculated Parameters	SYS DIA Pulse IHB	SYS DIA Pulse IHB	SYS DIA Pulse IHB	Same
Display component	KD-743V& KD-743B: LCD KD-752: LCD with backlight	LCD	LCD	KD-743V& KD-743B are same with predicate device KD-752 add additional backlight
Average function	KD-743V& KD-743B: 1. Average value of all results in the current user memory zone. 2. Average the value of the latest 3 times KD-752: 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	1. Average value of all results in the current user memory zone. 2. Average the value of the latest 3 times	average value of all the results measured from 5 o'clock to 9 o'clock in last 7 days	KD-743V& KD-743B are same with predicate device KD-753 KD-752 add more functions

Item	Subject Device (KD-743V, KD-743B, KD-752)	Predicate Device (KD-753 K183535)	Predicate Device (KD-721) (K163276)	Comparison Result
	the results in last 7 days PM			
Other Displayed Information	Date Time Memory Battery usage Blood pressure classification	Date Time Memory Battery usage Blood pressure classification	Date Time Memory Battery usage Bluetooth symbol Blood pressure classification (Displayed on device)	Similar
Electrical Power				
DC Mains	3V	3V	3V	Same
Battery	2 ×1.5V SIZE AAA	2 ×1.5V SIZE AAA	2 ×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	KD-743V& KD-743B: Measure during deflating KD-752: Measure during inflating	Measure during deflating	Measure during inflation	KD-743V& KD-743B are same with predicate device KD-753 KD-752 are same with predicate device KD-721
Pressure Accuracy	Within ±3mmHg	Within ±3mmHg	Within ±3mmHg	Same

Item	Subject Device (KD-743V, KD-743B, KD-752)	Predicate Device (KD-753 K183535)	Predicate Device (KD-721) (K163276)	Comparison Result
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 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 raise 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-743V and KD-743B has the same algorithm and design principle with cleared device KD-7961 (K090769), so the clinical test report of KD-7961 can be used as a reference when considering the clinical effect of KD-743V and KD-743B.

The proposed devices KD-752 has the same algorithm and design principle with cleared device KD-972 (K121470), and so the clinical test report of KD-972 can be used as a reference when considering the clinical effect of KD-752.

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-743V, KD-743B, KD-752), is substantially equivalent to the Fully Automatic Electronic Blood Pressure Monitor KD-753 whose 510(k) number is K183535 and KD-721 whose 510(k) number is K163276.

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 is different, and MCU used is different.

However, the tests in this submission demonstrates that these 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 K183535 and K163276.