August 4, 2025

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

Re: K251113

Trade/Device Name: iHealth Compare Wireless Blood Pressure Monitor (BP-300C);
iHealth Compare Pro Wireless Blood Pressure Monitor (BP-300CV);
iHealth Compare S Wireless Blood Pressure Monitor (BP-300V);
iHealth Wireless Blood Pressure Monitor (BPX1);
iHealth Blood Pressure Monitor (KD-595);
iHealth Track Pro Connected Blood Pressure Monitor (KN-550LT);
Semi Automatic Blood Pressure Monitor (KD-388N);
Arm Blood Pressure Monitor(KD-553);
Arm Blood Pressure Monitor(KD-557BR);
Arm Blood Pressure Monitor(KD-558);
Arm Blood Pressure Monitor(KD-558BR);
Arm Blood Pressure Monitor (KD-5031N);
Arm Blood Pressure Monitor (KD-5810);
Arm Blood Pressure Monitor (KD-5810B);
Arm Blood Pressure Monitor (KD-5811);
Arm Blood Pressure Monitor (KD-5811A);
Arm Blood Pressure Monitor (KD-5811V);
Arm Blood Pressure Monitor (KD-5815);
Arm Blood Pressure Monitor (KD-5920);
Arm Blood Pressure Monitor (KD-5920L);
Arm Blood Pressure Monitor (KD-5920TL);
Arm Blood Pressure Monitor (KD-5923);
iHealth Clear Wireless Blood Pressure Monitor (BPM1)

Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: July 7, 2025
Received: July 7, 2025

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 (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.

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

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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251113

Please provide the device trade name(s).

iHealth Compare Wireless Blood Pressure Monitor (BP-300C);
iHealth Compare Pro Wireless Blood Pressure Monitor (BP-300CV);
iHealth Compare S Wireless Blood Pressure Monitor (BP-300V);
iHealth Wireless Blood Pressure Monitor (BPX1);
iHealth Blood Pressure Monitor (KD-595);
iHealth Track Pro Connected Blood Pressure Monitor (KN-550LT);
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Arm Blood Pressure Monitor (KD-5920);
Arm Blood Pressure Monitor (KD-5920L);
Arm Blood Pressure Monitor (KD-5920TL);
Arm Blood Pressure Monitor (KD-5923);
iHealth Clear Wireless Blood Pressure Monitor (BPM1)

Please provide your Indications for Use below.

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 noninvasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is limited to 15cm-48cm (approx. 5.9″-18.9″).

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (Part 21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) SUMMARY

(In accordance with 21 CFR 807.92)

1.0 Applicant 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:	04/11/2025

2.0 Device Information

Device Name:	BP-300C: iHealth Compare Wireless Blood Pressure Monitor BP-300CV: iHealth Compare Pro Wireless Blood Pressure Monitor BP-300V: iHealth Compare S Wireless Blood Pressure Monitor BPX1: iHealth Wireless Blood Pressure Monitor KD-595: iHealth Blood Pressure Monitor KN-550LT: iHealth Track Pro Connected Blood Pressure Monitor KD-388N: Semi Automatic Blood Pressure Monitor KD-553, KD-557BR, KD-558, KD-558BR, KD-5031N, KD-5810, KD-5810B, KD-5811, KD-5811A, KD-5811V, KD-5815, KD-5920, KD-5920L, KD-5920TL, KD-5923: Arm Blood Pressure Monitor BPM1: iHealth Clear Wireless Blood Pressure Monitor

Common Name:	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 Name:	Fully Automatic Electronic Blood Pressure Monitor
510(k) Number:	K234041
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 15cm - 48cm (approx.5.9″ ~18.9″).

6.0 Device Description

Fully Automatic Electronic Blood Pressure Monitor (BP-300C, BP-300CV,

BP-300V, BPM1, BPX1, KD-338N, KD-553, KD-557BR, KD-558, KD-558BR, KD-595, KD-5031N, KD-5810, KD-5810B, KD-5811, KD-5811A, KD-5811V, KD-5815, KD-5920, KD-5920L, KD-5920TL, KD-5923, KN-550LT) is designed and manufactured according to IEC 80601-2-30.

The operational principle is based on Oscillo-metric and silicon integrates pressure sensor technology. It can calculate the systolic and diastolic blood pressure and display the result. 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** **Model: KD-5811BT** **510(k) No.: K234041**	**Comparison Result**
Name and Model	iHealth Compare Wireless Blood Pressure Monitor iHealth Track Pro Connected Blood Pressure Monitor Semi Automatic Blood Pressure Monitor Arm Blood Pressure Monitor BPM1: iHealth Clear Wireless Blood Pressure Monitor	Fully Automatic Electronic Blood Pressure Monitor	--
Intended Use	Fully Automatic Electronic Blood Pressure Monitor is for use by	Fully Automatic Electronic Blood Pressure Monitor is for	The cuff range of subject device is different from the predicate device, but the

	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 15cm-48cm (approx. 5.9”-18.9”).	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-42cm (approx. 6 11/16”-16 17/32”)	clinical report submitted demonstrates that the subject devices are as safe and effective as the predicate device.
Rx or OTC	OTC	OTC	Same
Population	Adult	Adult	Same
Cuff Location	Upper arm	Upper arm	Same
Physical Attributes			
Weight (exclude batteries and cuff)	About 328g About 290g About 330g About 200g About 220g About 300g About 211g About 166g About 235g About 221g About 232g About 237g About 239g About 223g About 189g About 225g About 233g About 191g About180g About 350g	About 239g	The electrical safety report and EMC report submitted demonstrate that the subject devices are as safe and effective as the predicate device.
Dimensions	144.5mm×115mm×60.7mm 136mm×106mm×61mm 98mm×98mm×46mm 153mm×108mm×60mm 136mm×94mm×52mm 165mm×96mm×65mm 138mm×98mm×48mm 107mm×80mm×52mm 150mm×95mm×41mm 139.4mm×93.8mm×43.4	139.4mm×93.8mm×43.4mm	The electrical safety report and EMC report submitted demonstrate that the subject devices are as safe and effective as the predicate device.

	mm 138mm×98mm×48.9mm 136mm×120mm×61mm 136mm×100mm×64mm 139.4mm×93.8mm×41.8 mm 119mm×118mm×51mm		
Memory	2×360 times 1×99 times 120 times 1×60 times 1×90 times 2×60 times 4×30 times 2×120 times 2×200 times	2×120 times	The software validation report submitted demonstrates the subject device are as safe and effective as the predicate device.
Displayed Calculated Parameters	SYS DIA Pulse IHB	SYS DIA Pulse IHB	Same
Display component	LCD with backlight LCD without backlight LED without backlight	LCD With backlight	The electrical safety report submitted demonstrates that the subject devices are as safe and effective as the predicate device.
Average function	The average value of the last three results in the current user memory zone The average value in the morning of this week. It can display the morning average data from the 1 to 10 weeks ago. The average value of all the readings for the selected user The average value of all the readings for the selected user The average value of all the results which are measured from 5 o'clock to 9 o'clock in the last 7 days The average value of all the results which are measured from 18 o'clock to 20 o'clock in the last 7 days No Average function	1. The average value of the last three results in the current user memory zone 2. The average value of all the readings for the selected user 3. The average value of all the results which are measured from 5 o'clock to 9 o'clock in the last 7 days 4. The average value of all the results which are measured from 18 o'clock to 20 o'clock in the last 7 days	Average functions are not core functions and key performance. The subject devices are as safe and effective as the predicate device in achieving its intended use.
Other display information	All Models: Battery usage	Battery usage	Same
	Date/ Time	Date/ Time	Display "Date/ Time" are not the core functions and key

	None		performance. The subject devices are as safe and effective as the predicate device in achieving its intended use.
	Blood pressure level None	Blood pressure level	Display "Blood pressure level" are not the core functions and key performance. The subject devices are as safe and effective as the predicate device in achieving its intended use.
	Cuff wrap "OK" symbol Cuff wrap "loose" symbol None	Cuff wrap "OK" symbol	Show the cuff wrap symbol in different with predicate device have been validated, the software validation report submitted demonstrates the subject device are as safe and effective as the predicate device. Display "Cuff wrap symbol" are not the core functions and key performance. The subject devices which do not display this information are as safe and effective as the predicate device in achieving its intended use.
	Body movement symbol None	Body movement symbol	Display "Body movement symbol" are not the core functions and key performance. The devices do not display this information are as safe and effective as the predicate device in achieving its intended use.
	Bluetooth symbol None	Bluetooth symbol	The other models do not have Bluetooth function do not display this information.
	Status Marking None	None	The models which have added status marking display compared with predicate device have been software validated. The software validation report submitted demonstrates these devices are as safe and effective as the predicate device.
Wireless Function	Bluetooth Wi-Fi None	Bluetooth	The model which has a different wireless function with predicate device have been tested. The software validation report and wireless coexistence testing report submitted demonstrates the device is as safe and effective

			as the predicate device. Wireless function are not the core functions and key performance. The models do not have wireless function are as safe and effective as the predicate device in achieving its intended use.
Sound indication Function	Sound indication function None	None	The models which added sound indication function compared with predicate device have been tested. The software validation report submitted demonstrates these devices are as safe and effective as the predicate device.
Electrical Power			
DC Mains	5V 6V: No Medical AC adapter	5V	The models whose DC Mains are different with the predicate device have been tested. The electrical safety test report and EMC test report demonstrate these devices are as safe and effective as the predicate device.
Battery	4×1.5V SIZE AA 4×1.5V SIZE AAA 3×1.5V SIZE AA 1*3.7V Li-ion 1200mAh 1*3.7V Li-ion 2200mAh 1*3.7V Li-ion 1800mAh	4×1.5V SIZE AA	The models whose battery are different with predicate device have been tested. The electrical safety test report and EMC test report demonstrate the subject device are as safe and effective as the predicate device.
Operation Limitation			
Temperature	5~40℃	5~40℃	Same
Humidity	≤85% RH	≤85% RH	Same
Storage Limitation			
Temperature	-20℃ to 55℃	-20℃ to 55℃	Same
Humidity	≤90% RH	≤90% RH	Same
Performance Parameter			
Pulse rate	40-180 times/min	40-180 times/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	Oscillo-metric	Oscillo-metric	Same
Measure process	Measure during deflating Measure during inflating	Measure during deflating	The models whose measure process are different from the predicate device have been tested, the clinical

			investigation report submitted demonstrates that the subject devices are as safe and effective as the predicate device.
Systolic Range	60-260 mmHg	60-260 mmHg	Same
Diastolic Range	40-199 mmHg	40-199 mmHg	Same
Pressure Accuracy	Within ±3 mmHg	Within ±3 mmHg	Same
Cuff pressure Range	0-300 mmHg	0-300 mmHg	Same
Over pressure Limit	300 mmHg	300 mmHg	Same
Algorithm	Oscillometric	Oscillometric	Same

There are no significant differences between the subject device and the predicate device. They are identical in terms of intended use, materials, design, and manufacturing methods.

8.0 Discussion of Non-Clinical Testing

Non-clinical tests were conducted to verify that the subject device met all design specifications. The test results demonstrated that the subject 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+AMD1: 2020, 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: 2015+AMD1: 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: 2018, Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers.

The tests above demonstrate that the subject devices do not raise new questions of safety and effectiveness as compared to the predicate device.

9.0 Discussion of Clinical Testing

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

The clinical study was conducted in accordance with ISO 81060-2:2018+Amd-1:2020. A total of 231 patients (107 males and 124 females) were enrolled in the study, standard auscultation method was used as the reference blood pressure monitor measuring, the same arm 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 Comparison to the Predicate Device and Conclusion

The conclusion drawn from the nonclinical tests and clinical test demonstrate that the subject devices are substantially equivalent to the predicate device.

The subject devices are very similar to the predicate device in the intended use, design principle, materials, performance and applicable standards. Their appearance, memory capacity, display information, Electrical Power are different. However, the tests in this submission demonstrate that these differences do not raise any new questions of safety and effectiveness. And the subject device is as safe, effective and performs as well or better than the legally marketed predicate device.