



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

May 11, 2017

Andon Health Co.,ltd  
Liu Yi  
President  
No 3, Jin Ping St, Ya An Rd  
Nankai District  
Tianjin, 300190 CN

Re: K163276

Trade/Device Name: KD-721 and KD-723 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: April 6, 2017

Received: April 10, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a large, light blue, semi-transparent "FDA" watermark.

for

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K163276

Device Name

KD-721 and KD-723 Fully Automatic Electronic Blood Pressure Monitor

Indications for Use (Describe)

KD-721 and KD-723 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

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of SMDA and 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,  
P.R. China  
Phone number: 86-22-6052 6161  
Fax number: 86-22-6052 6162  
Contact: Liu Yi  
Date of Preparation: 11/15/2016

### **2.0 Device information**

Trade name: KD-721 and KD-723 Fully Automatic  
Electronic Blood Pressure Monitor

Common name: Noninvasive blood pressure measurement system

Classification name: Noninvasive blood pressure measurement system

### **3.0 Classification**

Production code: DXN- Noninvasive blood pressure measurement system.

Regulation number: 870.1130

Classification: II

Panel: Cardiovascular

### **4.0 Predicate device information**

Manufacturer: Andon Health Co., Ltd.

Device: iHealth View BP7S Wireless Blood Pressure Wrist Monitor

510(k) number: K152379

## **5.0 Intended use**

KD-721 and KD-723 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.

The intended use and the indication for use of KD-721 and KD-723, as described in its labeling are the same as the predicate device BP7S (K152379).

## **6.0 Device description**

KD-721 and KD-723 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, 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 Summary comparing technological characteristics with predicate device**

| <b>Technological Characteristics</b> | <b>Comparison result</b> |
|--------------------------------------|--------------------------|
| Design principle                     | Identical                |
| Appearance                           | Similar                  |
| Patients contact Materials           | Similar                  |
| Performance                          | Similar                  |
| Biocompatibility                     | Identical                |
| Mechanical safety                    | Identical                |
| Standards met                        | Identical                |
| Electrical safety                    | Identical                |
| EMC                                  | Identical                |
| Function                             | Similar                  |

## **8.0 Discussion of non-clinical and clinical test performed**

### ***Non-clinical Tests have been done as follows:***

- a. Electromagnetic compatibility test according to IEC 60601-1-2;
- b. Electrical safety according test to IEC 60601-1;
- c. Safety and performance characteristics of the test according to IEC 80601-2-30

None of the test demonstrates that KD-721 and KD-723 Fully Automatic Electronic Blood Pressure Monitor bring new questions of safety and effectiveness.

### ***Clinical Tests discussion***

KD-721/723 and KD-972(cleared in 2012 as K121470) are blood pressure monitors based on oscillometric and silicon integrates pressure sensor technology, when inflating the cuff, systolic and diastolic signal will be collected, using the algorithm to get final value and record. The algorithm version of both the new device and KD-972 is: BPM-WAU V2.0-201109, and the cuff size used is exactly the same, so the clinical test report of KD-972(that conformed to ANSI/AAMI/ISO 81060-2:2009 & 2013) can be used for evaluating KD-721/723.

## **9.0 Performance summary**

KD-721 and KD-723 Fully Automatic Electronic Blood Pressure Monitor conforms to 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 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

## **10.0 Comparison to the predicate device and the conclusion**

Our device KD-721 and KD-723 Fully Automatic Electronic are substantially equivalent to iHealth BP7S Wireless Blood Pressure Wrist Monitor whose 510(k) number is K152379.

| Item                            | Predicate Device                                                      | Subject Device                                                                       | Device                                                                | Comparison                                                                                                                               |
|---------------------------------|-----------------------------------------------------------------------|--------------------------------------------------------------------------------------|-----------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|
| Name and mode                   | BP7S Wireless Blood Pressure Wrist Monitor                            | KD-721 Wireless Blood Pressure Wrist Monitor                                         | KD-723 Wireless Blood Pressure Wrist Monitor                          | The name is different because the model is different.                                                                                    |
| Intended Use                    | Monitor and display diastolic, systolic blood pressure and pulse rate | Monitor and display diastolic, systolic blood pressure and pulse rate                | Monitor and display diastolic, systolic blood pressure and pulse rate | Same                                                                                                                                     |
| Rx or OTC                       | OTC                                                                   | OTC                                                                                  | OTC                                                                   | Same                                                                                                                                     |
| Population                      | Adult                                                                 | Adult                                                                                | Adult                                                                 | Same                                                                                                                                     |
| Cuff Location                   | Wrist                                                                 | Wrist                                                                                | Wrist                                                                 | Same                                                                                                                                     |
| <b>Physical Attributes</b>      |                                                                       |                                                                                      |                                                                       |                                                                                                                                          |
| Weight                          | About 114g (include cuff)                                             | About 67g (exclude batteries)                                                        | About 69g (exclude batteries)                                         | The weight and is different, because the appearance is changed. But the test conform that this does not impact safety and effectiveness. |
| Dimensions                      | 72mmX74mmX17.6mm                                                      | 78mm×60mm×28mm                                                                       | 80mm×60mm×22mm                                                        |                                                                                                                                          |
| Memory                          | NA                                                                    | 2×60 times                                                                           | 2×60 times                                                            | Although the memory function is changed, there is no impact on safety and effectiveness for this change.                                 |
| Displayed Calculated Parameters | SYS<br>DIA<br>Pulse<br>IHB                                            | SYS<br>DIA<br>Pulse<br>IHB                                                           | SYS<br>DIA<br>Pulse<br>IHB                                            | Same                                                                                                                                     |
| Display component               | 1 LCD<br>2 Display on Smart Phone                                     | 1 LCD<br>2 Display on Smart Phone                                                    | 1 LCD<br>2 Display on Smart Phone                                     | Same                                                                                                                                     |
| Average function                | No average function                                                   | average value of all the results measured from 5 o'clock to 9 o'clock in last 7 days | Averaging all the results                                             | Although the average function is changed , this will not impact on safety and effectiveness.                                             |
| Other Displayed                 | Date Time                                                             | Date Time                                                                            | Date Time                                                             | Same                                                                                                                                     |

|                                |                                                                                                                                                                                 |                                                                                                          |                                                                                                          |                                                                                                                                |
|--------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|
| Information                    | Memory<br>Battery usage<br>Bluetooth symbol<br>charge symbol<br>sync symbol<br>(Displayed on device)                                                                            | Memory<br>Battery usage<br>Bluetooth symbol<br>Blood pressure<br>classification<br>(Displayed on device) | Memory<br>Battery usage<br>Bluetooth symbol<br>Blood pressure<br>classification<br>(Displayed on device) |                                                                                                                                |
| Other Features                 | Transmit data to smart phone via Bluetooth<br>WHO classification                                                                                                                | Transmit data to smart phone via Bluetooth<br>JNC classification                                         | Transmit data to smart phone via Bluetooth<br>WHO classification                                         | Same data transmission<br>The classification of KD-721 is different, but this change will not affect safety and effectiveness. |
| <b>Apps on smart phone</b>     |                                                                                                                                                                                 |                                                                                                          |                                                                                                          |                                                                                                                                |
| Function on app                | Storage test result/<br>Read memories in App/Delete memories in app/<br>Draw table and graph/Set alarm in app/Set the personal information in app/<br>Share history data in app | Storage and display test results only                                                                    | Storage and display test results only                                                                    | The new device can only store test results and display, but this change will not affect safety and effectiveness               |
| <b>Electrical Power</b>        |                                                                                                                                                                                 |                                                                                                          |                                                                                                          |                                                                                                                                |
| Battery                        | 1*3.7V Li-ion<br>400mAh                                                                                                                                                         | 2x1.5V SIZE AAA                                                                                          | 2x1.5V SIZE AAA                                                                                          | The battery is changed, t but this will not affect safety and effectiveness.                                                   |
| <b>Environmental Operation</b> |                                                                                                                                                                                 |                                                                                                          |                                                                                                          |                                                                                                                                |
| Temperature                    | 10~40℃                                                                                                                                                                          | 10~40℃                                                                                                   | 10~40℃                                                                                                   | Same                                                                                                                           |
| Humidity                       | ≤85%                                                                                                                                                                            | ≤85%                                                                                                     | ≤85%                                                                                                     | Same                                                                                                                           |
| <b>Environmental Storage</b>   |                                                                                                                                                                                 |                                                                                                          |                                                                                                          |                                                                                                                                |
| Temperature                    | -20~55℃                                                                                                                                                                         | -20~50℃                                                                                                  | -20~50℃                                                                                                  | Although the storage temperature of KD-721 and KD-723 is changed, this will not affect safety and effectiveness                |
| Humidity                       | ≤85%                                                                                                                                                                            | ≤85%                                                                                                     | ≤85%                                                                                                     | Same                                                                                                                           |
| <b>Performance NIBP</b>        |                                                                                                                                                                                 |                                                                                                          |                                                                                                          |                                                                                                                                |
| Pulse Rate Range               | 40 ---<br>180times/min                                                                                                                                                          | 40 ---<br>180times/min                                                                                   | 40 ---<br>180times/min                                                                                   | Same                                                                                                                           |
| Pulse Rate Accuracy            | Within ±5%                                                                                                                                                                      | Within ±5%                                                                                               | Within ±5%                                                                                               | Same                                                                                                                           |

|                     |                          |                          |                          |                                                                                     |
|---------------------|--------------------------|--------------------------|--------------------------|-------------------------------------------------------------------------------------|
| Technique/Method    | Oscillometric            | Oscillometric            | Oscillometric            | Same                                                                                |
| Measure process     | Measure during inflating | Measure during inflating | Measure during inflating | Same                                                                                |
| Systolic Range      | 60-260mmHg               | 60-260mmHg               | 60-260mmHg               | Same                                                                                |
| Diastolic Range     | 40-199mmHg               | 40-199mmHg               | 40-199mmHg               | Same                                                                                |
| Pressure Accuracy   | Within $\pm 3$ mmHg      | Within $\pm 3$ mmHg      | Within $\pm 3$ mmHg      | Same                                                                                |
| Cuff Pressure Range | 0-300mmHg                | 0-300mmHg                | 0-300mmHg                | Same                                                                                |
| Overpressure Limit  | 300mmHg                  | 300mmHg                  | 300mmHg                  | Same                                                                                |
| Microprocessor      | MB9AFB44N                | $\mu$ PD78F0485          | $\mu$ PD78F0485          | Although the MCU is different, this change will not affect safety and effectiveness |
| Algorithm           | Amplitude                | Amplitude                | Amplitude                | Same                                                                                |

KD-721 and KD-723 is very similar with its predicate device in the intended use, the design principle, the data transmission mode, the material, the performance and the applicable standards. Only their appearance, the memory capacity, the average function, the power and the MCU are different.

However, the test in this submission provides demonstrates that these small differences do not raise any new questions of safety and effectiveness.