June 4, 2019

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

Re: K183535
Trade/Device Name: KD-753, KD-738BR, KD-733 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: February 19, 2019
Received: May 9, 2019

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,

for

Matthew Hillebrenner
Director (Acting)
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183535

Device Name

KD-753, KD-738BR, KD-733 Fully Automatic Electronic Blood Pressure Monitor

Indications for Use *(Describe)*

KD-753, KD-738BR, KD-733 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: 11/28/2018

2.0 Device information

Trade name: KD-753, KD-738BR, KD-733 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

Primary Predicate:
Manufacturer: Andon Health Co., Ltd.
Device: KD-7920 Fully Automatic Electronic Blood Pressure Monitor
510(k) number: K162915

Reference Predicate:
Manufacturer: Andon Health Co., Ltd.
Device: KD-7901 Fully Automatic Electronic Blood Pressure Monitor
510(k) number: K092510

5.0 Intended use

KD-753, KD-738BR, KD-733 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-753, KD-738BR, KD-733 , as described in its labeling are the same as the predicate device KD-7920(K162915).

6.0 Device description

KD-753, KD-738BR, KD-733 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

Item	Subject Device	Predicate Device	Conclusion
Name and mode	Fully Automatic Electronic Blood Pressure Monitor	Fully Automatic Electronic Blood Pressure Monitor	Same
Model	KD-753 KD-738BR KD-733	KD-7920	The model is different
Rx or OTC	OTC	OTC	Same
Population	Adult	Adult	Same
Cuff Location	Wrist	Wrist	Same

Physical Attributes			
Weight	KD-753: 71g KD-738BR: 80g KD-733: 78.7g	69.5g	Changed
Dimensions (mm)	KD-753: 83mm x 74mm x 26mm KD-738BR: 83mm x 64mm x 28mm KD-733: 87mm×66.3mm×31.5mm	80mm x 60mm x 31mm	changed
Memory	1×120 times 1×60 times 2×60 times 4×30 times	4 x 30 times	Added memory function on meter
Displayed Calculated Parameters	SYS DIA Pulse IHB	SYS DIA Pulse IHB	Same
Display component	LCD	LCD	Same
Average function	KD-753: 1.Average value of all results in the current user memory zone. 2. Average the value of the latest 3 times. KD-738BR: Average the value of the latest 3 times. KD-733: Average value of all results in the current user memory zone.	Average value of all the results which is measured from 5 o'clock to 9 o'clock and 18 o'clock to 20 o'clock in last 7 days.	Average function is different
Other Displayed Information	Date Time Memory Battery usage Blood pressure classification	Date Time Memory Battery usage Blood pressure classification	Same
Electrical Power			
DC Mains	3 V_{DC}	3 V_{DC}	Same
Battery	2 x 1.5 V_{DC} AAA size	2 x 1.5 V_{DC} AAA size	
Environmental			

Operation			
Temperature	10~40℃	10~40℃	Same
Humidity	≤85%	≤85%	
Environmental Storage			
Temperature	-20~50℃	-20~50℃	Same
Humidity	≤85%	≤85%	
Performance NIBP			
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
Systolic Range	60-260mmHg	60-260mmHg	Same
Diastolic Range	40-199mmHg	40-199mmHg	Same
Pressure Accuracy	Within ±3mmHg	Within ±3mmHg	Same
Cuff Pressure Range	0-300mmHg	0-300mmHg	Same
Over pressure Limit	300mmHg	300mmHg	Same
Algorithm	Amplitude	Amplitude	Same

8.0 Discussion of non-clinical and clinical test performed

Non-clinical Tests

Bench testing was conducted to demonstrate that the device meets its requirements and specification. The following performance tests were completed:

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

The proposed devices KD-753, KD-738BR, KD-733 Fully Automatic Electronic Blood Pressure Monitor meets all the applicable requirements.

Clinical Tests

Clinical test has been performed in accordance with ISO 81060-2. 85 patients

(40 males and 45 females) were invited for the study, standard auscultation method was used as the reference blood pressure monitor measuring, and same sequential method was chosen. Accuracy of the blood pressure monitors was verified by meeting criteria 1 and criteria 2 of ISO 81060-2.

9.0 Performance summary

KD-753, KD-738BR, KD-733 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
- ANSI/AAMI/ISO 81060-2:2013, Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type

10.0 Comparison to the predicate device and the conclusion

Our device KD-753, KD-738BR, KD-733 Fully Automatic Electronic Blood Pressure Monitor are substantially equivalent to the predicate device KD-7920 Fully Automatic Electronic Blood Pressure Monitor.

The intended use, the design principle, the material of the new devices is exactly the same as the predicate device, their appearance, memory capacity, average function and MCU used is different.

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