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

February 17, 2017

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

Re: K162915
Trade/Device Name: 7920 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: December 23, 2016
Received: December 29, 2016

Dear Liu Yi:

This letter corrects our substantially equivalent letter of February 8, 2017.

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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162915

Device Name

7920 Fully Automatic Electronic Blood Pressure Monitor

Indications for Use *(Describe)*

KD-7920 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: 9/23/2016

2.0 Device information

Trade name: 7920 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-7964 Fully Automatic Electronic Blood Pressure Monitor
510(k) number: K102906

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-7920 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-7920, as described in its labeling are the same as the predicate device KD-7964(K102906).

6.0 Device description

KD-7920 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 (K162915)	Predicate Device (K102906)	Conclusion
Models	KD-7920	KD-7964	–
Population	Adult	Adult	Same
Cuff location	Wrist	Wrist	Same
Indications for Use	KD-7920 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	KD-7964 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	Same

	non-invasive technique in which an inflatable cuff is wrapped around the wrist. The cuff circumference is limited to 14cm-25cm.	non-invasive technique in which an inflatable cuff is wrapped around the wrist. The cuff circumference is limited to 14cm-25cm.	
RX or OTC	OTC	OTC	Same
Physical attributes			
Weight	69.5g	133g (w/o batteries)	The appearance of the new device is changed, so the weight and dimension are also changed, the electrical safety test report and the EMC test report confirm that all the new device is as safe and effective as the predicate device
Dimensions (mm)	80 x 60 x 31	90 x 68 x 30	
Memory	4 x 30 times	2 x 60 times	The memory times of the new devices is changed, but the software validation documentation confirms that all the new device is the same effective and safe as the predicate device
Displayed and calculated parameters	Systolic, Diastolic, Pulse, Irregular heartbeat	Systolic, Diastolic, Pulse, Irregular heartbeat	Same
Display	LCD	LCD	Same
Electrical			
Power rating	$3V_{DC}$	$3V_{DC}$	Same
Battery	2 x 1.5 V_{DC} AAA size	2 x 1.5 V_{DC} AAA size	Same
Performance			

Pulse rate	40 – 180 times/min	40 – 180 times/min	Same
Pulse rate accuracy	±5%	±5%	Same
BP monitoring method	Oscillometric	Oscillometric	Same
Measurement process	Taken during deflation	Taken during deflation	Same
Systolic range	60 – 260 mmHg	60 – 260 mmHg	Same
Diastolic range	40 – 199 mmHg	40 – 199 mmHg	Same
Overpressure limit	300 mmHg	300 mmHg	Same
Algorithm	Amplitude (Same as K092510)	Amplitude (same as K092510)	Same

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

Clinical Tests were done as follows:
Accuracy of the electronic blood pressure monitors was verified by meeting Criteria 1 and 2 of ISO 81060-2

None of the test demonstrates that KD-7920 Fully Automatic Electronic Blood Pressure Monitor bring new questions of safety and effectiveness.

9.0 Performance summary

KD-7920 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 60601-1-2:2007, 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
- ISO 81060-2: Non-invasive sphygmomanometers —Part 2: Clinical investigation of automated measurement type

10.0 Comparison to the predicate device and the conclusion

Our device KD-7920 Fully Automatic Electronic Blood Pressure Monitor are substantially equivalent to the predicate device KD-7964 Fully Automatic Electronic Blood Pressure Monitor.

KD-7920 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.

KD-7920 uses the same design principle, blood pressure cuff and same algorithm as the KD-7901 blood pressure monitor. KD-7901 is also manufactured by Andon Health Co., Ltd and has been cleared by FDA with 510K number of K092510.