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

August 10, 2016

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

Re: K160565
Trade/Device Name: KD-388N, KD-5031L, KD-5031M, KD-5031N, KD-525EN, KD-575N, KD-5917D, KD-5917N, KD- 595B, KD-5961B, KD-5963NG, KD-559 and KD-516 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 26, 2016
Received: March 4, 2016

Dear Ms. 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 yours,

for 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)*
K160565

Device Name

KD-388N, KD-5031L, KD-5031M, KD-5031N, KD-525EN, KD-575N, KD-5917D, KD-5917N, KD-595B, KD-5961B, KD-5963NG, KD-559 and KD-516 Fully Automatic Electronic Blood Pressure Monitor

Indications for Use *(Describe)*

KD-388N, KD-5031L, KD-5031M, KD-5031N, KD-525EN, KD-575N, KD-5917D, KD-5917N, KD-595B, KD-5961B, KD-5963NG, KD-559 and KD-516 Fully Automatic Electronic Blood Pressure Monitor are 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 22cm-48cm.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K160565

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 Application: 02/26/2016

2.0 Device information

Trade name: KD-388N, KD-5031L, KD-5031M, KD-5031N, KD-525EN, KD-575N, KD-5917D, KD-5917N, KD-595B, KD-5961B, KD-5963NG, KD-559 and KD-516 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: KD-513LU Fully Automatic Electronic Blood Pressure Monitor
510(k) number: K121372

5.0 Device description

KD-388N, KD-5031L, KD-5031M, KD-5031N, KD-525EN, KD-575N, KD-5917D, KD-5917N, KD-595B, KD-5961B, KD-5963NG, KD-559 and

KD-516 Fully Automatic Electronic Blood Pressure Monitor are 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 22cm-48cm.

The operational principle is based on oscillometric and silicon integrates pressure sensor technology. it can calculate the systolic and diastolic blood pressure, the measurements results can also be classified by the function of blood pressure classification indicator. Achieves its function by an LCD.

6.0 Intended use

KD-388N, KD-5031L, KD-5031M, KD-5031N, KD-525EN, KD-575N, KD-5917D, KD-5917N, KD-595B, KD-5961B, KD-5963NG, KD-559 and KD-516 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 22cm-48cm.
The intended use and the indication for use of these monitors, as described in their labelings are the same as the predicate device KD-513LU.

7.0 Summary comparing technological characteristics with predicate device

Technological Characteristics	**Comparison result**
Design principle	Identical
Appearance	The weight(excluding batteries) and dimensions are changed.
Patients contact Materials	Identical
Function	The memory time, function of display IHB, vioce and touch function, averaging function, time format displayed are changed.
Biocompatibility	Identical

Mechanical safety	Identical
Energy source	Identical
Standards met	Identical
Electrical safety	Identical
EMC	Identical
Performance	The cuff pressure range and microprocessor are changed.
Environmental	The temperature and humidity for operation, storage and transport are changed.

8.0 Performance summary

KD-388N, KD-5031L, KD-5031M, KD-5031N, KD-525EN, KD-575N, KD-5917D, KD-5917N, KD-595B, KD-5961B, KD-5963NG, KD-559 and KD-516 Fully Automatic Electronic Blood Pressure Monitor will conform to the following standards before marketing:

- IEC60601-1:2005+CORR.1(2006)+CORR.2(2007)/EN60601-1:2006/A11: 2011, Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-2:2007/EN 60601-1-2:2007+AC:2010, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - 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 Non-Invasive Sphygmomanometers
- ANSI/AAMI/ISO 81060-2:2009, Non-invasive sphygmomanometer – part 2: Clinical validation of automated measurement type

9.0 Comparison to the predicate device and the conclusion

Our device KD-388N, KD-5031L, KD-5031M, KD-5031N, KD-525EN, KD-575N, KD-5917D, KD-5917N, KD-595B, KD-5961B, KD-5963NG, KD-559 and KD-516 Fully Automatic Electronic Blood Pressure Monitor is substantially equivalent to the Fully Automatic Electronic Blood Pressure Monitor KD-513LU whose 510(k) number is K121372.

These devices are very similar in the intended use, the design principle, the material, the performance and the applicable standards. Only their appearance, the memory time, and the user interface are different.

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