



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 2, 2016

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

Re: K160014
Trade/Device Name: iHealth Track Blood Pressure Monitor (KN-550BT)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: December 30, 2015
Received: January 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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a faint, light-colored watermark of the FDA logo.

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)

K160014

Device Name

iHealth Track Blood Pressure Monitor (KN-550BT)

Indications for Use (Describe)

iHealth Track Blood Pressure Monitor(KN-550BT) is for use by medical professionals or at home and are 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"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."

K160014

Page 1 of 4

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: 12/15/2015

2.0 Device information

Trade name: iHealth Track Blood Pressure Monitor (KN-550BT)

Device name: iHealth Track Blood Pressure Monitor

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-927 Fully Automatic Electronic Blood Pressure Monitor

510(k) number: K141984

5.0 Intended use

iHealth Track Blood Pressure Monitor(KN-550BT) is for use by medical professionals or at home and are 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 iHealth Track Blood Pressure Monitor(KN-550BT), as described in its labeling are the same as the predicate device KD-927 (K141984).

6.0 Device description

iHealth Track Blood Pressure Monitor(KN-550BT) 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, 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. More over, it also obtains the function of averaging the measurement results. The new devices achieves its function by LCD or iOS/Andriod devices.

7.0 Summary comparing technological characteristics with predicate device

Technological Characteristics	Comparison result
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 KN-550BT Track Blood Pressure Monitor bring new questions of safety and effectiveness.

9.0 Performance summary

iHealth Track Blood Pressure Monitor(KN-550BT) 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/(R)2012, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests (Edition 3)
- IEC 80601-2-30 Edition 1.1 2013-07, Medical Electrical Equipment - Part 2-30: Particular Requirements For The Basic Safety And Essential Performance Of Automated Non-Invasive Sphygmomanometers

10.0 Comparison to the predicate device and the conclusion

iHealth Track Blood Pressure Monitor(KN-550BT) is substantially equivalent to the Fully Automatic Electronic Blood Pressure Monitor KD-927 whose 510(k) number is K141984.

K160014
Page 4 of 4

The new device KN-550BT is very similar with its predicate device in the intended use, the design principle, the material, the performance and the applicable standards. Only their appearance, the memory capacity, electrical power, measure process, average measure function and the MCU are different, and a new software platform has been added.

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