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

September 24, 2015

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

Re: K152003
Trade/Device Name: iHealth BP3L Wireless Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: August 25, 2015
Received: August 28, 2015

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 yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number : K152003

Device name: iHealth BP3L Wireless Blood Pressure Monitor

Indications for use:

iHealth BP3L Wireless 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.

Prescription use _____ AND/OR Over-The-Counter Use YES
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-COUNTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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: 07/14/2015

2.0 Device information

Trade name: iHealth BP3L Wireless Blood Pressure Monitor

Device name: Wireless 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: iHealth BP3 Fully Automatic Arm Cuff Electronic Blood Pressure Dock
510(k) number: K102939

5.0 Intended use

iHealth BP3L Wireless 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 iHealth BP3L Wireless Blood Pressure Monitor, as described in its labeling are the same as the predicate device BP3 (K102939).

6.0 Device description

iHealth BP3L Wireless Blood Pressure Monitors are 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. The new devices achieves its function by an iOS or Andriod devices. .

7.0 Summary comparing technological characteristics with predicate device

Item	Predicate device BP3 (K102939)	Subject device BP3L(K152003)
Intended use and indication for use	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.	Same as predicate
Method of measurement	Oscillometric	Same as predicate
Unit Weight	About 260g	About 240g
Average function	Yes	No

Memory function	Yes	No
Power Supply	5V Li-ion	Same as predicate
Accuracy	Pressure ± 3mmHg Pulse ± 5%	Same as predicate
Range of measurement	Cuff pressure Range 0 ~ 295 mmHg Determination Range 30 ~ 280 mmHg	Cuff pressure Range 0 ~ 300 mmHg Determination Range 40 ~ 260 mmHg
Storage Environment	-20~55℃ <95%RH	-20~55℃ ≤85%RH
Operating Environment	0~35℃ <90%RH	10℃～40℃ ≤85%RH
Data transmission	iPhone 30 pin	Bluetooth
Measurement display	iOS device	iOS device or Android device
Software platform	iOS	iOS and Android
Performance Standard	SP-10	ISO 80601-2-30

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 BP3L and BP7S Wireless Blood Pressure Monitor bring new questions of safety and effectiveness.

9.0 Performance summary

iHealth BP3L Wireless Blood Pressure Monitor conforms to the following standards:

- AAMI ANSI ES 60601-1:2005/(R) 2012 And C1:2009(R)2012 And A2:2010 (Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests)
- IEC60601-1-2 Edition 3: 2007-03, (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+Cor.2010/EN 80601-2-30:2010(Medical electrical equipment –Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers)AAMI IEC80601-2-30:2002, Manual, electronic or automated sphygmomanometers.

10.0 Comparison to the predicate device and the conclusion

BP3L Wireless Blood Pressure Monitor is substantially equivalent to the Fully Automatic Arm Cuff Electronic Blood Pressure Dock BP3 whose 510(k) number is K102939.

The new device BP3L is very similar with its predicate device in the intended use, the design principle, the material, the performance and the applicable standards. Only their data transmission function, the MCU and the memory function 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.