510(k) Summary

FEB 2 3 2011

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: 09/27/2010

2.0 Device information

Trade name: iHealth BP3 Fully Automatic Arm Cuff Electronic Blood Pressure Dock

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-930 Fully Automatic Electronic Blood Pressure Monitor
510(k) number: K101950

5.0 Device description

iHealth BP3 Fully Automatic Arm Cuff Electronic Blood Pressure Dock 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.
iHealth BP3 Fully Automatic Arm Cuff Electronic Blood Pressure Dock is designed and manufactured according to ANSI/AAMI SP10--manual, electronic or automated sphygmanometers.

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.

iHealth BP3 Fully Automatic Arm Cuff Electronic Blood Pressure Dock achieves its function by integrate the device with an iPhone, ipod or ipad. For it does not contain an LCD or other display components, so It's necessary for the new device to connect to an iPhone, ipod or ipad containing a support software to constitute a complete blood pressure measurement system.

6.0 Intended use

iHealth BP3 Fully Automatic Arm Cuff Electronic Blood Pressure Dock 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 the iHealth BP3 Fully Automatic Arm Cuff Electronic Blood Pressure Dock, as described in its labeling are the same as the predicate device KD-930.

7.0 Summary comparing technological characteristics with predicate device

Technological Characteristics	Comparison result
Design principle	Identical
Appearance	Similar
Patients contact Materials	Identical
Performance	Similar
Biocompatibility	Identical
Mechanical safety	Identical
Energy source	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 and IEC 60601-1-1
c. FCC test according to FCC part 15 (2009)
d. Safety and performance characteristics of the test according to SP10

None of the test demonstrates that iHealth BP3 Fully Automatic Arm Cuff Electronic Blood Pressure Dock brings new questions of safety and effectiveness.

Clinical Test Concerning the Compliance of ANSI/AAMI SP10

Compared to deflation detection of its predicate device KD-930, iHealth BP3 Fully Automatic Arm Cuff Electronic Blood Pressure Dock is an inflation detection device, so the arithmetic is changed. As a result, a new clinical test is done in accordance with ANSI/AAMI SP10, and the device met all applicable requirements of the standard.

9.0 Performance summary

iHealth BP3 Fully Automatic Arm Cuff Electronic Blood Pressure Dock conforms to the following standards:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995.
- UL 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 2003.
- IEC 60601-1-1, Medical Electrical Equipment - Part 1: General Requirements for Safety – 1. Collateral standard: Safety Requirements for Medical Electrical Systems, 2000.
- EN 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests, 2007.
- AAMI SP10:2002, Manual, electronic or automated sphygmomanometers.
- AAMI / ANSI SP10:2002/A1:2003 --, Amendment 1 to ANSI/AAMI SP10:2002 Manual, electronic, or automated sphygmomanometers.
- AAMI / ANSI SP10:2002/A2:2006 --, Amendment 2 to ANSI/AAMI SP10:2002 Manual, electronic, or automated sphygmomanometers.

10.0 Comparison to the predicate device and the conclusion

Our device iHealth BP3 Fully Automatic Arm Cuff Electronic Blood Pressure Dock is substantially equivalent to the Fully Automatic Electronic Blood Pressure Monitor KD-930 whose 510(k) number is K101950.

The two 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. The measure process is also changed, that is the new device will get the measurement results when the device is inflating, while KD-930 gets the result during the deflating period. What's more, iHealth BP3 Fully Automatic Arm Cuff Electronic Blood Pressure Dock can achieve its function with an iphone, ipod or ipad, while KD-930 can only connect an iphone to achieve its function.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Andon Health Co., Ltd.
C/O Mr. Liu Yi, President
No. 3 Jinping Street Ya'an Road
Nankai District, Tianjin 300190
China

FEB 2 3 2011

Re: K102939
Trade Name: iHealth BP3 Fully Automatic Arm Cuff Electronic Blood Pressure Dock
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: Not Dated
Received: February 15, 2011

Dear Mr. 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 : K102939

Device name: iHealth BP3 Fully Automatic Arm Cuff Electronic Blood Pressure Dock

Indications for use:

iHealth BP3 Fully Automatic Arm Cuff Electronic Blood Pressure Dock 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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K102939