K121470
p1/3

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.

JUN 14 2012

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 Ext 8060
Fax number: 86-22-6052 6162
Contact: Liu Yi

Date of Application: 05/08/2012

2.0 Device information

Trade name: iHealth BP7-Wireless Blood Pressure Wrist Monitor
Device name: KD-972 Fully Automatic Wireless Blood Pressure Wrist 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-7964 Fully Automatic Electronic Blood Pressure Monitor

510(k) number: K102906

5.0 Device description

KD-972 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 wrist. The cuff circumference is limited to 13.5cm-22cm.

It is designed and manufactured according to IEC 80601-2-30- Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers.

The operational principle is based on oscillometric and silicon integrates pressure sensor technology. it can calculate the systolic and diastolic blood pressure, the measurement 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.

KD-972 Fully Automatic Wireless Blood Pressure Wrist Monitor achieves its function by integrate the device with an iPhone, iPod touch 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 touch or iPad containing a support software to constitute a complete blood pressure measurement system. And the new device connect iPhone, iPod or iPad through bluetooth.

6.0 Intended use

KD-972 Fully Automatic Wireless Blood Pressure Wrist 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 13.5cm-22cm.

The intended use and the indication for use of KD-972, as described in the labeling are the same as its predicate device KD-7964.

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 Performance summary

KD-972 Fully Automatic Wireless Blood Pressure Wrist Monitor 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.
- EN 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests, 2007.
- IEC 80601-2-30, Medical electrical equipment-Part 2-30:Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanmeters,2009.

9.0 Comparison to the predicate device and the conclusion

Our device KD-972 Fully Automatic Wireless Blood Pressure Wrist Monitor is substantially equivalent to the Fully Automatic Electronic Blood Pressure Monitor KD-7964 whose 510(k) number is K102906.

KD-972 and KD-7964 are very similar in the intended use, the design principle, the performance and the applicable standards. Only their appearance, the memory time, the average function 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 -7964 gets the result during the deflating period. The data transfer method of the new device KD-972 is changed to Bluetooth and the data displayed on iPhone, while KD-7964 transfer the data to PC while receive available command.

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

JUN 14 2012

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

Re: K121470
Trade/Device Name: Fully Automatic Wireless Blood Pressure Wrist Monitor, KD-972
Regulatory Number: 21 CFR 870.1130
Regulation Name: Non-invasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: May 14, 2012
Received: May 17, 2012

Dear Ms. 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 : _____

Device name: KD-972 Fully Automatic Wireless Blood Pressure Wrist Monitor

Indications for use:

KD-972 Fully Automatic Wireless Blood Pressure Wrist 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 13.5cm-22cm.

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 K121470