510(k) Summary

MAR 15 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: 12/23/2010

2.0 Device information

Device name:

(1) KD-734 series Fully Automatic Electronic Blood Pressure Monitor
Model No: KD-734XY(X =A~Z, Y= blank or A~Z)

The model in KD-734 series are the modification to KD-734, and the small modification will rise no new 510(k) according to FDA's guidance document < Deciding When to Submit a 510(k) for a Change to an Existing Device>.
(Example, maybe KD-734M will be a modification to the KD-734 which will change the memory time, and KD-734N will delete the average function, etc.)

(2) KD-735 series Fully Automatic Electronic Blood Pressure Monitor
Model No: KD-734XY(X =A~Z, Y= blank or A~Z)

The model in KD-735 series are the modification to KD-735, and the small modification will rise no new 510(k) according to FDA's guidance document < Deciding When to Submit a 510(k) for a Change to an Existing Device>.
(Example, maybe KD-735M will be a modification to the KD-735 which will change the memory time, and KD-735N will delete the average function, etc.)

(3) KD-7908 Fully Automatic Electronic Blood Pressure Monitor

(4) KD-7908V Fully Automatic Electronic Blood Pressure Monitor

(5) KD-792RT Fully Automatic Electronic Blood Pressure Monitor

3.0 Classification

Production code: DXN- Noninvasive blood pressure measurement system.
Regulation number: 870.1130
Classification: II
Panel: Cardiovascular

4.0 Predicate device information

1	Manufacturer: Andon Health Co., Ltd. Device: KD-7962 Fully Automatic Electronic Blood Pressure Monitor 510(k) number: K091997
2	Manufacturer: Andon Health Co., Ltd. Device: KD-738 Fully Automatic Electronic Blood Pressure Monitor 510(k) number: K092045

5.0 Device description

KD-734 series, KD-735 series, KD-7908, KD-7908V and KD-792RT 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 wrist. The cuff circumference is limited to 14cm-25cm.

They are designed and manufactured according to ANSI/AAMI SP10--manual, electronic or automated sphygmanometers.

The operational principle is based on oscillometric and silicon integrate pressure sensor technology. It can calculate the systolic and diastolic blood pressure, and display the result on the LCD. If any irregular heartbeat is detected, it can also be shown on the LCD.

6.0 Intended use

KD-734 series, KD-735 series, KD-7908, KD-7908V and KD-792RT 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 wrist. The cuff circumference is limited to 14cm-25cm.

The intended use and the indication for use of KD-734 series, KD-735 series, KD-7908, KD-7908V and KD-792RT, as described in the labeling are the same as their predicated devices KD-738 and KD-7962.

7.0 Summary comparing technological characteristics with predicate device

KD-734 series, KD-735 series, KD-7908, KD-7908V and KD-792RT Fully Automatic Electronic Blood Pressure Monitor all use the same operational principle as their predicate device. The operational principle is based on oscillometric and silicon integrate pressure sensor technology, it can calculate the systolic and diastolic blood pressure, and display the result on the LCD. Their energy source are the same as the predicate device KD-738, which is

2×1.5V⎓ SIZE AAA.

The contact materials and contact duration of the new devices are the same as their predicate device KD-738, so the biocompatibility is exactly the same as the predicate device.

The function of KD-734, KD-735 and KD-792RT are exactly the same as their predicate device KD-738, except that KD-792RT use 12-hour time keeping system while KD-738 use 24-hour time keeping system.

Compared to KD-738, KD-7908 and KD-7908V added the average function, KD-7908V also use 12-hour time keeping system. More over, KD-7908V obtains a voice function, which is the same as one of its predicate device KD-7962.

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 SP10

None of the test demonstrates that KD-734, KD-735, KD-7908, KD-7908V and KD-792RT bring new questions of safety and effectiveness.

Clinical Test Concerning the Compliance of ANSI/AAMI SP10

From the technical point of view, the subject device KD-734 series, KD-735 series, KD-7908, KD-7908V and KD-792RT are identical to their predicate device KD-738 and KD-7962. The difference between the subject devices and their predicate devices do not affect the clinical accuracy in terms of blood pressure detection. The clinical test report of KD-7901(K092510) is applicable to our subject device.

9.0 Performance summary

KD-734 series, KD-735 series, KD-7908, KD-7908V and KD-792RT Fully Automatic Electronic Blood Pressure 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.
- 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.

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10.0 Comparison to the predicate device and the conclusion

Our device KD-734 series, KD-735 series, KD-7908 and KD-792RT Fully Automatic Electronic Blood Pressure Monitor are substantially equivalent to the Fully Automatic Electronic Blood Pressure Monitor KD-738 whose 510(k) number is K092045. And KD-7908V Fully Automatic Electronic Blood Pressure Monitor is substantially equivalent to the Fully Automatic Electronic Blood Pressure Monitor KD-738 (K092045) and KD-7962 whose 510(k) number is 091997

KD-734 and KD-735 are very similar with the predicate device KD-738 in the intended use, the design principle, the material, the performance and the applicable standards, only their appearance is different from KD-738.

KD-7908 is very similar with the predicate device KD-738 in the intended use, the design principle, the material, the performance and the applicable standards, only the appearance is different from KD-738, the memory time is changed from 60 times to 2x60 times and the MCU is also changed. What's more, a function of averaging the last thirty times measurement is added to KD-7908.

KD-792RT is very similar with the predicate device KD-738 in the intended use, the design principle, the material, the performance and the applicable standards, only the appearance and the MCU is different from KD-738.

KD-7908V, is very similar with the predicate device KD-738 and KD-7962 in the intended use, the design principle, the material, the performance and the applicable standards. The function of averaging the last three time measurement and the voice function are the same as KD-7962. However, the appearance is different from the predicate devices. Compared to KD-738, the memory time is changed from 60 times to 2x60 times, and the MCU is also changed.

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

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

MAR 15 2011

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

Re: K110018
Trade/Device Name: KD-734 series, KD-735 series, KD-7908, KD-7908V and KD-792RT Fully Automated Electronic Blood Pressure Monitor
Regulatory Number: 21 CFR 870.1130
Regulation Name: Non-invasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: February 12, 2011
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.

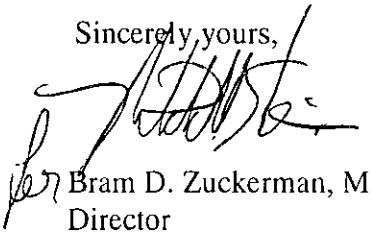
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



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

Enclosure

K110018

Statement of Indications for Use

510(k) Number : _____

Device name: KD-734 series, KD-735 series, KD-7908, KD-7908V and KD-792RT Fully Automatic Electronic Blood Pressure Monitor

Indications for use:

KD-734 series, KD-735 series, KD-7908, KD-7908V and KD-792RT 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 wrist. The cuff circumference is limited to 14cm-25cm.

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)

for BZuckerman

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K110018