K083246
p1/2

510(k) Summary

JAN 29 2009

Identification of the submitter:

Submitter:	Andon Health Co., Ltd. No 31, Changjiang Road, Nankai District, Tianjin, P.R. China, 300193
Telephone number:	86-22-6052 6161
Fax number:	86-22-6052 6162
Contact:	Liu Yi
Date of Application:	10/29/08

Identification of the product:

Device proprietary Name:	Fully Automatic Electronic Blood Pressure Monitor
Common name:	Noninvasive blood pressure measurement systems
Classification name:	Noninvasive blood pressure measurement system Class II per 21 CFR 870.1130

Marketed Devices to which equivalence is claimed:

Device	manufacture	510(k) number
KD-591	Andon Health Co., Ltd	K080319

Device description:

KD-5961 Fully Automatic Electronic Blood Pressure Monitor is Non-invasive blood pressure measurement system for only one person each time. Based on oscillometric and silicon integrate pressure sensor technology, the device is used to monitor systolic, diastolic blood pressure and pulse rate which will be shown on a LCD with an electronic interface module. Buckling a cuff around the left upper arm, which cuff circumference is limited to 22cm-48cm, the device can analyze the signals promptly and display the test results. It has some other functions, such as LCD backlighting, touch button, 120 memory recall / 2 users and calculating average of last 3 readings.

Intended use:

KD-5961 Fully Automatic Electronic Blood Pressure Monitor is intended for use by medical professionals or at home to monitor and display diastolic, systolic blood pressure and pulse rate of adult each time, with the cuff around the left upper arm according to the instruction in the user's guide manual, which is same as predicated device.

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Summary comparing technological characteristics with predicate device:

KD-5961 Fully Automatic Electronic Blood Pressure Monitor has the same principle with predicated device, which utilizes Oscilliometric measurement method to monitor the blood pressure and the result can be shown on the LCD.

The modifications that were made are:

1. Appearance
2. Change into touch button from original one.
3. LCD backlighting
4. Change into 120 memory recall / 2 users (2x60) from 1x60
5. Memory average function: calculating average of last 3 readings

Please find the following tabulated comparison supporting that the proposed device is substantially equivalent to the predicated device.

FDA file reference number	**510K# K080319**
Technological Characteristics	**Comparison result**
Indications for use	Identical
Target population	Identical
Design	Similar
Materials	Identical
Performance	Identical
Sterility	Not Applicable
Biocompatibility	Identical
Mechanical safety	Identical
Chemical safety	Not Applicable
Energy used and/or delivered	Identical
Where used	Identical
Standards met	Identical
Electrical safety	Identical

Device testing:

KD-5961 Fully Automatic Electronic Blood Pressure Monitor meets the following standards:

- ANSI/AAMI SP-10 standard
- EN60601-1 Medical electrical equipment Part 1: General requirements for safety
- EN60601-1-2 Electromagnetic Compatibility

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 29 2009

Andon Health Co., Ltd.
c/o Ms. Liu Yi
No 31, Changjiang Road,
Nankai District, Tianjin, P.R.
China, 300193

Re: K083246
Trade/Device Name: KD-5961 Fully Automatic Electronic Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: December 19, 2008
Received: December 29, 2008

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.

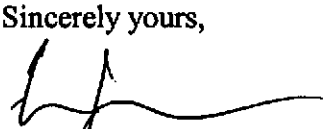
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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 : _____

Applicant: Andon Health Co., Ltd

Device name: KD-5961 Fully Automatic Electronic Blood Pressure Monitor

Indications for use:

KD-5961 Fully Automatic Electronic 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)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K083246