K070828
R1/2

510(k) Summary

AUG 15 2007

Identification of the submitter:

Submitter:	Kodon (Tianjin) Electronic & Electrical Apparatus Co., LTD No 31, Changjiang Road, Nankai District, Tianjin, P.R. China, 300193
Telephone number:	86-22-6052 8012
Fax number:	86-22-6052 6162
Contact:	Liu Yi
Date of Application:	07/02/07

Identification of the product:

Trade Name:	Fully Automatic Electronic Blood Pressure Monitor, Models: KD-593, KD-595, KD-596, KD-598
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-622	Kodon (Tianjin) Electronic and Electrical Apparatus Co., Ltd.	K030358

Device description:

Fully Automatic Blood Pressure Monitor is a 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 automatically inflated and released by an internal pump, the device can analyze the signals promptly and display the results and remember circularly for some sets of data. It can storage and show 60 times measuring result with the day and time. Specially, it has the function of blood pressure level classification.

Intended use:

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 on adult each time, with the cuff around the left upper arm according to the instruction in the user's guide manual.

Comparison of technological characteristics of new device to predicate devices:

The design of Fully Automatic Measurement Electronic Blood Pressure Monitor utilizes Oscilliometric measurement method, with an electronic interface module and a silicon integrate pressure sensor and a cuff automatically inflated and released by an internal pump over the left upper arm to obtain blood pressure signals in the same manner as the predicate device.

In addition, we adopt a new technological method in developing the device so that it has a series of new functions, such as blood pressure level classification and date and time displayed in large screen.

Clinical Tests:

Clinical tests were performed and complied the accuracy requirements of ANSI/AAMISP10-2002. The results meet or exceed the accuracy requirements of ANSI/AAMISP10-2002.

Non-clinical Tests:

All non-clinical tests coincide the following standards, including Electromagnetic Compatibility test□Product Safety test and Biocompatibility test.

EN60601-1-2□2001

Medical electrical equipment----Part 1-2:General requirements for safety□ Collateral standards: Electromagnetic compatibility; Requirements and test.

IEC60601-1: 1998+A1:1991+A2:1995

Medical electrical equipment---Part 1: General requirements for basic safety and essential performance

ISO 10993-5

Biological evaluation of medical device----part 5: Test for in vitro cytotoxicity.

ISO 10993-10

Biological evaluation of medical device----part 10: Tests for irritation and delayed type hypersensitivity.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2007

Kodon (Tianjin) Electronic & Electrical Apparatus, Co.
c/o Mr. Liu Yi
No. 31, Changjiang Road,
Nankai District
Tianjin,
China 300193

Re: K070828
Trade Name: Fully Automatic Electronic Blood Pressure Monitor, Models KD-593, KD-595, KD-596, KD-598
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-invasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: Not provided
Received: July 6, 2007

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 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 Biometric's (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: K070828

Applicant: Kodon (Tianjin) Electronic & Electrical Apparatus Co., LTD

Device name: Fully Automatic Electronic Blood Pressure Monitor, Models: KD-593, KD-595, KD-596, KD-598

Indications for use:

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-30cm.

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)

B Summers

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K070828