510(k) Summary
K110281

FEB 15 2011

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR 807.92

1.0 Submitter's Information

Establishment Registration Name and address:

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2.0 Device Information

Type of 510(k) submission:	Traditional
Device Common Name:	Noninvasive blood pressure measurement system
Trade Name:	Arm Automatic Blood Pressure Meter
Model:	FT-C21Y, FT-C22Y, FT-C23Y, FT-C24Y, FT C11B, FT-C12B, FT-C21Y-V, FT-C22Y-V, FT-C23Y-V, FT-C24Y-V, FT-C11B-V, FT-C12B-V
Classification name:	System, measurement, blood-pressure, non invasive
Review Panel:	Cardiovascular
Product Code:	DXN
Regulation Class:	II
Regulation Number:	870.1130

3.0 Predicate Device Information

Sponsor:	Kodon (Tianjin) Electronic & Electrical Apparatus Co., LTD
Device:	Fully Automatic Electronic Blood Pressure Monitor, Model: KD-595
510(K)	Number: K070828

4.0 Device description

Fudakang Arm Automatic Blood Pressure Meter 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 sets measuring results with the day and time. Specially, the device has the function of blood pressure level classification.

The models FT-C21Y-V, FT-C22Y-V, FT-C23Y-V, FT-C24Y-V, FT-C11B-V, and FT-C12B-V also have voice function. They can read the result and sound in English by a reading IC.

5.0 Intended Use

Fudakang Arm Automatic Blood Pressure Meter 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.

6.0 Performance Summary

Bench Testing

Fudakang Arm Automatic Blood Pressure Meter conforms to the following standards:

- IEC 60601-1, Medical Electrical Equipment -Part 1: General Requirements for Safety, 1988+A1:1991+A2:1995
- IEC 60601-1-2, Medical electrical equipment -Part 1-2: General requirements for basic safety and essential performance -Collateral standard: Electromagnetic compatibility -Requirements and tests, 2007
- ANSI/AAMI SP10, Manual, electronic or automated sphygmomanometers, 2002+A1:2003+A2:2006+(R)2008
- ISO 10993-1, Biological evaluation of medical devices --Part 1: Evaluation and testing, 2003
- ISO 10993-5, Biological evaluation of medical devices --Part 5: Tests for In Vitro cytotoxicity, 2009
- ISO 10993-10, Biological evaluation of medical devices --Part 10: Tests for irritation and delayed-type hypersensitivity, 2002+A1:2006

Clinical Testing

The device was tested to and complies with the AAMI SP10:2002 + A1:2003 + A2:2006 + (R)2008 standard. According to "Clause 4.4.5.B Overall system efficacy", using the auscultatory method (Clause 4.4.5.1.1B Method 1) to verify overall efficacy of the system. We selected 100 patient subjects; each subject contributes 3 data sets, total 300 observations. They compared the measurement result of the subject device and auscultatory result from a physician.

The test result meets the following requirement: For systolic and diastolic pressures, treated separately, the mean difference of the 255 individual paired measurements of the test system and the comparison system shall be ± 5 mmHg or less, with a standard deviation of 8 mmHg or less.

7.0 Comparison to predicate device

Compare with predicate device, they are very similar in design principle, intended use, functions, material and the applicable standards. The differences between subject device and predicate device do not raise and new questions of safety or effectiveness.

(1) The Operating Environment and Storage Environment of Fudakang Arm NIBP are a little difference from Kodon Arm NIBP. They are both compliance with IEC 60601-1 requirements. So the difference will not raise any safety or effectiveness issue.
(2) The key number of Fudakang Arm NIBP is different from Kodon Arm NIBP. But both of them can work normally, and comply with IEC 60601-1 requirements. So the difference will not raise any safety or effectiveness issue.

Conclusions: The subject devices have all features of the predicate device. The few differences do not affect the safety and effectiveness of the subject devices. Thus, the subject devices are substantially equivalent to the predicate devices.

8.0 Conclusion:

The subject devices have all features of the predicate devices. The few differences do not affect the safety and effectiveness of the subject devices. Thus, the subject devices are substantially equivalent to the predicate devices.

9.0 Summary prepared date: 04 February 2011

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

Fudakang Industrial Co., Ltd.
C/O Ned Devine
Underwriters Laboratories, Inc.
333 Pfingsten Road
Northbrook, IL 60062

FEB 15 2011

Re: K110281
Trade/Device Name: Arm Automatic Blood Pressure Meter, Models FT-C21Y, FT-C22Y, FT-C23Y, FT-C24Y, FT-C11B, FT-C12B, FT-C21Y-V, FT-C22Y-V, FT-C23Y-V, FT-C24Y-V, FT-C11B-V, and FT-C12B-V
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: January 10, 2011
Received: January 31, 2011

Dear Mr. Devine:

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

Indications for Use

510(k) Number (if known): K110281

Device Name: Arm Automatic Blood Pressure Meter
Models: FT-C21Y, FT-C22Y, FT-C23Y, FT-C24Y, FT-C11B, FT-C12B, FT-C21Y-V, FT-C22Y-V, FT-C23Y-V, FT-C24Y-V, FT-C11B-V, FT-C12B-V.

Indications for Use:

Fudakang Arm Automatic Blood Pressure Meter 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 arm. The cuff circumference is limited to 22-30cm.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K110281