DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 17, 2015

Fudakang Industrial Co., Ltd
c/o Mr. Field Fu
Senior Regulatory Specialist
4th Floor, Jinhui Building Nanhai Blvd, Nanshan District
Shenzhen, 518100 CN

Re: K150430
Trade/Device Name: Arm Blood Pressure Monitor, Wrist Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: December 31, 2014
Received: February 19, 2015

Dear Mr. Field Fu,

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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

Indications for Use

510(k) Number: K150430

Device Name: System, measurement, blood-pressure, non-invasive

Model:

- ✧ Arm Blood Pressure Monitor
  Models: FT-C21Y, FT-C22Y, FT-C23Y, FT-C24Y, FT-C11B, FT-C12B, FT-C21Y-V, FT-C22Y-V, FTC-23Y-V, FT-C24Y-V, FT-C11B-V, FT-C12B-V, FT-C11B-UR and FT-C11B-BT.
- ✧ Wrist Blood Pressure Monitor
  Models: FT-B11W, FT-B12W, FT-B13W, FT-B14W, FTB21Y, FT-B22Y, FT-B11W-V, FT-B12W-V, FT-B13W-V, FT-B14W-V, FT-B21Y-V, FT-B22Y-V, FT-B13W-UR and FT-B13W-BT.

Indications for Use:

Fudakang Arm Blood Pressure Monitor and Wrist Blood Pressure Monitor are non-invasive blood measurement system intended to measure the diastolic, systolic blood pressures and pulse rate of an adult individual in hospitals, hospital-type facilities and home environments.
The Fudakang BT series Blood Pressure Monitors are of Bluetooth transmission function, which enable user to transfer the measurement record from the device to a mobile phone or PC through Bluetooth.
Fudakang Arm Blood Pressure Monitor and Wrist Blood Pressure Monitor are not intended to be diagnostic device.

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)

SECTION 05 510(K) Summary

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

The assigned 510(k) number is: _____ (applicant leave blank)

Submission Date:	Sep 28, 2014
Submitter:	Fudakang Industrial Co., Ltd Address: No.8 Yinghe Road, Yuanjiangyuan Management Zone, Changping Town, Dongguan, Guangdong, China.
***Submitter Contact*:**	Shenzhen Joyantech Consulting Co., Ltd. 2032#，International Mayor Communication Center, Shizhou zhong Road 55#,Nanshan District, Shenzhen,China. Contact person: Mr. Field.Fu E-Mail: cefda13485@163.com
***Manufacturing Site*:**	Fudakang Industrial Co., Ltd Address: No.8 Yinghe Road, Yuanjiangyuan Management Zone, Changping Town, Dongguan, Guangdong, China.
Common Name:	Non-invasive Sphygmomanometer
Trade Name & Models of the device:	✧ Arm Blood Pressure Monitor Models: FT-C21Y, FT-C22Y, FT-C23Y, FT-C24Y, FT-C11B, FT-C12B, FT-C21Y-V, FT-C22Y-V, FTC-23Y-V, FT-C24Y-V, FT-C11B-V, FT-C12B-V, FT-C11B-UR and FT-C11B-BT. ✧ Wrist Blood Pressure Monitor Models: FT-B11W, FT-B12W, FT-B13W, FT-B14W, FTB21Y, FT-B22Y, FT-B11W-V, FT-B12W-V, FT-B13W-V, FT-B14W-V, FT-B21Y-V, FT-B22Y-V, FT-B13W-UR and FT-B13W-BT
Classification Name:	System, measurement, blood-pressure, non-invasive
Regulation:	21 CFR § 870.1130;
Product Code:	DXN
Device Class:	II
Predicate Devices:	✧ QardioArm, model A 100 (K140067) ✧ Wrist Measurement Electronic Blood Pressure Monitor, Models: KD-791, KD-792, KD-793, KD-795, KD-796, KD-797, KD-798 (K070826)

Intended Use/Indications for use:

Fudakang Arm Blood Pressure Monitor and Wrist Blood Pressure Monitor are non-invasive blood measurement system intended to measure the diastolic, systolic blood pressures and pulse rate of an adult individual in hospitals, hospital-type facilities and home environments. The Fudakang BT series Blood Pressure Monitors are of Bluetooth transmission function, which enable user to transfer the measurement record from the device to a mobile phone or PC through Bluetooth.
Fudakang Arm Blood Pressure Monitor and Wrist Blood Pressure Monitor are not intended to be diagnostic device.

Device Description:

Fudakang Blood Pressure Monitor is battery driven automatic non-invasive Blood Pressure Monitor.
It consists of the Main Control Unit, LCD and attachments. The device can automatically complete the inflation, deflation and BP measurement, which intended to measure the diastolic, systolic blood pressures and pulse rate for an adult individual via the oscillometric technique.
Fudakang Blood Pressure Monitor includes two types of automatic non-invasive Blood Pressure Monitor, Arm Automatic Blood Pressure Monitor and Wrist Fully Automatic Blood Pressure Monitor. The Arm Blood Pressure Monitor utilizes an inflatable cuff that is wrapped around the upper arm; the cuff circumference is limited to 22cm-30cm (8.66 in - 11.8 in). The Wrist Blood Pressure Monitor utilizes an inflatable cuff wrapped around the wrist, the cuff circumference is limited to 13.5cm- 19.5cm (5.31in -7.67 in).
The BT series Blood Pressure Monitors are of Bluetooth transmission function, which enable user to transfer the measurement record from the device to a mobile phone or PC through Bluetooth.

Clinical and Non-clinical Tests

1) Clinical Test Summary

One hundred and twenty three patients (65 males and 58 females) participate in the clinical study. Same arm simultaneous method was adopted during the clinical testing for arm type blood pressure monitor and Same arm sequential method was used in the course of the clinical study for wrist type blood pressure monitor. The manual Mercury Sphygmomanometer was used as a reference device for the both clinical testing. All the subjects are volunteer to take part in the clinical study. The results showed the accuracy of the blood pressure monitor made by Fudakang Industrial Co., Ltd. is within acceptable scope specified in ISO 81060-2.

2) Non-Clinical Test Summary

Several non-clinical tests were performed on Fudakang Arm type and Wrist type Blood Pressure Monitor Series Models, the results showed that all requirements were met. The tests includes the follows:

- *Electrical safety, EMC, FCC, Wireless coexistence and Home healthcare environment test reports*

- ✧ IEC 60601-1: 2005.1: 2006+CORR. 2:2007+AM1:2012
- ✧ IEC 60601-1-2: 2007
- ✧ ANSI C63.4
- ✧ CFR 47 FCC PART 15 (SUBPART B and C 2013)
- ✧ 47 CFR Part 1.1307(2013)
- ✧ 47 CFR Part 2.1093(2013)
- ✧ EN 300328 v1.8.1
- ✧ IEC 60601-1-11 Edition 1.0 2010-04

■ *Performance*

- ✧ IEC 80601-2-30:2009+A1:2013

■ *Biocompatibility*

- ✧ ISO 10993-5:2009
- ✧ ISO 10993-10:2002/Amd.1:2006.

Summary of the Substantially Equivalent

The Fudakang Noninvasive blood pressure monitor is substantially equivalent to the Blood Pressure Monitor (K140067) and the Noninvasive blood pressure measurement systems (K070826).