DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 09, 2017

Shenzhen Combei Technology Co., Ltd
% Migo Yang
Consultant
Shenzhen Joyantech Consulting Co, Ltd.
1122#, International Mayor Communication Center, Baishizhong
Nanshan District, Shenzhen, 518000 TW

Re: K163606
Trade/Device Name: Digital Blood Pressure Monitor-automatic Upper Arm Style: BP100A, BP200A, BPCB0A 3A, BP800A, BPCB0A-2A, BP866A, BP105A, BP106A, BP108A, BP116A, BP118A, BP880A, BP168A, BP126A, BP156A;
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: April 1, 2017
Received: April 10, 2017

Dear Migo Yang:

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,

for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163606

Device Name
Digital Blood Pressure Monitor: Automatic Upper Arm Style: BP100A, BP200A, BPCB0A-3A, BP800A, BPCB0A-2A, BP866A, BP105A, BP106A, BP108A, BP116A, BP118A, BP880A, BP168A, BP126A, BP156A;

Indications for Use *(Describe)*
The subject device intended to measure the diastolic, systolic blood pressures and pulse rate of an adult individual in hospitals, hospital-type facilities and home environments by using a non-invasive oscillometric technique in which an inflatable cuff (size: 22~32cm(8.7~12.6in) is wrapped around the single upper arm.
The Subject device is not intended to be diagnostic device.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

This summary of 510(k) information is submitted as required by requirements of SMDA and 21 CFR §807.92.

1 Administrative Information

Submission Date	Oct 8, 2016
Manufacturer information	Submitter's Name: Shenzhen Combei Technology Co.,Ltd Address: Floor 5, Block B, Building G, Jinxiongda Science Park, South Huanguan Road, Guanlan, Longhua New District, Shenzhen, 518110, Guangdong, China Contact person: Huaguang.Meng TEL: 0755-29588956 FAX: 0755-28588961 E-Mail: huaguangmeng@combei.com.cn
Submission Correspondent	Contact person: Miss Migo.Yang E-Mail: migo@cefda.com Shenzhen Joyantech Consulting Co., Ltd. 1122#，International Mayor Communication Center, Baishizhong Road 55#, Nanshan District, Shenzhen, Guangdong, P.R.China. Contact person: Mr. Field.Fu E-Mail: cefda13485@163.com Shenzhen Joyantech Consulting Co., Ltd. 1122#，International Mayor Communication Center, Baishizhong Road 55#, Nanshan District, Shenzhen, Guangdong, P.R.China
Establishment registration number	NA

2 Device Information

Common name of the device	System, Measurement, Blood-Pressure, Non-Invasive
Trade name of the device	Digital Blood Pressure Monitor- Automatic Upper Arm Style;
Type/Model of the	Automatic Upper Arm Style: BP100A, BP200A, BPCB0A-

device	3A, BP800A, BPCB0A-2A, BP866A, BP105A, BP106A, BP108A, BP116A, BP118A, BP880A, BP168A, BP126A, BP156A;
Classification information	Classification panel: Cardiovascular Classification name: System, Measurement, Blood-Pressure, Non-Invasive Regulation Number: 870.1130 Device Class: II Product Code: DXN
type of 510(k) submission	Traditional

3 Predicate Device Information

Sponsor:	Fudakang Industrial Co., Ltd
Device:	Arm blood pressure monitor
510(K) Number:	K150430

4 Device Descriptions

The Subject device 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.

The Automatic Upper Arm style utilizes an inflatable cuff that is wrapped around the upper arm; the cuff circumference is limited to: 22cm~32cm (8.7in~12.6in).

5 Intended Use

The subject device intended to measure the diastolic, systolic blood pressures and pulse rate of an adult individual in hospitals, hospital-type facilities and home environments by using a non-invasive oscillometric

technique in which an inflatable cuff (size: 22~32cm(8.7~12.6in) is wrapped around the single upper arm.
The Subject device is not intended to be diagnostic device.

6 Indications for Use

The subject device intended to measure the diastolic, systolic blood pressures and pulse rate of an adult individual in hospitals, hospital-type facilities and home environments by using a non-invasive oscillometric technique in which an inflatable cuff (size: 22~32cm(8.7~12.6in) is wrapped around the single upper arm.
The Subject device is not intended to be diagnostic device.

7 SE Comparison

Table 1. Substantial Equivalence Comparison

Characteristics	Subject device	Predicate device (k150430)	Remark
Device Name	Digital Blood Pressure Monitor-Automatic Upper Arm Style	Arm Blood Pressure Monitor	NA
Device Model	BP100A, BP200A, BPCB0A-3A, BP800A, BPCB0A-2A, BP866A, BP105A, BP106A, BP108A, BP116A, BP118A, BP880A, BP168A, BP126A, BP156A;	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, FT-C11B-BT	NA
Manufacturer	Shenzhen Combei Technology Co.,LTD	Fudakang Industrial Co., Ltd	NA
Intended Use/ Indication for Use	The Subject device is 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.	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.	same
	The Subject device is not intended to be diagnostic device.	Fudakang Arm Blood Pressure Monitor and Wrist Blood Pressure Monitor are not intended to be diagnostic device	
	NA	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.	
Intended Population	adult		same
Intended Anatomical site	upper arm		same
Prescription & OTC	OTC		same
Working Principle	Oscillometric method		same
Internal Power supply	4- size “AA” alkaline Batteries	4- size “AA” alkaline Batteries	same

Characteristics	Subject device	Predicate device (k150430)	Remark
Working Current	≤30mV		same
Contact Material	ABS, PMMA		same
Memory Function	2×120 memory	1×60 memory	SE
Cuff Size	22cm~32cm (8.7in~12.6in)		Same
Measuring range	Pressure: 30 to 280 mmHg (in 1 mmHg increment);	Pressure: (40mmHg~280mmHg);	Similar Note01
	Pulse: 40 to 200 beat/minute	Pulse rate range(40-160) hypo/minute	
Accuracy	Pressure: ±3mmHg; Pulse: ±5%	Pressure: ±5mmHg; Pulse ±5%.	SE
Operating Environment	5~40℃,		same
	15%~85%RH		same
Storage & Transport Environment	-10~55℃		same
	10%~95%RH		same

Note01: The subject device has a larger measuring range of pressure and pulse than predicate device. Both the subject device and predicate device have been tested by ISO81060-2.

The subject device is as same as predicate device in Working Principle, Intended use/Indications for Use, Intended patient population, Intended application site, Intended Environments, Working Current, Cuff size, Operating Environment Storage & Transport Environment. Only their Measuring range are a little bit different. However, the minor difference does not raise any safety or effectiveness issue based on tests.

Thus, the subject device is Substantially Equivalent (SE) to the predicate device which is legally marketed in US.

8 Brief discussions of the non-clinical tests

The subject device conforms to the following guidances and standards:

- ✧ Non-Invasive Blood Pressure (NIBP) Monitor Guidance
- ✧ IEC 60601-1:2005+A1:2012: Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance;
- ✧ IEC 60601-1-2:2014 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests.
- ✧ IEC 60601-1-11: 2010 Medical Electrical Equipment - Part 1-11: General

Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment;

- ISO 10993-5: 2009 /(R)2014 Biological evaluation of medical devices – Part 5: Tests for In Vitro cytotoxicity;
- ISO 10993-10: 2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization;
- IEC 80601-2-30: 2013 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

9 Brief discussions of clinical tests

- ISO 81060-2:2013 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type;

In this clinical investigation, eighty seven patients (36 males and 51 females) participated in the clinical study. Same arm sequential method was adopted during the clinical testing. The manual Mercury Sphygmomanometer was used as a reference device. All the subjects were volunteer to take part in the clinical study, all the subjects completed the clinical study without any AE or side-effect. The results showed the accuracy of the blood pressure monitor is within acceptable scope specified in ISO 81060-2.

10 Other information (such as required by FDA guidance)

No other information.

11 Conclusions

The subject device: Digital Blood Pressure Monitor-Automatic Upper Arm Style; manufactured by Shenzhen Combei Technology Co.,Ltd is respectively substantially equivalent to the predicate device Arm Blood Pressure Monitor manufactured by Fudakang Industrial CO.,LTD(K150430).