August 29, 2018

Shenzhen Combei Technology Co., Ltd.
% Field Fu
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1122#, International Mayor Communication Center, Baishizhong Road 55#,
Nanshan District, Shenzhen, Guangdong, 518000, P.R. CHINA

Re: K181104
Trade/Device Name: Arm type Blood Pressure Monitor, Digital Blood Pressure Monitor-Automatic Upper Arm Style
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: July 25, 2018
Received: August 2, 2018

Dear 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Stephen C. Browning -S5

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181104

Device Name
Arm type Blood Pressure Monitor
Digital Blood Pressure Monitor-Automatic Upper Arm Style

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 with a single upper arm cuff (22-42 cm).
The device detects the appearance of irregular heart beats during measurement and gives a warning signal with readings.
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	Mar. 8, 2018
Manufacturer information	Submitter's Name: Shenzhen Combei Technology Co.,Ltd Address: 11-5B No.105, Huanguan South Road, Dahe Community, Guanlan, Longhua New District, Shenzhen, 518110 Guangdong, China Contact person: Kevin Fong TEL: 0755-29588956 FAX: 0755-28588961 E-Mail: kevin.fong@163.com
Submission Correspondent	Contact person: Miss Lucy.Yan E-Mail: Lucy@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	Arm type Blood Pressure Monitor Digital Blood Pressure Monitor-Automatic Upper Arm Style
Type/Model of the device	BP100A, BP156A , BPCB0A-2A, BP156A –A, BP163A, BP200A, BP116A, BP118A, BP106A, BP810A, BP800A, BP866A, BP660A, BPT801, BP101A, BP102A, BP103A,

Classification information	BP105A, BP108A, BP820A, BPCB0A-3H, BPCB0A-2H, BPCB0A-3A, BP880A, BP168A, BP126A, BP122A, BP136A 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:	Truly Instrument Limited
Device:	Truly Automatic Arm Blood Pressure Monitor
510(K) Number:	K091434

4 Device Descriptions

Combei Blood Pressure Monitor are designed to measure the systolic and diastolic blood pressure and pulse rate of an individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. Our method to define systolic and diastolic pressure is similar to the auscultatory method but uses an electronic pressure sensor rather than a stethoscope and mercury manometer. The sensor converts tiny alterations in cuff pressure to electrical signals, by analyzing those signals to define the systolic and diastolic blood pressure and calculating pulse rate, which is a well-known technique in the market called the "oscillometric method".

The main components of the Blood Pressure Monitor are the main unit and cuff unit. ABS is used to outer housing of the main unit. The preformed cuff unit, which is applicable to arm circumference approximately between 220 and 420 mm, includes the inflatable bladder and nylon shell. All models of the arm blood pressure monitor use a single size of cuff. The device consists of the microprocessor, the pressure sensor, the operation keys, the pump, the electromagnetic deflation control valve, Bluetooth tranismiision (optional) and the LCD. The subject devices are powered by four AA alkaline batteries or adatpter. The device also compares the longest and the shortest time intervals of detected pulse waves to mean time interval and displays a warning signal with the reading to indicate the detection of irregular pulse rhythm when the difference of the time intervals is over a specified range.

5 Intended Use/ 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 with a single upper arm cuff (22-42 cm).
The device detects the appearance of irregular heart beats during measurement and gives a warning signal with readings.
The Subject device is not intended to be diagnostic device.

6 SE Comparison

Table 1. Substantial Equivalence Comparison

Characteristics	Subject device		Predicate device (K091434)	Remark
Device Name	Arm type Blood Pressure Monitor	Digital Blood Pressure Monitor-Automatic Upper Arm Style	Truly Automatic Arm Blood Pressure Monitor DB series	NA
Device Model	BP100A, BP156A, BPCB0A-2A, BP156A –A, BP163A, BP200A, BP116A, BP118A, BP106A, BP810A, BP800A, BP866A, BP660A, BPT801, BP101A, BP102A, BP103A, BP105A, BP108A, BP820A, BPCB0A-3H, BPCB0A-2H, BPCB0A-3A, BP880A, BP168A, BP126A,	BP100A, BP156A , BPCB0A-2A, BP156A -A and BP163A	DB21, DB22, DB23, DB31, DB32, DB61M, DB62M, DB63M, DB71M	NA

	BP122A, BP136A		
Manufacturer	Shenzhen Combei Technology Co.,LTD	Truly Instrument Limited	NA
Intended Use/ Indication 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 with a single upper arm cuff (22-42 cm). The device detects the appearance of irregular heart beats during measurement and gives a warning signal with readings. The Subject device is not intended to be diagnostic device.	Truly Automatic Arm Blood Pressure Monitor DB series, Models DB21, DB22, DB23, DB31, DB32, DB61M, DB62M, DB63M, DB71M are a series devices intended to measure the systolic and diastolic blood pressure 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 devices features include irregular pulse rhythm detection during measurement, and display a warning signal with the reading once the irregular heartbeat is detected.	SE

Intended Population	adult	adult	same
Intended Anatomical site	upper arm	upper arm	same
Prescription & OTC	OTC	OTC	same
Working Principle	Oscillometric method	Oscillometric method	same
Pressurization Source	Automatic internal pump	Automatic internal pump	
Internal Power supply	4- size “AA” alkaline Batteries	4- size “AA” alkaline Batteries	same
Memory Function	up to 199 memories (SYS, DIA, Pulse)	DB21：2×60； DB22：2×50； DB23：4×99； DB31：2×60； DB32：1×99； DB61M：4×99； DB62M：4×99； DB63M：4×99； DB71M：4×99	SE
Cuff Size	220mm~420mm	220mm~340mm	Similar Note01
Measuring range	Pressure: 30 to 280 mmHg (in 1 mmHg increment);	Pressure: (20mmHg~280 mmHg)	Similar Note02
	Pulse: 40 to 200 beat/minute	Pulse rate range(40-195) beats/minute	
Mesauring resolution	1 mmHg	1 mmHg	same
Accuracy	Pressure: ±3mmHg; Pulse: ±5%	Pressure: ±3mmHg; Pulse ±5%.	same
Irregular Heartbeat Detection	The subject devices have the IHB function.	DB22, DB23, DB61M, DB62M, DB63M, DB71M have the IHB feature.	same

Operating Environment	5~40℃,	10~40℃,	Similar Note03
	15%~85%RH	15%~90%RH	
Bluetooth transmission (optional)	Some moels BP100A, BP156A , BPCB0A-2A, BP156A -A and BP163A has optinal wireless function with blutooth LE.	No.	Different Note04

Note01: The subject devices have the larger arm circumference than predicate device, but the subject devices have been tested by ISO 81060-2.
Note02: The subject device has a smaller measuring range of pressure and larger measuring range of pulse than predicate device, but the subject devices have been validated all the full claimed range.
Note03: The subject device has a larger measuring range of temperature and smaller measuring range of humidity than predicate device, but the subject devices have been validated all the full claimed range.
Note04: The subject device has optional bluetooth function but the predicated device has no wireless function. FCC and wireless coexistence about the wireless performance have been validated.

The subject device is as same as predicate device in Working Principle, Intended patient population, intended application site, measuring accuracy. Only their Cuff size, measuring range and operating environment are a little bit different (refer to Note01 to Note 03) which had been validated by FCC and wireless coexistence. The subject device has a bluetooth function (Note 04) which had been validated. However, the differences would not raise any safety or effectiveness issue based on tests in this submission.

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

7 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
- CFR 47 FCC PART 15. 247 Operation within the bands 902-928 MHz, 2400-2483.5 MHz, and 5725-5850 MHz.

8 Brief discussions of clinical tests

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

In this clinical investigation, 85 patients (52 males and 33 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.

9 Other information (such as required by FDA guidance)

No other information.

11 Conclusions

The subject device:

Arm type Blood Pressure Monitor, 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(K091434).