DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 19, 2017

Shenzhen Pump Medical System Co., Ltd.
Ms. Migo Yang
Clinical Registration Specialist
2/f West, M-7 Sinosteel Building, Maqueling Estate
Hi-tech Industrial Park
Nanshan District, Shenzhen, 518057 CN

Re: K161712
Trade/Device Name: Arm automatic blood pressure monitor, Model: BF3213(0B), BF1214(0B), BF6123A, BF6148A, BF6055B
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: May 23, 2016
Received: June 21, 2016

Dear Ms. Migo Yang,

This letter corrects our substantially equivalent letter of April 5, 2017.

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

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)*
K161712

Device Name
Arm automatic blood pressure monitor, Model: BF3213(0B), BF1214(0B), BF6123A, BF6148A, BF6055B;

Indications for Use *(Describe)*
It is a device intended to measure the systolic, diastolic blood pressure and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable cuff (available sizes: 22cm~44cm (8.7in~17.3in)) is wrapped around the single upper arm.

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) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K161712

1. Submitter's Identification:

SHENZHEN PUMP MEDICAL SYSTEM CO., LTD.
2/F, M-7 Sinosteel Building, Maqueling Estate, Hi-Tech Industrial Park,
Nanshan District, Shenzhen,
PEOPLE'S REPUBLIC OF CHINA

Contact: Xie Qiongyu
Tel:86-0755-26710795
Fax:86-0755-26498210
E-mail: xieqy@bpump.com.cn

2. Name of the Device:

Trade Name: Arm automatic blood pressure monitor
Model: BF3213(0B), BF1214(0B), BF6123A, BF6148A, BF6055B;
Regulation Description: Non-invasive blood pressure measurement system.
Regulation Number: 21 CFR 870.1130
Regulation Class: II
Product Code: DXN
Review Panel: Cardiovascular

3. Information for the 510(k) Cleared Device(Predicate device):

Arm automatic blood pressure monitor, Model: BE6034, BE6134, K151258, SHENZHEN PUMP MEDICAL SYSTEM CO., LTD.

4. Description of the device

Arm automatic blood pressure monitor is based on pressure vibration method. Blood pressure cuff use the air pump to inflate, then the arteries are extruded by the cuff with pressure. Pressure sensor collects the pressure in the cuff, and then converts it to digital signal to the CPU. Then the software calculates the systolic and diastolic blood pressure and pulse rate.

The arm automatic blood pressure monitor, Model: BF3213(0B), BF1214(0B), BF6123A, BF6148A, BF6055B; has the same basic principles, main function, performance and intended use, and they are consistent in product structure and material.

5. Intended Use:

Arm automatic blood pressure monitor, model: BF3213(0B), BF1214(0B), BF6123A, BF6148A, BF6055B; is intended for measuring systolic, diastolic blood pressure and pulse rate of an adult over the counter.

6. Indications for Use:

Arm automatic blood pressure monitor, Model: BF3213(0B), BF1214(0B), BF6123A, BF6148A, BF6055B; is intended to measure the systolic, diastolic blood pressure and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable cuff (available sizes: 22cm to 44cm (8.7in to 17.3in)) is wrapped around the single upper arm.

7. Comparison to the 510(k) Cleared Device (Predicate device):

The subject device, Arm automatic blood pressure monitor, Model: BF3213(0B), BF1214(0B), BF6123A, BF6148A, BF6055B;and the predicate device: Arm automatic blood pressure monitor, Model: BE6034, BE6134 uses the same oscillometric method within the software algorithm to determine the systolic and diastolic blood pressure and pulse rate. Upper arm cuff is inflated automatically by air pump and the pressures are transferred via tubing to a sensor in the unit.

They differ by the appearance , the Bluetooth function and the way of energy supply. The appearance of subject device is a little different from predicate device; The appearance of subject device has Bluetooth function while the subject device has not the Bluetooth function. The only way of energy supply of predicate device is battery while the way of energy supply of subject device can be both battery and adapter. But those differences do not affect the accuracy or normal use of this device because they use the same fundamental scientific technology based on clinical declaration of identity and the declaration of clinical identity.

The subject device: Arm automatic blood pressure monitor, Model: BF3213(0B), BF1214(0B), BF6123A, BF6148A, BF6055B; uses the same oscillometric method as the predicate device: Arm automatic blood pressure monitor, Model: BE 6034, BE6134 to determinate the systolic and diastolic blood pressure and pulse rate. They have the same intended use. Based upon the aforementioned information, these devices are substantially equivalent.

Please refer to table below for comparison.

No	Items	Model					
		BE6034, BE6134	BF3213(0B)	BF1214(0B)	BF6123A	BF6148A	BF6055B
1	Manufacturer	SHENZHEN PUMP MEDICAL SYSTEM CO.,LTD.	SHENZHEN PUMP MEDICAL SYSTEM CO.,LTD.	SHENZHEN PUMP MEDICAL SYSTEM CO.,LTD.	SHENZHEN PUMP MEDICAL SYSTEM CO.,LTD.	SHENZHEN PUMP MEDICAL SYSTEM CO.,LTD.	SHENZHEN PUMP MEDICAL SYSTEM CO.,LTD.
2	Intended Use	It is a device intended to measure the systolic, diastolic blood pressure and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable cuff (available sizes: 22cm to 44cm (8.7in to 17.3in)) is wrapped around the single upper arm.	It is a device intended to measure the systolic, diastolic blood pressure and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable cuff (available sizes: 22cm to 44cm (8.7in to 17.3in)) is wrapped around the single upper arm.	It is a device intended to measure the systolic, diastolic blood pressure and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable cuff (available sizes: 22cm to 44cm (8.7in to 17.3in)) is wrapped around the single upper arm.	It is a device intended to measure the systolic, diastolic blood pressure and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable cuff (available sizes: 22cm to 44cm (8.7in to 17.3in)) is wrapped around the single upper arm.	It is a device intended to measure the systolic, diastolic blood pressure and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable cuff (available sizes: 22cm to 44cm (8.7in to 17.3in)) is wrapped around the single upper arm.	It is a device intended to measure the systolic, diastolic blood pressure and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable cuff (available sizes: 22cm to 44cm (8.7in to 17.3in)) is wrapped around the single upper arm.
3	Indications for Use	It is intended for measuring systolic, diastolic blood pressure and pulse rate of	It is intended for measuring systolic, diastolic blood pressure and	It is intended for measuring systolic, diastolic blood pressure and	It is intended for measuring systolic, diastolic blood pressure and	It is intended for measuring systolic, diastolic blood pressure and	It is intended for measuring systolic, diastolic blood pressure and

No	Items	Model					
		BE6034, BE6134	**BF3213(0B)**	**BF1214(0B)**	**BF6123A**	**BF6148A**	**BF6055B**
		an adult over the counter.	pulse rate of an adult over the counter.	pulse rate of an adult over the counter.	pulse rate of an adult over the counter.	pulse rate of an adult over the counter.	pulse rate of an adult over the counter.
4	Patient population	Adult	Adult	Adult	Adult	Adult	Adult
5	Environment of use	Home	Home	Home	Home	Home	Home
6	Measuring Principle	Oscillometric Method	Oscillometric Method	Oscillometric Method	Oscillometric Method	Oscillometric Method	Oscillometric Method
7	Measurement Range	Pressure: 0mmHg~280mmHg (0kPa~37.3kPa) Pulse: 40 bpm ~180 bpm	Pressure: 0mmHg~280mmHg (0kPa~37.3kPa) Pulse: 40 bpm ~180 bpm	Pressure: 0mmHg~280mmHg (0kPa~37.3kPa) Pulse: 40 bpm ~180 bpm	Pressure: 0mmHg~280mmHg (0kPa~37.3kPa) Pulse: 40 bpm ~180 bpm	Pressure: 0mmHg~280mmHg (0kPa~37.3kPa) Pulse: 40 bpm ~180 bpm	Pressure: 0mmHg~280 mmHg (0kPa~37.3kPa) Pulse: 40 bpm ~180 bpm
8	Accuracy	Pressure: ±3mmHg(±0.4kPa) Pulse: ±5%	Pressure: ±3mmHg(±0.4 kPa) Pulse: ±5%	Pressure: ±3mmHg(±0.4k Pa) Pulse: ±5%	Pressure: ±3mmHg(±0.4k Pa) Pulse: ±5%	Pressure: ±3mmHg(±0.4k Pa) Pulse: ±5%	Pressure: ±3mmHg(±0. 4kPa) Pulse: ±5%
9	Display	TN-LCD Digital Display	TN-LCD Digital Display	TN-LCD Digital Display	TN-LCD Digital Display	TN-LCD Digital Display	TN-LCD Digital Display
10	Memory	2 Memory sets, 60 readings each set.	2 Memory sets, 60 readings each set.	2 Memory sets, 60 readings each set.	2 Memory sets, 60 readings each set.	2 Memory sets, 60 readings each set.	2 Memory sets, 60 readings each set.
11	Power Source	4 AA Alkaline battery	4 AA Alkaline battery or AC Adapter (Input: AC 100-240 V, 50/60Hz,400mA; Output :	4 AA Alkaline battery or AC Adapter (Input: AC 100-240 V, 50/60Hz,400mA ; Output : D.C.	4 AA Alkaline battery or AC Adapter (Input: AC 100-240 V, 50/60Hz,400mA ; Output : D.C.	4 AA Alkaline battery or AC Adapter (Input: AC 100-240 V, 50/60Hz,400mA ; Output : D.C.	4 AA Alkaline battery or AC Adapter (Input: AC 100-240 V, 50/60Hz,400 mA; Output :

No	Items	Model					
		BE6034, BE6134	**BF3213(0B)**	**BF1214(0B)**	**BF6123A**	**BF6148A**	**BF6055B**
			D.C. 6.0V, 0.5A;)	6.0V, 0.5A;)	6.0V, 0.5A;)	6.0V, 0.5A;)	D.C. 6.0V, 0.5A;)
12	Broadcast Function	BE6034: YES; BE6134: No	No	No	No	No	No
13	Operating Environment	Temperature：+5℃～+40℃；Humidity：15%-93% Pressure: 70.0kPa～106.0kPa Altitude: ≤ 3 000 m	Temperature：+5℃～+40℃；Humidity：15%-93% Pressure: 70.0kPa～106.0kPa Altitude: ≤ 3 000 m	Temperature：+5℃～+40℃；Humidity：15%-93% Pressure: 70.0kPa～106.0kPa Altitude: ≤ 3 000 m	Temperature：+5℃～+40℃；Humidity：15%-93% Pressure: 70.0kPa～106.0kPa Altitude: ≤ 3 000 m	Temperature：+5℃～+40℃；Humidity：15%-93% Pressure: 70.0kPa～106.0kPa Altitude: ≤ 3 000 m	Temperature：+5℃～+40℃；Humidity：15%-93% Pressure: 70.0kPa～106.0kPa Altitude: ≤ 3 000 m
14	Storage and Transport Environment	Temperature：-25℃～+70℃；Humidity：10%～95% Pressure:50.0kPa～106.0kPa	Temperature：-25℃～+70℃；Humidity：10%～95% Pressure:50.0kPa～106.0kPa	Temperature：-25℃～+70℃；Humidity：10%～95% Pressure:50.0kPa～106.0kPa	Temperature：-25℃～+70℃；Humidity：10%～95% Pressure:50.0kPa～106.0kPa	Temperature：-25℃～+70℃；Humidity：10%～95% Pressure:50.0kPa～106.0kPa	Temperature：-25℃～+70℃；Humidity：10%～95% Pressure:50.0kPa～106.0kPa
15	Weight	360g (Without batteries)	278g(without batteries)	355g(without batteries)	341g(without batteries)	342g(without batteries)	381g(without batteries)
16	Size	140 mm×116mm×81 mm	138mm×110mm×68mm	140mm×116mm×81mm	154mm×124mm×65mm	141mm×114mm×67mm	157mm×113mm×60mm
17	Bluetooth function	No	Yes	Yes	Yes	Yes	Yes
18	Algorithm	Identical	Identical	Identical	Identical	Identical	Identical

The product specification of subject device and predicate device is identical in Intended Use, Indication for Use, Patient population, Environment of use, Measuring Principle, Measurement Range, Accuracy, Memory, Operating Environment, Storage and Transport Environment;

The subject device and predicate device are similar in Display, Broadcast Function: BF3213(0B) has 85×57(mm) standard screen; BE6034, BE6134 BF1214(0B), BF6123A, BF6148A, BF6055B has 94×80(mm) supersize screen; Model BE6034 has Broadcast Function; BE6134, BF3213(0B), BF1214(0B), BF6123A, BF6148A, BF6055B does not have Broadcast Function; But the minor discrepancies mentioned above do not affect the safety or effectiveness of the device.

The subject device and predicate device are differing in Power Source, Weight, Size; Comparing to the predicate device, the subject device has additional power Adapter; Besides, the subject device also has different appearance, which result in different weight and size; But the differences mentioned above do not affect the safety or effectiveness of the device.

The subject device are Substantially Equivalent (SE) to the predicate device which are US legally market devices.

8. Discussion of Non Clinical tests Performed for Determination of Substantial Equivalence: are as follows:

Testing information demonstrating substantial equivalence to the predicate device and safety and effectiveness of the Arm automatic blood pressure monitor, model: BF3213(0B), BF1214(0B), BF6123B, BF6148B, BF6155B; in the intended environment of use is supported by testing that was conducted in accordance with the FDA guidance "Reviewer Guidance for Premarket Notification Submissions", which outlines Electrical, Mechanical and Environmental Performance requirements.

The following testing was conducted:

a. IEC 60601-1 Test
b. IEC 60601-1-2 Test
c. IEC 60601-1-11 Test
d. IEC 80601-2-30 Test

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was our conclusion that Arm automatic blood pressure monitor, Model: BF3213(0B), BF1214(0B), BF6123A, BF6148A, BF6055B B; tested met all relevant requirements of the aforementioned tests.

9. Discussion of Clinical Tests Performed

The subject device: Arm automatic blood pressure monitor, Model: BF3213(0B), BF1214(0B), BF6123A, BF6148A, BF6055B; are identical to the predicate device: Arm automatic blood pressure monitor, Model: BE6034, BE6134 from the technical point of view. The differences between them do not relate to blood pressure measurement technology, so the clinical accuracy in terms of blood pressure detection will not be affected. Therefore repeated clinical test in accordance with the standard IEC 80601-2-30:2009 & A1:2013 is unnecessary.

10. Software Information

Software validation was conducted in accordance with a moderate level of concern designation in accordance with the FDA November 2005 document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

11. Conclusion

We have demonstrated that there are no significant differences between the subject device: Arm automatic blood pressure monitor (Model: BF3213(0B), BF1214(0B), BF6123A, BF6148A, BF6055B;), and the predicate device: Arm automatic blood pressure monitor (Model: BE6034, BE6134), in terms of safety and effectiveness based on electrical, mechanical and environmental test results per the FDA guidance "Non-Invasive Blood Pressure (NIBP) Monitor Guidance", and the IEC 80601-2-30:2009 + A1:2013.