



Food and Drug Administration  
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February 18, 2016

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

Re: K151258

Trade/Device Name: Arm Automatic Blood Pressure Monitor, Model: BE6034, BE6134  
Regulation Number: 21 CFR 870.1130  
Regulation Name: Noninvasive Blood Pressure Measurement System  
Regulatory Class: Class II  
Product Code: DXN  
Dated: January 5, 2016  
Received: January 19, 2016

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 yours,

**Kenneth J. Cavanaugh -S**

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)  
K151258

Device Name

Arm automatic blood pressure monitor, Model: BE6034, BE6134, Noninvasive blood pressure measurement system.

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 to 44cm (8.7in to 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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

### FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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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: K151258

### 1. Submitter's Identification

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Nanshan District,  
518057 Shenzhen,  
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Date Prepared: 2016-2-12

### 2. Name of the Device

Trade Name: Arm automatic blood pressure monitor  
Model No.: BE6034, BE6134  
Regulation Description: Noninvasive 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: BF1110, BF1112, BF1113 and BF1115, K130325, 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 uses the air pump to inflate, and 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, diastolic blood pressure and pulse rate.

The arm automatic blood pressure monitor, Model: BE6034, BE6134 has the same basic principles, main function, performance and intended use, and they are consistent in product structure and material.

## **5. Intended Use**

It is intended for measuring systolic, diastolic blood pressure and pulse rate of an adult over the counter.

## **6. Indications for Use**

It is a device intended to measure the systolic, diastolic blood pressure, 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 model BE 6034, BE6134 and the predicate device model BF1110, BF1112, BF1113, BF1115 use the same oscillometric method within the software algorithm to determine the systolic, diastolic blood pressure and pulse rate. Upper arm cuff is inflated automatically by air pump and the pressure is transferred via tube into a sensor in these two units.

They differ by the appearance and the way of energy supply. The appearance of subject device is little different from predicate device; The only way of energy supply of subject device is battery while both battery and DC energy are available for predicate device. But those differences either affect the accuracy or the normal use of subject device because they use the same fundamental scientific technology based on clinical declaration of identity.

The subject devices, model BE 6034, BE6134 use the same oscillometric method as the predicate device BF1110, BF1112, BF1113 and BF1115 to determine the systolic, diastolic blood pressure and pulse rate. They have the same function and intended use. Based upon the aforementioned information, these devices are substantially equivalent.

Please refer to table below for comparison.

<b>Items</b>	<b>Arm automatic blood pressure monitor</b>		<b>Arm automatic blood pressure monitor</b>
Manufacturer	SHENZHEN PUMP MEDICAL SYSTEM CO.,LTD.		SHENZHEN PUMP MEDICAL SYSTEM CO.,LTD.
Model Specification	BE6034	BE6134	BF1112
Intended Use	It is intended for measuring adult blood pressure and pulse rate		It is intended for measuring adult blood pressure and pulse rate
Indications for Use	It is a device intended to measure the systolic, diastolic blood pressure, 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, 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.
Patient population	Adult		Adult
Environment of use	Home		Home
Measuring Principle	Oscillometric Method		Oscillometric Method
Measurement Range	Pressure: 0mmHg~280mmHg (0kPa~37.3kPa) Pulse: 40bpm ~180 bpm		Pressure: 0mmHg-280mmHg (0kPa-37.3kPa) Pulse Rate: 40bpm-80bpm
Accuracy	Pressure: ±3mmHg(±0.4kPa) Pulse: ±5%		Pressure:±3mmHg (±0.4kPa) Pulse Rate: ±5%
Display	TN-LCD Digital Display		TN-LCD Digital Display
Screen Size	99mm×86mm		85mm×57mm
Memory	2 Memory sets, 60 reading each set.		1 Memory set, 90 reading each set.
Broadcast Function	Yes	No	No
Power Source	4 AA Alkaline battery		4 AA Alkaline battery or AC Adaptor (AC 100-240 V)
Operating Environment	Temperature: +5℃~+40℃; Humidity: 15%-93% Pressure: 70.0kPa~106.0kPa Altitude: ≤ 3 000 m		Temperature: +5℃~+40℃; Humidity: ≤93%RH
Storage and Transport Environment	Temperature: -25℃~+70℃; Humidity: 10%~95% Pressure:50.0kPa~106.0kPa		Temperature: -25℃~+70℃; Humidity: 10%~95%
Weight	360g(Without batteries)		294g(Without batteries)
Size	140 mm×116mm×81 mm		140mm×110mm×70mm

The subject device is Substantially Equivalent (SE) to the predicate device which is US legal.

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

Testing information demonstrates substantial equivalence to the predicate device and safety and effectiveness of the Arm automatic blood pressure monitor, Model:BE6034, BE6134 in the intended environment of use is supported by testing conducted in accordance with the FDA November 1993 Draft "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 & IEC 80601-2-30 Clause 202 Test
- c. IEC 60601-1-11 Test
- d. IEC 60601-2-30 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: BE6034, BE6134 tested met all relevant requirements of the aforementioned tests.

## **9. Discussion of Clinical Tests Performed:**

The subject device, Model BE6034, BE6134 is from the technical point of view, identical to the predicate blood pressure monitor, Model BF1110, BF1112, BF1113 and BF1115. 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(The standard IEC 80601-2-30:2009 & A1:2013has substituted the clinical requirements of ANSI/AAMI SP10) 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 is no significant differences between the Arm automatic blood pressure monitor (Model: BE6034, BE6134), and the predicate device: Arm automatic blood pressure monitor (Model: BF1110, BF1112, BF1113 and BF1115), in terms of safety and effectiveness based on electrical, mechanical and environmental test results. And they are substantially equivalent to the earlier identified predicate device.