



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

December 17, 2015

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

Re: K151810  
Trade/Device Name: Bpump Blood Pressure Cuff, Model: BC1000, BC8000, Blood Pressure Cuff  
Regulation Number: 21 CFR 870.1120  
Regulation Name: Blood Pressure Cuff  
Regulatory Class: Class II  
Product Code: DXQ  
Dated: June 15, 2015  
Received: July 2, 2015

Dear Ms. 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

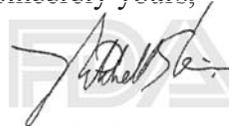
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go 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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a faint, large, light-colored "FDA" watermark.

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)

K151810

Device Name

Bpump Blood Pressure Cuff, Model: BC1000, BC8000, Blood Pressure Cuff.

Indications for Use (Describe)

The Bpump Blood Pressure Cuff, Model: BC1000, BC8000, are intended to be wrapped on the upper arm and used with a non-invasive blood pressure monitor system to complete the measurement of blood parameters on adults.

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: K151810

Date Summary Prepared: Oct 16, 2015

### 1. Submitter's Identification:

SHENZHEN PUMP MEDICAL SYSTEM CO., LTD.  
2/F, M-7 Sinosteel Building, Maqueling Estate, Hi-Tech Industrial Park,  
Nanshan District,  
518057 Shenzhen,  
PEOPLE'S REPUBLIC OF CHINA

Contact: Xie Qiongyu

Tel: 86-0755-26710795

Fax: 86-0755-26498210

E-mail: xieqy@bpump.com.cn

### 2. Device Information:

Trade Name: Bpump Blood Pressure Cuff

Model No.: BC1000, BC8000

Common Name/Classification Name: Blood Pressure Cuff

Product Code: DXQ

Regulation Number: 21 CFR 870.1120

Regulation Class: Class II

Review Panel: Cardiovascular

**3. Predicate Device:**

510(k) Number: K133117

Trade Name: Andon Blood Pressure Cuff

Common Name/Classification Name: Blood Pressure Cuff

Product Code: DXQ

Regulation Number: 21 CFR 870.1120

Regulation Class: Class II

Review Panel: Cardiovascular

Manufactured By: Andon Health Co., Ltd.

**4. Indication for Use**

The Bpump Blood Pressure Cuff, Model: BC1000, BC8000, are intended to be wrapped on the upper arm and used with a non-invasive blood pressure monitor system to complete the measurement of blood parameters on adults.

**5. Intended Use**

The Bpump Blood Pressure Cuff, Model: BC1000, BC8000, are intended to be wrapped on the upper arm and used with a non-invasive blood pressure monitor system to complete the measurement of blood parameters on adults.

**6. Description of the device:**

The proposed device, Bpump Blood Pressure Cuff, is a rectangle soft inelastic sleeve reusable with a bladder. There is a single-tube connected to the bladder and the Non Invasive Blood Pressure Monitor for inflating and deflating. The device should be connected to a Non Invasive Blood Pressure Monitor to complete the function. There are two sizes for different arm range as follows:

<b>Model</b>	<b>Arm range</b>
BC1000	22cm~36cm (8.7in ~14.2in)
BC8000	32cm~44cm (12.6in~17.3in)

## 7. Summary Comparing Technological Characteristics with Predicate Device

The proposed changes described in this submission do not affect the intended use of the device and/or alter the fundamental scientific technology of the legally marketed predicate device described in the K1 33177. Please refer to table below for comparing result:

Technological Characteristics	Comparing Result
Intended Use	Identical
Indications For Use	Identical
Patient Population	Identical
Environment of Use	Identical
Tube Configuration	Identical
Sterility	Identical
Applicable Arm Circumference	Similar
Standards Applied	Similar

The subject device and predicate device are identical in intended use, Indications for Use, Patient Population, Environment of Use, Tube Configuration, Sterility, Standards; The subject device and predicate device are similar in Applicable Arm Circumference and Standards Applied. But the minor discrepancies mentioned above do not affect the safety or effectiveness of the subject device.

## 8. Discussion of non-clinical and clinical test performed

### Non-clinical Tests have been done as follows:

- a. Safety and performance characteristics of the test according to IEC 80601-2-30
  - b. Biocompatibility test performed according to ISO 10993-5 and ISO 10993-10
- None of the test demonstrates that the Bpump Blood Pressure Cuff brings new questions of safety or effectiveness.

### Clinical Test Concerning the Compliance of ANSI/AAMI/ISO 81060-2

Clinical test has been done in accordance with IEC 80601-2-30 and ANSI/AAMI/ISO 81060-2, and the test result shows, the device met all applicable requirements of the standard.

## 9. Performance:

### Guidances

There is a guidance named "Guidance for Industry: Non-Automated Sphygmomanometer (Blood Pressure Cuff) Guidance Version I, November 19, 1998" for product code DXQ, which scope does not include any automated non-invasive blood pressure monitors whether using the oscillometric method or any other method. So, we concluded that the guidance is inapplicable to the subject device.

### Standards

The Bpump Blood Pressure Cuff conforms to the following standards:

- IEC 80601-2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
- ANSI/AAMI/ISO 81060-2: Non-invasive sphygmomanometers - part 2: Clinical validation of automated measurement type.
- ISO 10993-1: Biological evaluation of medical devices - Part I: Evaluation and testing within a risk management process
- ISO 10993-5: Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity.
- ISO 10993-10: Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

## 10. Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Part 807, and based on the information provided in this premarket notification, **SHENZHEN PUMP MEDICAL SYSTEM** concludes that the subject device, the **Bpump Blood Pressure Cuff**, is safe, effective and substantially equivalent to **Andon Blood Pressure Cuff (K133117)**.