



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 24, 2016

Suzhou Sunspiri Co., Ltd.
% Long Yang
Coo
Shenzhen Hlongmed Biotech Company Limited
R1508, East Building, Yihai Plaza, Chuangye Road,
Nanshan District
Shenzhen, 518054 CN

Re: K153033
Trade/Device Name: Digital Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: May 13, 2016
Received: May 19, 2016

Dear Long 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

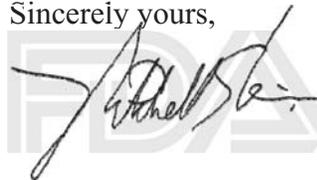
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go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

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)

Device Name

Digital Blood Pressure Monitor

Models: JWS Series, including: JDS-189, JDS-500, JDS-500A, JDS-500E, JDS-600, JDS-700, JDS-703, JDS-704, JDS-800, BM20

Indications for Use (Describe)

This device is intended to measure the blood pressure and pulse rate on upper arms of 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)

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

Date Prepared: June 22, 2016

1. Submitter

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2. Submission Correspondent

1) Ms. Jing Zhang (QA manager)

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2) Mr. Long Yang (COO)

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3. Proposed Device Information

Trade name: Digital Blood Pressure Monitor

Model: JDS Series, including: JDS-189, JDS-500, JDS-500A, JDS-500E, JDS-600,
JDS-700, JDS-703, JDS-704, JDS-800, BM20

Common name: Digital Blood Pressure Monitor

Classification name: Noninvasive Blood Pressure Measurement System

Review Panel: Cardiovascular System Devices Panel (74)

Product Code: DXN

Regulation Class: II

Regulation Number: 870.1130

4. Predicate Device Information

Company Name: Shenzhen Pump Medical System Co., Ltd.

Device Name: Arm Automatic Blood Pressure Monitor, model BF1115

510(k) number: K130325

5. Device Description

The Digital Blood Pressure Monitor is Arm-type fully automatic Digital Blood Pressure Monitor and used the oscillometric method for non-invasive measurement of blood-pressure at home.

The equipment is non-transit-operable, portable equipment, not used at the conditions of patient movement in normal use. The unit is powered by internal dry battery.

Digital 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.

Digital Blood Pressure Monitor, JDS-189, JDS-500, JDS-500A, JDS-500E, JDS-600, JDS-700, JDS-703, JDS-704, JDS-800, BM 20 in term of intended use measurement method, structure, and specifications are totally same, only the appearance, memory space has difference.

6. Intended use/Indications for use:

This device is intended to measure the blood pressure and pulse rate on upper arms of adults.

7. Testing data and clinical study

Laboratory testing was conducted to validate and verify that Digital Blood Pressure Monitor met all requirements of related international standards, including electrical safety, EMC, biocompatibility, specification. Results of these tests demonstrate compliance to the requirements of the bellow consensus standards.

Clinical study has been evaluated according to ANSI/AAMI/ISO 81060-2.

Applied Standard:

- **Electrical Safety requirement:** AAMI / ANSI ES 60601-1:2005
- **Performance requirement:** IEC80601-2-30
- **Electromagnetic Compatibility Requirements:** IEC 60601-1-2
- **Home-used medical equipment requirements:** IEC 60601 -1 -11
- **Biocompatibility Evaluation for NIBP Cuff:** ISO 10993-5, ISO 10993-10
- **Clinical Evaluation:** ANSI/AAMI/ISO 81060-2

8. Comparison to Predicate Device

Trade Name	Digital Blood Pressure Monitor	Arm Automatic Blood Pressure Monitor
Model	JDS-189, JDS-500, JDS-500A, JDS-500E, JDS-600, JDS-700, JDS-703, JDS-704, JDS-800, BM 20	BF1115
Indications for use	This device is intended to measure the blood pressure and pulse rate on upper arms of adults.	It is intended for measuring adult blood pressure and pulse rate.
Target population	Adult	Adult
Environment of use	Home	Home
Technology	Oscillometric method	Oscillometric method
Measurement Method	Non-invasive	Non-invasive
Measurement localization	Upper arm	Upper arm
Memory Space	2 × 30(BM20, JDS-189, JDS-500, JDS-500A, JDS-500E, JDS-600) / 1 × 99(JDS-700)/ 2 × 60(JDS-703, JDS-704)/ 2 × 50(JDS-800)	50 sets of measurement values(blood pressure and pulse rate) for each user(Memory 1 and Memory 2)
Measuring parameters	blood pressure (systolic and diastolic) and heart rate	blood pressure (systolic and diastolic) and heart rate

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Measurement range	Pressure: 0 – 300 mmHg Pulse: 40 –180 beats/min	Pressure: 0 to 280 mmHg Pulse: 40 to 180 pulses/min
Measurement accuracy	Pressure: ± 3 mmHg Pulse: $\pm 5\%$ of the displayed value	Pressure: ± 3 mmHg Pulse: $\pm 5\%$ of the displayed value
Inflation Mode	Automatic by Internal Pump	Automatic by Internal Pump
Deflation Mode	Automatic by Valve	Automatic by Valve
Measurable circumference	22-32cm	22-36cm
Display	LCD, digital display	LCD, digital display
Energy source	4 AA Alkaline batteries	4 AA Alkaline batteries or AC adaptor(AC 100 ~ 240V)
Operating environment	+10 ~+40 °C , $\leq 85\%$ RH	+5~+40°C , $\leq 93\%$ RH
Storage environment	-5 ~ +50 °C, $\leq 85\%$ RH	-25~+70°C , 10~95%RH

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

9. Conclusion

Digital Blood Pressure Monitor has the same intended use, the same technological characteristics as the predicate device. Moreover, non-clinical testing & clinical testing contained in this submission demonstrated that any difference in their technological characteristics does not raise any new issues of safety and effectiveness.

In a word, Digital Blood Pressure Monitor is substantial equivalent to the predicate device.