DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

May 6, 2016

Suzhou Sunspirit Co., Ltd.
% Long Yang
COO
Shenzhen Hlongmed Biotech Company Limited
R150-08, East Building, Yihai Plaza, Chuangye Road,
Nanshan District
Shenzhen, 518054 CN

Re: K152415
Trade/Device Name: Digital Blood Pressure Monitor models JWS-1000, JWS-970, JWS-950, JWS-940, JWS-706, JWS-705, JWS-704, JWS- JWS-703, JWS-701, JWS-700, BC20, and BC40
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: March 30, 2016
Received: April 5, 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,

Shawn W. Forrest -S
2016.05.06 17:10:25 -04'00'

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152415

Device Name
Digital Blood Pressure Monitor
Models: JWS Series, including: JWS-1000, JWS-970, JWS-950, JWS-940, JWS-706, JWS-705, JWS-704, JWS-703, JWS-701, JWS-700, JWS-600, BC20, BC40

Indications for Use *(Describe)*

It can be used as medical assistant instrument at home or in medical center for adult population for measuring systolic and diastolic blood pressure and heart rate.

The device is intended for use in only adult population, not applied to the other populations such as neonatal baby.

It can not be used while the wrist (arm) has bleeding or wound to avoid the blood flowing from the wound in pressurizing.

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.

510(k) Summary

Date Prepared: July 31, 2015

1. Submitter:

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3. Proposed Device Information:

Trade name: Digital Blood Pressure Monitor

Model: JWS Series, including: JWS-1000, JWS-970, JWS-950, JWS-940, JWS-706, JWS-705, JWS-704, JWS-703, JWS-701, JWS-700, JWS-600, BC20, BC40

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 KINGYIELD TECHNOLOGY CO., LTD.

Device Name: BP201 Wrist Blood Pressure Monitor

510(k) number: K083043

5. Device Description:

Digital Blood Pressure Monitor is a fully automatic non-invasive blood pressure monitor which measures systolic and diastolic blood pressure and heart rate of adult population using the oscillometric method by inflating an inflatable cuff on the wrist.

Digital Blood Pressure Monitor JWS-1000, JWS-970, JWS-950, JWS-940, JWS-706, JWS-705, JWS-704, JWS-703, JWS-701, JWS-700, JWS-600, BC20, BC40 have the same technology, main function, performance and intended use, and they are consistent in product structure and material.

6. Intended use:

Digital Blood Pressure Monitor is intended to be used as a medical assistant instrument at home or in a medical center for adult populations for measuring blood pressure and heart rate.

The device is intended for using in only adult population, not applied to the other populations such as neonatal baby.

It cannot be used while the wrist (arm) has bleeding or wound to avoid the blood flowing from the wound in pressurizing.

7. Performance and Technological Characteristics:

7.1 Performance Summary

In terms of operating specification, Safety & EMC requirements, the device conform to

applicable standards including IEC80601-2-30: 2009 +Amendment 1:2013, ANSI/AAMI/ISO 81060-2:2009, BS EN1060-4: 2004, AAMI / ANSI ES 60601-1:2005/(R)2012 +A1：2012 and C1:2009/(R)2012 and, a2:2010/(r)2012, IEC 60601-1-2 Edition 3: 2007-03, A comparison study with a device that uses auscultatory method used by trained observers was performed to validate the performance of Digital Blood Pressure Monitor. The comparison study demonstrated that the clinical repeatability of Digital Blood Pressure Monitor is statistically and clinically acceptable.

7.2 Technological Characteristics

Digital Blood Pressure Monitor uses an inflated cuff which is wrapped around the wrist. The cuff is inflated by a built-in air pump. The systolic and diastolic blood pressures are determined by Oscillometric method. The inflation rate is controlled by MCU at a constant rate. The user can release the cuff to stop measuring by pressing the "ON/OFF" button at any time while measuring. The measuring result is displayed in LCD.

8. Substantial equivalence discussion

8.1. About the non-clinical tests

Digital Blood Pressure Monitor has the same intended use, the same technological characteristics as the predicate device BP201, such as Measurement localization, Measuring parameters, Measurement range, Measurement Accuracy, Inflation, Deflation, Power source.

The main differences are the physical size, shape and weight, Memory space Measurable circumference of wrist, Operate environment, Storage environment and there is no any new issue of safety and effectiveness.

So the non-clinical performance information demonstrates the equivalence of the non-clinical performance.

In a word, Digital Blood Pressure Monitor is equivalent to the predicate device for the non-clinical performance.

8.2. About the clinical tests

The device complies with the ANSI/AAMI/ISO 81060-2:2009 standard and BS

EN1060-4: 2004 in its entirety. Thus Digital Blood Pressure Monitor & the predicate device BP201 are substantially equivalent.

9. Conclusion

Digital Blood Pressure Monitor has the same intended use, the same technological characteristics as the predicate device BP201. 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 BP201.