March 9, 2018

Xuzhou Yongkang Electronic Science Technology Co., Ltd.
% Ray Wang
General Manager
Beijing Believe Technology Service Co., Ltd.
5-1206, Build 332, DaFangJu, No.25 BanBiDian Rd.
LiYuan Town, TongZhou District, Beijing, 101121 China

Re: K162616
Trade/Device Name: Wrist Type Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: Class II
Product Code: DXN
Dated: January 21, 2018
Received: January 25, 2018

Dear Ray Wang:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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)*

K162616

Device Name
Wrist Type Blood Pressure Monitor

Indications for Use *(Describe)*

The Wrist Type Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person via non-invasive oscillometric technique in which an inflatable cuff is wrapped around the Wrist. It can be used at medical facilities or at home.

The cuff size is 310 mm x 75 mm, and the intended wrist circumference is 13.5 - 19.5 cm.

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.

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

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Tab #3 510(k) Summary

This 510(k) Summary of 510(k) substantial equivalence information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K162616

1. Date of Preparation

   01/21/2018

2. Sponsor

Xuzhou Yongkang Electronic Science Technology Co., Ltd

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3. Submission Correspondent

Mr. Ray Wang

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4. Identification of Proposed Device

Trade Name: Wrist Type Blood Pressure Monitor
Common Name: Blood Pressure Monitor
Model(s): YK-BPW1

Regulatory Information:
Classification Name: System, measurement, blood-pressure, non-invasive;
Classification: II;
Product Code: DXN;
Regulation Number: 21 CFR 870.1130；
Review Panel: Cardiovascular;

Indication For Use Statement:
The Wrist Type Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person via non-invasive oscillometric technique in which an inflatable cuff is wrapped around the Wrist. It can be used at medical facilities or at home. The cuff size is 310 mm x 75 mm, and the intended wrist circumference is 13.5 - 19.5 cm.

5. Device Description

The proposed device, Wrist Type Blood Pressure Monitor, is a battery driven automatic non-invasive blood pressure monitor.
The Wrist Type Blood Pressure Monitor can automatically complete the inflation, deflation and measurement of systolic and diastolic blood pressure as well as the pulse rate of adult person.
User can set different user ID for data storage, which can be set as two independent groups of measured blood pressure data;
User can set the time as year, month, day, hour and minute;
User can enable or disable the function of voice broadcast about measurement result;
User can select the unit of the measurement: mmHg or KPa;
The device has the data storage function for data reviewing, including the data of systolic pressure, diastolic pressure, pulse rate and measurement time.
The device has low power indicator to indicate the states of low batteries power.

6. Identification of Predicate Device

Predicate #
510(k) Number: K131569
Product Name: PG 800A Series Electronic Blood Pressure Monitor
Manufacturer: Shenzhen Pango Electronic Co., Ltd.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

IEC 60601-1:2012, Medical electrical equipment– Part 1: General requirements for basic safety, and essential performance.
IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.
ISO 80601-2-30:2013, Medical Electrical Equipment - Part 2-30: Particular Requirements For The Basic Safety And Essential Performance Of Automated Non-Invasive Sphygmomanometers.
ISO 10993-5: 2009, Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity.
ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

8. Clinical Test Conclusion

The clinical trials for YK-BPW1 were performed according to *ISO 81060-2:2013, Non-Invasive Sphygmomanometers - Part 2: Clinical Validation of Automated Measurement Type, and* relevant volunteers were collected to conduct actual clinical trial of blood pressure measurement.
There were 150 subjects been selected to participate in the trial, and Auscultation was applied as gold standard with the qualified calibrated mercurial sphygmomanometer used as control group for comparison with the proposed device.
The results shown that the accuracy of proposed device meet the requirements of ISO 81060-2:2013 within the ±5mmHg.

9. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

ITEM	Proposed Device	Predicate Device K131569	Remark
Product Code	DXN	DXN	SE
Regulation No.	21 CFR 870.1130	21 CFR 870. 1130	SE
Class	2	2	SE
Intended Use	The Wrist Type Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person via non-invasive oscillometric technique in which an inflatable cuff is wrapped around the Wrist. It can be used at medical facilities or at home. The cuff size is 310 mm x 75 mm, and the intended wrist circumference is 13.5 - 19.5 cm.	The PG-800A Series Electronic Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person via non-invasive oscillometric technique in which an inflatable cuff is wrapped around the wrist. It can be used at medical facilities or at home. The intended wrist circumference is 13.5-19.5 cm.	SE
Application Site	Wrist	Wrist	SE
Patient Population	Adult	Adult	SE
Measurements Item	SYS,DYS,Pulse	SYS,DYS,Pulse	SE
Principle	Oscillometric	Oscillometric	SE
Main Component	LCD / Key / Cuff / MCU / Pump / Batteries	LCD / Key / Cuff / MCU / Pump / Batteries	SE

Table 2 Performance Comparison

ITEM	Proposed Device	Predicate Device K131569	Remark
BP Range	20-280 mmHg	30-280 mmHg	SE
BP Accuracy	±3 mmHg	±3 mmHg	SE
PR Range	40-199	40-199 bpm	SE
Operation Condition	5-40 ℃ 15%-80% RH 50kPa～105kPa	5-40 ℃ 30%-80% RH Atmosphere Pressure	SE
Storage Condition	-20-55 ℃ ≤90% RH 50kPa～105kPa	-20-55 ℃ 10%-90% RH Atmosphere Pressure	SE
Data Storage	SYS, DIA, PR, Measurement Time, No.	SYS, DIA, PR, Measurement Time, No.	SE
Performance Standard	Comply with ISO 80601-2-30	Comply with AAMI SP10	SE
Cuff Size	310 x 75 mm	30.8 cm (length) x 8 cm (width)	Analysis
Power Supply	2 x AAA	Two AAA or LR03 Batteries	SE
Voltage	3V	3V	SE

Analysis

The proposed device is substantially equivalent to the predicate device. Based on the nonclinical and clinical tests performed, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device.

Table 3Safety Comparison

ITEM	Proposed Device	Predicate Device K131569	Remark
Electrical Safety	Comply with IEC 60601-1	Comply with IEC 60601-1	SE
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SE
Biocompatibility	Comply with ISO 10993-1	Comply with ISO 10993-1	SE
Label and Labeling	Conforms to FDA Regulatory Requirements	Conforms to FDA Regulatory Requirements	SE
Level of Concern of the Software	Moderate	Moderate	SE

10. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.