March 2, 2018

Shenzhen Jiacom Technology Co., Ltd.
% Diana Hong, General Manager
Mid-Link Consulting Co., Ltd.
P.O. Box 120-119
Shanghai, 200120 China

Re: K172972
Trade/Device Name: Wrist Type Automatic Blood Pressure Monitor, Models: BP165W, BP168W, BP180W, BP186W and BP188W
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: January 30, 2018
Received: February 1, 2018

Dear Diana Hong:

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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K172972

Device Name
Wrist Type Automatic Blood Pressure Monitor, Models: BP165W, BP168W, BP180W, BP186W and BP188W

Indications for Use *(Describe)*
Wrist Type Automatic Blood Pressure Monitor is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population who can understand the instruction manual with the wrist circumference range printed on the wrist cuff. 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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K172972

1. Date of Preparation: 01/16/2018

2. Sponsor Identification

**Shenzhen Jiacom Technology Co., Ltd**
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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Betty Xiao (Alternative Contact Person)

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4. Identification of Proposed Device

Trade Name: Wrist Type Automatic Blood Pressure Monitor
Common Name: Wrist Blood Pressure Monitor
Models: BP165W, BP168W, BP180W, BP186W and BP188W

Regulatory information:
Classification Name: Noninvasive blood pressure measurement system
Classification: 2
Product Code: DXN
Regulation Number: 21 CFR 870.1130
Review Panel: Cardiovascular

Intended Use Statement:
Wrist Type Automatic Blood Pressure Monitor is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population who can understand the instruction manual with the wrist circumference range printed on the wrist cuff. The intended wrist circumference is 13.5-19.5 cm.

Device Description

The proposed device, Wrist Type Automatic Blood Pressure Monitor, is a battery driven automatic non-invasive blood pressure monitor. It can automatically complete the inflation, deflation and measurement, which can measure systolic and diastolic blood pressure and pulse rate of the adult person at wrist within its claimed range and accuracy via the oscillometric technique. User can select the unit of the measurement: mmHg or KPa.

The device has the data storage function in order for data reviewing, including the systolic pressure, diastolic pressure, pulse rate and measurement time. It has a bar indicating function, which can indicate the WHO (World Health Organization) Blood Pressure Classification of the measured blood pressure by referencing Diastolic Blood Pressure issued at Journal of Hypertension 1999. Vol 17, No.2.

The proposed device is intended to be used in medical facilities or at home. And it is provided non-sterile, and not to be sterilized by the user prior to use.

The proposed blood pressure monitor includes 5 models, which are BP165W, BP168W, BP180W, BP186W and BP 188W. All models follow the same software, measurement principle and NIBP algorithm. The main differences are product appearance and key numbers.

5. Identification of Predicate Device

510(k) Number: K131569

Product Name: Electronic Blood Pressure Monitor, PG-800A Series

6. 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:

- AAMI / ANSI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012, Medical electrical equipment – Part 1: General requirements for basic safety, and essential performance.
- IEC 60601-1-2 Edition 4.0 2014-02, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests.
- IEC 60601-1-11 Edition 2.0 2015-01, Medical Electrical Equipment - Part 1-11: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment
- IEC 80601-2-30 Edition 1.1 2013-07, 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.

7. Clinical Test Conclusion

The clinical accuracy of the proposed device was evaluated per the following standard. The test results demonstrated that the proposed device comply with the standard requirements.

ISO 81060-2 Second Edition 2013-05-01, Non-Invasive Sphygmomanometers - Part 2: Clinical Validation Of Automated Measurement Type.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

| Item | Proposed Device | Predicate Device<br>K131569 |
|---|---|---|
| Product Code | DXN | DXN |
| Regulation Number | 21 CFR 870.1130 | 21 CFR 870.1130 |
| Class | II | II |
| Intended Use | Wrist Type Automatic Blood Pressure Monitor is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population who can understand the instruction manual with the wrist circumference range printed on the wrist cuff. The intended wrist circumference is 13.5-19.5 cm. | 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. |
| Measurement Site | wrist | wrist |
| Patient Population | Adult | Adult |
| Measurement Item | Systolic Pressure, Diastolic Pressure, Pulse Rate | Systolic Pressure, Diastolic Pressure, Pulse Rate |
| Measurement Method | Oscillometric | Oscillometric |
| Component | LCD / Key / Cuff / MCU / Pump / Batteries | LCD / Key / Cuff / MCU / Pump / Batteries |
| Blood Pressure Range | 30 ~ 280 mmHg | 30 ~ 280 mmHg |
| Pulse Rate Range | 40 ~ 200 bpm | 40 ~ 199 bpm |
| WHO BP Classification | Yes<br>Per WHO Classification | Yes<br>Per WHO Classification |
| Wrist circumference | 13.5-19.5 cm | 13.5-19.5 cm |
| Particular Performance | Comply with IEC 80601-2-30:2009 and ISO 81060-2:2013 | Comply with ANSI/AAMI SP10 |
| Electrical Safety | Comply with IEC 60601-1 | Comply with IEC 60601-1 |
| EMC | Comply with IEC 60601-1-2 | Comply with IEC 60601-1-2 |
| Biocompatibility | No Cytotoxicity, sensitization, or irritation | Comply with ISO 10993 requirements |
| Software Level Concern | Moderate | Moderate |

The proposed device and its predicate devices have the identical indented use, components, principle and

performance. The difference between the proposed device and the predicate device do not raise any question regarding its safety and effectiveness.

9. Substantially Equivalent (SE) Conclusion

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