January 26, 2018

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

Re: K172896
Trade/Device Name: Arm Type Automatic Blood Pressure Monitor BP310A, BP313A, BP351A, BP362A, BP366A, BP369A, BP380A, BP389A, BP-JC312
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: December 25, 2017
Received: December 28, 2017

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172896

Device Name
Arm Type Automatic Blood Pressure Monitor
BP310A, BP313A, BP351A, BP362A, BP366A, BP369A, BP380A, BP389A, BP-JC312

Indications for Use *(Describe)*
Arm Type Automatic Blood Pressure Monitor is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population via non-invasive oscillometric technique in which an inflatable cuff is wrapped around the arm. It can be used at medical facilities or at home. The intended arm circumference is 22-32 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.

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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."

Tab #7 510(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: K172896

1. Date of Preparation: 12/20/2017

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: Arm Type Automatic Blood Pressure Monitor
Common Name: Arm Blood Pressure Monitor
Models: BP310A, BP313A, BP351A, BP362A, BP366A, BP369A, BP380A, BP389A, BP-JC312

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:
Arm Type Automatic Blood Pressure Monitor is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population via non-invasive oscillometric technique in which an inflatable cuff is wrapped around the arm. It can be used at medical facilities or at home. The intended arm circumference is 22-32 cm.

Device Description

The proposed device, Arm 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 upper arm 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 9 models, which are BP310A, BP313A, BP351A, BP362A, BP366A, BP369A, BP380A, BP389A, and BP-JC312. 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: K131558
Product Name: Electronic Blood Pressure Monitor

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 K131558
Product Code	DXN	DXN
Regulation Number	21 CFR 870.1130	21 CFR 870.1130
Class	II	II
Intended Use	Arm Type Automatic Blood Pressure Monitor is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population via non-invasive oscillometric technique in which an inflatable cuff is wrapped around the arm. It can be used at medical facilities or at home. The intended arm circumference is 22-32 cm.	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 arm. It can be used at medical facilities or at home. The intended arm circumference is 22-32 cm.
Measurement Site	Upper arm	Upper arm
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
Size	BP310A: L133.2mm*W102.6mm*H65mm BP313A: L137mm*W121mm*H90mm BP351A: L136mm*W95mm*H65mm BP362A: L133mm*W103mm*H63mm BP366A: L145mm*W105mm*H53mm BP369A: L130mm*W108mm*H53mm BP380A: L125mm*W71mm*H61mm BP389A: L141.7mm*W96.5mm*H53mm BP-JC312: L137mm*W121mm*H90mm	PG-800B6D: L138mm*W121mm*H83mm
Weight	BP310A: Approx. 390g(with batteries) BP313A: Approx. 313g(with batteries) BP351A: Approx.412g(with batteries) BP362A: Approx.362(with batteries) BP366A: Approx.405g(with batteries)	PG-800B6D: About 430g excluding batteries

	BP369A: Approx.415g(with batteries) BP380A: Approx.368g(with batteries) BP389A: Approx.368g(with batteries) BP-JC312: Approx.417g(with batteries)	
Display	Systolic pressure, diastolic pressure, unit of pressure, pulse rate, irregular heartbeat, pulse indicator, date, time, WHO BP classification indicating bar, low battery indicator, memory	Systolic pressure, diastolic pressure, unit of pressure, pulse rate, pulse indicator, date, time, WHO BP classification indicating bar, low battery indicator, memory
Blood Pressure Range	30 ~ 280 mmHg	30 ~ 280 mmHg
Blood Pressure Accuracy	3 mmHg	3 mmHg
Pulse Rate Range	40 ~ 200 bpm	40 ~ 199 bpm
Pulse Rate Accuracy	±5%	±5%
WHO BP Classification	Yes Per WHO Classification	Yes Per WHO Classification
Arm circumference	22-32mm	22-32mm
Particular Performance	Comply with IEC 80601-2-30:2009 and ISO 81060-2:2013	Comply with ANSI/AAMI SP10
Power Supply	four AA batteries	four AA or LR6 batteries
Voltage	6V	6V
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
Patient-contact component and material	Cuff: Terylene Tube: Polyvinyl chloride (PVC)	Cuff – Nylon Enclosure – ABS Key - ABS
Biocompatibility	No Cytotoxicity, sensitization, or irritation	Comply with ISO 10993 requirements
Software Level Concern	Moderate	Moderate
Labeling	Conforms to 21CFR part 801	Conforms to 21CFR part 801

The size, weight, and Pulse Rate Range of proposed device and predicate device are different. But the difference is very slight, and size, weight and Pulse Rate Range of proposed device is clearly indicated in user manual. Therefore, this difference will not result in any safety and effectiveness issue of the proposed device.

The proposed device displays the irregular heartbeat, while the predicate device does not display. The

function of irregular heartbeat display has been validated per Software testing. Therefore, this difference will not result in any safety and effectiveness issue of the proposed device.

The SP10 standard is no longer an FDA recognized consensus standard for evaluating the safety and performance of NIBP system, therefore the particular performance proposed device was conducted according to IEC 80601-2-30, the test results demonstrated that the proposed device meet the requirements of IEC 80601-2-30. In addition, the clinical investigation of the proposed device has been conducted according to ISO 81060-2:2013 to demonstrate the clinical accuracy. Therefore this difference on the particular performance will not affect the safety and effectiveness of the proposed device.

The patient contact components and materials of the proposed and predicate device are different. But both of them comply with ISO 10993 requirements. Therefore, this difference will not result in any safety and effectiveness issue of the proposed device.

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.