August 31, 2022

Jiangxi AICARE Medical Technology Co., Ltd
% Bing Huang
Registration engineer
Feiying Drug and Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center, No. 3101-90,
Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K221040
Trade/Device Name: Electronic Sphygmomanometers, (Model: X1, X2, X5, X6, X7, X8, X11)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: June 15, 2022
Received: June 22, 2022

Dear Bing Huang:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221040

Device Name
Electronic Sphygmomanometers (Model: X1,X2,X5,X6,X7,X8,X11)

Indications for Use *(Describe)*
Electronic Sphygmomanometers is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person and adolescents age 18 through 21 years of age .It can be used at medical facilities or at home.

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

This summary of 510(k) safety and effectiveness information is submitted in accordance with requirements of Title 21, CFR Section 807.92.

1) Applicant information:

510(k) owner's name:	Jiangxi AICARE Medical Technology Co., Ltd.
Address:	No.6, South Side of Nanhuan Road Qianping Industrial Park, Le'an County, Fuzhou City, 344300 Jiangxi Province, China
Contact person:	Lizhu Xiao
Phone number:	+86 794 6577516
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Email:	xiaolizhu@spt-tek.com
Date of summary prepared:	August 4, 2022

2) Proprietary name of the device

Trade name/model:	Electronic Sphygmomanometers /X1, X2, X5, X6, X7, X8, X11
Common name:	Noninvasive blood pressure measurement system
Regulation number:	21 CFR 870.1130
Product code:	DXN
Review panel:	Cardiovascular
Regulation class:	Class II

3) Predicate and reference device

- **Predicate device**

Sponsor	ShenZhen ZhengKang Technology Co., Ltd
Device Name and Model	Upper Arm Blood Pressure Monitor Model: ZK-B868, ZK-B869, ZK-B872, ZK-B876
510(k) Number	K191894
Product Code	DXN
Regulation Number	21CFR870.1130.
Regulation Class	II

- **Reference device**

Sponsor	JOYTECH Healthcare Co., Ltd	Jiangsu Yuyue Mecical Equipment& Supply Co., Ltd
Device Name and Model	Arm-type Fully Automatic Digital Blood Pressure Monitor	Electronic Blood Pressure Monitor : YE620B, YE620D,

	Model: DBP-1307b, DBP-1305b, DBP-1318b, DBP-1319b, DBP-1332b, DBP-1333b, DBP-1307b, DBP-1257b, DBP-1358b, DBP-1359b	YE660E, YE660F andYE680B
510(k) Number	K200649	K200939
Product Code	DXN	DXN
Regulation Number	21CFR870.1130	21CFR870.1130
Regulation Class	II	II

4) Description/ Design of device:

The Electronic Sphygmomanometers, including X1, X2, X5, X6, X7, X8, X11, is suitable for measurement of systolic blood pressure, diastolic blood pressure and the pulse rate of adult person and adolescents 18 to 21 years old with arm circumference ranging from 22 cm to 42 cm by the oscillometric technique. The error is controlled within the range specified in IEC 80601-2-30 Non-invasive automated monitor. User can select the blood pressure unit mmHg or kPa. The initial inflation pressure of the cuff is zero pressure. When start the device, the cuff will be inflated and deflated.

The device consists of the microprocessor, pressure sensor, operation keys, pump, deflation control valve, LCD screen and cuff. And all models are powered by 4 AAA dry batteries (DC 6V).

The device has a memory function that automatically stores 2*99 sets data of the latest measurements. It can also display the latest measurement result. Additionally, the device also can read the data through voice broadcast function.

The seven models have the same intended use, working principle, measuring range, accuracy, cuff, and conformance standard; only appearance have some difference.

Materials

Component name	Material of Component	Body Contact Category	Contact Duration
Cuff	Nylon polyester	Surface skin contact	Less than 24 hours

We have directly purchased cuff from qualified supplier which has obtained Biocompatibility test reports. For details, please refer to “Biocompatibility Discussion”.

5) Intended use / indications:

Electronic Sphygmomanometers is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person and adolescents age 18 through 21 years of age .It can be used at medical facilities or at home.

6) Technological characteristics and substantial equivalence:

Item	Proposed device	Predicate device	Reference device1	Reference device2	Remark
Trade name	Electronic Sphygmomanometers (Model:X1,X2,X5, X6,X7,X8,X11)	Upper Arm Blood Pressure Monitor (Model:ZK-B868, ZK-B869, ZK-B872, ZK-B876)	Arm-type Fully Automatic Digital Blood Pressure Monitor (Model: DBP-1307b, DBP-1305b, DBP-1318b, DBP-1319b, DBP-1332b, DBP-1333b, DBP-1307b, DBP-1257b, DBP-1358b, DBP-1359b)	Electronic Blood Pressure Monitor : YE620B, YE620D, YE660E, YE660F andYE680B	/
510 (k) number	K221040	K191894	K200649	K200939	/
Manufacturer	Jiangxi AICARE Medical Technology Co., Ltd.	ShenZhen ZhengKang Technology Co., Ltd.	JOYTECH Healthcare Co., Ltd.	Jiangsu Yuyue Medical Equipment& Supply Co., Ltd	/
Regulation number	21 CFR 870.1130	21 CFR 870.1130	21 CFR 870.1130	21 CFR 870.1130	Same
Regulation description	Noninvasive blood pressure measurement system	Noninvasive blood pressure measurement system	Noninvasive blood pressure measurement system	Noninvasive blood pressure measurement system	Same
Product code	DXN	DXN	DXN	DXN	Same
Class	II	II	II	II	Same

Indications for use/ Intended use	Electronic Sphygmomanometers is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person and adolescents age 18 through 21 years of age .It can be used at medical facilities or at home.	This Upper Arm Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person. It can be used at medical facilities or at home.	The Full Automatic Blood Pressure Monitors are intended to measure blood pressure (systolic and diastolic) and pulse rate of adults and adolescents age 12 through 21 years of age.	Electronic blood pressure monitor is intended to measure the blood pressure and pulse rate adult in household or medical facilities. (Not suitable for neonate, pregnancy or pre-eclampsia)	Similar **Note 1**
Patient population	Adult and 18 through 21 years of age	Adult	Adult and 12 through 21 years of age	Adult	Similar **Note 1**
Location for use	OTC	OTC	OTC	OTC	Same
Environment of use	Medical facilities or home	Medical facilities or home	/	household or medical facilities	Same
Operation principle	Oscillometric	Oscillometric	Oscillometric	Oscillometric	Same
Measurement rane	Pressure: 0～295mmHg, Pulse Rate: (40 ～ 160) times per minute	Pressure: 0～295mmHg Pulse Rate: 40～195 bpm	Systolic Pressure:60mmHg ～280 mmHg Diastolic Pressure: 30 mmHg ～ 200 mmHg Pulse:30 ～ 180 Beats/Minute	Pressure:0 ～ 300 mmHg Pules:40 ～ 200beats/min	Similar
Accuracy	Pressure: ± 3mmHg(± 0.4kPa), or 2% of the reading Pulse Rate:±5%	Pressure: ± 3mmHg(± 0.4kPa) Pulse Rate:±5%	Static Pressure: ±3mmHg Pulse:±5%	Pressure: ± 3mmHg(± 0.4kPa) Pulse Rate:±5% of reading value	Same
Display screen	LCD	LCD	LCD	LCD	Same
Scale selection	mmHg/kPa	mmHg/kPa	mmHg	mmHg/kPa	Same

Cuff circumference	22cm-42cm	22cm-32cm	22-36cm	Type A(22cm-32cm, 22cm-45cm optional) Type B A(22cm-32cm, 22cm-45cm optional)	Similar **Note 2**
Memory	2*99sets	2*99 sets	/	Up to 99x2 sets of data	Same
Power supply	Battery:4AAA batteries(DC 6V) or optional adapter with USB cable(DV5V/500m A)	Battery:4AA batteries (DC6V)-(ZK-B868) 4AAA batteries (DC6V)-(ZK-869/ZK-872/ZK-B876) or optional adapter with USB cable(DV5V/500mA)	For models DBP-1318b, DBP-1257b, DBP-1358b,DBP-1359b:4×1.5V AAA battery or Medical AC adapter (DC 6V,600mA)(recommended, not Provided); For other models:4 × 1.5V AA battery or Medical AC adapter (DC 6V,600mA)(recommended	4 AA batteries or 6V/600mA AC adater	Same
Operating Environment	Temperature:+5 ℃～+40 ℃; Humidity:15 ～ 90%RH Atmospheric pressure: 70 kpa ~ 106 kpa	Temperature:+5 ℃～+40 ℃; Humidity:15 ～ 80%RH	Temp.: +10 ℃～+40 ℃ Humidity:15 ～ 93%RH Atmospheric:700hPa～1060hPa	Temperature:+5 ℃～+40 ℃; Humidity:15 ～ 90%RH	Similar
Storage Environment	Temperature:-25 ℃～+55 ℃; Humidity:10 ～ 95%RH	Temperature:-20 ℃～+55 ℃; Humidity:10 ～ 93%RH	Temp.: -25 ℃～+55 ℃ Humidity: ≤ 90%RH	Temperature:-20 ℃～+55 ℃; Humidity:15 ～ 90%RH(no condensation)	Similar
Type of transmission	Non-transmission	Non-transmission	Bluetooth	/	Same
Compliance with	ANSI AAMI ES	IEC 60601-1; IEC 60601-1-2;	AAMI/ANSI ES 60601-1	IEC 60601-1; IEC60601-1-2;	Same

	60601-1;				
voluntary standards	IEC 60601-1-2; IEC 60601-1-11; IEC 80601-2-30; ISO 10993-1,-5,10; ISO 81060-2	IEC 60601-1-11; IEC 80601-2-30; ISO 10993-1,-5,10; ISO 81060-2	IEC 80601-2-30:2009 IEC 60601-1-11 IEC 60601-1-2 EN 300328 EISI EN 301489-1 EISI EN 301489-17	IEC60601-1-6; IEC60601-1-11; ANSI AAM IEC80601-2-30; ISO 81060-2	

Comparison in details:

Note 1: Although the patient population is a little different between the proposed and predicate device, but it's within the scope of Reference device 1, the difference is insignificant and do not affect safety and effectiveness. And the proposed device has been validated to be in conformity with its claimed range.

Note 2: Although the Cuff circumference is a little different between the proposed and predicate device, but it's within the scope of Reference device 2, the difference is insignificant and do not affect safety and effectiveness. And the proposed device has been validated to be in conformity with its claimed range

Conclusion:

Electronic Sphygmomanometers is substantially equivalent to the predicate device.

7) Test summary:

The following performance data is provided in support of the substantial equivalence determination.

Non-Clinical Study:

Non-clinical tests were conducted to verify that the proposed device meets the same design specifications which supports the conclusion that it's Substantially Equivalent (SE) to the predicate device.. The testing results demonstrate that the proposed device complies with the following standards:

Electrical and EMC Safety:

The electrical safety and EMC safety testing was performed as per the following standards and passed:

- ANSI AAMI ES 60601-1, Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2, 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, 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

Performance Data:

The performance testing was performed as per the following standards and passed:

- IEC 80601-2-30, Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
- ISO 81060-2, Non-invasive sphygmomanometers - Part 2: clinical validation of automated measurement type [Including: Amendment 1(2020)]
- FDA Guidance No-Invasive Blood Pressure (NIBP) Monitor Guidance

Software:

We have also conducted Software verification and validation test according to the requirements of the FDA "Guidance for Pre Market Submissions and for Software Contained in Medical Devices".

Biocompatibility Testing:

The biocompatibility evaluating for the body-contacting component (arm cuff) of this device was conducted in accordance with the "Use of International Standard ISO 10933-1, Biological Evaluation of Medical Device – Part 1: Evaluation and Testing Within a Risk Management Process", as recongnized by FDA. The arm cuff has performed and passed the Biocompatibility test. So we have reason to believe that the arm cuff is safe for the users. The arm cuff complies with the following standards:

- ISO 10993-5, Biological Evaluation of Medical Devices - Part 5: Tests for InVitro Cytotoxicity
- ISO 10993-10, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization.

Clinical Study:

We conducted a comparative clinical study to verify the performance of the proposed device and predicate device as well as a mercury sphygmomanometer according to ISO 81060-2. The study demonstrated a significant correlation in the performance of proposed device and predicate device. The design of the proposed device specifications is substantially the same as the predicate.

All the labeling and characteristics of the Electronic Sphygmomanometers are the same as the predicate device, and most normal blood pressure monitors currently on the market. The proposed device and predicate device both use similar measuring methodologies and components to achieve the measurements.

8) Conclusion

Based on the above analysis and non-clinical/clinical tests performed, it can be concluded that the proposed device Electronic Sphygmomanometers is as safe, as effective, and performs as well as the legally marketed predicate device, K191894, Upper Arm Blood Pressure Monitor Model: ZK-B868, ZK-B869, ZK-B872, ZK-B876.