February 21, 2020

ShenZhen ZhengKang Technology Co., Ltd.
℅ Becky Chen
Registered Engineer
Feiying Drug & Medical Consulting Technical Service Group
B-3F 3005, Bldg.1, Southward Ruifeng Business Center
No 22 Guimiao Rd.
ShenZhen City, 518100
CHINA

Re: K191894
Trade/Device Name: Upper Arm Blood Pressure Monitor, Models: ZK-B868, ZK-B869, ZK-B872, ZK-B876
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: January 16, 2020
Received: January 22, 2020

Dear Becky Chen:

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,

for

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191894

Device Name
Upper Arm Blood Pressure Monitor (Model: ZK-B868, ZK-B869, ZK-B872, ZK-B876)

Indications for Use *(Describe)*
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.

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."

510 (k) Summary

This "510(k) 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:	ShenZhen ZhengKang Technology Co., Ltd.
Address:	3/F, Building A, No. 3 FuXing Yi Lane, HeHua Community, PingHu Street, LongGang District, ShenZhen City, GuangDong, China
Contact person:	Huayong Yang
Phone number:	+86 755 8326 0864
Fax number:	+86 755 8326 0864
Email:	893488645@qq.com
Date of summary prepared:	July 11, 2019
Reason for the submission:	New device, there were no prior submissions for the device.

(2) Proprietary name of the device

Trade name/model:	Upper Arm Blood Pressure Monitor / Model: ZK-B868, ZK-B869, ZK-B872, ZK-B876
Common name:	Noninvasive blood pressure measurement system
Regulation number:	21CFR 870.1130
Product code:	DXN
Review panel:	Cardiovascular
Regulation class:	Class II

(3) Predicate device

Sponsor	Shenzhen Jamr Medical Technology CO., Limited
Device Name and Model	Digital Blood Pressure Monitor Models: B01, B02, B05 & B06T
510(k) Number	K172171
Product Code	DXN
Regulation Number	21CFR 870.1130
Regulation Class	Class II

(4) Description/ Design of device:

The Upper Arm Blood Pressure Monitor, including ZK-B868, ZK-B869, ZK-B872 and ZK-B876, can automatically complete the inflation, deflation and measurement, which can

measure systolic and diastolic blood pressure as well as the pulse rate of adult person with arm circumference ranging from 22 cm to 32cm by the oscillometric technique. 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 arm cuff. The ZK-B868 is powered by 4 AA dry batteries (DC 6V), other models are powered by 4 AAA dry batteries (DC 6V).

The device has a memory function that automatically stores some 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 four models have the same intended use, working principle, measuring range, accuracy, cuff, conformance standard; only in appearance and power supply have some difference.

(5) Intended use / indications:

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.

(6) Materials

Component name	Material of Component	Body Contact Category	Contact Duration
Arm cuff	420D polyester	Surface skin contact	Less than 24 hours

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

(7) Technological characteristics and substantial equivalence:

Item	Targeted device	Predicate device	Remark
Trade name	Upper Arm Blood Pressure Monitor (Models: ZK-B868, ZK-B869, ZK-B872, ZK-B876)	Digital Blood Pressure Monitor (Models: B01, B02, B05 & B06T)	/
510 (k) number	Pending	K172171	/
Regulation number	21CFR 870.1130	21 CFR 870.1130	Same
Regulation description	Noninvasive blood pressure measurement system	Noninvasive blood pressure measurement system	Same
Product code	DXN	DXN	Same
Class	II	II	Same
Indications for	This Upper Arm Blood	Digital blood pressure	Same

Item	Targeted device	Predicate device	Remark
use/ Intended use	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.	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.	
Intended patient	Adult	Adult	Same
Location for use	OTC	OTC	Same
Environment of use	Medical facilities or home	Medical facilities or home	Same
Operation principle	Oscillometric	Oscillometric	Same
Measurement range	Pressure: 0-295mmHg Pulse Rate: 40-195bpm	Pressure: 0-280mmHg Pulse Rate: 40-199bpm	Similar Note 1
Accuracy	Pressure: ±3mmHg(±0.4kPa) Pulse Rate: ±5%	Pressure: ±3mmHg(±0.4kPa) Pulse Rate: ±5%	Same
Display screen	LCD	LCD	Same
Scale selection	mmHg/KPa	mmHg/KPa	Same
Cuff circumference	22cm~32cm	22cm~40 cm	Similar - Within the scope of predicate device
Memory	2*99 sets	2*120 sets (B01/02/05) 1*99 sets (B06T)	Similar - Within the scope of predicate device
Irregular pulse detection	Yes	Yes (B01/02/05) No (B06T)	Same
Power supply	Battery: 4 AA batteries (DC6V)-(ZK-B868) 4 AAA batteries (DC6V)-(ZK-B869	4 AAA batteries (6V DC)-(B01/02/05) Built-in high capacity lithium battery 3.7V 800 mAh-B06T	Similar Note 2

Item	Targeted device	Predicate device	Remark
	/ZK-B872 /ZK-B876) OR optional adapter with USB cable (DV5V/500mA)		
Operating Environment	Temperature: +5℃~+40℃; Humidity: 15～80%RH	Temperature: +5℃~+40℃; Humidity: 10～93%RH	Similar
Storage Environment	Temperature: -20℃~+55℃; Humidity: 10～93%RH	Temperature: -25℃~+70℃; Humidity: 10～93%RH	Similar
Type of transmission	Non-transmission	Transmission by Bluetooth (B06T) non-Transmission (B01/02/05)	Same
Compliance with voluntary standards	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-11; IEC 80601-2-30; ISO 10993-1,-5,-10 ISO 81060-2	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-11; IEC 80601-2-30; ISO 10993-1,-5,-10 ISO 81060-2	Same

Comparison in details:

Note 1:

Although the pressure measurement range is a little different between the targeted and predicate device, the difference is insignificant and do not affect safety and effectiveness. And the targeted device have been validated all the full claimed range.

Note 2:

Although power supply is different between the targeted and predicate device, the difference is insignificant and do not affect safety and effectiveness.

Conclusion:

Upper Arm Blood Pressure Monitor is substantial equivalent to the predicate device.

(8) Performance Data:

The following performance data have been conducted to verify that the Upper Arm Blood Pressure Monitor meets all design specifications which supports the conclusion that it's Substantially Equivalent (SE) to the predicate device. The testing results demonstrate that the targeted device complies with the following standards:

Biocompatibility Testing:

The biocompatibility evaluation for the body-contacting component (arm cuff) of this

device was conducted in accordance with the "Use of International Standard ISO 10993-1, 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.

Electrical and EMC Safety:

The electrical safety and EMC safety testing was performed to, and passed, the following standards:

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

Performance:

The performance testing was performed to, and passed, the following standards:

- 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

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".

Summary:

Based on the above performance as documented in this application, the Upper Arm Blood Pressure Monitor was found to have a safety and effectiveness profile that is similar to the predicate device.

(9) Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the comparison of intended use, design, materials and performance, the Upper Arm Blood Pressure Monitor is to be concluded substantial equivalent to its predicate devices.