June 15, 2024

Zhongshan Jinli Electronic Weighing Equipment Co., Ltd.
℅ Liz Li, Counselor
Shenzhen Joyantech Consulting Co., Ltd.
1713A, 17th Floor, Block A, Zhongguan Times Square, Liuxian Avenue, Xili Town, Nanshan District
Shenzhen, Guangdong 518000
China

Re: K231116
Trade/Device Name: Multi-parameter detector
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN, DQA, FLL, PUH
Dated: September 11, 2023
Received: September 20, 2023

Dear Liz Li:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Stephen C. Browning -S

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)*
K231116

Device Name
Multi-parameter detector

Indications for Use *(Describe)*
The Multi-parameter detector is intended to be used for measuring and displaying of non-invasive blood pressure (NIBP), non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), forehead temperature (TEMP), weight and height in adults.
The Multi-parameter detector is also intended to estimate body mass index (BMI), Body fat percentage, visceral fat grade, basal metabolism and free fat mass (muscle mass, bone mass and body water percentage) using the BIA (Bio-electrical Impedance Analysis) method.

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

1. Contact Details

1.1 Applicant information

Applicant Name	Zhongshan Jinli Electronic Weighing Equipment Co., Ltd.
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Phone No.	+86-760-28133793
Contact person	Jerry Liang
Contact person's e-mail	jerry@kinleehealth.com
Date Prepared	Dec.30.2023

1.2 Submission Correspondent

卓远天成	Shenzhen Joyantech Consulting Co., Ltd. 1713A, 17th Floor, Block A, Zhongguan Times Square, Liuxian Avenue, Xili Town, Nanshan District, Shenzhen, Guangdong Province, China
Phone No.	+86 755-86069197
Contact person	Liz Li
Contact person's e-mail	liz@cefda.com
Website	http://www.cefda.com

2. Device information

Device Trade name	Multi-parameter detector
Device Common name	Multi-parameter detector
Classification	II
Classification name	System, Measurement, Blood-Pressure, Non-Invasive
Product code	DXN
Subsequent Product Codes	DQA, FLL, PUH
Regulation No.	21 CFR 870.1130

3. Primary Predicate Device

Trade Name	Microlife Upper Arm Automatic Digital Blood Pressure Monitor
510(k) Number	K222979
Product Code	DXN
Regulation No.	21 CFR 870.1130
Manufacturer	Microlife Intellectual Property GmbH

4. Secondary Predicate Device

Trade Name	Vitals360® Multi-Vitals Mobile Monitor
510(k) Number	K210086
Product Code	MWI
Subsequent Product Codes	DQA, DSH DXN, FLL
Regulation No.	21 CFR 870.2300
Manufacturer	VoCare, Inc.

5. Device Description

The Multi-parameter detector is a device designed for measuring of the patient's physiological parameters. The Multi-parameter detector can monitor the patient's blood oxygen saturation (SpO2) and pulse rate (PR) non-invasively by the photoelectric method. It can also measure non-invasive blood pressure (NIBP, the pressures of systolic and diastolic) by the oscillating method and body temperature (TEMP) by the infrared radiation energy technology.

The Multi-parameter detector are non-invasive body composition analyzers. The devices employ BIA (Bio-electrical Impedance Analysis) method and then measure body composition using an experimentally derived algorithm.

The Multi-parameter detector integrates an FDA market cleared devices, All-in-One Health Monitor (K170047) for measurement of oxygen saturation of arterial hemoglobin (SpO2).

6. Intended use

The Multi-parameter detector is intended to be used for measuring and displaying of non-invasive blood pressure (NIBP), non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), forehead temperature (TEMP), weight and height in adults.

The Multi-parameter detector is also intended to estimate body mass index (BMI), Body fat percentage, visceral fat grade, basal metabolism and free fat mass (muscle mass, bone mass and body water percentage) using the BIA (Bio-electrical Impedance Analysis) method.

7. Substantial Equivalence Comparison

Item	Proposed Device	Primary Predicate Device (K222979)	Secondary Predicate Device (K210086)	Comments
Trade name	Multi-parameter detector	Microlife Upper Arm Automatic Digital Blood Pressure Monitor	Vitals360® Multi-Vitals Mobile Monitor	N/A
Classification	II	II	II	Same
Product Code	DXN	DXN	MWI	Similar
Subsequent Product Codes	DQA, FLL, PUH	N/A	DQA, DSH DXN, FLL	
Intended use/Indications for use	The Multi-parameter detector is intended to be used for measuring and displaying of non-invasive blood pressure (NIBP), non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), forehead temperature (TEMP), weight and height in adults. The Multi-parameter detector is intended to estimate body mass index (BMI), Body fat percentage, visceral fat grade, basal metabolism and free fat mass (muscle mass, bone mass and body water percentage) using the BIA (Bio-electrical Impedance Analysis) method.	The Upper Arm Blood Pressure Monitor, Model BP3KV1-5W is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable cuff is wrapped around the upper arm for a circumference range from 22 to 52cm. The device is suitable for use by adults, including adults with conditions of diabetes, pregnancy, or pre-eclampsia. The device detects the appearance of irregular heartbeat during measurement and gives a warning signal with the reading once the irregular heartbeat is detected. The device can be used in connection with a smart phone via Bluetooth or with a personal computer (PC) via USB. The measurement data can be transferred to a smart phone running the Microlife Connected Health+ mobile software (App) or a PC running the Microlife BP Analyzer+ (BPA+) software.	Vitals360® device is intended to be used for measuring, displaying, reviewing and storing of non-invasive blood pressure (NIBP), non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), forehead temperature (TEMP), ECG, weight and height in adults no less than 18 years of age. This VITALS360® device is intended for use by trained adults only who can use smartphones proficiently. This VITALS360® device is intended for use in a clinical or home environment. This VITALS360® device is a reusable device following thorough cleaning between uses.	Different

Environment of Use	Hospital outpatient clinic and experience room.	Home	Clinical or home environment	Same
OTC or Rx	Rx	OTC	Rx	Identical to the secondary
Patient Population	Adult	Adult	No less than 18 years of age.	Similar
Power Source	100V-240V～50Hz/60Hz 1.0A	4 AA batteries, Or AC adapter 6 V DC 600 mA	(100-240) VAC, 50/60Hz, 0.5A	Identical to the secondary

NIBP				
Code: DXN				
Features	Proposed Device	Primary Predicate Device (K072325)	Secondary Predicate Device (K210086)	Comments
Method	Oscillometric method	Oscillometric method	Oscillometric method	Same
Pressure measurement range - Systolic	60mmHg-260mmHg	60 mmHg-255 mmHg	60 mmHg-230mmHg	Similar
Pressure measurement range - Diastolic	30mmHg-200mmHg	40mmHg-200mmHg	40 mmHg-130mmHg	
Accuracy or pressure indicator	±3mmHg	Pressure within ± 3 mmHg or 2% of reading >200mmHg	Mean deviation values: ±5 mmHg. Standard deviation ≤ 8 mmHg.	
Cuff pressure range	0～300mmHg	0～299mmHg	0～300mmHg	Identical to the secondary

SpO2				
Code: DQA				
Features	Proposed Device	Primary Predicate Device (K072325)	Secondary Predicate Device (K210086)	Comments
Measuring range	70%～100%	N/A	70%~100%	Identical to the secondary
Accuracy	±3%	N/A	±2% (during 90~100%), ±4% (during 70~89%)	Different

TEMP				
Code: FLL				
Features	Proposed Device	Primary Predicate Device (K072325)	Secondary Predicate Device (K210086)	Comments
Fundamental scientific technology	Infrared technology	N/A	Infrared technology	Identical to the secondary
Unit of measure	°C /°F	N/A	°C /°F	Identical to the secondary
Measurement site	Forehead	N/A	Forehead	Identical to the secondary
Temperature measurement range	22.0°C～42.9°C (71.6°F~109.2°F)	N/A	34.0°C ~43.0°C (93.2°F~109.4°F)	Different
Temperature measurement accuracy	22°C～42.9°C ±0.3°C	N/A	±0.3°C	Identical to the secondary

Body composition				
Code: PUH				
Features	Proposed Device	Primary Predicate Device (K072325)	Secondary Predicate Device (K210086)	Comments
Technology	BIA (bioelectrical impedance analysis)	N/A	N/A	Different
Operating frequency range	50kHz/250kHz			
Electrode type	Tactile			
Number/Placement of Electrodes	8 electrodes Placed on Hands and feet (Tetra-polar Electrode method)			
Patient Position	Upright			
Impedance measurement range	200Ω~800Ω			

Measuring heigh	80~205cm			
Measuring weight	5Kg~300Kg			

The subject device, Multi-parameter detector, is substantially equivalent to the predicate device K222979 and K210086. This conclusion is based upon comparison on intended use and technological characteristics. Any difference between devices do not raise any new issues or concerns of safety or effectiveness.

8. Non-clinical Testing

The following data were provided in support of the substantial equivalence determination:

1) Electrical Safety, Electromagnetic Compatibility

IEC 60601-1:2005, AMDI:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1-11:2015 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 60601-1-2:2014 Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances -- Requirements and tests

2) Performance testing

IEC 80601-2-30: 2018 Medical electrical equipment - Part 2: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

ISO 80601-2-61: 2017 Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

ISO 80601-2-56: 2017 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.

ASTM E 1965-98 Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature

In addition, we tested the following items according to our internal standards.

- Height
- Weight
- Impedance

3) Biocompatibility test

Biocompatibility testing was conducted in accordance with the 2020 FDA guidance “Use of International Standard ISO 10993, Biological Evaluation of Medical Device Part 1: Evaluation and Testing.”

The subject device has passed biocompatibility testing in according to following standards.

ISO 10993-5:2019 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

4) Software validation

The subject device contains an embedded software system.

Software verification and validation testing were conducted as recommended by FDA's Guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

5) Human Factor Engineering and Usability Engineering Evaluation

The usability document of the subject device was determined according to IEC 62366-1:2015 & FDA guidance of Applying Human Factors and Usability Engineering to Medical Devices

9. Clinical testing

Clinical studies were conducted to verify the accuracy of subject device. The clinical studies were conducted per following standards:

1) ISO 81060-2: 2018 Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type
2) ISO 80601-2-56: 2017+AMD1: 2018 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.

The Multi-parameter detector integrates an FDA market cleared devices, All-in-One Health Monitor (K170047) for measurement of oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). The SpO_2 and PR cleared under K170047 were originally cleared under K063641, which is in compliance with ISO 9919: 2005.

The pulse oximeter accuracy was tested in ten healthy subjects, aged 22-40, with skin tones varying from Fitzpatrick 2-6. 3 subjects had dark skin with Fitzpatrick 5 or 6. The Arms of 70%-100% is 1.49, it meets the accuracy claims of ±3%.

Therefore, there is no test of these two parts (SpO_2 and PR) in this clinical test.

Clinical testing has been performed under an approved protocol with subject informed consent. Clinical test results support device accuracy claims for the specified measurement range.

The Clinical studies was a single-center, randomized, self-controlled clinical trial for accuracy validation. Compared with registered mercury thermometer and desktop sphygmomanometer, the accuracy of body temperature and blood pressure measurement was used as the main effectiveness observation indications, and easy for use and device stability were used as the main safety observation indications to evaluate the safety and effectiveness of the Multi-parameter detector (body temperature and blood pressure) produced by Zhongshan Jinli Electronic Weighing Equipment Co., Ltd.

In the evaluation of the accuracy of temperature measurement, 105 subjects did not exceed the maximum allowable error of ±0.2℃ in the temperature display range of 35.0℃~ 42.0℃, and the clinical repeatability did not exceed the range of ±0.3℃, which met the temperature measurement standards.

In the evaluation of the accuracy of Blood Pressure Measurement, a total of 119 subjects completed the experiment. The average value of the difference between the blood pressure value (systolic or diastolic blood pressure) measured by the test device and the reference blood pressure measurement value is within the range of ±5.0mmHg, and the standard deviation is not greater than 8.0mmHg, which meets the standard requirements.

The interface friendliness of the device and the satisfaction rate of the operation response time were both 100.00%. The satisfaction rate of the whole device function and stability evaluation index was 100.00%. There were no adverse events and serious adverse events in the clinical trial, and the incidence rate was 0.00%, and the device has good safety.

10. Other information (such as required by FDA guidance/Test)

N/A

11. Conclusions

Performance testing and compliance with voluntary standards demonstrate that the proposed subject device is substantially equivalent to the predicate devices.