September 18, 2023

Shenzhen Finicare Co., Ltd.
% Boyle Wang, Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM.1801,No.161,East Lujiazui Rd.,Pudong
Shanghai, Shanghai 200120
China

Re: K231367
Trade/Device Name: Wrist Electronic Blood Pressure Monitor (Model FC-BP200, FC-BP201, FC-BP210,FC-BP211, FC-BP220, FC-BP221)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: August 21, 2023
Received: August 25, 2023

Dear Boyle Wang:

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,

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)*
K231367

Device Name
Wrist Electronic Blood Pressure Monitor (Model:FC-BP200, FC-BP201, FC-BP210,FC-BP211, FC-BP220, FC-BP221)

Indications for Use *(Describe)*
This blood pressure monitor (Model: FC-BP200, FC-BP201, FC-BP210, FC-BP211, FC-BP220, FC-BP221) is intended to be used to measure blood pressure (systolic and diastolic) and heart rate from the wrist by using the oscillometric method. The device detects the appearance of irregular heartbeats during measurement and gives a symbol with reading. The device is intended for using in only adult population, not applied to the other populations such as neonatal baby. It can't be used while the wrist (arm) has bleeding or wound to avoid the blood flowing from the wound in pressurizing. The wrist circumference is limited to 13.5cm - 21.5cm.

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.

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510(k) Summary

K231367

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

1.0 Submitter's Information

Name: Shenzhen Finicare Co., Ltd.
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Designated Submission Correspondent

Contact: Mr. Boyle Wang
Name: Shanghai Truthful Information Technology Co., Ltd.
Address: Room 1801, No. 161 East Lu Jiazui Rd., Pudong,Shanghai, 200120 China
Tel: +86-21-50313932
Email: Info@truthful.com.cn

Date of Preparation: Aug.23,2023

2.0 Device Information

Trade name: Wrist Electronic Blood Pressure Monitor
Common name: Noninvasive Blood Pressure Measurement System
Classification name: Noninvasive Blood Pressure Measurement System
Model(s): FC-BP200, FC-BP201, FC-BP210, FC-BP211, FC-BP220, FC-BP221
Production code: DXN
Regulation number: 21 CFR 870.1130
Classification: Class II
Panel: Cardiovascular

3.0 Predicate Device Information

Manufacturer: Shenzhen Kingyield Technology Co., Ltd.
Trade/Device name: Bluetooth Blood Pressure Monitor, BPW1

510(k) number: K182018

4.0 Indication for Use Statement

This blood pressure monitor (Model: FC-BP200, FC-BP201, FC-BP210, FC-BP211, FC-BP220, FC-BP221) is intended to be used to measure blood pressure (systolic and diastolic) and heart rate from the wrist by using the oscillometric method. The device detects the appearance of irregular heartbeats during measurement and gives a symbol with reading. The device is intended for using in only adult population, not applied to the other populations such as neonatal baby. It can't be used while the wrist (arm) has bleeding or wound to avoid the blood flowing from the wound in pressurizing. The wrist circumference is limited to 13.5cm - 21.5cm.

5.0 Device Description

The subject device, Wrist Electronic Blood Pressure Monitor, is an automatic non-invasive blood pressure monitor which can be driven by AAA alkaline battery, DC3V. It uses an inflatable cuff which is wrapped around the patient’s wrist to measure the systolic and diastolic blood pressure as well as the pulse rate of adult at household, not for neonate or pregnancy.

The unit uses the oscillometric method of blood pressure measurement. It means the unit detects the movement of your blood through your brachial artery, and converts your blood pressure into a digital reading. The unit is simple to use because a stethoscope is not needed while using an oscillometric monitor.

The unit stores the blood pressure and pulse rate in the memory after completing a measurement each time. 2x120 sets of measurement values can be stored automatically. The unit also calculates an average reading based on the values of the latest 3 times measurement.

This blood pressure monitor has the function of blood pressure classification according to WHO recommendation, which is convenient for you to judge whether your blood pressure is normal or not.

This blood pressure monitor has voice broadcast function. During measurement and recall the memory, there will be voice operation tips.

The device detects an Irregular Heart Beat (IHB) (a Heartbeat that is more than 25% slower or 25% faster from the average Heartbeat) two or more times during the measurement, the irregular heartbeat Symbol will appear on the display with the measurement values.

The device features a built-in "Bluetooth Data Transmission" function, which enables

the device automatically transmit measuring results through Bluetooth LE4.2 to paired Bluetooth-enabled device (FC-BP200, FC-BP210, FC-BP220 and FC-BP221 applied).

There is a maximum pressure safety setting at 300 mmHg, when the pressure is more than 300mmHg, the device will exhaust fast automatically.

No operation for 2 minute the device will shut down automatically.

The device includes model FC-BP200, FC-BP201, FC-BP210, FC-BP211, FC-BP220, FC-BP221. Six models are identical in terms of software design, cuff type and measurement range. The schematic circuit diagram are identical in all models except for model FC-BP220. Six models PCB layout are different because of different appearance (such as structure, buttons layout, etc.) and function.

6.0 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:
ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012(Cons. Text) [Incl. AMD2:2021] - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]
IEC 60601-1-2:2020, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.
IEC 60601-1-11:2020, 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 80601-2-30:2018, Medical Electrical Equipment - Part 2-30: Particular Requirements For The Basic Safety And Essential Performance Of Automated Non-Invasive Sphygmomanometers.
EN 300328:2019 Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques.
EN 301489-1:2019 ElectroMagnetic Compatibility (EMC)standard for radio equipment and services;Part 1:Common technical requirements.
EN 301489-17:2020 Electromagnetic compatibility and Radio spectrum Matters (ERM);ElectroMagnetic Compatibility (EMC) standard for radio equipment; Part 17: Specific conditions or Broadband Data Transmission Systems.
EN 62479:2010 Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic

fields (10 MHZ to 300 GHZ)
IEC 62304:2015 standard and FDA Guidance for the Content of Pre-Market Submission for Software Contained in Medical Devices standard.

7.0 Clinical Test Conclusion

Performance testing has been carried out to demonstrate that this device meets the performance specifications for its intended use.
The clinical trials for the Wrist Electronic Blood Pressure Monitor were performed according the standard of ISO 81060-2:2018, Non-Invasive Sphygmomanometers - Part 2: Clinical Validation of Automated Measurement Type, and relevant volunteers were collected to conduct actual clinical trial of blood pressure measurement.
There were 130 subjects been selected to participate in the trial, and Auscultation was applied as gold standard with the qualified calibrated mercurial sphygmomanometer used as control group for comparison with the subject device.
The results shown that the accuracy of proposed device meet the requirements of ISO 81060-2:2018 within the ±5mmHg.And the subject device comply with the standard requirements and the accuracy the manufacture declared.

8.0 Technological Characteristic Comparison Table

Table1-General Comparison

Item	Subject Device K231367	Predicate Device K182018	Remark
Manufacturer	Shenzhen Finicare Co., Ltd.	Shenzhen Kingyield technology Co., Ltd	/
Product Name	Wrist Electronic Blood Pressure Monitor FC-BP200, FC-BP201, FC-BP210,FC-BP211, FC-BP220, FC-BP221	Bluetooth blood pressure monitor, BPW1	/
Product Code	DXN	DXN	Same
Regulation No.	21 CFR 870.1130	21 CFR 870.1130	Same
Class	II	II	Same
Intended Use/Indication for Use	This blood pressure monitor (Model: FC-BP200, FC-BP201, FC-BP210, FC-BP211, FC-BP220, FC-BP221) is intended to be used to measure blood pressure (systolic and diastolic) and heart rate from the wrist by using the oscillometric method. The device detects the appearance of irregular heartbeats during measurement and gives a symbol with reading. The device is intended for using in only adult population, not applied to the other populations such as neonatal baby. It can't be used while the wrist (arm) has bleeding or wound to avoid the blood flowing from the wound in pressurizing. The wrist circumference is limited to 13.5cm - 21.5cm.	This blood pressure monitor is intended to be used to measure blood pressure (systolic and diastolic) and heart rate from the wrist by using the oscillometric method. The device detects the appearance of irregular heartbeats during measurement and gives a symbol with reading. The device is intended for using in only adult population, not applied to the other populations such as neonatal baby. It can't be used while the wrist (arm) has bleeding or wound to avoid the blood flowing from the wound in pressurizing. The wrist circumference is limited to 13.5cm - 21.5cm	Same
Application Site	Wrist	Wrist	Same
Wrist Circumference	13.5cm - 21.5cm	13.5cm - 21.5cm	Same
Patients Contacting Materials	Patient contact materials of the cuff: Brushed Fabric According to ISO-10993	Zinc alloy for the case of the device and ABS for Button. Biocompatible materials are used for the applied parts (Bladder + wristband) According to ISO-10993	Different
Patient Population	Adult	Adult	Same
Measurements Item	SYS,DYS,Pulse	SYS,DYS,Pulse	Same
Display	LCD Digital Display	LCD	Same
Design Method	Oscillometric Method	Oscillometric Method	Same

Analysis:

The material of the wrist cuff of the subject device is different with that of the predicate device. Biocompatibility testing was carried out and the test results shown the materials of both devices are complied with the requirements of ISO 10993-1.

Table 2 Performance Comparison

Item	Subject Device	Predicate Device K182018	Remark
Max Cuff pressure	300 mmHg	300mmHg	Same
BP Range	0-299 mmHg	0 ~ 299 mmHg	Same
BP Accuracy	±3 mmHg	±3 mmHg	Same
PR Range	40-180 beats/min	40 ~ 180 beats/min	Same
Pulse Accuracy	±5% of reading value	±5% of reading value	Same
Irregular heartbeat detection	More than ±25% to the mean interval of pulse intervals.	More than ±25% to the mean interval of pulse intervals.	Same
Inflation Method	Automatic inflation by pump	By air pump	Same
Deflation Method	Automatic rapid deflation	Not apply	Different
Memory Size	2x120 set of data	30 set	Different
Operation Condition	10~40℃ Humidity: 15~85%RHz` Atmospheric pressure: 70 - 106kPa	10～40℃, Humidity:15～90％RH Atmospheric: 106kPa~80kPa	Different
Storage Condition	-20~60 ℃ Humidity: 10 to 95% RH	-20℃~ 55℃, 0~95%RH (noncondensing)	Different
Power Supply	2 AAA alkaline batteries, DC3V	Li-ion Rechargeable battery with 250 charging cycles	Different
Performance Standard	Comply with IEC 80601-2-30	Comply with IEC 80601-2-30	Same

Analysis:
The subject and predicate device have same general intended use, similar design features and performance specifications.
The differences in Memory Size do not raise different questions of safety or effectiveness since the device complied with the requirement of IEC 80601-2-30.
The differences in Operation Condition and Storage Condition between both devices are insignificant in terms of safety and effectiveness. Also, the little difference in power supply according to the Electrical Safety and EMC test result, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device. So we think the subject device is substantially equivalent to the predicate device.

Table 3 Safety Comparison

Item	Proposed Device	Predicate Device K182018	Remark

Electrical Safety	Comply with ANSI AAMI ES60601-1	Comply with IEC 60601-1	Same
Home Use	Comply with IEC 60601-1-11	Comply with IEC 60601-1-11	Same
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Same
FCC conformity	FCC 47 part 15 subject B FCC 47 CFR Part 15, Subpart C	FCC 47 CFR part 15,Subject B FCC 47 CFR Part 15, Subpart C FCC 47 CFR Part 1.1307 FCC 47 CFR Part 2.1093	Same
ERM conformity	EN 301489-1:2017; EN301489-17:2017	EN 301489-1:2017; EN 301489-17:2017	Same
RF conformity	EN300328:2016	EN300328:2016	Same
Health	EN62479:2010	EN62479:2010	Same
Biocompatibility	Comply with ISO 10993-1, FDA Guidance	Comply with ISO 10993-1, FDA Guidance	Same

9.0 Conclusion

The conclusions drawn from the comparison and analysis above demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed predicated device and raises no new questions of safety or effectiveness. The differences between both devices are insignificant in terms of safety and effectiveness.