October 4, 2024

Shenzhen Finicare Co., Ltd.
% Boyle Wang
General Manager
Shanghai Truthful Information Technology Co., Ltd.
Room 608, No. 738 Shangcheng Rd., Pudong
Shanghai, 200120
China

Re: K242721
Trade/Device Name: Upper Arm Electronic Blood Pressure Monitor (FC-BP103, FC-BP106, FC-BP113, FC-BP120, FC-BP121, FC-BP130, FC-BP131)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: September 10, 2024
Received: September 10, 2024

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 (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,
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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: 0MB No. 0910-0120
Expiration Date: 07/31/2026
See *PRA Statement below.*

Submission Number *(if known)*

K242721

Device Name

Upper Arm Electronic Blood Pressure Monitor (FC-BP103, FC-BP106, FC-BP113,FC-BP120,FC-BP121,FC-BP130,FC-BP131)

Indications for Use *(Describe)*

Upper Arm Electronic Blood Pressure Monitor, Models FC-BP103, FC-BP106,FC-BP113, FC-BP120, FC-BP121, FC-BP130, FC-BP131 are intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm.
The devices' features include irregular pulse rhythm detection during measurement, and will display a alert signal with the reading when irregular heartbeat is detected.
The devices' feature includes Bluetooth function to transmit data to an external Bluetooth device with wireless communication.

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

K242721

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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Tel: 86-755-23013503
Contact: Chao Li

Designated Submission Correspondent

Contact: Mr. Boyle Wang
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Tel: +86-21-50313932
Email: Info@truthful.com.cn

Date of Preparation: Oct.04,2024

2.0 Device Information

Trade name: Upper Arm Electronic Blood Pressure Monitor
Common name: Noninvasive Blood Pressure Measurement System
Classification name: Noninvasive Blood Pressure Measurement System
Model(s): FC-BP103, FC-BP106,FC-BP113, FC-BP120, FC-BP121, FC-BP130, FC-BP131
Production code: DXN
Regulation number: 21 CFR 870.1130
Classification: Class II
Panel: Cardiovascular

3.0 Predicate Device Information

Manufacturer: Shenzhen Finicare Co., Ltd.
Trade name: Upper Arm Electronic Blood Pressure Monitor, Model:

FC-BP100,FC-BP101,FC-BP102,FC-BP110,FC-BP111, FC-BP112

510(k) number: K220113

4.0 Indication for Use Statement

Upper Arm Electronic Blood Pressure Monitor, Models FC-BP103, FC-BP106, FC-BP113, FC-BP120, FC-BP121, FC-BP130, FC-BP131 are intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The devices' features include irregular pulse rhythm detection during measurement, and will display a alert signal with the reading when irregular heartbeat is detected. The devices' feature includes Bluetooth function to transmit data to an external Bluetooth device with wireless communication.

5.0 Device Description

The subject device, Upper Arm Electronic Blood Pressure Monitor, is an automatic non-invasive blood pressure monitor which can be driven by 4 AA batteries or type-C USB (optional). It uses an inflatable cuff which is wrapped around the patient's upper arm 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 earliest record will be deleted automatically to save the latest measurement value when more than the measurement values. 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, 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 HeartBeat (IRB) (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 to paired Bluetooth-enabled device (FC-BP121 and FC-BP130 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-BP103, FC-BP106,FC-BP113, FC-BP120, FC-BP121, FC-BP130, FC-BP131,they are same except the appearance.

6.0 Technological Characteristics

Principle of Operation

There is no change in the principle of operation as part of this submission from the previous clearance under K220113. The module still utilizes the same principles of operation for blood pressure governed by the following principles:

Oscillometric method is used in the subject device to measure blood pressure, the concrete working principle is: the cuff is pressurized to block the brachial blood flow and then slowly decompress, with a small pulse of sound and pressure in the arm. In wave method is to rely on the instrument recognition from the arm to the cuff of small pulse, and the difference, through multiple processing, form a scan reflect the envelope of pulse peak, which blood pressure values are obtained.

Mechanism of Action for Achieving the Intended Effect

There is no change to the Mechanism of Action of the Upper Arm Electronic Blood Pressure Monitor from the previous clearance K220113- Upper Arm Electronic Blood Pressure Monitor (Model: FC-BP100, FC-BP101,FC-BP102,FC-BP110,FC-BP111, FC-BP112).

7.0 Summary of Technological Characteristics of the Subject Device Compared to the Predicate Device

The subject device, Upper Arm Electronic Blood Pressure Monitor (Model: FC-BP103, FC-BP106,FC-BP113,FC-BP120,FC-BP121,FC-BP130,FC-BP131) and the predicate device, Upper Arm Electronic Blood Pressure Monitor (Model: FC-BP100,FC-BP101, FC-BP102,FC-BP110,FC-BP111,FC-BP112),have the following key similarities:

- Both devices have the same intended use
- Both devices are indicated for the same patient population
- Both devices have the same principle of operation and mechanism of action

The subject device and the predicate device have the following differences:

-- The appearance of the subject device is different with that of the predicate device. But this difference does not affect the basic safety and essential performance, the subject and the predicate are the same and substantially equivalent.
-- Subject device is updating memory size to store 2x120 sets of blood pressure data, while the predicate device supports storage of 2x90 sets of blood pressure. Other than this, no changes made to the measurement algorithm, pressure sensor, cuff design, or calibration method. The device continues to operate on the same firmware, with the same embedded system. Functional testing was conducted to verify that the device can successfully store and access 2x120 sets of data. So this change won't affect the substantial equivalence.

8.0 Non-clinical Testing

In this current submission, just add 7 model FC-BP103, FC-IR106, FC-BP113, FC-BP120, FC-BP121, FC-BP130, FC-BP131 to the legally marketed predicate device K220113. The subject device and the predicate device have the same intended use, patient population, principle of operation, and mechanism of action. The only differences are that the subject device has a different appearance and an updated memory size to store 2x120 sets of blood pressure data, compared to 2x90 sets in the predicate device. However, no changes were made to the measurement algorithm, pressure sensor, cuff design, calibration method, firmware, or embedded system. Functional testing was conducted to verify that the increase in memory capacity and the ability to store and retrieve 2x120 sets of data. No issues identified during verification. Therefore, no additional non-clinical testing was considered necessary to support substantial equivalence.

Performance Bench Testing
As there are no hardware or software changes as part of this submission from the previous clearance, no performance bench testing was included as part of this submission.

Biocompatibility Testing
The proposed Upper Arm Electronic Blood Pressure Monitor does not introduce any new direct or indirect patient contacting materials including new color additive, as compared to the previous clearance predicate Upper Arm Electronic Blood Pressure Monitor. So the biocompatibility testing reports provided and reviewed in K220113 remain valid and can support the subject Upper Arm Electronic Blood Pressure Monitor.

Electromagnetic Compatibility, Electrical Safety, Environmental, Mechanical and Cleaning
As there were no changes to the hardware or software as part of this submission from the previous clearance, no Electromagnetic Compatibility, Electrical Safety, Environmental, Mechanical and Cleaning testing was included with this submission.

Software Verification and Validation Testing

Updated memory size to store 2x120 sets of blood pressure data. No changes made to the measurement algorithm, pressure sensor, cuff design, or calibration method. Verification and validation activities confirmed that the change is limited to storage capacity without introducing new risks or performance deviations.

9.0 Clinical Test Conclusion

As the subject device utilizes the same monitoring technology as the predicate device, there is no change on the sensors, cuffs, algorithms, measurement accuracy of the candidate device, additional testing was not considered necessary to support the substantial equivalence.

10.0 Technological Characteristic Comparison Table

Table1-General Comparison

Item	Subject Device K242721	Predicate Device K220113	Remark
Manufacturer	Shenzhen Finicare Co., Ltd.	Shenzhen Finicare Co., Ltd.	/
Product Name	Upper Arm Electronic Blood Pressure Monitor: FC-BP103, FC-BP106,FC-BP113, FC-BP120, FC-BP121, FC-BP130, FC-BP131	Upper Arm Electronic Blood Pressure Monitor: FC-BP100, FC-BP101, FC-BP102, FC-BP110, FC-BP111, FC-BP112	/
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	Upper Arm Electronic Blood Pressure Monitor, Models FC-BP103, FC-BP106, FC-BP113, FC-BP120, FC-BP121, FC-BP130, FC-BP131 are intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The devices' features include irregular pulse rhythm detection during measurement, and will display a alert signal with the reading when irregular heartbeat is detected. The devices' feature includes Bluetooth function to transmit data to an external Bluetooth device with wireless communication.	Upper Arm Electronic Blood Pressure Monitor, Models FC-BP100,FC-BP101,FC-BP102,FC-BP110,FC-BP111,FC-BP112 are intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The devices' features include irregular pulse rhythm detection during measurement, and will display a alert signal with the reading when irregular heartbeat is detected. The devices' feature includes Bluetooth function to transmit data to an external Bluetooth device with wireless communication.	Same
Application Site	Upper Arm	Upper Arm	Same
Cuff Circumference	22-42cm	22-42cm	Same
Patients Contacting Materials	Patient contact materials of the cuff: 210D Nylon TPU According to ISO-10993	Patient contact materials of the cuff: 210D Nylon TPU According to ISO-10993	Same
Patient Population	Adult	Adult	Same
Measurements Item	SYS,DYS,Pulse	SYS,DYS,Pulse	Same
Display	LCD Digital Display	LCD Digital Display	Same
Design Method	Oscillometric Method	Oscillometric Method	Same

Table 2 Performance Comparison

Item	Subject Device K242721	Predicate Device K220113	Remark

Max Cuff pressure	300mmHg	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	Automatic inflation by pump	Same
Deflation Method	Automatic rapid deflation	Automatic rapid deflation	Same
Memory Size	2x120 set of data	2x90 set of data	Different
Operation Condition	10~40℃ 15~85%RH	10~40℃ 15~85%RH	Same
Storage Condition	-20~55 ℃ 0~95% RH	-20~55 ℃ 0~95% RH	Same
Performance Standard	Comply with IEC 80601-2-30	Comply with IEC 80601-2-30	Same
Power Supply	4 AA batteries or DC6V,or USB Type C（DC5V1A）	4 AA batteries or DC6V,or USB Type C（DC5V1A）	Same

Table 3 Safety Comparison

Item	Proposed Device K242721	Predicate Device K220113	Remark
Electrical Safety	Comply with IEC 60601-1	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 part 15 subject B	Same
ERM conformity	EN 301489-1:2017; EN301489-17:2017	EN3014891:2017; EN301489-17:2017	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

11.0 Conclusion

The conclusions drawn from the comparison and analysis above demonstrate that the subject device is substantially equivalent to the legally marketed predicated device.