Ningbo Ranor Medical Science & Technology Co., Ltd.
℅ Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM.608, No.738, Shangcheng Rd., Pudong
Shanghai, 200120 CN

July 16, 2020

Re: K193456
Trade/Device Name: Arm Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: October 25, 2019
Received: December 13, 2019

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,

for LT Stephen Browning
Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*
K193456

Device Name
Arm Blood Pressure Monitor

Indications for Use *(Describe)*
The Arm blood pressure monitor is for home use for measuring blood pressure and pulse rate. It is suitable for adult, not for neonate or pregnancy.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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 summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

1.0 Submitter's Information

Name: Ningbo Ranor Medical Science & Technology Co., Ltd.
Address: No. 127 Fenghui Road, Wangchun Industrial Park, Haishu District, Ningbo, China
Tel: 86-574-89258788
Fax: 86- 574-88219485
Contact: Emma Hu
Date of Preparation: Jul.14,2020

Designated Submission Correspondent

Mr. Boyle Wang
Shanghai Truthful Information Technology Co., Ltd.
Room 608, No. 738 Shangcheng Rd., Pudong Shanghai, 200120 China
Tel: +86-21-50313932
Email: Info@truthful.com.cn

2.0 Device Information

Trade name: Arm Blood Pressure Monitor
Common name: Noninvasive Blood Pressure Measurement System
Classification name: Noninvasive Blood Pressure Measurement System
Model(s): RN-032A,RN-032C

3.0 Classification

Production code: DXN
Regulation number: 21 CFR 870.1130
Classification: Class II
Panel: Cardiovascular

4.0 Predicate Device Information

Manufacturer: Jiangsu Yuyue Medical Equipment & Supply Co., Ltd
Device: Upper Arm Type Electronic Blood Pressure Monitor Series, Electronic Blood Pressure Monitor: YE650A, YE650D,

YE660B, YE670A and YE670D
510(k) number: K170605

5.0 Indication for Use Statement

The Arm blood pressure monitor is for home use for measuring blood pressure and pulse rate. It is suitable for adult, not for neonate or pregnancy.

6.0 Device Description

The proposed device, Arm Blood Pressure Monitor, is an automatic non-invasive Blood Pressure Monitor which can be driven by dry batteries. 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, not for neonate or pregnancy.

The proposed device consists of the main body and the arm belt, suitable for home use for measuring blood pressure and pulse rate. It is suitable for adult, not for neonate or pregnancy.

This blood pressure monitor has the memory function of 60 groups of measuring data of two people, which can save the data separately. It can display the average reading of the latest 3 groups of measurement results.

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 according to the World Health Organization/ International Society for hypertension(WHO/ISH) guidelines on the treatment of hypertension dated in 1999.

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

Cuff supporting the use of Arm Blood Pressure Monitor is M5303(small adult)/M5304(adult)/ M5305(big adult) provided by Xuzhou Maikang Science and Technology Ltd., and cleared by the CE(Declaration of Conformity for Class I)/ISO and FDA(K151290).

7.0 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:
IEC 60601-1:2012, Medical electrical equipment-Part 1: General requirements

for basic safety, and essential performance.
IEC 60601-1-2:2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.
IEC 60601-1-11:2015, 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 80601-2-30:2013, Medical Electrical Equipment - Part 2-30: Particular Requirements For The Basic Safety And Essential Performance Of Automated Non-Invasive Sphygmomanometers.
IEC 62304:2015 standard and FDA Guidance for the Content of Pre-Market Submission for Software Contained in Medical Devices standard.

8.0 Clinical Test Conclusion

Performance testing has been carried out to demonstrate that this device meets the performance specifications for its intend use.
The clinical trials for the Arm 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 150 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 proposed device.
The results shown that the accuracy of proposed device meet the requirements of ISO 81060-2:2018 within the ±3mmHg.And the proposed device comply with the standard requirements and the accuracy the manufacture declared.

9.0 Technological Characteristic Comparison Table

Table2-General Comparison

Item	Proposed device K193456	Predicated device K170605	Remark
Product Code	DXN	DXN	SE
Regulation No.	21 CFR 870.1130	21 CFR 870.1130	SE
Class	II	II	SE
Intended Use	The Arm blood pressure monitor is for home use for measuring blood pressure and pulse rate. It is suitable for adult, not for neonate or pregnancy.	Electronic blood pressure monitor is intended to measure the blood pressure and pulse rate of adult at household or medical center. (Not suitable for neonate, pregnancy or pre-eclampsia).	SE
Application Site	Upper Arm	Upper Arm	SE
Cuff Circumference	220mm ～ 320mm	220mm ～ 320mm	SE
Patients Contacting Materials	Arm Cuff -M5303(small adult)/M5304(adult)/ M5305(big adult) provided by Xuzhou Maikang Science and Technology Ltd., and cleared by FDA (K151290).	Patient contact materials of the cuff have been tested in accordance with ISO10993 and FDA guidance.	SE
Patient Population	Adult	Adult	SE
Measurements Item	SYS,DYS,Pulse	SYS,DYS,Pulse	SE
Display	LCD Digital Display	LCD Digital Display	SE
Design Method	Oscillometric Method	Oscillometric Method	SE
Main Component	LCD / Key / Cuff / MCU / Pump / Batteries	LCD / Key / Cuff / MCU / Pump / Batteries	SE

Table3 Performance Comparison

Item	Proposed Device	Predicate Device K170605	Remark
BP Range	0-299 mmHg	0-280 mmHg	Analysis

BP Accuracy	±3 mmHg	±3 mmHg	SE
PR Range	40-180 beats/min	40 ~ 200 beats/min	Analysis
Pulse Accuracy	±5% of reading value	±5% of reading value	SE
Inflation Method	Automatic by electronic pump	Automatic by electronic pump	SE
Deflation Method	Automatic Pressure Release Valve	Automatic Pressure Release Valve	SE
Memory Size	2x60 set of data	Up to 60sets of data	Analysis
Operation Condition	5-40 ℃ 15%-80% RH 80kPa～106kPa	10-40 ℃ 15%-90% RH (no condensation)	Analysis
Storage Condition	-20-55 ℃ ≤95% RH 50kPa～105kPa	-20-55 ℃ 15%-90% RH (no condensation)	Analysis
Data Storage	SYS, DIA, PR, Measurement Time, No.	SYS, DIA, PR, Measurement Time, No.	SE
Performance Standard	Comply with IEC 80601-2-30	Comply with IEC 80601-2-30	SE
Power Supply	4 AAA batteries	4 AA batteries	Analysis

Analysis:

The proposed device is substantially equivalent to the predicate device. The differences between both devices are insignificant in terms of safety and effectiveness. Based on the nonclinical and clinical tests performed, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device.

Table4 Safety Comparison

Item	**Proposed Device**	**Predicate Device K170605**	**Remark**
Electrical Safety	Comply with IEC 60601-1	Comply with IEC 60601-1	SE
Home Use	Comply with IEC 60601-1-11	Comply with IEC 60601-1-11	SE
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SE
Biocompatibility	Comply with ISO 10993-1, FDA Guidance	Comply with ISO 10993-1, FDA Guidance, Tests included Cytotoxicity, Sensitization and Intracutaneous	SE

		Reactivity	
Label and Labeling	Conforms to FDA Regulatory Requirements	Conforms to FDA Regulatory Requirements	SE
Level of Concern of the Software	Moderate	Moderate	SE

10.0 Conclusion

The conclusions drawn from the comparison and analysis above demonstrate that the proposed 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.