December 30, 2020

Conmo Electronic Company Limited
% Charlie Mack
Principal Engineer
International Regulatory Consultants
2950 E Lindrick Drive
Chandler, Arizona 85249

Re: K202372
Trade/Device Name: Upper Arm Electronic Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: November 23, 2020
Received: December 1, 2020

Dear Charlie Mack:

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

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)*

K202372

Device Name
Upper Arm Electronic Blood Pressure Monitor, BM100-EN

Indications for Use *(Describe)*
Upper Arm 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).

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:

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

Date: August 13, 2020

1. Company and Correspondent submitting this 510(k):

Name – Conmo Electronic Company Limited
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Contact – Mrs. Alice Qi
General Manager

US Agent and Correspondent
Mr. Charles Mack
Principal Engineer
IRC USA
2950 E Lindrick Drive, Chandler, Arizona 85249 USA
Tel: 931-6254938
Email: charliemack@irc-us.com

2. Device:

Trade/proprietary name:	Upper Arm Electronic Blood Pressure Monitor Model BM100-EN
Common Name:	Non-invasive blood pressure measurement system
Classification Name:	System, measurement, blood-pressure, non-invasive
Product Code:	DXN
Regulation Number:	21CFR870.1130
Device Class:	2

3. Predicate Device :

Manufacturer	Predicate Device	510(k) Number
Jiangsu Yuyue Medical Equipment& Supply Co., Ltd	Upper Arm Type Electronic Blood Pressure Monitor Series, Electronic Blood Pressure Monitor: YE670D	K170605

4. Reason for Submission: New Device

5. Device Description:

The Upper Arm Electronic Blood Pressure Monitor, Model BM100-EN operation is based on the oscillometric method. This method takes advantage of the pressure pulsations taken during measurements. An occluding cuff is placed on the left arm and is connected to an air pump and a pressure sensor. The cuff is inflated until a pressure higher than the typical systolic value is reached, then the cuff is slowly deflated. As the cuff deflates, when systolic pressure value approaches, pulsations start to appear. These pulsations represent the pressure changes due to heart ventricle contraction and can be used to calculate the heartbeat rate. Pulsations grow in amplitude until mean arterial pressure (MAP) is reached, then decrease until they disappear.

The blood pressure information is displayed as digital information on the device's screen.

6. Indication for use:
   The Upper Arm Electronic Blood Pressure Monitor is intended to measure the blood pressure and pulse rate of adults at a household or medical center. (Not suitable for neonate, pregnancy or pre-eclampsia).

7. Comparison with the predicate device:
   Conmo Electronic Company Limited believes that the Upper Arm Electronic Blood Pressure Monitor, BM100-EN is substantially equivalent to the Jiangsu Yuyue Medical Equipment& Supply Co., Ltd Upper Arm Type Electronic Blood Pressure Monitor Series, Electronic Blood Pressure Monitor: YE670D, FDA 510(k) clearance K170605.

Characteristics	Submitted Device	Predicate Device	Difference Discussion
Device Name and model	Upper Arm Electronic Blood Pressure Monitor, BM100-EN	Upper Arm Type Electronic Blood Pressure Monitor YE670D	N/A
Manufacturer	CONMO ELECTRONIC COMPANY LIMITED	Jiangsu Yuyue Medical Equipment & Supply Co., Ltd	N/A
510(K) Number	Pending	K170605	N/A
Indication for Use	The Upper Arm Electronic Blood Pressure Monitor is intended to measure the blood pressure and pulse rate of adults at a household or medical center. (Not suitable for neonate, pregnancy or pre-eclampsia).	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).	Identical
Clinical Use	household or medical center	household or medical center	Identical
Patient Population	Adult	Adult	Identical
Measurement Type	Upper arm	Upper arm	Identical
Measurement Method	Non-invasive, Sociometric	Non-invasive, Sociometric	Identical
Cuff Circumference	220mm ～ 320mm	220mm ～ 320mm	Identical
Power Source	4x1.5V	4x1.5V	Identical
Measurement Pressure Range	0~295mmHg (0-39.3kPa)	0~280mmHg (0-37.3kPa)	The Pressure Range of BM100-EN is wider than Predicate Devices, but still complies with IEC 80601-2-30
Range Accuracy	±3 mmHg (±0.4kPa)	±3 mmHg (±0.4kPa)	Identical
Measurement Pulse Range	40 ~ 180 beats/min	40 ~ 200 beats/min	The Pulse Range of BM100-EN is narrower than Predicate Devices, but still complies with IEC 80601-2-30
Pulse Rate Measurement Accuracy	±5% of reading value	±5% of reading value	Identical
Number of Users	2	2	Identical
Memory Space	99	60	The difference does not raise any new questions of safety and effectiveness.
Number of buttons	3	3	Identical

Characteristics	Submitted Device	Predicate Device	Difference Discussion
Controls	User 1/ Confirm Guest/Setting User 2/Plus	SET Button, Plus/Minus Button, START/PULSE Button	The control difference does not raise any new questions of safety and effectiveness.
Display Type	LCD	LCD	Identical
Pressurization Mode	Automatic Inflation	Automatic Inflation	Identical
Deflation Mode	Automatic Pressure Release Valve	Automatic Pressure Release Valve	Identical
Display Content	Cuff Pressure, Pulse, Date, Time, Systolic/Diastolic Pressure, error message, Measurements result in memory, Irregular Heart Beat Feature, Body movement detection Cuff Wrapping Detection	Cuff Pressure, Pulse, Date, Time, Systolic/Diastolic Pressure, error message, Measurements result in memory, Irregular Heart Beat Feature, Body movement detection Cuff Wrapping Detection	Identical
Operation Environments	Temperature: +10 ºC~ +40 ºC Humidity: 15% RH~ 85% RH(no condensation)	Temperature: +10 ºC~ +40 ºC Humidity: 15% RH~ 90% RH(no condensation)	The operating environment difference does not raise any new questions of safety and effectiveness.
Storage Environments	Temperature: -20 ºC~ +55 ºC Humidity: 15% RH~ 85% RH(no condensation)	Temperature: -20 ºC~ +55 ºC Humidity: 15% RH~ 90% RH(no condensation)	The storage environment difference does not raise any new questions of safety and effectiveness.
Performance	ANSI/AAMI/ISO 81060-2 IEC 80601-2-30	ANSI/AAMI/ISO 81060-2 IEC 80601-2-30	Identical
Biocompatibility	ISO 10993-1, FDA Guidance, Tests included Cytotoxicity, Sensitization and Intracutaneous Reactivity	ISO 10993-1, FDA Guidance, Tests included Cytotoxicity, Sensitization and Intracutaneous Reactivity	Identical
Electrical Safety	IEC 60601-1	IEC 60601-1	Identical
EMC	IEC 60601-1-2	IEC 60601-1-2	Identical
Home Use	IEC 60601-1-11	IEC 60601-1-11	Identical
Prescription or OTC	OTC	OTC	Identical

Testing Summary:

The following performance data is provided in support of the substantial equivalence determination.

Non-Clinical Study:
Non-clinical tests were conducted to verify that the proposed device meets the same design specifications as the predicate Yuyue Medical Equipment device. The test results demonstrate that the proposed device complies with the following standards:

Safety and EMC
Testing was performed to verify the basic safety and essential performance of the Upper Arm Electronic Blood Pressure Monitor, BM100-EN. The following tests were performed:

- IEC 60601-1: 2005+A1: 2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2014 Medical devices part 1-2: General requirements for basic safety and essential performance – Collateral standards: electromagnetic compatibility – Test and requirements
- IEC 60601-1-11 Edition 2.0 2015-01, 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.

The test results demonstrate the device complies with the necessary safety and essential performance standards requirements.

Performance Data:

The subject Upper Arm Electronic Blood Pressure Monitor, BM100-EN was subjected to the following tests and passed all test criteria:

- IEC 80601-2-30 Edition 2.0 Medical electrical equipment - Part 2-30: Particular Performance 2018-03 requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
- ISO 81060-2 Non-invasive sphygmomanometers - Part 2: Clinical validation NIBP Performance Second edition 2013-05-01 of automated measurement type
- FDA Guidance Non-Invasive Blood Pressure (NIBP) Monitor Guidance

Software Verification and Validation

Software documentation, including verification & validation, was provided following FDA Guidance: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices for software with a moderate level of concern.

Cleaning Validation

The device was cleaned following the procedure defined in the User's Manual. The device was checked for performance following the cleaning and met all performance requirements following the cleaning.

Shelf Life:

The Upper Arm Blood Pressure Monitor BM100-EN, is not subject to the shelf life, as the device doesn't contain any sterile or degradable components.

Biocompatibility

The subject Upper Arm Electronic Blood Pressure Monitor, BM100-EN, uses similar material to the predicate Yuyue Medical Equipment device. Biocompatibility testing was performed to demonstrate compliance with the same biocompatibility standards as performed by the predicate device.

The Upper Arm Blood Pressure Monitor, Model BM100-EN device is classified per ISO 10993-1: 2009 Annex 1 Biological evaluation tests as follows:
Surface Device – Contact Skin – Contact Duration <24h

Based on this classification, the following cytotoxicity, skin irritation and sensitization tests were conducted per the following standards:

- ISO 10993-5: 2009 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 Delayed-Type Hypersensitivity

The test results confirm compliance with the requirements of the standards.

Sterility Information:
The device is not delivered sterile, nor is it required to be sterilized for use.

Package and Shelf Life:
The Upper Arm Blood Pressure Monitor, Model BM100-EN, is not subject to the shelf life, as the device contains no sterile or degradable components.

Clinical Study:
We conducted a comparative clinical study to verify the performance of the subject device and predicate device as well as a mercury sphygmomanometer according to ISO 81060-2:2013. The study demonstrates a correlation in the performance of subject device and predicate device. was significantly correlated

The design of the submitted device specifications is substantially the same as the predicate.

All the labeling and characteristics of the submitted Upper Arm Electronic Blood Pressure Monitor, BM100-EN, is the same as the predicate device, and most normal blood pressure monitors currently on the market. The submitted device and predicate both use similar measuring methodologies and components to achieve the measurements.

10. Conclusions:

Following the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, Conmo Electronic Company Limited concludes that the Upper Arm Electronic Blood Pressure Monitor, BM100-EN is substantially equivalent to predicate Yuyue Medical Equipment, Inc's device as described herein.

Conmo Electronic Company Limited will update and include in a summary any other information deemed reasonably necessary by the FDA.

END