October 17, 2022

Jiangsu Yuyue Medical Equipment & Supply CO.,LTD.
Yinzhen Zhu
Medical Device Registered Engineer
No.1 Baisheng Road Development Zone
Danyang, Jiangsu 212300
China

Re: K221372
Trade/Device Name: YUWELL® 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: September 9, 2022
Received: September 9, 2022

Dear Yinzhen Zhu:

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,

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)*
K221372

Device Name
YUWELL® Electronic Blood Pressure Monitor

Indications for Use *(Describe)*
This product is intended to measure the blood pressure and pulse rate of adult more than 12 years old and with wrist circumference ranging from 13.5 cm to 19.5 cm 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.

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510(K) SUMMARY

OWNER/SUBMITTER'S INFORMATION

Company Name	:	Jiangsu Yuyue Medical Equipment& Supply Co., Ltd.
Company Address	:	No.1 Baisheng Road Development Zone, Danyang, Jiangsu 212300 CHINA
Contact	:	Yinzhen Zhu
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Email	:	zhu.yz@yuyue.com.cn
Date prepared	:	April 15, 2022

TRADE NAME, COMMON NAME, CLASSIFICATION

Trade Name	:	YUWELL® Electronic Blood Pressure Monitor
Common Name	:	Electronic Blood Pressure Monitor
Classification Name	:	System, Measurement, Blood-pressure, Non-invasive
Product Code	:	DXN
Regulation Number	:	870.1130
Device Class	:	Class II

IDENTIFICATION OF PREDICATE DEVICES(S)

The identification of predicates within this submission is as follow:

Manufacturer	:	Omron Healthcare, Inc.
Trade Name	:	Wrist Blood Pressure Monitor Model BP4350
Common Name	:	Wrist Blood Pressure Monitor Model BP4350
Classification Name	:	System, Measurement, Blood-pressure, Non-invasive
Product Code	:	DXN
Regulation Number	:	870.1130
Device Class	:	Class II
FDA 510 (k) #	:	K182166

DESCRIPTION OF THE DEVICE

The YUWELL® Blood Pressure Monitor (Model: YE8800AR, YE8800CR) is a rechargeable lithium battery-powered, automatic, noninvasive, wrist-worn blood pressure measuring system intended for over-the-counter (OTC) use. YE8800AR, YE8800CR is designed for wrist circumference ranging from 13.5 cm to 19.5 cm. The systolic and diastolic blood pressures are measured using the oscillometric method, where the cuff is inflated with an air pump and deflates via an exhaust valve.

During inflation, the cuff pressure is monitored, and pulse waveform data is extracted. The extracted pulse waveform data is then further analyzed by software which determines pulse rate, as well as systolic and diastolic blood pressure.

INTENDED USE

This product is intended to measure the blood pressure and pulse rate of adult more than 12 years old and with wrist circumference ranging from 13.5 cm to 19.5 cm at household or medical center (not suitable for neonate, pregnancy or pre-eclampsia.)

TECHNOLOGICAL CHARACTERISTIC

The YUWELL® Blood Pressure Monitors (Model: YE8800AR, YE8800CR) are intended for medical professional and lay person at household or medical center and employ the oscillometric method for measuring blood pressure and pulse rate. The devices have a cuff pressure range of 0 to 300 mmHg and pulse rate range of 40 to 200 beats/min. It is intended for a wrist circumference range of 13.5 cm– 19.5 cm. The accuracy of pressure reading is ±3 mmHg, and accuracy of pulse rate is ±5%. Besides, the devices have multiple auxiliary functions for correct and convenient operation, including movement error indication, cuff wrapping detection, prompt for correct measurement of position (optional), irregular heartbeats indication, recorded measurement results check, display unit setting, display time and date setting, voice broadcast (optional), Bluetooth transmission (optional and only for YE8800AR), etc.

The YUWELL® Blood Pressure Monitors (Model: YE8800AR, YE8800CR) can be connected to an AC adapter and USB cable for charging. The AC adapter and USB cable which comply with IEC 60601-1:2012 are optional according to customer's order.

SUBSTANTIAL EQUIVALENCE

Comparison of technological characteristics

Description	**Proposed Device**	**Predicate Device**	**SE Discussion**
Manufacturer	Jiangsu Yuyue Medical Equipment& Supply Co., Ltd.	Omron Healthcare, Inc.	-
Product Name	Electronic Blood Pressure Monitor	Wrist Blood Pressure Monitor Model BP4350	-
Model Number	YE8800AR, YE8800CR	BP4350	-
K Number	K221372	K182166	-
Regulation No.	21 CFR 870.1130	21 CFR 870.1130	Identical
Product Code	DXN	DXN	Identical
Classification	II	II	Identical
Intended Use/ Indications for Use	This product is intended to measure the blood pressure and pulse rate of	The device is a digital monitor intended for use in measuring blood	Note No.1

	adult more than 12 years old and with wrist circumference ranging from 13.5 cm to 19.5 cm at household or medical center (not suitable for neonate, pregnancy or pre-eclampsia.)	pressure and pulse rate in adult patient population with wrist circumference ranging from 5.3 inches to 8.5 inches (13.5 cm to 21.5 cm). The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.	
Patients Population	Adult whom more than 12 years old (not suitable for neonate, pregnancy or pre-eclampsia.)	Adults	Note No.2
Environment of Use	Household or medical center	Home	Note No.3
Performance Specifications			
Principle of Operation/ Measuring method	Oscillation mensuration	Cuff oscillation method	Identical
Measurement Range	• Pressure range: 0~300 mmHg • Pulse rate: 40~200 beats/min • Diastolic: 40-210 mmHg • Systolic: 60~260 mmHg	• Pressure range: 0~299 mmHg • Pulse rate: 40~180 beats/min • Diastolic: 40-215 mmHg • Systolic: 60~260 mmHg	Note No.4
Pressure Sensor	Semiconductor pressure sensor	Semiconductor pressure sensor	Identical
Applicable Cuff (Wrist Circumference)	13.5~19.5 cm	13.5~21.5 cm	Note No.5
Accuracy of Pressure Indicator	Within ±3 mmHg	Within ±3 mmHg	Identical
Accuracy of Pulse Rate	Within ±5% of reading	Within ±5% of reading	Identical
Inflation Method	Automatic inflation with piezoelectric pump	Automatic inflation with piezoelectric pump	Identical
Deflation Method	Automatic rapid deflation value	Automatic rapid deflation value	Identical
Display	LCD digital display	LCD digital display	Identical
Power source	Rechargeable lithium battery	2 "AAA" batteries	Note No.6
Operating Conditions	• +5 ℃~+40 ℃ • 15% ~ 90% RH (no-condensation)	• +10 ℃~+40 ℃ • 15% ~ 90% RH (no-condensation)	Note No.7

	• 70 kPa ~ 106 kPa	• 80 kPa ~ 106 kPa	
Storage Conditions	• -20 ℃~+55 ℃ • 15% ~ 90% RH (no-condensation) • 70 kPa ~ 106 kPa	• -20 ℃~+60 ℃ • 10% ~ 90% RH (no-condensation)	Note No.8
Dimensions (mm)	Approx.L89 mm x W62 mm x H21 mm	91 mm x 63 mm x 13 mm (not including the wrist cuff)	Note No.9
Weight (g)	About 109 g	Approximately 91 g (not including batteries)	Note No.10
Operation Mode	Continuous operation	Continuous operation	Identical
IP Classification	IP22	IP22	Identical
Electric Classification	Class II or internally powered ME equipment, type BF application part (cuff is applied part)	Internally powered ME equipment, Type BF (wrist cuff)	Note No.11
Service Life	5 years (6 times each day)	5 years	Identical
Rating	AC adapter：input 100-240V~ 50/60Hz 0.35A MAX, output 5V⎓1000mA Battery：DC 3.7V	DC 3 V 3.0 W	Note No.12
Features			
Time and Date Setting	YES	YES	Identical
Voice Broadcast	Optional	NO	Note No.13
Unit Setting	YES Note: Display measurement results by "mmHg" or "kPa".	NO Note: Display measurement results by "mmHg" only.	Note No.14
Prompt for Correct Measurement of Position	Optional	YES	Identical
Indication for Irregular Heartbeats	YES	YES	Identical
Wrong Operation Indication	YES	YES	Identical
Cuff Detection	YES	YES	Identical
Deflation icon	YES	YES	Identical
Inflation icon	YES	NO	Note No.15
Shut Down Automatically	In 3 minutes without any operation	In 2 minutes without any operation	Note No.16
View Average	View average value of latest three times	• Viewing the average of the latest 2 or 3 readings	Note No.17

Value	measurement	taken within the most recent 10 minutes timeframe • View the weekly average readings taken in the morning over the past 4 weeks	
Memory Size	Up to 74 sets of data	Up to 100 sets of data per user	Note No.18
Delete The Recorded Data	YES	YES	Identical
Bluetooth Transmission	Optional Note: Only for YE8800AR	YES	Note No.19
Indication for Low Battery	YES	YES	Identical
Indication for Run Out of Battery	YES	YES	Identical
Safety and Performance			
Performance	Comply ANSI/AAMI/ISO 81060-2 and IEC 80601-2-30	Comply ANSI/AAMI/ISO 81060-2 and IEC 80601-2-30	Identical
Electrical Safety	Comply IEC 60601-1, IEC 60601-1-6 and IEC 60601-1-11	Comply IEC 60601-1, IEC 60601-1-6 and IEC 60601-1-11	Identical
EMC	Comply IEC 60601-1-2	Comply IEC 60601-1-2	Identical
Embedded Software	Comply IEC 60601-1 and IEC 62304	Comply IEC 60601-1 and IEC 62304	Identical
Biocompatibility	Comply ISO 10993 and FDA Guidance (Tested items including Cytotoxicity, Sensitization and Intracutaneous Reactivity)	Comply ISO 10993 and FDA Guidance (Tested items including Cytotoxicity, Sensitization and Intracutaneous Reactivity)	Identical
FCC	Comply with Part 15 of federal communications commission (FCC) rules	Comply with Part 15 of federal communications commission (FCC) rules	Identical

DISCUSSION OF DIFFERENCES

Note ID	Justification
Note No.1, Note No.2, Note No.3 and Note No.5	1) According to clause 5.1.3 of ANSI/AAMI/ISO 81060-2:2018, adults or adolescent patients mean greater than 12 years old. Additionally, adult means human being older than 12 based on clause 3.1 of ANSI/AAMI SP-10:2002. So, both the proposed device and predicate device are intended for adult whom more than 12 years old. However, the proposed device which is not suitable for neonate, pregnancy or pre-eclampsia tightens the applicable population, thus decreases risks for those particular population. In conclusion, the minor difference above will not

	influence the safety and effectiveness of the devices. 2) While the proposed device is designed for household and medical center use and the predicate device is for home use, the difference will not influence the safety and effectiveness of the devices because household environment is more complex. 3) The applicable wrist circumference of proposed device is narrower than the predicate device, it will not raise any new or different safety or effectiveness. 4) The proposed device can also detect the appearance of irregular heartbeats during measurement and gives a warning signal with readings, which is mentioned in "Features" and stated as "Indication for irregular heartbeats". So, both devices are identical for this.
Note No.4	The pressure range and pulse rate of the proposed device are larger than the predicate device, while the diastolic pressure range of the proposed device is narrower. Both contain the blood pressure and pulse range of most people, and the measurement range of proposed device is fully verified according to IEC 80601-2-30. Therefore, the differences do not bring additional risks.
Note No.6	Although the "Power Supply" of the proposed device is different from the predicate device, they all comply with IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11 and IEC 80601-2-30. Additionally, the rechargeable lithium battery of the proposed device complies of IEC 62133-2, so this difference will not raise any safety or effectiveness issue.
Note No.7 and Note No.8	Although the operating atmospheric pressure of the proposed device is slightly broader than the predicate device, while the storage temperature and humidity of the proposed device are little narrower, they all comply with IEC 60601-1, IEC 60601-1-11 and IEC 80601-2-30, so this difference will not raise any safety or effectiveness issue.
Note No.9 and Note No.10	Dimensions and weight of both devices are quite similar, and it nearly makes no difference on safety and effectiveness of the devices.
Note No.11 and Note No.12	Electric classification and rating of the two devices are different, because the proposed device is Class II or internally powered ME equipment, while the predicate device is internally powered ME equipment. However, they all comply with IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11 and IEC 80601-2-30, so this difference will not raise any safety or effectiveness issue.
Note No.13	The voice broadcast function provides an additional way to get measurement results except for visual. Therefore, option this function whether or not for the proposed device doesn't affect normal use of the device or influence the safety and effectiveness of the

	devices.
Note No.14	The proposed device can display measurement results by "mmHg" or "kPa", while the predicate device can display by "mmHg" only. The additional display unit meets the needs of more users and is verified according to IEC 80601-2-30, so the difference will not raise any new safety or effectiveness risk.
Note No.15	The inflation icon is to help users identify increase of pressure in cuff, corresponding to deflation icon indicating decrease of pressure, so this would not raise any safety and efficacy problems.
Note No.16	The proposed device has 3 minutes automatic power off time and it's longer than the 2 minutes of the predicate device. The design purpose is to give the user more time to review or record the data if needed. The difference will not raise any new safety or effectiveness risk.
Note No.17	Although the calculating methods of average measurement value are different, both the auxiliary functions contribute patients to check the previous results, and don't affect the main function, so this would not raise any safety and efficacy problems.
Note No.18	Although the memory size of the proposed device was 26 fewer than that of the predicate device, it was sufficient for users to view recent measurement results, so this would not raise any safety and efficacy problems.
Note No.19	The Bluetooth transmission aims to record and view measurement results on a mobile app when the device is not at hand. Therefore, lack of Bluetooth transmission for YE8800CR and optional of Bluetooth transmission based on users' order for YE8800AR don’t affect normal use of the device or influence the safety and effectiveness of the devices.

SUMMARY OF TESTING

1) Nonclinical Testing Summary

The design and manufacturing of YUWELL® Electronic Blood Pressure Monitor are subject to verification and validation testing in conformance with regulatory guidance and recognized consensus standards.

- Electrical safety test according to ANSI/AAMI/IEC 60601-1, IEC 60601-1-11 and IEC 80601-2-30 standards
- Electromagnetic compatibility test according to IEC 60601-1-2 standard
- Usability test according to IEC 60601-1-6 and IEC 62366 standards
- Performance test according to IEC 80601-2-30 standard
- Lithium battery report in accordance with IEC 62133-2

- Biocompatibility test according to ISO 10993 and the FDA guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"

- Software verification and validation test according to the requirements of the FDA "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and IEC 62304

- Bluetooth transmission complies with Part 15 of federal communications commission (FCC) rules

2) Clinical Testing summary

Clinical accuracy test was conducted on Yuwell YE8800AR, which has more complete functions compared with YE8800CR, according to the ANSI/AAMI/ISO 81060-2:2018 protocol in the general population. The device was assessed by using it on 85 participants, who fulfilled our inclusion criteria involving the ranges of wrist circumference and systolic and diastolic BP. The validation and data analysis were performed as per the protocol. In the ANSI/AAMI/ISO 81060-2:2018 validation procedure (criterion 1), the mean ± SD of the differences between the test device and reference BP was -1.7 ± 5.66/−1.0 ± 5.66 mmHg (systolic/diastolic). The mean differences between the two observers and the Yuwell YE8800AR were -1.7 ± 4.17 mmHg for systolic BP and −1.0 ± 4.99 mmHg for diastolic BP, according to criterion 2. The two ANSI/AAMI/ISO criteria were fulfilled. The Yuwell YE8800AR BP monitor fulfilled the requirements of the ANSI/AAMI/ISO validation standard.

CONCLUSION

Compared to the predicate device, the proposed device has similar intended use and performance, and equivalent testing standards, and all testing results have come back as positive results or pass for the proposed device, so the proposed device is as safety and effectiveness as the predicate device.

The differences above between the proposed device and predicate device do not affect the intended use, technology characteristics, safety and effectiveness. And no issues are raised regarding to safety and effectiveness.