March 5, 2026

Jiangsu Yuyue Medical Equipment & Supply Co., Ltd.
Zhang Fang (Fawn)
Director of Regulatory and Compliance
No.1 Baisheng Road Development Zone, Danyang
Zhenjiang, Jiangsu 212300
China

Re: K252779
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: February 5, 2026
Received: February 5, 2026

Dear Zhang Fang (Fawn):

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252779

Device Name
YUWELL® Electronic Blood Pressure Monitor

Indications for Use *(Describe)*
This device is intended to measure blood pressure and pulse rate in patients over 12 years old with an upper-arm circumference ranging from 22 cm to 45 cm (8.7 in to 17.7 in). It is not suitable for neonates, pregnant individuals, or patients with pre-eclampsia. The device can be used at home or in a healthcare facility.

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

Applicant/Sponsor Information

Applicant	:	JIANGSU YUYUE MEDICAL EQUIPMENT & SUPPLY CO., LTD.
Address	:	No.1 Baisheng Road Development Zone, Danyang, Jiangsu 212300 CHINA
Manufacturing Facility	:	No.1 Baisheng Road Development Zone, Danyang, Jiangsu 212300 CHINA
Contact of Correspondent	:	Fang (Fawn) Zhang
Phone	:	(206) 639-1311
Email	:	fawn.zhang@yuwell.com

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	:	21 CFR 870.1130
Device Class	:	2

Identification of Predicate Device

The identification of predicates within this submission is as follows:

Manufacturer	:	Omron Healthcare, Inc.
Trade Name	:	Evolv Model BP7000 Upper Arm Blood Pressure Monitor
Common Name	:	Evolv Model BP7000 Upper Arm Blood Pressure Monitor
Classification Name	:	System, Measurement, Blood-pressure, Non-invasive
Product Code	:	DXN
Regulation Number	:	21 CFR 870.1130
Device Class	:	2
FDA 510 (k) #	:	K162092

Description of the Device

YUWELL® Blood Pressure Monitor (Model: YE630CR) is a rechargeable lithium battery-powered, automatic, noninvasive upper-arm blood pressure measuring system intended for over-the-counter (OTC) use. YE630CR is designed for people with upper arm circumference ranging from 22 cm to 45 cm (8.7 in to 17.7 in). The systolic and diastolic

blood pressures are measured using the oscillometric method, where the cuff is inflated by an air pump and it deflates via an exhaust valve. During inflation, the cuff pressure is monitored, and the pulse waveform data is captured. The pulse waveform data is then further analyzed by software which determines pulse rate, as well as the systolic and diastolic blood pressures.

Proposed Indications for Use

This device is intended to measure blood pressure and pulse rate in patients over 12 years old with an upper-arm circumference ranging from 22 cm to 45 cm (8.7 in to 17.7 in). It is not suitable for neonates, pregnant individuals, or patients with pre-eclampsia. The device can be used at home or in a healthcare facility.

Technological Characteristics

The YUWELL® Blood Pressure Monitors (Model: YE630CR) are intended for medical professionals and lay persons to use at healthcare facilities or at home. The device applies the oscillometric method for blood pressure and pulse rate measurements. The device has multiple auxiliary functions for accurate measurement and convenient operation, such as indication for movement error, indication for irregular heartbeat (optional), detection for cuff wearing, recorded measurement results check, display unit setting, display time and date setting, voice broadcast (optional), Bluetooth transmission (optional), etc.

Here, irregular heartbeat (IHB) means more than two pulse waves are identified where the instantaneous heart rate exceeds the average heart rate by 25% during blood pressure measurement. When an irregular heartbeat (IHB) detected, it indicates that the measurement results may be inaccurate.

The YUWELL® Blood Pressure Monitors (Model: YE630CR) can be connected to an AC adapter and USB cable for charging. The AC adapter and USB cable which comply with IEC 60601-1 are optional according to customer's order.

Substantial Equivalence

Comparison of technological characteristics:

Description	**Subject Device**	**Predicate Device**	**SE Comparison**
Manufacturer	JIANGSU YUYUE MEDICAL EQUIPMENT & SUPPLY CO.,LTD.	Omron Healthcare, Inc.	-
Product Name	Yuwell Electronic Blood Pressure Monitor	Evolv Model BP7000 Upper Arm Blood Pressure Monitor	-

Model Number	YE630CR	BP7000	-
K Number	-	K162092	-
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 device is intended to measure blood pressure and pulse rate in patients over 12 years old with an upper-arm circumference ranging from 22 cm to 45 cm (8.7 in to 17.7 in). It is not suitable for neonates, pregnant individuals, or patients with pre-eclampsia. The device can be used at home or in a healthcare facility.	The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with arm circumference ranging from 9 inches to 12 inches (22 cm to 42 cm). The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.	Note No.1
Patients Population	Patients over 12 years old (not suitable for neonates, pregnant individuals, or patients with pre-eclampsia)	Adults	Note No.2
Environment of Use	Household or medical center	Home	Note No.3
Performance Specifications			
Principle of Operation	Oscillation mensuration	Cuff oscillation method	Identical
Measurement Range	• Cuff pressure range: 0~300 mmHg • Pulse rate: 40~200 beats/min • Diastolic pressure: 20-210 mmHg • Systolic pressure: 40~260 mmHg	• Cuff pressure range: 0~299 mmHg • Pulse rate: 40~180 beats/min	Note No.4
Applicable Cuff (Arm Circumference)	22~45 cm	22~42 cm	Note No.5
Accuracy of	Within ±3 mmHg	Within ±3 mmHg	Identical

Pressure Indicator			
Accuracy of Pulse Rate	Within ±5% of reading	Within ±5% of reading	Identical
Inflation	Automatic inflation with an electric pump	Fuzzy-logic controlled by an electric pump	Identical
Deflation	Automatic rapid deflation	Automatic rapid deflation	Identical
Display	OLED display	OLED display	Identical
Power source	Rechargeable lithium battery	4 "AAA" batteries	Note No.6
Operating Conditions	• +5 ℃ ~ +40 ℃ • 15% ~ 90%, non-condensing • 70 kPa ~ 106 kPa	• +10 ℃~+40 ℃ • 15% ~ 90%, no-condensing • 80 kPa ~ 106 kPa	Note No.7
Storage Conditions	• -25 ℃ to +5 ℃, and • +5 ℃ to + 35 ℃ at a relative humidity up to 90%, non-condensing • ＞35 ℃ to 70 ℃ at a water vapor pressure up to 5 kPa	• -20 ℃~+60 ℃ • 10% ~ 90% (no-condensing)	Note No.8
Dimensions (mm)	Approx. 125*62*24 (without cuff)	Approximately 85*120*20(not including the arm cuff)	Note No.9
Weight (g)	About 257 g (without cuff)	Approximately 240 g (not including batteries)	Note No.10
IP Classification	IP22	IP22	Identical
Electric Classification	Class II and internally powered, type BF applied part (cuff is applied part)	Internally powered ME equipment, Type BF (cuff)	Note No.11
Service Life	5 years (6 times each day) for the monitor	5 years for the monitor	Identical
Power supply	AC adapter：input 100-240V~ 50/60Hz 0.35A MAX, output 5V ⎓1A Battery: 3.7V	4 “AAA” batteries	Note No.12
Features			
Time and Date Setting	YES	NO	Note No.13
Voice Broadcast	Optional	NO	Note No.14
Unit Setting	YES Note: Display measurement results by	NO Note: Display measurement results by	Note No.15

	"mmHg" or "kPa".	"mmHg" only.	
Indications for Irregular Heartbeats	YES	YES	Identical
Indication for Movement Error	YES	YES	Identical
Detection for Cuff Wearing	YES	YES	Identical
Deflation Icon	YES	YES	Identical
Shut Down Automatically	In 3 minutes without any operation	In 2 minutes without any operation	Note No.16
Memory Size	Up to 50 sets of data	Up to 100 sets of data	Note No.17
Bluetooth Transmission	Optional	Optional	Identical
Safety and Performance			
Performance	Comply with ISO 81060-2 and IEC 80601-2-30	Comply with ISO 81060-2	Note No.18
Electrical Safety	Comply with IEC 60601-1, IEC 60601-1-6, IEC 60601-1-8 and IEC 60601-1-11	Electrical safety test	Note No.19
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Identical
Biocompatibility	Comply with ISO 10993 and FDA Guidance (Tested items including Cytotoxicity, Sensitization and Intracutaneous Reactivity)	Comply with 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 Difference

Note ID	Justification
Note No.1, Note No.2, Note 3 and Note No.5	1) According to clause 5.1.3 of ISO 81060-2:2018+AMD1:2020, the clinical investigation requirements for adults and adolescents over age 12 are essentially the same. Object evidence supports that the subject device has met the requirements in ISO 81060-2:2018+AMD1:2020 as that of the predicate device. Therefore, the subject and the predicate

	devices are substantially equivalent as both have met the requirements in ISO 81060-2:2018+AMD1:2020. 2) While the subject device is for home and hospital use, and the predicate device is only for home use, the difference will not influence the safety and effectiveness of the devices, because when the device is used in the hospital, trained healthcare professionals will be the operator/user, who can ensure proper use of the device. 3) The intended arm circumference of the subject device is longer than that of the predicate device; however, the subject device's arm circumference complies with ISO 81060-2:2018+AMD1:2020, so the subject and the predicate devices are substantially equivalent despite of their difference in the intended patient population with different arm circumference. 4) The subject device can detect irregular heartbeats during measurements and gives warning signs "Indications for Irregular Heartbeats". Therefore, the subject and the predicate devices are substantially equivalent in this regard.
Note No.4	1) The subject device's cuff pressure range is 0 to 300 mmHg, whereas that of the predictive device is 0 to 299 mmHg. The slight difference does not present additional risks. 2) The subject device's pulse rate range is bigger than that of the predicate device, but both contain the pulse range of the majority of the population. Therefore, the differences do not lead to additional risks. 3) The subject device specifies diastolic and systolic pressure range, while the predictive device doesn't. The blood pressure measurement range of subject device complies with IEC 80601-2-30. Therefore, the differences do not lead to additional risks.
Note No.6	Although the subject device's power supply is different from that of the predicate device, both power supplies comply with IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11, and IEC 80601-2-30. Additionally, the subject device's rechargeable lithium battery complies with IEC 62133-2. Therefore, the subject device and the predicate device are substantially equivalent despite their difference in power supply.
Note No.7 and Note No.8	The subject device's operating atmospheric pressure is slightly broader than that of the predicate device, and the subject device's storage temperature and humidity are narrower than that of the predicate device. While there are differences, all these parameters for both devices comply with IEC 60601-1, IEC 60601-1-11, and IEC 80601-2-30. Therefore, the subject device is as safe and effective as the predicate device.
Note No.9	The dimensions and weight of the subject and the predicate devices are quite

and Note No.10	similar. These parameters do not affect the safety and the effectiveness of the subject device. Thus, the subject device is substantially equivalent to the predicate device despite their differences in these parameters.
Note No.11 and Note No.12	The subject and predicate devices' electric classification and power supply are different, as the subject device is both Class II and internally powered ME equipment, while the predicate device is only internally powered. Although the subject device offers an additional power supply option, testing has demonstrated that the subject device complies with IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11, and IEC 80601-2-30, so this addition does not present additional risks in the safety and effectiveness of the subject device. Thus, the subject device is substantially equivalent to the predicate device.
Note No.13	The subject device allows users to set time and date and it displays so accordingly, but the predicate device does not offer this feature. As this feature is independent of the blood pressure algorithm, it does not present additional risks to the safety and effectiveness of the subject device. Thus, the subject device is substantially equivalent to the predicate device despite of this additional feature.
Note No.14	The subject device provides an optional audio reporting feature, whereas the predicate device does not. As this feature is independent of the blood pressure algorithm, it does not present additional risks to the safety and effectiveness of the device. Thus, the subject device is substantially equivalent to the predicate device despite of this additional feature.
Note No.15	The subject device can display measurement results by "mmHg" or "kPa", while the predicate device can display by "mmHg" only. The additional display unit does not affect the safety or effectiveness of the subject device. In addition, this feature is validated according to IEC 80601-2-30, so the subject device is as safe and effective as the predicate device despite of this additional feature.
Note No.16	The subject device will be automatically powered off in 3 minutes, whereas the predicate device does so in 2 minutes. The reason for the design is to give the user more time to review or record the data. This feature does not affect the safety or effectiveness of the subject device. Thus, the subject device is substantially equivalent to the predicate device despite its longer automatic power off time.
Note No.17	Although the memory capacity of the subject device was less than that of the predicate device, it was sufficient for users to view recent measurement results, so this difference does not present additional risks to the safety or

	effectiveness of the subject device. Thus, the subject device is substantially equivalent to the predicate device despite of less memory capacity.
Note No.18	The subject device complies with IEC 80601-2-30, while the predicate device does not explicitly state whether it complies with this standard. Considering the standard is particular for the subject device and recognized by the FDA, compliance to the standard does not affect that the subject device is substantially to the predicate device.
Note No.19	The predicate device does not state the standard name of its electrical safety test, but all the standards that the subject device claims to comply with are recognized by FDA, so the subject device is as safe and effective as the predicate device.

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 60601-1-8, IEC 60601-1-11 and IEC 80601-2-30 standards
- Electromagnetic compatibility test according to IEC 60601-1-2 and IEC TS 60601-4-2 standards
- Usability test according to IEC 60601-1-6 and IEC 62366-1 standards
- Performance test according to IEC 80601-2-30 standard
- Lithium battery report in accordance with IEC 62133-2
- The irregular heartbeat (IHB) feature of the subject device serves as a signal quality indicator for inaccurate measurements. This feature has been validated through testing using a blood pressure simulator. To set up the test, the blood pressure simulator was set to the arrhythmia mode. First, the simulator's output waveforms were verified to meet the definition of an irregular pulse wave and the preset values were recorded. Second, the subject device's readings were compared against the simulator's preset values. Third, ten sets of measurements were compiled in each arrhythmia mode, and the mean absolute deviation between the subject device readings and the simulator's preset values was calculated. The mean absolute deviation for both systolic and diastolic pressure exceeded 5 mmHg, it demonstrated that the blood pressure measurement was inaccurate when the IHB symbol was present.
- 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 per FDA guidance "Content of Premarket Submissions for Device Software Functions" and "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" and IEC 62304
- Bluetooth transmission complies with Part 15 of federal communications commission (FCC) rules

2) Clinical Testing summary

i) Blood Pressure Clinical Testing

The accuracy of Yuwell ®YE630CR has been demonstrated through a clinical study per ISO 81060-2:2018+AMD1:2020 in the intended patient population, which is individuals over 12 years old. The study included ninety-three (93) subjects, who met the study inclusion criteria for upper arm circumference and systolic and diastolic BP. Validation and data analysis were performed per protocol. In the ISO 81060-2:2018+AMD1:2020 validation procedure (criterion 1), the mean ± SD of the differences between the test device and the reference BP was -3.2 ± 6.83/-1.1 ± 6.23 mmHg (systolic/diastolic). The mean differences between the two observers and the test device readings were -3.2 ± 5.97 mmHg for systolic BP and -1.1 ± 5.66 mmHg for diastolic BP (criterion 2). The clinical study results have met both ISO criteria, and thus validated the accuracy of Yuwell® YE630CR blood pressure monitor.

ii) Pulse Rate Clinical Testing

A clinical validation study was conducted to evaluate the pulse rate (PR) measurement accuracy of the subject device by comparison with manually annotated electrocardiogram (ECG) recordings. The study had a total of thirty-five (35) subjects enrolled, and their age ranged from 21 to 38. Their validated pulse rate ranged from 59 to 104 bpm with no subjects excluded from the analysis. The study method is as such: Following a 5-minute seated rest, the subject's pulse rate was measured simultaneously by the subject device and a reference ECG. There were three (3) repeated measurements per subject, yielding 35x3=105 data sets that resulted in a mean error of -0.85 bpm, a standard deviation of 2.04 bpm, and an overall root mean square error of 2.20 bpm. Bland-Altman analysis revealed all the observed differences were within the pre-defined acceptance criterion of ±5%. These results demonstrated good agreement between the device PR outputs and the ECG reference values across the validated range.

Conclusion

Compared to the predicate device, the subject device has similar intended use and technical characteristics as the predicate device. All testing results have demonstrated that the subject device is as safe and effective as the predicate device. Therefore, they are substantially equivalent.