February 23, 2026

Jiangsu Yuyue Medical Equipment& Supply Co., Ltd.
Zhang Fang (Fawn)
Director of Regulatory and Compliance
#1 Baisheng Rd. Development Zone
Danyang, Jiangsu 212300
China

Re: K253228
Trade/Device Name: YUWELL® Electronic Blood Pressure Monitor (YE650AR)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: Class II
Product Code: DXN
Dated: February 6, 2026
Received: February 6, 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,

JENNIFER W. SHIH -S

for 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253228

Please provide the device trade name(s).

YUWELL® Electronic Blood Pressure Monitor (YE650AR)

Please provide your Indications for Use below.

This product is indicated for measuring blood pressure and pulse rate in patients older than 12 years. 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.

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (Part 21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K253228

510(k) Summary

Prepared on: 2026-02-06

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	JIANGSU YUYUE MEDICAL EQUIPMENT & SUPPLY CO., LTD.
Applicant Address	NO.1 Baisheng Road Development Zone, Danyang, Jiangsu 212300 CHINA Danyang Jiangsu 212300 China
Applicant Contact Telephone	(206) 639-1311
Applicant Contact	Dr. Zhang Fang (Fawn)
Applicant Contact Email	fawn.zhang@yuwell.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	YUWELL® Electronic Blood Pressure Monitor (YE650AR)
Common Name	Noninvasive blood pressure measurement system
Classification Name	System, Measurement, Blood-Pressure, Non-Invasive
Regulation Number	870.1130
Product Code(s)	DXN

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K200939	Electronic Blood Pressure Monitor: YE620B, YE620D, YE660E, YE660F and YE680B	DXN

Device Description Summary

21 CFR 807.92(a)(4)

YUWELL® Blood Pressure Monitor (Model: YE650AR) is a rechargeable lithium battery-powered, automatic, noninvasive, upper-arm blood pressure measuring system intended for over-the-counter (OTC) use. YE650AR is designed for upper arm circumference ranging from 22 cm to 32cm (8.7 in to 12.5 in) or 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 with an air pump and deflates via an exhaust valve. During deflation, the cuff pressure is monitored, and pulse waveform data is captured. The pulse waveform data is then further analyzed by software which determines pulse rate, as well as systolic and diastolic blood pressure.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

This product is indicated for measuring blood pressure and pulse rate in patients older than 12 years. 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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use of the subject device is the same as that of the predicate device, which is to measure the blood pressure and pulse rate of adult (not suitable for neonate, pregnancy or pre-eclampsia). The difference between them only in the expression of the intended patient population and the use environment.

The subject device has different indications for use in comparison to the predicate device in two ways, which are (1) the intended patient population (2) the use environment; however, these differences do not constitute a new intended use, because (1) according to clause 5.1.3 of ISO 81060-2:2018+AMD1:2020, the clinical investigation requirements for adults and patient's older than 12 years are essentially the same (2) just for clarification, the use environment is the same for the subject and the predicate devices, except the language of

descriptions differ.

Technological Comparison

21 CFR 807.92(a)(6)

The subject device has the same technological characteristics such as the principle of operation, measurement site, cuff circumference, contacting materials, blood pressure measuring range and precision, cuff pressure range, pulse measuring range and precision, pressurization source, pressure sensor and operating environment as the predicate device.
The subject device differs from the predicate device in the following technical characteristics, (1) the subject device offers one cuff type (2) the storage environment of the subject device is broader than that of the predicate device (3) the energy source of the subject device is lithium battery, while that of the predicate device is AA batteries (4) the output of AC adapter is for the subject device and the predicate device (5) the subject device has memory capability, bluetooth function, and three-color backlight display functions whereas the predicate devices does not.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The non-clinical testing to support substantial equivalence are (1) functional testing for the cuff, which was verified per ISO 81060-2 (2) data transmission testing,which was verified per Cybersecuirty in Medical Devices and FCC (3) electrical safety testing, which was verified per IEC 60601-1, IEC 60601-1-2, IEC TS 60601-4-2, IEC 60601-1-6, IEC 60601-1-8, IEC 60601-1-11, ISO 10993-1/5/10/23 (4) function testing, which was verified per requirement of IFU.

Not Applicable

This nonclinical test combining with safety and performance tests demonstrate that the subject device is as safe, as effective, and performs as well as the predicate device.