December 15, 2023

Wenzhou Yosun Medical Technology Co.,Ltd
Xiao Yuan Lan, Regulatory Affair Manager
No.17 Shahong Road, Lingmen Beibaixiang Town
Yueqing
Wenzhou, Zhejiang 325603
China

Re: K231478
Trade/Device Name: Digital Blood Pressure Monitor (Model: YB-800)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: November 21, 2023
Received: November 21, 2023

Dear Xiao Yuan Lan:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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.

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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*

K231478

Device Name

Digital Blood Pressure Monitor (Model:YB-800)

Indications for Use *(Describe)*

The Digital Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure, as well as the pulse rate of adults via non-invasive oscillometric technique in which an inflatable CUFF (22-32cm) is wrapped around the upper arm at medical facilities or at home, it's supplied for OTC use.

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

**Prepared in accordance with the requirements of 21 CFR Part 807.92**

| | |
|---|---|
| **1. Applicant** | Wenzhou Yosun Medical Technology Co.,Ltd<br>No.17, Shahong Road, Lingmen Beibaixiang Town,Yueqing Wenzhou 325603 Zhejiang P.R. China<br>086-0577-61896987 |
| **Contact Person** | XiaoYuan Lan, 610826399@qq.com |
| **Prepare date** | 2023-04-15 |
| **2. Device name and classification** | **Device Name:** Digital Blood Pressure Monitor<br>**Models:** YB-800<br>**Classification Name:**<br>21 CFR 870.1130<br>Noninvasive Blood Pressure Measurement System<br>**Product code:** DXN<br>**Regulatory Class:** Class II |
| **3.Predicate Device(s)** | Shenzhen Jamr Technology Co., Ltd. Upper Arm Type Blood Pressure Monitor, Model F1701T, K220886 |
| **4. Device Description** | The arm-type electronic blood pressure monitor uses fuzzy logic intelligence to detect both upper and lower pressure value simultaneously. The personalized optimal inflation level determines the result of each measurement.<br>This equipment is composed of a main body and a cuff. The main body is composed of a central processing unit, a pressure sensor, an air pump, a solenoid valve, a uniform speed vent valve, a PCB board, and an LCD liquid crystal display. |
| **5. Indications for Use** | The Digital Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure, as well as the pulse rate of adults via non-invasive oscillometric technique in which an inflatable CUFF (22-32cm) is wrapped around the upper arm at medical facilities or at home, it's supplied for OTC use. |

## 6. Predicate Device Comparison

Comparison to the predicate devices, the subject device has same intended use, similar product design, same performance effectiveness, performance safety as the predicate device.

Please refer to following table to find differences between the subject device and predicate device.

**Table 1 Comparison between the predicate PG-800B36 and the subject device**

| ITEM | Proposed Device YB-800 | Predicate Device K22086/ F1701T | Comparison Result |
|---|---|---|---|
| Device Name | Digital Blood Pressure Monitor | Upper Arm Type Blood Pressure Monitor | -- |
| Appearance |  |   | --- |
| Manufacturer | Wenzhou Yosun Medical Technology Co.,Ltd | Shenzhen Jamr Technology Co.,Ltd | --- |
| Indications for Use | The Digital Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure, as well as the pulse rate of adults via non-invasive oscillometric technique in which an inflatable CUFF (22-32cm) is wrapped around the upper arm at medical facilities or at home, it's supplied for OTC use. | The Upper Arm Type Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult by using the arm cuff (22-42cm), it can be used in medical facilities or at home. It is supplied for OTC use. | Same |
| Prescription & OTC | OTC | OTC | Same |
| Contraindication | Not Known | Use of this instrument on patients under dialysis therapy or on anticoagulant, antiplatelets, or steroids could cause internal bleeding. | Different[1] (Note 1) |
| Clinical Use | Medical Facilities and Home Use | Medical Facilities and Home Use | Same |
| Patient Population | Adults | Adults | Same |
| Measurement site | Upper arm | Upper arm | Same |
| Measurement Principle | Oscillometric | Oscillometric | Same |

| | | | | | |
|---|---|---|---|---|---|
| Components | LCD / Key / Cuff / MCU / Pump / Batteries | | LCD / Key / Cuff / MCU / Pump / Batteries | | Same |
| Memory | 120 memories for 2 users (SYS, DIA, Pulse) | | Automatically stores the last 120 measurements for measure | | Same |
| Mode of operation | Continuous operation | | Continuous operation | | Same |
| Power Source | 4x1.5V AA Alkaline Batteries | | 3x1.5V AA Alkaline Batteries | | Different[1] (Note 1) |
| Mode of operation | Continuous operation | | Continuous operation | | Same |
| Safety classifications | Type BF applied part | | Type BF applied part | | Same |
| Measurement Range | Blood Pressure | 0 ~ 300 mmHg | Blood Pressure | 0 ~ 295 mmHg | Different[2] (Note 2) |
| | Pulse Rate | 40 -199bpm | Pulse Rate | 40-180 bpm | |
| Accuracy | Static Pressure | ±3 mmHg | Static Pressure | ±3 mmHg | Same |
| | Pulse Rate | ±5% | Pulse Rate | ±5% | |
| Arm Circumference | 22 cm~32cm | | 22 cm~42 cm | | Different[2] (Note 2) |
| Patient Contact Material | Cuff –Flannelette/Sticky fabric | | Cuff –Nylon | | Different[3] (Note 3) |
| Physical Dimensions (Length*Width*Height) | Approx: 131mm*111mm*79mm | | 109*121.5 * 52.5mm | | Different[4] (Note 4) |
| Weight | About 265g（including battery and cuff） | | 290g (batteries and AC adapter is not included) | | |
| Safety and essential performance | IEC 60601-1<br>IEC 60601-1-2<br>IEC 60601-1-11<br>ISO 80601-2-30<br>ISO 81060-2 | | IEC 60601-1<br>IEC 60601-1-2<br>IEC 60601-1-11<br>ISO 80601-2-30<br>ISO 81060-2 | | Same |
| Biocompatibility | ISO 10993-1;<br>ISO 10993-5;<br>ISO 10993-23; | | ISO 10993-1;<br>ISO 10993-5;<br>ISO 10993-10 | | Same |
| Operation Environments | ＋5℃~＋40℃, 15%RH~80%RH,80 kPa~105 kPa | | ＋5℃~＋40℃, 15%RH~93%RH,70 kPa~106 kPa | | Different[5] (Note 5) |
| Storage Environments | －20℃~＋55℃, 10%RH~90%RH,80 kPa~106 kPa | | －25℃~＋70℃, ≤93%RH, 70 kPa~106 kPa | | |

**COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES [807.92(a)(6)]**

The proposed device and the predicate device have similar technological characteristics. Both devices are battery-operated arm blood pressure monitors intended for adult use and employ the oscillometric method for measuring blood pressure and pulse. The devices share the same accuracy range of pressure reading of ±3 mmHg and the same accuracy range for pulse rate reading of ± 5%.

There are minor differences in technical specifications and features between the YB-800 proposed device and predicate device would be discussed below:

**SUBSTANTIAL EQUIVALENCE**

The contraindication of the proposed device is different form the predicate device. And they both work with alkaline batteries though the voltage of proposed device is bigger than the predicate. The device is verified through IEC 60601-1, IEC 60601-1-2 and IEC 80601-2-30 and no additional safety and effectiveness issues was introduced. (Note 1)

The range of pressure and the pulse rate is wider than the predicate device while the arm circumference is narrower than predicate device. They have the same accuracy. The differences are very slightly and they 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 2)

Though the cuff material is different from the predicate, the cuff of proposed device was biocompatible according to ISO 10993 tests. No new safety and effectiveness issues raised. (Note 3)

Minor differences in the dimensions and weight do not impact the safety or performance of blood pressure or pulse rate measurements (Note 4).

Although the operating humidity and atmospheric pressure of the proposed device is slightly narrower than the predicate device, and the storage temperature, humidity and atmospheric pressure of the proposed device are also 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 5)

Any differences in the technological characteristics between the devices do not raise any different questions of safety or effectiveness. Thus, the proposed device is substantially equivalent to the predicate device.

**Performance Testing:**

Performance data includes “Non-Clinical Data” and “Clinical Data”, brief description of which are shown as below.

**Non-Clinical Data:**

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

**Biocompatibility testing**

The biocompatibility evaluation for the Digital Blood Pressure Monitor and the NIBP CUFF were conducted in accordance with the International Standard ISO 10993-1 “Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA. The worst case of the whole system is considered tissue contacting for duration of less than 24 hours. And the battery of testing included the following tests:

- Cytotoxicity
- Skin Sensitization
- Skin Irritation

**Electrical safety and electromagnetic compatibility (EMC)**

Electrical safety and EMC testing were conducted on the Arm-type Electronic Blood Pressure Monitor, consisting of all the modules and accessories in the system. The system complies with the IEC 60601-1: 2012 *Medical electrical equipment Part 1: General requirements for basic safety and essential performance* for safety and the IEC 60601-1-2: 2014 *Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests* standard for EMC.

**Bench Testing**

Bench testing was conducted on the Arm-type Electronic Blood Pressure Monitor, consisting of all the accessories in the system. The system complies with the IEC 60601-1-11: 2010 *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*, ISO 80601-2-30: 2009 *Medical electrical equipment* —Part 2-30: Requirements for basic safety and essential performance of automated non-invasive sphygmomanometers.

**Software Verification and Validation Testing**

Software verification and validation testing were conducted and documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.” The software for this device was considered as a “major” level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

**Clinical data**

YB-800 was tested to ISO 81060-2: 2018 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type. The study included 85 adult subjects (41 females, 44 males) with an age range of 16 to 70 years. All data’s mean error and standard deviation of differences for systolic, diastolic pressure is not over the limits of ISO 81060-2: 2018. No adverse effect and/or complication is found in this study.

**Summary**

Based on the non-clinical and clinical performance as documented in the device development, the subject devices were found to have a safety and effectiveness profile that is same to the predicate device.

**Conclusion**

Verification and validation testing was conducted on the subject device and all testing passed pre-specified criteria. This premarket notification submission demonstrates that the Digital Blood Pressure Monitor (YB-800) is substantially equivalent to the predicate devices(K220886).