August 16, 2022

Jiangsu Yuyue Medical Equipment & Supply Co., Ltd.
Yuzhuo Wang
Medical Device Registered Engineer
Yunyang Industrial Park
Danyang, Jiangsu 212300
China

Re: K212385
Trade/Device Name: YUWELL Finger Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: July 12, 2022
Received: July 18, 2022

Dear Yuzhuo Wang:

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 Todd Courtney
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K212385

Device Name
YUWELL® Finger Pulse Oximeter:YX102, YX103, YX301, YX306

Indications for Use *(Describe)*
The YUWELL® Finger Pulse Oximeter is a non-invasive, non-sterile, reusable, spot checking device which can measure and display SpO2 and pulse rate through finger. It is intended for adults and children (weight >30 kg) and is expected for home and hospital inspection. The device is not for continuous monitoring,use during motion or for patients with low perfusion.

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

1. OWNER/SUBMITTER'S INFORMATION

Company Name:	JIANGSU YUYUE MEDICAL EQUIPMENT & SUPPLY CO.,LTD.
Company Address:	Yunyang Industrial Park 212300 Danyang Jiangsu PEOPLE'S REPUBLIC OF CHINA
Contact:	Wang, Yuzhuo
Phone:	0511-86900827
Fax:	0511-86900991
Email:	wang.yz@yuyue.com.cn
Date prepared:	July 12, 2022

2. TRADE NAME, COMMON NAME, CLASSIFICATION

Trade Name:	YUWELL® Finger Pulse Oximeter
Common Name:	Finger Pulse Oximeter
Model:	YX102, YX103, YX301, YX306
Product Code :	DQA
Regulation Number:	21 CFR 870.2700
Classification Name:	Oximeter
Device Classification:	Class II
FDA 510 (k) #:	K212385

3. DENTIFICATION OF PREDICATE DEVICE(S)

The identification of predicates within this submission is as follow:

Manufacturer:	Beijing Choice Electronic Technology Co., Ltd.
Trade Name:	Fingertip Pulse Oximeter
Common Name:	Pulse Oximeter
Product Code:	DQA
Regulation Number:	21 CFR 870.2700
Classification Name:	Oximeter
Device Classification:	Class II
FDA 510 (k) #:	K101577

4、DESCRIPTION OF THE DEVICE

The YUWELL® Finger Pulse Oximeter is a non-invasive, non-sterile, reusable, spot checking device which can measure and display SpO_2 and pulse rate through finger. It is intended for adults and children (weight >30 kg) and is expected for home and hospital inspection. The device is not for continuous monitoring, use during motion or for patients with low perfusion.

The YUWELL® Finger Pulse Oximeter features in small volume, low power consumption, convenient operation and portable. It is only necessary for patient to put one of his fingers into a fingertip photoelectric sensor for measurement, and then the screen will display the measured

value of Pulse Oxygen Saturation（SpO_2) and pulse rate(PR) .The device consists of electronic circuits, plastic housing，OLED/LED display(differentiated by models) and button（YX301,YX306 equipped, YX102,YX103 not equipped) which powered by two alkaline AAA batteries. The device does not include alarms.

5、INTENDED USE

The YUWELL® Finger Pulse Oximeter is a non-invasive, non-sterile, reusable, spot checking device which can measure and display SpO_2 and pulse rate through finger. It is intended for adults and children (weight > 30kg) and is expected for home and hospital inspection. The device is not for continuous monitoring, use during motion or for patients with low perfusion.

6、TECHNOLOGICAL CHARACTERISTIC

Principle of the Oximeter is as follows: An experience formula of data process is established taking use of Lambert Beer law according to Spectrum Absorption Characteristics of deoxyhaemoglobin (HHb) and Oxyhemoglobin (O_2Hb) in glow and near-infrared zones. Operation principle of the instrument is Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of light (red light and infrared light) can be focused onto human nail tip through perspective clamp finger-type sensor. Then measured signal can be obtained by a photosensitive element, information acquired through which will be shown display through process in electronic circuits and microprocessor.

7、SUBSTANTIAL EQUIVALENCE

Comparison of technological characteristics

Description	**Subject Device (K212385)**	**Predicate Device (K101577)**	**Remark**
Manufacturer	JIANGSU YUYUE MEDICAL EQUIPMENT & SUPPLY CO.,LTD.	Beijing Choice Electronic Technology Co., Ltd.	-
Product Name	Finger Pulse Oximeter	Fingertip Pulse Oximeter	-
Model	YX102,YX103,YX301,YX306	MD300C63	-
Intended Use	The YUWELL® Finger Pulse Oximeter is a non-invasive, non-sterile, reusable, spot checking device which can measure and display SpO_2 and pulse rate through finger. It is intended for adults and children (weight > 30kg) and is expected for home and hospital inspection. The device is not for continuous monitoring, use during motion or for patients with low perfusion.	Fingertip pulse oximeter is a portable, non-invasive devices intended for spot- checking of arterial hemoglobin oxygen saturation (SpO_2) and pulse rate of adult and pediatric patient at home, and hospital (including clinical use in internist/surgery, Anesthesia, and intensive care units). Not for continuous monitoring.	Note 1

Patient populations	adults and children (weight >30 kg)	adult and pediatric patient	Note 1
Measuring characteristics	Spot-checking Not for continuous monitoring, use during motion or for patients with low perfusion.	Spot-checking Not for continuous monitoring, using during motion or using with low perfusion.	Same
Application sites	Finger	Finger	Same
Components	Power supply module, detector and emitter LED, signal collection and processor module, display module.	Detector and emitter LED, signal amplify unit, CPU, data display unit and power unit.	Same
Product principle	An experience formula of data process is established taking use of Lambert Beer law according to Spectrum Absorption Characteristics of deoxyhaemoglobin(HHb) and Oxyhemoglobin(O_2Hb) in glow and near-infrared zones. Operation principle of the instrument is Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of light (red light and infrared light) can be focused onto human nail tip through perspective clamp finger-type sensor. Then measured signal can be obtained by a photosensitive element, information acquired through which will be shown display through process in electronic circuits and microprocessor.	An mathematical formula is established making use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive hemoglobin (RHb) and Oxyhemoglobin (HbO_2) in glow and near-infrared zones. Operation principle of the instrument: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of light (660nm glow and 940nm near infrared light) can be focused onto a human nail tip through a clamping finger-type sensor. A measured signal obtained by a photosensitive element, will be shown on the oximerer's display through process in electronic circuits and microprocessor.	Same
Measurement wavelength-Red	YX102, YX103, YX306: 660±8nm	660± 2nm	Note 2

light	YX301: 660 ± 20nm		
Measurement wavelength-Infrared light	YX102,YX103,YX306: 905 ± 25nm	940± 10nm	
	YX301: 940 ± 25nm		
Display Type	YX102, YX103: LED	OLED	Note 3
	YX301, YX306: OLED		Same
Power Supply	2*AAA alkaline batteries	2*AAA alkaline batteries	Same
Battery Working Time	YX102, YX103, YX306: Two AAA batteries can be operated continuously for 17 hours	Two AAA alkaline batteries can be operated continuously for 30 hours.	Note 4
	YX301: Two AAA batteries can be operated continuously for 45 hours		
Display Content	YX102, YX103: SpO_2, PR, Pulse bar, Low battery	SpO_2, PR, Power low indicator, Pulse bar graph, Waveform	Note 5
	YX301, YX306: SpO_2, PR, Pulse volume wave, Pulse bar, Battery level, Symbol of gravity sensing mode		
User Interface	YX102, YX103: 1 display direction	4 display directions	Note 6
	YX301, YX306: 4 display directions		Same
SpO_2 Display Range	0%~100%	0~100%	Same
SpO_2 Measurement Range	70%~100%	70%~100%	
SpO_2 Accuracy	70% ~ 80%, 80%~90%, 90%~100%, ± 2%; < 70%, no definition	70%~100%, ± 2%; 0~69% no definition	
SpO_2 Resolution	1%	1%	Same
PR Display Range	25bpm~250bpm	0bpm~254bpm	Note 7
PR Measurement Range	25bpm~250bpm	30bpm~235bpm	
PR Accuracy	±1% or ±1 bpm(larger)	30bpm~99bpm, ± 2bpm; 100bpm~235bpm, ± 2%	
PR Resolution	1bpm	1bpm	Same

Sterile	No	No	Same
Operation environment	Ambient temperature: 5℃~40℃; Relative humidity: ≤80％; Atmospheric pressure: 860hPa~1060hPa.	Operation Temperature: 5℃ ~40℃ Ambient Humidity: ≤80% no condensation in operation; Atmospheric pressure: Not mentioned	Note 8
Storage & Transport environment	Ambient temperature: -20℃ ~ +55℃; Relative humidity: ≤93％, no condensation; Atmospheric pressure: 500hPa~1060hPa.	Storage Temperature:-20℃ ~ +55℃; Ambient Humidity: ≤93% no condensation in storage; Atmospheric pressure: Not mentioned	
Contacting material	Enclosure：ABS	Enclosure：ABS	Same
	Fingertip Cushion：Medical Silicone Gel	Fingertip Cushion and Button : Medical Silicone Gel	Same
	YX301 Button: PC		Note 9
	YX102, YX103 Button: None		
	YX306 Button: ABS		
Performance	ISO 80601-2-61	ISO 9919	Note 10
Electrical Safety	IEC 60601-1 IEC 60601-1-11	IEC 60601-1 Not mentioned in IEC 60601-1-11	Note 11
EMC	IEC 60601-1-2	IEC 60601-1-2	Same

Analysis:

Note 1: The intended user, use place and measuring mode of the subject device and predicate device are the same. The difference is that the specific use places of the hospital is listed in the predicate device. The intended use of the subject device and the predicate device are substantially equivalent.

Note 2: According to the principle of the product, red light and infrared light of different wavelengths are used to calculate the oxygen saturation measurement value through a fitting curve verified by a large amount of data. The performance of the subject equipment based on the selected wavelength and the determined fitting curve conforms to the standard ISO 80601-2-61 and FDA Guidance: Pulse Oximeters-Premarket Notification Submissions: Guidance for Industry and Food and Drug Administration Staff. Therefore, the difference in light of wavelength will not affect the substantial equivalence.

Note 3: Different from the OLED display type of the predicate device, the products of the YX102 and YX103 models are LED display types. Different display type will influence many aspects, such as working time, current, etc. However, the differences will not affect the substantial equivalence of the subject device.

Note 4: Battery working time is related to the consumption of electronic components. Different power consumption will lead to different working hours, but the working time is sufficient to meet the needs of use. So, the differences will not affect the substantial equivalence of the subject device.
Note 5: Whether it is pulse bar graph or waveform, it is a way of normalizing the original data; Symbol of gravity sensing mode represents the viewing direction of the current display interface. The display content depends on the display module, which is independent of data collection and data processing. Therefore, the difference in display content will not affect the accuracy and stability of the product data, and does not affect the substantial equivalence.
Note 6: Compared with the predicate device. YX102 and YX103 cannot change its display directions because of its display method, so there is only one display direction. But it does not affect the accuracy and stability of the product data.
Note 7: The pulse rate display range, measurement range and accuracy of the subject device is different from the predicate device. But the subject device complies with the claimed range and accuracy according to bench test report.
Note 8: There is a difference in atmospheric pressure and Relative humidity between the subject device and the predicate. But the subject device has been verified for environmental requirements in accordance with IEC 60601-1, IEC 60601-1-11 and ISO 80601-2-61 standards. Therefore, the subject device is confirmed to be as safe and as effective as the predicate.
Note 9: The button material of YX301, YX306 and MD300C63 are PC, ABS and medical silicone gel respectively. The material of the power button does not affect the function and performance of the product. And all the materials of the subject device have been evaluated in accordance with ISO 10993-1. Therefore, the difference in button materials will not affect the substantial equivalence.
Note 10: The ISO 80601-2-61 cancels and replaces the ISO 9919. Subject product meets current standards. So, the subject device is confirmed to be as safe and as effective as the predicate.
Note 11: The subject device can be used in a home environment. Therefore, the test was carried out according to the IEC 60601-1-11, and the results showed that the requirements were met, indicating that this difference would not affect the substantial equivalence of the subject device.

8、PERFORMANCE DATA

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

Software

Software verification and validation were provided in compliance with FDA Guidance for the Content of the Premarket Submission for Software Contained in Medical Devices. These verification and validations demonstrate that the subject device work functionally and the software for the device is considered as a "moderate" level of concern, as defined by the FDA guidance.

Biocompatibility testing

The biocompatibility evaluation for the YUWELL® Finger Pulse Oximeter was conducted in accordance with the FDA for Industry and Food and Drug Administration Staff "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices -Part 1: Evaluation and Testing within a risk management process". The biocompatibility testing included the following tests:

- Cytotoxicity

- Irritation
- Sensitization

Cleaning Validation

Cleaning and disinfection validation testing was conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling".

Non-clinical data

The Pulse Oximeter has been tested according to the following standards:

- IEC 60601-1-2005+CORR.1:2006+CORR.2:2007+A1:2012, Medical Electrical Equipment Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility Requirements and tests
- IEC 60601-1-11: 2015, 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 80601-2-61: 2017 Medical Electrical Equipment - Part 2-61: Particular Requirements for Basic Safety and Essential Performance of Pulse Oximeter Equipment.
- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.
- FDA Guidance for Pulse Oximeters - Premarket Notification Submissions [510(k)s].

Clinical Study

Clinical studies were conducted to verify the accuracy of proposed device. The clinical studies were conducted per following standards:

- ISO 80601-2-61: 2017 Medical Electrical Equipment - Part 2-61: Particular Requirements for Basic Safety and Essential Performance of Pulse Oximeter Equipment.
- Pulse Oximeters-Premarket Notification Submissions: Guidance for Industry and Food and Drug Administration Staff

The purpose of the clinical trial was to evaluate the SpO_2 accuracy performance of the required cleared Pulse Oximeter during stationary (non-motion) conditions over a wide range of arterial blood oxygen saturation levels as compared to arterial blood CO-Oximetry. 12 healthy adult volunteer subjects (ages 18-50yr, with light to dark pigmentation) were included in the study conducted to evaluate the SpO_2 accuracy performance of proposed devices. Each system was evaluated during steady state/non-motion conditions with various levels of induced hypoxia resulting in stable oxygen saturation levels between 100% and 70% SaO_2. Arterial blood samples were drawn during simultaneous data collection from the test devices. The blood was immediately analyzed on reference CO-Oximetry providing functional SaO_2 for the basis of the SpO_2 accuracy comparison. The SpO_2 accuracy performance results showed the fingertip pulse oximeter to have an Arms less than 3% during steady state conditions over the range of 70-100%.

Based on the non-clinical and clinical performance as documented in the system development, the subject devices were found to substantially equivalent to the predicate device.

9、CONCLUSION

The subject device has similar intended use and performance, equivalence testing standards, and all testing results have come back as positive results or pass for the subject device, which the subject device is as safety and effectiveness as the predicate device.

The subject device is substantial equivalence to the predicate device.