September 25, 2025

Shanghai Berry Electronic Tech Co., Ltd
% Boyle Wang
General Manager
Shanghai Truthful Information Technology Co., Ltd.
RM. 1801, No. 161 East Lujiazui Rd., Pudong
Shanghai, Shanghai 200120
China

Re: K250837
Trade/Device Name: Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: August 12, 2025
Received: August 19, 2025

Dear Boyle 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 (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.

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,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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.	K250837

Please provide the device trade name(s).

Pulse Oximeter

Please provide your Indications for Use below.

The Pulse Oximeter is intended for spot-checking in measuring and displaying functional arterial hemoglobin (SpO2) and pulse rate. It is intended for adult, adolescent, child users in hospitals, hospital facilities and home healthcare environments.

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) Summary

K250837

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR 807.92.

1.0 Submitter's Information

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Contact: Mr. Boyle Wang
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Email: Info@truthful.com.cn

Date of Preparation: Jul.31,2025

2.0 Device Information

Trade name: Pulse Oximeter
Common name: Pulse Oximeter
Classification name: Oximeter
Model(s): BM20
Production code: DQA
Regulation number: 21 CFR 870.2700
Classification: Class II
Panel: Anesthesiology

3.0 Predicate Device Information

Manufacturer: Beijing Choice Electronic Technology Co., Ltd.

Trade name: Fingertip Pulse Oximeter
510(k) number: K181503

4.0 Indication for Use Statement

The Pulse Oximeter is intended for spot-checking in measuring and displaying functional arterial hemoglobin (SpO2) and pulse rate. It is intended for adult, adolescent, child users in hospitals, hospital facilities and home healthcare environments.

5.0 Device Description

The Pulse Oximeter model BM20, can display the SpO2 and PR, plethysmogram wave and other indication parameters, such as pulse battery power status and the PI. The model BM20 Pulse Oximeter include the mainboard, display and lithium battery. It has small size, light weight, easy to carry. It adopts low power consumption design, and has the function of battery capacity display.
The pulse oximeter, model BM20, is designed for spot checking of the pulse oxygen saturation and pulse rate for adults, pediatric and adolescent patients in professional healthcare facility or home conditions when physician follow-up and operated by a physician. And it is not intended to be used under motion or low perfusion scenarios.
This medical device can be reused. Not for continuously monitoring.

6.0 Technological Characteristic Comparison Table

Table1-General Comparison

Item	Subject Device K250837	Predicate Device K181503	Remark
Product Name	Pulse Oximeter	Fingertip Pulse Oximeter	--
Product Code	DQA	DQA	Same
Regulation No.	21CFR 870.2700	21CFR 870.2700	Same
Class	Class II	Class II	Same
Model	BM20	MD300CI218	--
Intended Use/Indication for Use	The Pulse Oximeter is intended for spot-checking in measuring and displaying functional arterial hemoglobin (SpO2) and pulse rate. It is intended for adult, adolescent, child users in hospitals, hospital facilities and home healthcare environments.	The MD300C318T2 is intended for spot checking in measuring and displaying functional arterial hemoglobin (SpO2) and pulse rate. It is intended for adult, adolescent, child and infant users in hospitals, hospital facilities and home healthcare environments.	Same
Principle	The operating principle is based on light transmission through the hemoglobin. The light transmission of a substance is determined by the Beer-Lambert law, which determines the concentration of a solute (oxyhemoglobin) in a solvent	The fingertip pulse oximeter works by applying a sensor to a pulsating arteriolar vascular bed. The sensor contains a dual light source and photo detector. The one wavelength of light source is 660nm, which is red light; the other is 905nm, which is infrared-red	Same

	(hemoglobin) can be determined by light absorption. The blood stain depends on the blood oxygen levels, and the blood with high oxygen concentration presents red color due to high concentration of oxyhemoglobin. When the concentration is reduced, the blood takes on a more bluish, due to a greater presence of deoxyhemoglobin (combination of hemoglobin molecules with carbon dioxide). That is, blood is based on spectrophotometry, measuring the amount of light transmitted through the capillaries of the patient, synchronized with the heart pulse.	light. Skin, bone, tissue and venous vessels normally absorb a constant amount of light over time. The photo detector in finger sensor collects and converts the light into electronic signal which is proportional to the light intensity. The arteriolar bed normally pulsates and absorbs variable amounts of light during systole and diastole, as blood volume increases and decreases. The ratio of light absorbed at systole and diastole is translated into an oxygen saturation measurement. This measurement is referred to as SpO2.	
Applied Population	Adult, adolescent, child and infant patients in hospitals, hospital-type facilities and homecare environment	Adult, adolescent, child and infant patients in hospitals, hospital-type facilities and homecare environment	Same
Application sites	Finger	Finger	Same
Display Type	OLED	OLED	Same
Display Content	Display the SpO2%, PR, battery indicator, pulse waveform	Display the SpO2%, PR, battery indicator, pulse waveform	Similar
Contacting material	Enclosure/ Power Button: ABS Fingertip Cushion(Clip pad): Silicone OLED display: PC material	Battery Cover/ Enclosure/ Power Button: ABS Fingertip Cushion: Medical Silicone Gel	Different

Analysis:

The biocompatibility evaluation has performed and passed on the subject device and the predicate device per 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.

Table 2 Performance Comparison

	Subject Device K250837	**Predicate Device K181503**	**Remark**
LED wavelength	Red= 660 nm; Infrared=940nm	Red= 660nm; Infrared= 905nm	Same
Power source	DC 3.7V lithium battery	2*1.5V AAA alkaline battery	Different (1)
SpO2 Display Range	0-100%	0%-100%	Same
SpO2 Measuring Range	70%~100%	70%~100%	Same
SpO2 Resolution	1%	1%	Same
SpO2 Accuracy	80~100%, ±2%; 70%~79%, ±3%; 0% to 69%: unspecified	70~100%, ±2%; 0% to 69%: no definition	Similar
PR Measuring Range	25-250BPM	30-250BPM	Same
PR Resolution	1 bpm	1 bpm	Same

PR Accuracy	± 2bpm	30bpm~99bpm, ±2bpm; 100bpm~250bpm, ±2%	Same
Single or Multi-patient Usage	Multi-patient Usage	Multi-patient Usage	Same
Transmitter	Not Applied	Bluetooth Compliance: Version 4.0	Different (2)
Operating Temperature	+5~+40℃	5℃~40℃	Same
Relative Humidity	15~80%RH (non-condensing); 10~90%RH (non-condensing) in storage	15% ~93%, no condensation in operation; ≤93% no condensation in storage	Similar (3)
Atmosphere Pressure	70kPa～106kPa	70kPa~106kpa	Same

Analysis:

) Although the Power supply specifications of the proposed device is different from the predicate device, but both the predicate device and the proposed device have passed the IEC60601-1 standard; we believe these differences will not raise different questions of the effectiveness and safety compared with the predicate device.

2) The subject device does not have the Bluetooth function which is different from predicate device. The Bluetooth is the independent function module; it will not affect other functions. Therefore, this difference does not affect substantially equivalence between subject device and predicate device on safety and effectiveness.

3) The Relative Humidity of subject device is within the scope of that of the predicate device, and has been verification according to standard ISO 60601-1 and ISO 60601-1-11. All the results can meet the standard requirements. Therefore, this difference does not affect substantially equivalence between subject device and predicate device on safety and effectiveness.

Table 3 Safety Comparison

Item	Subject Device K250837	Predicate Device K181503	Remark
Electrical Safety	Comply with IEC 60601-1 IEC 60601-1-11	Comply with IEC 60601-1 IEC 60601-1-11	Same
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Same
Performance	ISO 80601-2-61	ISO 80601-2-61	Same
Biocompatibility	Comply with ISO 10993-1, FDA Guidance	Comply with ISO 10993-1, FDA Guidance	Same

7.0 Non-clinical Testing Summary

The following performance data have been conducted to verify that the Oximeter meets all design specifications which supports the conclusion that it's Substantially Equivalent (SE) to the predicate device. The testing results demonstrate that the targeted device complies with the following standards:

Conclusions for Biocompatibility Testing

The biocompatibility evaluation for the oximeter was conducted in accordance with the FDA's Biocompatibility Guidance "Use of 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 permanent (>30 days).

And the testing included the following tests, results of which demonstrate the biological safety of the subject device:

Cytotoxicity (ISO 10993-5)

Sensitization (ISO 10993-10)

Irritation (ISO 10993-23)

Electrical and EMC Safety:

The electrical safety and EMC safety testing was performed to, and passed, the following standards:

➢ IEC 60601-1:2005/AMD2:2020, Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance

➢ IEC 60601-1-11:2020, 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

➢ IEC 60601-1-2:2020, Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance -- Collateral standard: Electromagnetic disturbances - Requirements and tests

➢ IEC TS 60601-4-2:2024, Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

Summary of Bench Testing

Bench testing was conducted and the results show that the subject device complies with the below standard:

➢ ISO 80601-2-61:2018, Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

Software Verification and Validation Testing

Software documentation including verification & validation was provided in accordance with FDA Guidance: Content of Premarket Submissions for Device Software Functions.

The Software Validation is in compliance with FDA Guidance.

Summary of Shelf Life and Cleaning Testing

The service life has been verified through accelerated aging. The service life is 4 years except the battery is reasonable and effective.

Cleaning and disinfection validation testing was conducted in accordance with FDA guidance “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling” issued March 17,2015. Moreover, the performance of the subject device shows no degradation after repeated cleaning and disinfection as suggested in the User manual.

8.0 Clinical Test Summary

The clinical study was conducted in accordance to ISO 80601-2-61. The subject device of this study was to verify the accuracy of pulse oximetry (SpO2) measured by the oximeter with a measurement range of 70-100% under no motion on 24 healthy adult volunteers.
Clinical hypoxia test results were obtained in human adult volunteers (the study population includes sufficient darkly pigmented subjects) to validate the accuracy of the subject devices versus arterial oxygen saturation (SaO2) as determined by co-oximetry. Twelve subjects were enrolled for the clinical study. The Fitzpatrick Scale and Monk’s Scale were used to determine their skin pigmentation scores. 6 dark subjects (Fitzpatrick Type 5-6/Monk Type 08-09) in this study allow a proper evaluation of the sensor accuracy in dark population. The study contains more than the minimum 400 data points, and the clinical study results support device accuracy claims for the specified saturation range.

The SpO2 accuracy performance results showed the subject Pulse Oximeter to have an ARMS of 2.08 during steady state conditions over the range of 70-100%.

9.0 Conclusion

The conclusions drawn from the comparison and analysis above demonstrate that the subject device is substantially equivalent to the legally marketed predicated device.