March 1, 2021

Shenzhen LEPU Intelligent Medical Equipment Co., Ltd.
% Arthur Goddard
President
FDA Regulatory and Quality Systems Consultant
31853 Cedar Road
Mayfield Heights, Ohio 44124-4445

Re: K202776
Trade/Device Name: Fingertip pulse oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: January 8, 2021
Received: January 25, 2021

Dear Arthur Goddard:

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,

Todd Courtney
Assistant Director
DHT1C: Division of ENT, 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)*
K202776

Device Name
Fingertip pulse oximeter

Indications for Use *(Describe)*
The Fingertip pulse oximeter is a handheld non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO2) and Pulse Rate of adult, adolescent and child patients in hospitals, hospital-type facilities, and homecare.

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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Section 5: 510(K) Summary

This summary of 510(K) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1900 and 21 CFR 807.92.

The assigned 510(K) Number: K202776

5. 510(K) Summary

5.1. Date of Preparation: September 11th, 2020

5.2. Sponsor

Shenzhen Lepu Intelligent Medical Equipment Co., Ltd.
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5.3. Submission Correspondent

Mr. Arthur Goddard
31853 Cedar Road, Ohio, 44124-4445, U.S.A.
Tel: (216) 233-5722
Email: asjgoddard@aol.com

5.4. Subject Device Identification

Subject Device Name: Fingertip pulse oximeter
Model: LOX100A, LOX100B, LOX100C, LOX100D
Common name: Oximeter
Classification Name(s): Oximeter
Product Code: DQA
Regulation Number: 21 CFR 870.2700
Review Panel: Anesthesiology
Classification: II

5.5. Predicate Device

510(k) Number: K161560
Device Name: Fingertip Pulse Oximeter MD300CN310
Manufacturer: Beijing Choice Electronic Technology Co., Ltd.

5.6. Indications for use

The Fingertip pulse oximeter is a handheld non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO2) and Pulse Rate of adult, adolescent and child patients in hospitals, hospital-type facilities, and homecare.

5.7. Device Description

Fingertip pulse oximeter, LOX100A, LOX100B, LOX100C, LOX100D, mainly include of signal acquisition module, signal processing module, prompt module, detector, and emitter LED, display and user interface module, power supply module, the device is used to measure the patient's blood oxygen saturation (SpO2) and pulse rate (PR). The device is mainly composed of main board PCB, lamp panel PCB, sensor, OLED screen, button, silicone gel pad and enclosure.

All the models, LOX100A, LOX100B, LOX100C, LOX100D of proposed device, have difference in appearance, but follow the same design principle and technical specification. The device is a stand-alone device, the device is intended only for spot checking, and the device is reusable and do not need sterilization and re-sterilization.

5.8. Predicate Devices and Subject Device Comparison

Table 5-1 Feature Comparison with Predicate Devices

Item	Subject Device Finger pulse oximeter	Predicate Device K161560 Fingertip Pulse Oximeter	Remark
Product Name	Finger Pulse Oximeter	Fingertip Pulse Oximeter	SE
Product Code	DQA	DQA	
Regulation Number	21 CFR 870.2700	21 CFR 870.2700	
Classification Name(s)	Oximeter	Oximeter	
Classification	II	II	
Indications for use	The Fingertip Pulse Oximeter is a handheld non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO2) and Pulse Rate of adult, adolescent and child patients in hospitals, hospital-type facilities, and homecare.	The Fingertip Pulse Oximeter MD300CN310 is a handheld non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO2) and Pulse Rate of adult, adolescent and child patients in hospitals, hospital-type facilities, and homecare.	SE

Item	Subject Device Finger pulse oximeter	Predicate Device K161560 Fingertip Pulse Oximeter	Remark
Intended patient population	Adult, adolescent and child patients	Adult, adolescent and child patients	SE
Intended application site	Fingertip	Fingertip	SE
Basic functions	Spot-checking of oxygen saturation of arterial hemoglobin (SpO2) and Pulse Rate	Spot-checking of oxygen saturation of arterial hemoglobin (SpO2) and Pulse Rate	SE
Components	Detector and emitter LED, Analog front-end IC, MCU, data display unit and power unit	Detector and emitter LED, signal amplify unit, CPU, data display unit and power unit	Discussion 1
Discussion 1: The device composition of the subject device and the predicate device is different in the signal processing unit, the predicate device is the signal amplify unit, and the target device is the Analog front-end IC. The function of the signal amplify unit is to convert the current signal of the receiving tube into a voltage signal, and then amplify the voltage signal. The voltage signal received by the CPU is the waveform and amplitude recognized after ADC conversion; The function of the Analog front-end IC is to directly amplify the current signal and then convert it into pulse signals of different frequencies. The MCU captures the pulse signal and converts the frequency signal into a waveform and amplitude signal. The essence of the two is the same, they both amplify the signal. In addition, we verify the performance of the subject device through clinical study (See Section 20 for details) and ISO80601-2-61 performance test (See Section 18 for details), and the verification results meet the requirements for device performance. So, the difference does not raise any new issues of safety or efficacy. The subject device can be considered to be substantially equivalent to that of the predicate device.			
Contacting Material			
Fingertip pad	Silicone Gel	Silicone Gel	SE
Enclosure	PCTG, PMMA	ABS	Discussion 2
Discussion 2: The Enclosure of the two devices is made of different materials. The materials used in subject device have excellent performance and safety, and can meet the requirements of the device for the material. The biological safety of all materials has been verified, including cytotoxicity, sensitization, and irritation tests. The test results meet the requirements of the ISO10993 series of standards (See Section 15 for details). So, the difference does not raise any new issues of safety or efficacy. The subject device can be considered to be substantially equivalent to that of the predicate device.			

Item	Subject Device Finger pulse oximeter	Predicate Device K161560 Fingertip Pulse Oximeter	Remark
Software Level of concern	Moderate	Moderate	SE
Working principle	The measuring principles of pulse oximeter is based on Lambert-Beer law. The emitter LED of oximeter contains a dual wavelength light source. One wavelength of light source is 660nm, which is red light source. The other is 905nm, which is near infrared light source. The dual wavelength light source alternately irradiates the surface of the finger, and the photo diode detector at the other end of the finger will detect the red light and near-infrared signal. In the process of pulse beating, with the increase and decrease of blood volume, different amplitude of light will be absorbed at the end of the detector. According to the absorption ratio of two kinds of wavelength light, DC signal and AC signal are extracted, and the oxygen saturation value and pulse rate value are obtained by the above signals.	The 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 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 SpO_2.	Discussion 3
Measurement wavelength-Red light	660±3nm	660±3nm	
Measurement wavelength-Infrared	905±10nm	905±10nm	

Item	Subject Device Finger pulse oximeter	Predicate Device K161560 Fingertip Pulse Oximeter	Remark
Discussion 3: Though the working principle expressions of the subject device and predicate device are a little different, the working principle is basically the same. Both the ratio of red light and infrared light of different wavelengths are converted into electronic signals through the sensor, thereby calculating the oxygen saturation measurement value. The wavelength of red light is 660nm and the wavelength of infrared light is 905nm. So, the difference does not raise any new issues of safety or efficacy. The subject device can be considered to be substantially equivalent to that of the predicate device.			

Table 5-2 Specification Comparison

Item	Subject Device Finger pulse oximeter	Predicate Device K161560 Fingertip Pulse Oximeter	Remark
Display Type	OLED	OLED	SE
Power supply	2*AAA batteries	2*AAA batteries	SE
Working Time	Approximately 25 hours of continuous operation	Approximately 24 hours of continuous operation	Discussion 4
Discussion 4: The working time of the subject device and the predicate device are slightly different. The working time of the predicate device is covered by the working time of the subject device. In addition, the working hours of the two devices are sufficient to meet the needs of use. So, the difference does not raise any new issues of safety or efficacy. The subject device can be considered to be substantially equivalent to that of the predicate device.			
User Interface	3 display modes	6 display modes	Discussion 5
Discussion 5: There are 3 display modes for the subject device and 6 display modes for the predicate device. The difference between them is the display direction. There are 2 display directions for the subject device, which form 3 display modes when combined with bar-graph and plethysmography. There are 4 display directions for the predicate device, which form 6 display modes when combined with bar-graph and plethysmography. The difference is only in display directions, and the display content on the screen is the same. So, the difference does not raise any new issues of safety or efficacy. The subject device can be considered to be substantially equivalent to that of the predicate device.			
Oxygen saturation			
SpO2 Measurement Range	70%~100%	70%~100%	SE
Accuracy	70%~100%: ±2%	70%~100%: ±2%;	Discussion 6

Item	Subject Device Finger pulse oximeter	Predicate Device K161560 Fingertip Pulse Oximeter	Remark
	70%~80%: ±2% 80%~90%: ±2% 90%~100%: ±2% No requirement for 70% below	0~69% no definition	
Discussion 6: The SpO2 accuracy of the subject device and the predicate device are described in different ways. The accuracy of SpO2 of the subject device is±2% at different levels (70%~80%, 80%~90%, 90%~100%, 70%~100%), which meets the requirements of ISO 80601-2-61. The accuracy of the predicate device at different levels is not mentioned. The accuracy of SpO2 of the two devices is 2% within the 70%~100% level. So, the difference does not raise any new issues of safety or efficacy. The subject device can be considered to be substantially equivalent to that of the predicate device.			
Resolution	1%	1%	SE
Low Perfusion	70%~100%: ±2% 70%~80%: ±2% 80%~90%: ±2% 90%~100%: ±2% No requirement for 70% below	Not mentioned	Discussion 7
Discussion 7: The accuracy of SpO2 at different levels (70%~80%, 80%~90%, 90%~100%, 70%~100%) of the subject device under low perfusion conditions is±2%, and the accuracy of SpO2 of the predicate device under low perfusion conditions is not mentioned. LEPU Intelligent Medical has verified the accuracy of SpO2 of the subject device under low perfusion conditions, and the results met the requirements of ISO 80601-2-61. So, the difference does not raise any new issues of safety or efficacy. The subject device can be considered to be substantially equivalent to that of the predicate device.			
Pulse rate			
Measuring range	30bpm~250bpm	30bpm~250bpm	SE
Accuracy	30bpm~250bpm ±2bpm or ±2% (which is larger)	30bpm~99bpm, ±2bpm; 100bpm~250bpm, ±2%	Discussion 8
Discussion 8: The pulse rate accuracy of the subject device and the predicate device are described in different ways. The detail comparison is shown in the table below:			

Pulse rate range	Subject device	Predicate device	Conclusion

Item	Subject Device Finger pulse oximeter	Predicate Device K161560 Fingertip Pulse Oximeter	Remark
30bpm~99bpm	±2bpm (±2bpm is larger than ±2%)	±2bpm	SE
100bpm~250bpm	±2% (±2% is larger than ±2bpm)	±2%	SE
So, the accuracy of pulse rate of the subject device and the predicate device are the same.			
Resolution	1bpm	1%	Discussion 9
Discussion 9: There is a difference between the resolution of the subject device and the predicate device. The display value of the pulse rate can only be an integer. Therefore, the minimum resolution setting is 1bpm. According to the requirement of the pulse rate unit in ISO 80601-2-61, it is the number of pulses per minute. The pulse rate resolution of the subject device is set to 1bpm to meet the requirements of ISO 80601-2-61 and actual use. So, the difference does not raise any new issues of safety or efficacy. The subject device can be considered to be substantially equivalent to that of the predicate device.			
Low perfusion	30bpm~250bpm ±2bpm or ±2% (which is larger)	Not mentioned	Discussion 10
Discussion 10: The accuracy of Pulse rate of the subject device under low perfusion conditions is±2bpm or ±2% (which is larger within 30bpm~250bpm), and the accuracy of Pulse rate of the predicate device under low perfusion conditions is not mentioned. LEPU Intelligent Medical has verified the accuracy of Pulse rate of the subject device under low perfusion conditions, and the results met the requirements of ISO 80601-2-61. So, the difference does not raise any new issues of safety or efficacy. The subject device can be considered to be substantially equivalent to that of the predicate device.			
Environment requirement			
Operating Temperature	5℃~40℃	5℃~40℃	Discussion 11
Storage/Transport temperature	-20℃~55℃	-25℃~70℃	
Relative Humidity	≤80%; No condensation in working status ≤93%; No condensation in storage status	15%~93% no condensation in operation; ≤93% no condensation in storage/transport	
Atmospheric pressure	70kPa-106 kPa	70kPa-106 kPa	
Discussion 11:			

Item	Subject Device Finger pulse oximeter	Predicate Device K161560 Fingertip Pulse Oximeter	Remark
The subject device and the predicate device are different in storage/transportation temperature and relative humidity. LEPU Intelligent Medical has verified the environmental requirements of the device in accordance with the requirements in ISO 80601-2-61, and the results meet the requirements. So, the difference does not raise any new issues of safety or efficacy. The subject device can be considered to be substantially equivalent to that of the predicate device.			

Table 5-3 Performance and Safety Comparison

Item	Subject Device Finger pulse oximeter	Predicate Device K161560 Fingertip Pulse Oximeter	Remark
Particular requirements for basic safety and essential performance	Meeting the requirements of ISO 80601-2-61	Meeting the requirements of ISO 80601-2-61	SE
Electrical Safety	Meeting the requirements of IEC 60601-1 and IEC 60601-1-11	Meeting the requirements of IEC 60601-1 and IEC 60601-1-11	SE
Electromagnetic Compatibility	Meeting the requirements of IEC 60601-1-2	Meeting the requirements of IEC 60601-1-2	SE
Biocompatibility	Meeting the requirements of ISO 10993-1, ISO 10993-5, ISO 10993-10	Not mentioned	Discussion 12
Clinical study	Meeting the requirements of Annex EE of ISO 80601-2-61	Meeting the requirements of Annex EE of ISO 80601-2-61	SE
Discussion 12: The fingertip pad and enclose of the subject device are in direct contact with the patient's tissue. According to the requirements of ISO10993 series standard and FDA Guidance: Pulse Oximeters - Premarket Notification Submissions [510(k)s], LEPU Intelligent Medical conducted the cytotoxicity test, irritation test and sensitization test on the device, and the test results met the requirements. So, the difference does not raise any new issues of safety or efficacy. The subject device can be considered to be substantially equivalent to that of the predicate device.			

5.9. Performance Tests Summary

Bench test were conducted to verify that the subject device met all design specifications, as was Substantially Equivalent (SE) to the predicate device.

- **Biocompatibility Testing**

  The Fingertip pulse oximeter was assessed against the International Standard ISO

10993-1, "Biological evaluation of medical devices. Part 1. Guidance on selection of tests." The subject device would be classified as a Surface Medical Device in contact with the intact skin for a Limited Duration (<24 hours). The following test were performed for any user contacting material:

Test	Standard	Results
Cytotoxicity Study using MTT Method	ISO 10993-5	Under the conditions of this study, the MEM extracts of test article would be considered no cytotoxicity potential. The negative controls, blank controls, and the positive controls performed as anticipated.
Skin Sensitization Study Guinea Pig Maximization Test	ISO 10993-10	Under the condition of this study, the test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig. The test article was not considered a sensitizer in the guinea pig maximization test.
Skin Irritation Study	ISO 10993-10	Under the conditions of this study, the irritation response category of the test article is classified as Negligible for polar extract and Negligible for non-polar extract.

- **Non-clinical Tests**

  The Fingertip pulse oximeter is tested per the following standard, to evaluate its performance. The test results demonstrated that the proposed device comply with the standard requirements.

  IEC 60601-1: 2005+AMD1:2012 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 disturbances - Requirements and tests.

  IEC 60601-1-11 Edition 2.0:2015-01 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 Second Edition 2017-12 Medical Electrical Equipment Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.

- **Clinical data**

  A clinical study was conducted per the requirement of Annex EE of ISO 80601-2-61 to validate the SpO2 accuracy of Fingertip pulse oximeter. The purpose of the clinical

study was to evaluate the SpO2 accuracy performance of the Fingertip pulse oximeter during stationary (non-motion) conditions over a wide range of arterial blood oxygen saturation levels as compared to arterial blood co-oximeter. 12 healthy adult volunteer subjects (ages 18-50yr, with light to dark pigmentation, include male and female) were included in the study conducted to evaluate the SpO2 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% SaO2. Arterial blood samples were drawn during simultaneous data collection from the test devices. The blood was immediately analyzed on reference co-oximeter providing functional SaO2 for the basis of the SpO2 accuracy comparison. The SpO2 accuracy performance results showed the Fingertip pulse oximeter to have an Arms of 1.52% during steady state conditions over the range of 70-100%.

- **Software**

  The software embedded in Fingertip pulse oximeter has been developed, documented, and validated in accordance with industry standards (IEC 62304 – Medical device software – Software life cycle processes) and FDA guidance (GUIDANCE FOR THE CONTENT OF PRE-MARKET SUBMISSIONS FOR SOFTWARE CONTAINED IN DEVICES). The software is of Moderate Level of Concern

- **Cleaning and disinfection validation**

  The Fingertip pulse oximeter is reusable, and Shenzhen LEPU Intelligent Medical Equipment Co., Ltd. has verified the cleaning and disinfection process of the device. The Cleaning and disinfection Validation is compliance with FDA Guidance to Compliance with FDA Guidance for the Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling.

5.10. Substantially Equivalent Conclusion

The subject device and the predicate device have the same intended use, and the technological differences do not raise different questions of safety and effectiveness. The subject device, Fingertip pulse oximeter, is determined to be Substantially Equivalent (SE) to the predicate device.