March 1, 2021

Shenzhen Med-link Electronics Tech Co., Ltd
Jialing Zhang
Regulatory Affairs Specialist
4th and 5th Floor, Building Two, Hualian Industrial Zone
Xinshi Community, Dalang Street
Shenzhen, Guangdong 518109
China

Re: K202743
Trade/Device Name: Med-Link Temp-pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: January 22, 2021
Received: January 25, 2021

Dear Jialing Zhang:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202743

Device Name
Med-link Pulse Oximeter

Indications for Use *(Describe)*
Med-link Pulse Oximeter is intended for spot checking in measuring and displaying functional arterial oxygen saturation (SpO2) and pulse rate of patients in hospitals, physician's office, clinical settings and home care environment. It's a reusable device intended for adults and pediatrics who are well or poorly perfused.

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."

Shenzhen Med-link Electronics Tech Co., Ltd.

510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

Type of submission: Traditional

The assigned 510(k) number is: K202743

1. Submitter information

Manufacturer Name: Shenzhen Med-link Electronics Tech Co., Ltd.

Address: 4th and 5th Floor, Building Two, Hualian Industrial Zone, Xinshi Community, Dalang Street, Longhua District, 518109 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Tel: 0086-755-61568825

Fax: 0086-755-61120055

Establishment Registration Number: 3006636961

2. Correspondent

Jialing Zhang (Regulatory Affairs Specialist, Primary Contact)

E-mail: user60@med-linket.com

Yi Liu

E-mail: user22@med-linket.com

3. Data of Preparation

22nd, Jan. 2021

4. Identification of the Device

Trade Name: Med-link Pulse Oximeter

Common Name: pulse oximeter

Classification Regulation: 21 CFR 870.2700

Product Code: DQA

Class: II

Review Panel: Anesthesiology

5. Identification of the Predicate Device

Table 1 Predicate Device Information

No.	Device Name	Common Name	Manufacturer	Classification and Code	Classification regulation	510(k) number
1	Nonin Onyx 3, Model9591	Finger Pulse Oximeter	Nonin Medical, Inc.	Class II, DQA	21 CFR 870.2700	K191403

6. Intended Use and Indications for Use of the Subject Device

Med-link Pulse Oximeter is intended for spot checking in measuring and displaying functional arterial oxygen saturation (SpO2) and pulse rate of patients in hospitals, physician's office, clinical settings and home care environment. It's a reusable device intended for adults and pediatrics who are well or poorly perfused.

7. Device Description

Med-Link Pulse Oximeter is to spot-check oxygen saturation in blood (SpO2) and pulse rate. The pulse oximeter is used on adults and pediatrics at hospital, clinics, and/or home. The device mainly consists of power supply module, detector and emitter LED, signal collection and processor module, display module, user interface and button control. There is no visual or audio alarm. The device is reusable and non-sterile. The device has only one model as AM801.

The device contains a dual light source (Red LED and Infrared red LED) and a photo detector. Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated in an oxygen saturation measurement (SpO2). Because a measurement of SpO2 is dependent on light from the device, excessive ambient light can interfere with this measurement. The wavelength of red LED is 660nm and infrared LED is 905nm with maximum optical output power of 15mW.

8. Comparison to the Predicate Device

Item	Proposed Device	Predicate Device	Verdict
Trade name	Med-link Pulse Oximeter	Nonin Onyx 3, Model9591 Finger Pulse Oximeter	/
510(K) Submitter	Shenzhen Med-link Electronics	Nonin Medical, Inc.	/

Item	Proposed Device	Predicate Device	Verdict
	Tech Co., Ltd.		
510(K) Number	K202743	K191403	/
Classification Regulation	21 CFR 870.2700	21 CFR 870.2700	Same
Classification and Code	Class II, DQA	Class II, DQA	Same
Common name	Pulse Oximeter	Finger Pulse Oximeter	Same
Type of Use	Prescription	Prescription	Same
Intended use	Med-link Pulse Oximeter is intended for spot checking in measuring and displaying functional arterial oxygen saturation (SpO2) and pulse rate of patients in hospitals, physician's office, clinical settings and home care environment. It's a reusable device intended for adults and pediatrics who are well or poorly perfused.	The Nonin® Model 9591 Onyx® 3 Finger Pulse Oximeter is a small, lightweight, portable and reusable spot-check device indicated for use in measuring and displaying functional oxygen saturation of aterial hemoglobin(%SpO2) and pulse rate of patients who are well or poorly perfused. The Respiration Rate parameter provides a non-invasive measurement of respiration rate, in breaths per minute. For %SpO2, and pulse rate, the 9591 is intended for use in hospitals, clinics, long-term care facilities, skilled nursing facilities, and home healthcare services. It is intended for adult and pediatric patients who are well or poorly perfused, with digits that are between 0.3~1.0 inch(0.8~2.5cm) thick, under non-motion conditions. For Respiration rate, the 9591 is intended for use in hospitals, clinics,	Different note 1

Item	Proposed Device	Predicate Device	Verdict
		long-term care facilities, skilled nursing facilities, and home healthcare services. It it intended for adult who are well perfused, with digits that are between 0.3~1.0 inch(0.8~2.5cm) thick, under non-motion conditions. It is not intended for use in high-acuity environments, such as ICU or operating rooms where continuous monitoring is expected.	
Operating Principle	The measurement of PULSE OXIMETER uses a multi-functional oxyhemoglobinometer to transmit some narrow spectrum light bands through blood samples, and to measure attenuation of spectrum with different wavelengths according to the characteristic that RHb, O2Hb, Met Hb and COHb absorb the light of different wavelength, thereby determining O2Hb saturation of different fractions. O2Hb saturation is called “fractional” O2Hb saturation. Present SpO2 oximeter transmits light of two wavelengths only, red light and infrared, to differentiate HbO2 from HbR. One side of the sensor contains two LEDs, and the other side contains a photoelectric detector. SpO2 oximeter measures HbO2 saturation in the blood by the light plethysmograph when the pulse	Pulse oximetry is a non-invasive method that passes red and infrared light through perfused tissue and detects the fluctuating signals caused by arterial pulses. Well-oxygenated blood is bright red, while poorly oxygenated blood is dark red. The pulse oximeter determines functional oxygen saturation of arterial hemoglobin (SpO2) from this color difference by measuring the ratio of absorbed red and infrared light as volume fluctuates with each pulse. Additionally, the pulse oximeter uses variations in the pulse volume fluctuation's amplitude, baseline shift, and timing to determine the respiratory rate.	Different note 1

Item	Proposed Device	Predicate Device	Verdict
	beats. The result is quite precise when HbO2 saturation is between 70% to 100%.		
Application site	Finger	Finger	Same
Usage	Reusable	Reusable	Same
SpO2 range	70% to 100%	0% to 100% SpO2	Different note 2
SpO2 resolution	1%	Not provided	Different note 2
SpO2 accuracy under good perfusion	90% to 100% range: ±2%; 70% to 89% range: ±3%; <70%: unspecified.	±2 digits	Different note 2
SpO2 accuracy under low perfusion	90% to 100% range: ±2%; 70% to 89% range: ±3%; <70%: unspecified.	±2 digits	Different note 2
Pulse rate range	30 to 245 bpm	18~321 BPM	Different note 2
Pulse rate resolution	1 bpm	Not provided	Different note 2
Pulse rate accuracy under good perfusion	±3 bpm	20 to 250 BPM±3 digits	Different note 2
Pulse rate accuracy under low perfusion	±3 bpm	40 to 240 BPM±3 digits	Different note 2
Applicable population	Adult and pediatric	Adult and pediatric	Same
Measurement wavelength	Red: approximately 660nm; Infrared: approximately 905nm	660 and 910 nanometers	Different note 3
Operation Environment	Temperature: 41°F~104°F(5°C~40°C); Humidity: ≤80%; atmospheric pressure: 86kPa～106kPa	Temperature: -5°C~40°C; humidity: 10~95% non-condensing;	Different note 4
Storage Environment	Temperature 14°F~104°F(-10°C~40°C); humidity ≤80%; atmospheric pressure: 86kPa～106kPa	Temperature: -40°C~70°C; humidity: 10~95% non-condensing;	Different note 4

Item	Proposed Device	Predicate Device	Verdict
Power requirements	1.5V (AAA) alkaline battery X2 (IEC Type LR03)	3V DC	Same
Battery life(operating)	2400 spot checks 20 hours continuous	2000 spot checks 25 hours continuous	Different note 5
Battery life(storage)	6 months, with batteries installed	1 month, with batteries installed	Different note 5
User interface	8 directions for display	Not provided	Different note 5
Display parameter	SpO2, Pulse Rate, Pulse Waveform Display, Bar Graph(Pulse Amplitude Indicator) and Battery Indicator	SpO2, Pulse Rate and Respiration Rate	Different note 5
Electrical-type and degree of protection	Type BF internally powered	Type BF internally powered	Same
Enclosure-degree of ingress protection against liquids	IPX2	IP32	Same
Measuring Mode	Spot-check	Spot-check	Same
Material	Enclosure: ABS; Lens: PC; Silica gel finger pad: Silica gel; Lower middle frame: ABS.	Enclosure: PC; Finger pads: TPE; Battery door: PC.	Different note 6
Electrical Safety	Comply with IEC 60601-1	Comply with IEC 60601-1	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	All the patient-contacting materials are evaluated by the biocompatibility standard ISO10993-5, ISO 10993-10.	ISO 10993-1	Same
Sterilization	Non-sterile	Non-sterile	Same

Note 1
The predicate device is a device with an additional function of measuring respiration rate, which the proposed device is not seeking claims for. Thus the difference of intended use and operating principle between the proposed device and the predicate device does not raise new questions of safety and effectiveness, nor would it affect the substantial equivalence between the two devices.

Note 2
Although the measurement ranges and accuracy of SpO2 and pulse rate are different between the proposed device and the predicate device, both devices meet the requirements of ISO 80601-2-61. Such a difference does not raise new questions of safety and effectiveness.

Note 3
Although the measurement wavelengths of the proposed device are different from those of the predicate device, our Pulse oximeter has been compared with the predicate device in intended use, operating principle, safety and performance standard, etc., such a difference doesn't affect the substantial equivalence among other items, nor does it raise new questions of safety and effectiveness.

Note 4
Although some specifications of operating & storage conditions are different for the proposed device and the predicate device, they are all complied with IEC 60601-1 and ISO 80601-2-61. The differences do not raise new questions of safety and effectiveness.

Note 5
Although the battery life for operation and storage, user interface and display parameters are different between the proposed device and the predicate device, these differences don't affect the essential performance and safety of both devices. The two devices have been compared in intended use, operating principle, safety and performance specifications, etc., which indicates the two devices are substantially equivalent.

Note 6
Although patient-contacting materials are different for the proposed device and the predicate device, both of them are complied with ISO 10993-5 and ISO 10993-10. The difference does not affect the safety and effectiveness.

9. Non-clinical Test

A series of safety and essential performance tests were performed to assess the safety and effectiveness of Med-link Pulse Oximeter. The tests listed above were conducted in accordance with
IEC 60601-1 Medical electrical equipment-Part 1: General requirements for basic safety, and essential performance.
ISO 80601-2-61 Medical electrical equipment-Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
IEC 60601-1-2 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 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

The patient-contacting components and materials are listed together with the corresponding test items in the following table. The contact duration is limited to be within 24 hours, and the type of contact belongs to surface medical device-intact skin. Based on use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", the device requires the following biocompatibility tests: ISO 10993-5:2009 Biological valuation of medical devices-Part 5: Test for In Vitro Cytotoxicity and ISO 10993-10:2010 Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization.

Patient-contacting Components	Contact Materials	Test items
Enclosure	ABS	Cytotoxicity Skin Sensitization Test Skin Irritation Test
Silica gel finger pad	Silica gel	
Lower middle frame	ABS	
Lens	PC	

The biocompatibility test results demonstrated that there's no cytotoxic potential, no evidence of significant irritation nor evidence of sensitization. The device meets the requirement of Biocompatibility.

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 "moderate" level of concern, since a malfunction of, or a latent design flaw in, the software device would lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to minor injury. The software was tested according to three steps including Function Module Test (Unit Level), Main Performance Test (Integration Level), and System Integrated Test (System Level). In all test processes, the following main functions are mainly verified: power on/off, low power prompt, measurement and result display, measurement range and accuracy, and display mode switch. All the tests were passed.

We have also conducted other performance tests including SpO2 and PR Accuracy Test, Weak Perfusion Test, Performance Test after Disinfection, Shelf-life Test Per Guidance for Industry and FDA Staff: Pulse Oximeters-Premarket Notification submission [510(k)s].

10. Clinical performance data

The clinical study was conducted in the Yue Bei People's Hospital in accordance to ISO 14155-1, ISO 14155-2, BS EN ISO 80601-2-61, and the FDA Guidance Document for Pulse Oximeters.

Objective: The purpose of this study was to evaluate the SpO2 accuracy performance of Shenzhen Med-link Pulse oximeter, during stationary (non-motion) conditions over a wide range of arterial blood oxygen saturation levels as compared to arterial blood CO-Oximetry.

Subjects: After Institutional Review Board (IRB) approval, 12 healthy adult volunteer subjects (ages 19-34yr, 45-102kg, 160-192cm, with light to dark pigmentation) were included in the study to evaluate the SpO2 accuracy performance of the Shenzhen Med-link Pulse oximeter.

Methods: 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-Oximetry providing functional SaO2 for the basis of the SpO2 accuracy comparison. Accuracy data was calculated using the root-mean-squared (ARMS value) for all subjects.

Adverse events and complications: There were no adverse events during the study.

Conclusion: The results show the Shenzhen Med-link Pulse oximeter to pass a SpO2 accuracy specification of 3 during steady state conditions over the range of 70-100%.

11. Conclusion

Based on the comparison and analysis in this submission, it can be concluded that: Med-link Pulse Oximeter is substantially equivalent to the predicate device.