April 9, 2020

S.L.P. Ltd.
% Paul Dryden
Consultant
S.L.P. Ltd. c/o ProMedic, LLC
131 Bay Point Dr. NE.
St Petersburg, Florida 67060

Re: K191574
Trade/Device Name: OxSAT 100
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: December 6, 2019
Received: December 9, 2019

Dear Paul Dryden:

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: June 30, 2020
See PRA Statement on last page.

510(k) Number *(if known)*

K191574

Device Name

OxSAT 100

Indications for Use *(Describe)*

The SLP OxSAT 100 Patient Oximeter Module is indicated for use in measuring and transmitting functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, and plethysmographic data to a compatible PSG and/or HST device. It is not intended for use with low perfused patients.

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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Date Prepared:	1-Apr-20
Sponsor:	Doron D. Patt S.L.P. Ltd 62 Anilewicz Street Tel-Aviv, Israel 67060 Tel: +972 (9) 834 6731
Proprietary or Trade Name:	OxSAT 100
Common/Usual Name:	Oximeter
Classification Name:	Oximeter DQA, Class II, CFR 870.2700
Predicate Device:	Nonin Model 4100, 510(k) K043359

Device Description:
The SLP OxSAT 100 is a pulse oximeter module that photoelectrically determines the oxygenation of blood in a part of the body, based upon the sensor placement.

The OxSAT 100 contains the electronics to interface to an attached sensor. The red and infrared light are transmitted through oxyhemoglobin and are sensed in the photoelectric cell. The red and infrared light is absorbed in different amounts depending on the oxygenation of the blood.

The OxSAT 100 has the ability to determine both the percent of saturated hemoglobin and the pulse rate. It performs these functions on adult and pediatric patient populations. It is designed for measuring and transmitting functional oxygen saturation of arterial hemoglobin (SpO2), Pulse rate and plethysmographic data to compatible polysomnogram (″PSG″) and/or home sleep testing (″HST″) devices.

Pulse amplitude is not displayed. The OxSAT 100 is powered by the host monitor. The wavelength of red LED is 660nm and Infrared LED is 910 nm with maximum optical output power of less than 1 mW.

TThe OxSAT 100 Module is not intended for use with skin contact and, therefore, has not been tested for biocompatibility. The OxSAT 100 is either attached to the outside of a belt on the patient or is set off to the side of the bed. An extension cable might be used with the sensors to avoid skin contact.

Indications for Use:
The SLP OxSAT 100 Patient Oximeter Module is indicated for use in measuring and transmitting functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, and plethysmographic data to a compatible PSG and/or HST device. It is not intended for use with low perfused patients.

Contraindications:
None

Substantial Equivalence Discussion

Table 1 compares the SLP OxSAT 100 to the predicate device for equivalence of:

Indications –
The SLP OxSAT 100 Patient Oximeter Module is indicated for use in measuring and transmitting functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, and plethysmographic data to a compatible PSG and/or HST device. It is not intended for low perfused patients.
Discussion – The indications are similar to the predicate Nonin Model 4100 Patient Oximeter Module. The host PSG and/or HST device will dictate the monitoring use.

Patient Population –
Both are intended for pediatrics (3 years and older) and adult populations.

Environment of Use –
The environment of use is the same.

Prescriptive –
Both are prescriptive.

Design and Technology –
The OxSAT 100 contains the electronics to interface to an attached sensor. The red and infrared light are transmitted through oxyhemoglobin and are sensed in the photoelectric cell. The red and infrared light is absorbed in different amounts depending on the oxygenation of the blood.

The OxSAT 100 has the ability to determine both the percent of saturated hemoglobin and the pulse rate.

Pulse amplitude is not displayed. The OxSAT 100 is powered by a host monitor. The wavelength of red LED is 660nm and Infrared LED is 910 nm with maximum optical output power of less than 1 mW.
Discussion –
The proposed device is powered by connection to a compatible device whereas the predicate device is self-powered and uses Bluetooth to transmit data to a compatible device. In either case no data is displayed by the proposed or predicate device itself.

Performance Specifications –
Both have equivalent specifications.

Compliance with standards –
The OxSAT 100 complies with AAMI ANSI ES60601-1, IEC 60601-1-2, and ISO-80601-2-61. The predicate complies with the same standards.

Performance Testing

Non-clinical -
We have performed bench tests and found that the OxSAT 100 met all requirements specifications and standards requirements and was found to be equivalent in comparison to the predicate. Testing includes the following:

- Verification Testing
- Testing for compliance to AAMI ES 60601-1
- Testing for compliance to IEC 60601-1-2,
- Testing for compliance to IEC 80601-2-61

The results demonstrate that the device performs as intended and is substantially equivalent to the performance of the predicate and in accordance with applicable standards.

Biocompatibility and Materials –
The only patient contacting materials of the OxSAT 100 are the sensors which have been previously cleared. The OxSAT 100 module is not intended for use with skin contact and, therefore, has not been tested for biocompatibility. The OxSAT 100 is either attached to the outside of a belt on the patient or is set off to the side of the bed. An extension cable might be used with the OxSAT 100 to avoid skin contact.

Host System Compatibility –
Testing demonstrated that the following host PSG and HST systems are compatible with the OxSAT 100. All host systems are considered as capable of continuous measurements.

Host System	**K#**	**Environment**
Embletta PDS	K041904	Hospital, Sleep Center
Alice 6	K040595	Hospital, Sleep Center, Other
Alice NightOne	K083874	Hospital, Sleep center, Home
Embla S4500	K024322	Hospital, sleep center, Other
Embla N7000	K024322	Hospital, sleep center, Other
ApneaLink Air	K143272	Hospital, Sleep center, Home
Compumedics	K000068	Hospital
Embletta MPR	K122516	Hospital, Sleep center, Home
Embleeta Gold	K073682	Hospital, Sleep center, Home

Clinical Testing -
Testing to ensure clinical accuracy of the device in accordance with ISO 80601-2-61. This testing and results showed compliance to the standard.

Differences –
The identified difference:

- Data transmission via cable vs. Bluetooth

The OxSAT 100 has been evaluated and tested and confirmed that the difference does not raise different questions of safety or effectiveness when compared to the predicate device for the proposed indications for use.

Substantial Equivalence Conclusion

The OxSAT 100 is substantially equivalent to the predicate in: indications for use, patient population, environment of use, technology characteristics, materials, specifications / performance and compliance with international standards.

Table 1 Device Comparison

CHARACTERISTICS	**OxSAT 100**	**Nonin Model 4100 Patient Oximeter Module (K043359)**	**Comments**
Indications for use	The SLP OxSAT 100 Patient Oximeter Module is indicated for use in measuring and transmitting functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, and plethysmographic data to a compatible PSG and/or HST device. It is not intended for low perfusion patients.	The Nonin® Bluetooth® -enabled Model 4100 Patient Oximeter Module is indicated for use in measuring and transmitting functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, and plethysmographic data to a compatible Bluetooth-enabled device.	Similar indications Both require connection to a compatible device to display collected data
Type of use	Continuous based on the host device	Spot checking Continuous	Similar
Motion	Non-motion	Non-motion	Similar
Patient Population	Pediatrics and Adults	Pediatrics and Adults	Similar
Perfusion	Well	Well Poorly	Similar
Environment of Use	Sleep Study setting and home use	Sleep study settings and home use	Similar
Technology	Transmissive	Transmissive	Similar
System components / Configurations			
Batteries	Powered by compatible device	2 x 1.5 AAA batteries	Similar
SpO_2 Display Range	0% to 100% SpO_2	0% to 100% SpO_2	Similar
Pulse rate declared accuracy range	20-300 BPM	18-300 BPM	Similar
Sensors	APK - K082846 Solaris - K100077	Nonin sensors	Similar

CHARACTERISTICS	OxSAT 100	Nonin Model 4100 Patient Oximeter Module (K043359)	Comments
Accuracy			
SpO_2	70-100% ± 2 digits	70-100% ± 2 digits	Similar
Pulse rate	± 3 digits	± 3 digits	
Display	On the compatible device	On the compatible device	
Data transmission	Direct connection to compatible device	Bluetooth to compatible device	
Application site	Digits	Digits	Similar
Operation mode	Depends upon the host device	Spot checking or continuous monitoring	Similar
LED wavelengths (multiple)	660 and 910 nm	660 and 910 nm	Similar
Functional and safety testing	ES 60601-1 IEC 60601-1-2 IEC 60601-1-11 ISO 80601-2-61	ES 60601-1 IEC 60601-1-2 IEC 60601-1-11 ISO 80601-2-61	Similar
Biocompatibility	The OxSAT 100 Module has not been tested for biocompatibility. Accessory sensors have been tested and are considered Surface Contact Skin Limited duration (<24 hours)	Surface contact Skin Limited duration (<24 hours)	Similar