DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 9, 2017

Oxitone Medical Ltd.
% Paul Dryden
Consultant
Promedic, LLC
24301 Woodsage Dr.
Bonita Springs, Florida 34134

Re: K163382
Trade/Device Name: Oxitone 1000
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: March 28, 2017
Received: March 29, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K163382

Device Name

Oxitone 1000

Indications for Use *(Describe)*

The Oxitone Model 1000 Pulse Oximeter is a small, wrist-worn device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (% SpO_2) and pulse rate.

It is intended for spot-checking of adult patients with wrist between 13-22 cm circumferences in hospitals, clinics, long-term care, and home use.

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
May 8, 2017

Official Contact: Leon Eisen, PhD Founder and CEO
Oxitone Medical Ltd.
17 Atir Yeda Street
Kfar Saba, Israel 4464312
Tel: +972 (9) 834 6731

Proprietary or Trade Name: Oxitone 1000

Common/Usual Name: Oximeter

Classification Name: Oximeter
DQA, Class II, CFR 870.2700

Predicate Device: Nonin Model 9590 - K112843
Reference Device: Nonin 8000R Forehead sensor – K050056

Device Description:
The Oxitone 1000 pulse oximeter is an instrument for photoelectrically determining the oxygenation of blood in a part of the body, in this case the wrist.

This Oxitone 1000 contains the electronics, interface and sensor. The Oxitone pulse oximeter is mounted on a watch-like device and measures oxygen saturation at the wrist location. The Oxitone pulse oximeter exploits a reflectance sensor that includes the photodetector located at the wearer's Ulnar Bone near the Ulnar Bulge and a bi-color light source (LED's) that are located around the top of the wearer's Ulnar "Bulge", to align the light source properly to the Ulnar Bulge the LEDs surrounded by elastic concave shape surface. The Red and infrared light being transmitted through the tissue is partially absorbed by the blood oxyhemoglobin and is sensed by the photodetector. The blood oxygen saturation is measured using the well-established technology where the red and infrared light is absorbed in different amounts depending on the oxygenation of the blood that enables to calculate the blood functional pulse oximetry.

The Oxitone 1000 has the ability to determine both the percent of saturated hemoglobin and the pulse rate. It performs these functions on adult patient populations. It is designed for spot checking both the SpO_2 and Pulse rate information. To perform this, the Oxitone 1000 displays digital values for both the SpO_2 and Pulse.

Pulse amplitude is not displayed. The Oxitone 1000 is powered by an integral rechargeable Lithium Ion battery pack. The wavelength of red LED is 640nm and Infrared LED is 940 nm with maximum optical output power of less than 1 mW.

The device incorporates a battery state indicator and provides a visual indication of low battery.

Indications for Use:
The Oxitone Model 1000 Pulse Oximeter is a small, wrist-worn device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (% SpO_2) and pulse rate.

It is intended for spot-checking of adult patients with wrist between 13-22 cm circumferences in hospitals, clinics, long-term care, and home use.

Contraindications:
None

Substantial Equivalence Discussion

The Oxitone 1000 Pulse Oximeter is similar to other small worn SpO_2 monitors. There are pulse oximeters that use sensors that measure SpO_2 at the extremities – fingers, toes, ear lobes, etc. They also have sensors which are placed on the forehead using reflectance technology for measuring SpO_2.

We have selected 2 devices for comparative purposes for demonstrating substantial equivalence. **Table 1** outlines the rationale.

Feature	Primary Predicate	Reference	Subject device
	Nonin Model 9590 (K112843)	Nonin PalmSAT with Purelight Forehead 8000R sensor (K050056)	Oxitone 1000
Classification	DQA CFR 870.2700 Pulse oximeter	DQA CFR 870.2700 Pulse oximeter	DQA CFR 870.2700 Pulse oximeter
Intended Use	Measure functional oxygen saturation of arterial hemoglobin (%SpO_2) and pulse rate For spot-checking	Measure functional oxygen saturation of arterial hemoglobin (%SpO_2) and pulse rate For spot-checking	Measure functional oxygen saturation of arterial hemoglobin (%SpO_2) and pulse rate For spot-checking
Patients	Adult Pediatrics	Adult Pediatrics	Adult
Sensor location	Digits	Digits Forehead	Wrist

Table 1 – Predicate and Reference Devices

The rationale for the selected devices is that the predicate has the indications for use and the reference shows that SpO_2 measurements can be measure in other anatomical locations other than digits.

We demonstrate device pereformance by testing the subject device according to ISO 80601-2-61 and the FDA's Guidance for Pulse Oximeters (March 4, 2013).

Table of Comparison and Differences

The Oxitone 1000 Pulse Oximeter is a small, wrist-worn device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (% SpO_2) and pulse rate.

It is intended for spot-checking of adult patients with wrist between 13-22 cm circumferences in hospitals, clinics, long-term care and home use.

The monitor features an easy-to-read display that presents patient data, status information, and alarms when appropriate.

The Oxitone 1000 permits spot checking of functional oxygen saturation (SpO_2) and Pulse Rate (PR) in clinical and non-clinical settings.

The software monitors the signals, computes the PR and SpO_2 values and displays the PR and SpO_2 values.

Table 2 outlines the features of the Oxitone 1000 and compares it to the predicate and reference devices to establish substantial equivalence.

Table 2 Device Comparison

CHARACTERISTICS	**Oxitone 1000**	**Predicate** **Nonin** **Model 9590 (K112843)**	**Reference** **Nonin PalmSAT with Forehead 8000R sensor (K050056)**
Indications for Use	The Oxitone Model 1000 Pulse Oximeter is a small, wrist-worn device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (% SpO_2) and pulse rate. It is intended for spot-checking of adult patients with wrist between 13-22 cm circumferences in hospitals, clinics, long-term care, and home use.	The Nonin Onyx Vantage 9590 Finger Pulse Oximeter is a small, lightweight, portable device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%Sp02) and pulse rate of patients who are well or poorly perfused. It is intended for spot-checking of adult and pediatric patients on digits, including the thumb and toes, that are between 0.3 -1.0 inch (0.8 - 2.5 cm) thick. The device's intended use environments include hospitals, clinics, long-term care facilities, skilled nursing facilities, emergency medical services, and home healthcare services.	Indicated for non-invasive spot-checking and/or continuous monitoring
Type of use	Spot checking	Spot-checking	Spot checking Continuous use
Motion	Non-motion	Not specified	Non-motion Motion
Patient Population	Adults	Adult Pediatric	Adult Pediatric
Perfusion	Well	Well Poorly	Well Poorly
Environment of Use	Hospitals, clinics, long-term care and home use	Hospitals, clinics, long-term care facilities, skilled nursing facilities, emergency medical services, and home healthcare services	Hospitals, long-term care and home use
Technology	Reflectance	Transmissive	Transmissive Reflectance

CHARACTERISTICS	**Oxitone 1000**	**Predicate** **Nonin** **Model 9590 (K112843)**	**Reference** **Nonin PalmSAT with Forehead 8000R sensor (K050056)**
System components / Configurations			
Batteries	Rechargeable Li-On	2 x 1.5 AAA batteries	Batteries Sensor has no power
SpO_2 Display Range	0% to 100% SpO_2	0% to 100% SpO_2	The referenced sensor can be placed on the forehead Determined by monitor
Pulse rate declared accuracy range	30-250 BPM	20-250 BPM	
Accuracy			
SpO_2 Accuracy Range	70% to 100 % ± 3%	70% to 100 % ± 3%	
Pulse rate	30-250 ± 3	20-250 ± 2	
Display			
LCD	Multi-pixel 3 digits	Multi-pixel 3 digits	
Pulse strength indicator	No pulse strength indicator. LCD, readings or dashes give pulse quality indication	Tricolor LED gives indication of quality	
Application site	Wrist	Digits	Digits Forehead
Data output	Front panel easy-to-read display (LCD)	Front panel and USB	Monitor dependent
Operation mode	Spot checking	Spot checking	Spot checking Continuous
LED wavelengths (multiple)	640-940 nm	660 and 910 nm	660-910 nm
Radiant Power	Red 1.05 mW IR 0.95 mW	Red 0.8 mW IR 1.2 mW	Determined by monitor
Type of protection	Internally powered	Internally powered	Class II
Degree of protection – sensor	Type BF – applied part	Type BF – applied part	Type BF – applied part
Functional and safety testing	ES 60601-1, IEC 60601-1-11, ISO 80601-2-61	IEC 60601-1, IEC 60601-1-11,, ISO 9919	IEC ISO 9919
Biocompatibility	Surface contact Skin Limited duration (<24 hrs)	Surface contact Skin Limited duration (<24 hrs)	Surface contact Skin Limited duration (<24 hrs)

Substantial Equivalence Discussion and Rationale

In **Table 2** we have compared the Oxitone 1000 to the predicate and reference devices for equivalence of:

Indications – The Oxitone Model 1000 Pulse Oximeter is a small, wrist-worn device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (% SpO_2) and pulse rate. It is intended for spot-checking of adult patients with wrist between 13-22 cm circumferences in hospitals, clinics, long-term care, and home use.
Discussion – The indications are similar to the predicate Nonin 9590 except the Nonin includes poor perfusion and pediatrics. The reference Nonin PalmSAT monitor, K050056, includes neonates but the use of the reference is for the Forehead sensor to demonstrate that other sensor location sites have been cleared.

Patient Population – Though the predicate Nonin 9590 is indicated for pediatrics. The Oxitone 1000 and predicate are both indicated for adults.

Environment of Use – The environment of use for the subject device is narrower than the predicate and reference, but can still be considered substantially equivalent.

Prescriptive – The Oxitone 1000 and Nonin 9590 predicate and reference Nonin PalmSAT with forehead sensor are prescriptive.

Design and Technology – The Oxitone 1000 and Nonin 9590 have equivalent technological and design features. They both calculate SpO_2 and pulse by use of the same technology – the ratio of red and infrared signals of light propagated through the tissue between light sources and detector. Both devices use Photoplethysmography (PPG) signals of red and infrared light through tissue to calculate SpO_2 and pulse rate

The Oxitone 1000 and Nonin 9590 differ in sensor placement, the Oxitone 1000 being placed on the wrist and the Nonin 9590 on a finger. This placement is similar to the reference device Nonin Purelight Forehead 8000R in that they are both based on reflected light (red and IR).

Oxitone's reflectance optical sensor so that the optical elements (LEDs and detector) are placed at the same side of the wrist thereby having the same optical path features are similar to the reflectance used for the forehead sensors.

Performance Specifications – The Oxitone 1000 and Nonin 9590 predicate have equivalent specifications. The reference sensor does not have listed specifications, its performance is based upon the monitor to which it is attached.

Compliance with standards The Oxitone 1000 complies with AAMI ANSI ES60601-1, IEC 60601-1-2, IEC 60601-1-11, ISO-80601-2-61, IEC 62471, and IEC 62133. The predicate complies with IEC 60601-1-2 and ISO 9919. The Oxitone 1000 complies with all applicable currently recognized standards.

Performance Testing

Non-clinical

Bench - We have performed bench tests and found that the Oxitone 1000 met all requirements specifications and standards requirements and was found to be equivalent in comparison to the predicate. Testing includes the following:

- Verification Testing
- AAMI ES 60601-1
- IEC 60601-1-2,
- IEC 60601-1-11
- IEC 80601-2-61

The results demonstrate that the devices perform as intended are substantially equivalent to the performance of the predicate and in accordance with applicable standards.

Biocompatibility – The patient contacting materials of the Oxitone 1000 have been tested in accordance with ISO 10993-1 and FDA Guidance. The tests included Cytotoxicity, Sensitization, and Irritation, which is similar to the predicate and reference devices.

Clinical Testing - Testing to insure clinical accuracy of the device in accordance with ISO 80601-2-61 was performed. This testing was performed on 10 patients with results showing compliance to the standard.

Differences –
The identified difference:

- Narrower environment of use
- Narrower patient population – adults only
- Narrower indications – non-motion only
- Detection on the wrist vs. digits of forehead

Have been evaluated and tested and confirm that these differences do not raise different questions of safety or effectiveness when compared to the predicate and reference devices for the proposed indications for use.

Substantial Equivalence Conclusion

The Oxitone 1000 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. The differences do not raise different questions of safety or effectiveness when compared to the predicate and reference devices for the proposed indications for use.