K122996

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Breathing New Life into Medicine

510(k) SUMMARY

APR 10 2013

Submitter	Xhale, Inc. (via Assurance Biosense, Inc - a wholly owned subsidiary) 701 Hebron Avenue Glastonbury, CT 06033 Phone: (860) 616-1610 Fax: (352) 375-3133
Contact Person	David Rich Sr. Vice President Phone: (860) 616-1610
Date Prepared	Feb 4, 2013
Trade Name	Assurance™ Alar Sensor
Regulation (Common) Name	Pulse Oximeter Sensor
Classification	Class II, 21CFR 870.2700, 21CFR 870.2900
Product Code	74 DQA, 74 DSA
Predicate Device(s)	Nellcor N-395 Pulse Oximeter System – K991823 Nellcor OxiMax-Fast Adhesive Forehead Sensor – K021089 Masimo E1 Ear Sensor – K121912

Device Description

The Assurance™ Alar Sensor is a disposable, single patient use Pulse Oximetry sensor designed to attach to the patient's nasal alar region – the fleshy region at the side of the nose. Skin contact and adhesive free sensor retention is via soft silicone rubber cushions encapsulating the optical components. The Assurance™ Alar Sensor with its associated patient cable, terminates in a DB-9 connector compatible with monitors employing Nellcor OxiSensor II SpO_2 technology such as the Nellcor N-395.

The sensor utilizes red and IR LED light sources of 660 nm and 890 nm respectively along with a silicon photodiode detector to detect changes in oxygen saturation in the blood. Since oxygen saturated blood absorbs different amounts of light at each wavelength (red and infrared) as compared with unsaturated blood, the amount of light absorbed at each wavelength by the blood in each pulse can be used to calculate oxygen saturation.

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Indications for Use

The Assurance™ Alar Sensor is indicated for single patient use for continuous noninvasive monitoring of functional arterial oxygen saturation and pulse rate from the nasal alar of adult and pediatric patients, (weighing >30kg). The sensor can be used in a variety of healthcare environments where compatible pulse oximetry monitors are indicated for use, under professional supervision.

Predicate Device(s) Comparison

Intended Use and Indications for Use

Attribute	Assurance™ Alar Sensor	Predicate Device (K121912) Masimo E1 Ear Sensor
Intended Use	Continuous noninvasive monitoring of functional arterial oxygen saturation and pulse rate.	Same
Indications for Use	The Assurance™ Alar Sensor is indicated for single patient use for continuous noninvasive monitoring of functional arterial oxygen saturation and pulse rate from the nasal alar of adult and pediatric patients, (weighing >30kg). The sensor can be used in a variety of healthcare environments where compatible pulse oximetry monitors are indicated for use, under professional supervision.	The Masimo El Ear Sensor is indicated for single patient use for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor) for use with adult and pediatric patients, (weighing > 30kg), who are well or poorly perfused, in hospitals, hospital-type facilities, mobile, and home environments.
Patient Population	Adults, Peds >66 lbs. / 30 kg.	Adults, Peds >66 lbs. / 30 kg.
Duration of Use	Single patient, multi-use	Single patient, multi-use

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Technology & Materials

Attributes	Assurance™ Alar Sensor	Predicate Device (K121912) Masimo E1 Ear Sensor
Principle of Operation	Spectrophotometric measurement of functional arterial Oxygen saturation by transmissive mode Pulse Oximetry	Spectrophotometric measurement of functional arterial Oxygen saturation by transmissive mode Pulse Oximetry
Reusable/Disposable	Disposable, Single Patient Use	Disposable, Single Patient Use
LEDs	Red (~660 nm) and IR (~880 nm)	Red (~660 nm) and IR (~880 nm)
LED drive	2 wire, anti-parallel	2 wire, anti-parallel
Detector	photodiode	photodiode
Connector	9 pin DB-9 style	9 pin DB-9 style
Skin Contact	Silicone rubber	Silicone rubber

Performance & Accuracy

Device	510(k)	Sensor Location	SpO_2 Accuracy (A_{RMS})	Pulse Rate Accuracy
Assurance™ Alar Sensor	-	Nose	70-100%: ± 2%	30-250 bpm: ± 3 bpm
Nellcor N-395 System: Oxisensor D-25 Oxisensor R-15 Dura Y & Ear clip D-YSE	K991823	 Finger Nose Ear	 70-100%: ± 2% 80-100%: ± 3.5% 70-100%: ± 2%	30-250 bpm: ± 3 bpm
Nellcor OxiMax Forehead	K021089	Forehead	70-100%: ± 2%	30-250 bpm: ± 3 bpm
Masimo E1 Ear Sensor	K121912	Ear	70-100%: ± 2.5%	30-250 bpm: ± 3 bpm

The Assurance™ Alar Sensor has been compared to the predicate device(s) and is viewed as substantially equivalent because:

- The intended use and indications for use are the same
- The principles of operation, optical components and materials are the same
- The performance and accuracy is the same or better

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Nonclinical Testing Summary

The following testing of the Assurance™ Alar Sensor was performed in accordance with the requirements of the design control regulations and established quality assurance procedures.

Biocompatibility of materials

Materials were evaluated per ISO 10993-1. The sensor is a surface device where materials have direct or incidental skin contact for less than 29 days.

- Surface Communicating, Skin, Prolonged duration
  - Cytotoxicity (tested per ISO 10993-5)
  - Sensitization (tested per ISO 10093-10)
  - Irritation (tested per ISO 10993-10)
- Pass / fail criteria was met for each respective ISO 10993 test

Discussion: All materials were tested according to ISO 10093-1 for the intended use level of patient contact and duration and found to meet the applicable requirements.

Electromagnetic Compatibility

The device was tested per IEC 60601-1-2.

- Emissions Testing
  - CISPR 11: Radiated Electromagnetic Emissions (2004)
- Immunity Testing
  - IEC 61000-4-2: Electrostatic Discharge Immunity (2001)
  - IEC 61000-4-3: Radiated Electromagnetic Field Immunity (2006)
  - IEC 61000-4-6: Radio-Frequency Common Mode Immunity

Discussion: The device met the requirements of IEC 60601-1-2 relevant to the device. The tests conformed to the requirements set forth in ISO 80601-2-61, Particular Requirements for Basic Safety and Essential Performance of Pulse Oximeter Equipment.

Electrical Safety Testing

Fluid Ingress / Spill Resistance

- The device was tested per ISO 80601-2-61 requirement of IEC 60601-1 Clause 11.6, overflow, spillage, leakage, ingress of water or particulate matter requirements.

Discussion: The device meets IPX1 requirements.

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Surface Temperature

- The device was tested per ISO 80601-2-61 Clause 201.11 and ANNEX BB: skin temperature requirements for protection against excessive temperatures.

Test	Max Temp (Right) (°C)	Max Temp (Left) (°C)
1	30.7	29.2
2	37.6	36.7
3	27.9	27.2
4	36.3	37.6
5	36.9	35.2

Discussion: The device passed the test with the skin temperatures under the device not exceeding 38°C, below the max temperature limit of 41°C.

Pulse Rate accuracy (low signal)

- The device was tested for accuracy of pulse rate over the range 30-250 bpm using an SpO_2 simulator at minimum perfusion settings under conditions of no motion.

Discussion: The device measured the pulse rate to within ± 3bpm over the range.

Inter-device Reliability and Accuracy

- A population of devices was tested under simulated conditions to assess the Inter-device Reliability and Accuracy. The devices were tested over the ranges; 85-99% SpO_2 and 40-140 bpm.

Discussion: The deviation between simulated and measured values across the population was $\leq$2% SpO_2 and $\leq$1 bpm. This performance is within the stated accuracies of ±2% SpO_2 and ± 3 bpm accordingly.

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Mechanical and Environmental Testing

Drop Test

- The device was tested per ISO 80601-2-61 requirement of IEC 60601-1 clause 15.3.4.1 drop test requirements for hand-held ME equipment.

Discussion: The device passed the drop test without damage and satisfied the test requirements.

Storage Temperature and Humidity

- The device was tested following storage at the extremes of temperature and humidity: -40°C to +70°C, 15% to 95% RH (non-condensing).

Discussion: The device was not affected by the ranges of temperature and humidity indicated as storage conditions.

Operating Temperature and Humidity

- The device function was evaluated over the range of temperature and humidity: -5°C to +40°C, 15% to 95% RH (non-condensing).

Discussion: The device function was not affected over the ranges of temperature and humidity indicated as operating conditions.

Clinical Testing Summary

Hypoxia Performance Testing

- Controlled desaturation testing was performed per ISO/IEC 80601-2-61 under no-motion conditions with 12 healthy volunteer subjects of varying age, gender, ethnicity and skin tone.
- Sensors were connected to Nellcor N-395 monitors representative of "Nellcor OxiSensor II SpO_2 technology". SpO_2 values were recorded from the monitors over the range of 70-100% SaO_2.
- Reference blood samples were drawn from an indwelling arterial catheter and analyzed on a Co-oximeter.

Discussion: Statistical analysis of 552 evenly distributed data pairs, yielded a device accuracy (A_{rms}) of 1.84% over the range 70-100% SaO_2.

Substantial Equivalence Conclusion

The sponsor has demonstrated through design and feature comparison, performance testing, and controlled desaturation testing, the Assurance™ Alar Sensor is substantially equivalent to the listed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 10, 2013

Mr. David Rich
Senior Vice President
Xhale, Incorporated
701 Hebron Avenue
GLASTONBURY CT 06033

Re: K122996
Trade/Device Name: Assurance Alar Sensor
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA, DSA
Dated: March 22, 2013
Received: March 27, 2013

Dear Mr. Rich:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Kwame O. Ulmer for
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Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122996

Device Name: Assurance Alar Sensor

Indications for use: The Assurance Alar Sensor is indicated for single patient use for continuously noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate from the nasal ala of adult and pediatric patients (weighing > 30kg), who are well or poorly perfused. The sensor can be used in a variety of healthcare environments where compatible pulse oximetry monitors are indicated for use, under professional supervision.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Lester W. Schultheis Jr
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(Division Sign-Off)
Division of Anesthesiology, General H... ...
Infection Control, Dental Devices

510(k) Number: K122996

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