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

March 17, 2015

Xhale Inc.
c/o Mr. Paul Dryden
Regulatory Consultant
3630 SW 47th Avenue, Suite 100
Gainesville, FL 32608

Re: K143216
Trade/Device Name: Assurance™ Alar / Nasal SpO_2 Sensor
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: February 12, 2015
Received: February 13, 2015

Dear Mr. 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" (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 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 yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K143216

Device Name

Assurance™ Nasal / Alar SpO_2 Sensor

Indications for Use *(Describe)*

The Assurance™ Nasal / Alar SpO_2 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.

Type of Use *(Select one or both, as applicable)*

XX Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

Date Prepared: 16-Mar-15

Xhale, Inc.
3630 SW 47th Ave, Suite 100
Gainesville, FL 32608
Phone: (352) 371-8488
Fax: (352) 375-3133

Official Contact: Jeffrey Hoebelheinrich
Director of Quality and Regulatory Affairs

Proprietary or Trade Name: Assurance™ Alar / Nasal SpO_2 Sensor

Common/Usual Name: Oximeter (Accessory – sensor)

Classification Name: Oximeter
Product Classification – DQA
21 CFR 870.2700
Class II

Predicate Devices: K122996 – Xhale Assurance™ Aral SpO_2 sensor
K060576 **–** Nellcor OxiMax sensors

Device Description:
The Alar / Nasal SpO_2 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 Alar / Nasal SpO_2 Sensor with its associated patient cable, terminates in a DB-9 connector compatible with monitors employing Nellcor SpO_2 technology.

The sensor utilizes red and IR LED light sources of 660 nm and 880 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.

Indications for Use:
The Assurance™ Nasal / Alar SpO_2 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.

Comparison to Predicates
The following table compares the predicates.

Attribute	**Xhale** **Alar SpO_2 sensor** **K122996**	**Nellcor** **OxiMax Sensors** **K060576**	**Proposed Xhale** **Alar / Nasal SpO_2 Sensor**
Indications for Use	The Assurance™ Alar SpO_2 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.	Indicated for single patient use for continuously noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. Neonate, pediatric, and adult who are well or poorly perfused, in hospitals, hospital-type facilites, intra-hospital transport, and home environments.	The Assurance™ Nasal / Alar SpO_2 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.
Environments of use	variety of healthcare environments where compatible pulse oximetry monitors are indicated for use, under professional supervision	hospitals, hospital-type facilaiites, intra-hospital transport, and home environments	variety of healthcare environments where compatible pulse oximetry monitors are indicated for use, under professional supervision
Patient population	adult and pediatric patients (weighing > 30kg)	Neonate, pediatric, and adult	adult and pediatric patients (weighing > 30kg)
Single patient use	Yes	Yes	Yes
Technology, Features and Specifications			
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	Spectrophotometric measurement of functional arterial oxygen saturation by transmissive mode pulse oximetry
LEDS	Red (~660 nm) and IR (~880 nm)	Red (~660 nm) and IR (~880 nm)	Red (~660 nm) and IR (~880 nm)
Detector	Photodiode	Photodiode	Photodiode
Connector	9 pin DB-9 style	9 pin DB-9 style	9 pin DB-9 style

Attribute	**Xhale Alar SpO_2 sensor K122996**	**Nellcor OxiMax Sensors K060576**	**Proposed Xhale Alar / Nasal SpO_2 Sensor**
Performance Testing – Clinical and Non-clinical			
Patient Contact Materials Classification	Materials in the gas pathway External Communicating Tissue Prolonged duration Materials in direct patient contact Surface Contact Mucosal Prolonged duration	Materials in the gas pathway External Communicating Tissue Prolonged duration Materials in direct patient contact Surface Contact Mucosal Prolonged duration	Materials in the gas pathway External Communicating Tissue Prolonged duration Materials in direct patient contact Surface Contact Mucosal Prolonged duration
SpO_2 Accuracy (A_{RMS})*	70-100% $\pm$ 2%	70-100% $\pm$ 2%	70-100% $\pm$ 3%
BPM	30-250 bpm $\pm$ 3 bpm	20-250 bpm $\pm$ 3 bpm	30-240 bpm $\pm$ 3 bpm
IEC 60601-1	Yes	-	Yes
IEC 60601-1-2	EMC	-	EMC
ISO 80601-2-61	Mechanical strength Storage and Operating Temperature and humidity Fluid ingress	-	Mechanical strength Storage and Operating Temperature and humidity Fluid ingress
Pulse rate accuracy	Yes	-	Yes
Inter-device reliability and accuracy	Yes	-	Yes

Substantial Equivalence Discussion

The table above compares the key features of the proposed Assurance™ Alar / Nasal SpO_2 Sensor as compared to the predicate Xhale Assurance™ Alar SpO_2 Sensor (K122996) and the predicate Nellcor OxiMax Sensor (K060576).

Discussion of Differences:

The differences between the proposed Alar / Nasal SpO_2 Sensor and the predicate Alar Sensor (K122996):

- The Alar / Nasal SpO_2 Sensor has 1 (one) wire connecting the sensor to the DB-9 connector.
    - The predicate device had a separate AB-N Adaptor Cable that was necessary to connect to a DB-9 port.
    - The proposed Alar / Nasal SpO_2 Sensor removed the need for the additional adaptor by direct connection of the sensor assembly to the cable with a DB-9 connector.
- The proposed Alar / Nasal SpO_2 Sensor has a PCB with embedded software that is directly connected to the DB-9 connector.
    - This allows the sensor to communicate with the compatible pulse oximetry equipment and display the SpO_2 and heart rate data on the screen.
- Pulse Rate Accuracy - Testing was performed for the accuracy of pulse rate over the range from 30-240 bpm using a SpO_2 simulator the results were identical pulse rate accuracy within $\pm$ 3 bpm over the tested range. We tested 30-240 bpm when the predicate Alar (K122996) was tested at 30-250 bpm. This test method difference is not significant as long as it is disclosed in the labeling and is equivalent to the predicate K122996 – Xhale Assurance™ Alar SpO_2 sensor.

Discussion – These differences can be viewed as substantially equivalent and do not raise any new safety or effectiveness concerns when compared to the predicate K122996 – Xhale Assurance™ Alar SpO_2 sensor.

In summary one can conclude that substantial equivalence is met based upon the following:

Indications for Use – The indications for use are identical for the proposed device when compared to the predicate – K122996 – Xhale Assurance™ Alar SpO_2 sensor.
Discussion – Each device is indicated for use as a pulse oximeter sensor.

Technology and construction – The technology is identical to the predicate K122996 – Xhale Assurance™ Alar SpO_2 sensor. The basic design, fabrication, constructions and materials are identical to the predicate K122996 – Xhale Assurance™ Alar SpO_2 sensor.
Discussion – The basic design, fabrication, constructions and materials are identical to the predicate K122996 – Xhale Assurance™ Alar SpO_2 sensor.

Patient Population – The patient population is identical to the predicate K122996 – Xhale Assurance™ Alar SpO_2 sensor.
Discussion – The patient population is identical – predicate and adults > 30kg.

Environment of Use – The environments of use are identical to the predicate K122996 – Xhale Assurance™ Alar SpO_2 sensor**.**
Discussion – Both devices are used in the identical settings.

Non-Clinical Testing Summary –

Pulse Rate Accuracy - Testing was performed for the accuracy of pulse rate over the range from 30-240 bpm using a SpO_2 simulator the results were identical pulse rate accuracy within + 3 bpm over the tested range.
Discussion – The Pulse Rate Accuracy is equivalent to the predicate K122996 – Xhale Assurance™ Alar SpO2 sensor**.**

Inter-device reliability and accuracy - Testing of the sensor across a range of test conditions and the testing showed the pulse rate to be within $\pm$ 3 bpm over the range.
Discussion – The inter-device reliability and accuracy is identical to the predicates K122996 – Xhale Assurance™ Alar SpO_2 sensor and K060576 – Nellcor OxiMax sensor.

Skin Temperature - Per ISO 80601-2-61 the maximum temperature limit is 41^{o}C. Testing showed that corrected for 35^{o}C the proposed sensor did not exceed this limit. Results ranged from 34.3 to 39.1^{o}C.
Discussion - The results are substantially equivalent to the predicates s K122996 – Xhale Assurance™ Alar SpO_2 sensor and K060576 – Nellcor OxiMax sensor.

Materials – The materials were tested per ISO 10993-1 for the submission K122996 and we have not changed the materials.
Discussion – The materials are identical to the predicate K122996 – Xhale Assurance™ Alar SpO_2.

Clinical Testing
We performed a controlled desaturation study with healthy volunteers per ISO 80601-2-61 and the results across the 8 oximetry platforms showed that the SpO_2 was within A_{RMS} specification of 3 under steady state / non-motion conditions for the range of 70-100%
Discussion – The clinical testing demonstrated that the performance is substantially equivalent to the predicates K122996 – Xhale Assurance™ Alar SpO_2 sensor and K060576 – Nellcor OxiMax sensor. ISO 80601-2-61 allows for an A_{RMS} range of up to $\pm$ 3% across the range of 70-100%.

Xhale Assurance A1x sensor with model tested	**A_{rms} SpO_2 70-100%**
Nellcor N-600x	1.8 (257 pts)
Philips Intellivue A04	1.5 (257 pts)
Nellcor N-595	2.1 (258 pts)
Philips Intellivue A02	2.2 (258 pts)
Nellcor N-395	1.7 (266 pts)
Philips Intellivue A01	1.7 (264 pts)
DataScope Passport 2	1.7 (279 pts)
GE Dash 3000	2.2 (279 pts)

Substantial Equivalence Conclusion -

The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate have been found to be substantially equivalent.