DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 27, 2017

Xhale, Inc.
% Paul Dryden
Consultant
ProMedic, LLC
24301 Woodsage Dr.
Bonita Springs, Florida 34134

Re: K171423
Trade/Device Name: Nasal Alar SpO_2 Sensor
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: May 11, 2017
Received: May 15, 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,

Mark S. Fellman -S

for

Lori A. Wiggins, MPT, CLT
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 below.

510(k) Number *(if known)*

K171423

Device Name

Nasal Alar SpO_2 Sensor

Indications for Use *(Describe)*

The 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 (at least 4 years and older and weighing $\geq$15 kg), 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Date Prepared: 25-Jul-17

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Official Contact: Jeffrey Hoebelheinrich
Director of Quality and Regulatory Affairs

Proprietary or Trade Name: Nasal Alar SpO_2 Sensor

Common/Usual Name: Oximeter (Accessory – sensor)

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

Predicate Device: K143216 – Xhale Assurance™ Alar / Nasal SpO_2 sensor

Device Description:
Xhale is seeking an expansion of indications to change patient population from a weight of $\geq$30 kg to at least 4 years and older and $\geq$15 kg.

The Nasal Alar SpO_2 Sensor itself is unchanged and identical to that submitted in K143216.

The Nasal Alar 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 Nasal Alar 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 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.

Indications for Use:
The 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 (at least 4 years and older and weighing $\geq$15 kg), 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 Predicate

The following table compares the predicate.

Attribute	**Xhale Assurance™ Alar / Nasal SpO_2 Sensor 510(k) K143216**	**Proposed Xhale Nasal Alar SpO_2 Sensor**	**Differences**
Indications for Use	The Assurance™ Alar / Nasal 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 ≥30 kg), 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.	The 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 (at least 4 years and older and weighing ≥15 kg), 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.	Changed minimum patient age to 4 years and older and weight to ≥15 kg
Environments of use	variety of healthcare environments where compatible pulse oximetry monitors are indicated for use, under professional supervision	variety of healthcare environments where compatible pulse oximetry monitors are indicated for use, under professional supervision	Identical
Patient population	adult and pediatric patients (weighing ≥30 kg)	adult and pediatric patients (at least 4 years and older and weighing ≥15 kg)	Changed minimum patient age to 4 years and older and weight to ≥15 kg
Single patient use	Yes	Yes	Identical
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	Identical
LEDS	Red (~660 nm) and IR (~880 nm)	Red (~660 nm) and IR (~880 nm)	Identical
Detector	Photodiode	Photodiode	Identical
Connector	9 pin DB-9 style	9 pin DB-9 style	Identical

Attribute	Xhale Assurance™ Alar / Nasal SpO_2 Sensor 510(k) K143216	Proposed Xhale Nasal Alar SpO_2 Sensor	Differences
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	Identical
SpO_2 Accuracy (A_{RMS})*	70-100% ± 3%*	70-100% ± 3%*	Identical
BPM	30-240 bpm ± 3 bpm	30-240 bpm ± 3 bpm	Identical
IEC 60601-1	Yes	Yes	Identical
IEC 60601-1-2	EMC	EMC	Identical
ISO 80601-2-61	Mechanical strength Storage and Operating Temperature and humidity Fluid ingress	Mechanical strength Storage and Operating Temperature and humidity Fluid ingress	Identical
Pulse rate accuracy	Yes	Yes	Identical
Inter-device reliability and accuracy	Yes	Yes	Identical

Substantial Equivalence Discussion

The table above compares the key features of the proposed Nasal Alar SpO_2 Sensor as compared to the predicate Xhale Assurance™ Alar / Nasal SpO_2 Sensor (K143216). In summary one can conclude that substantial equivalence is met based upon the following:

Indications for Use – The indications for use are similar for the proposed device when compared to the predicate – K143216 – Xhale Assurance™ Alar / Nasal SpO_2 sensor.
Discussion – Each device is indicated for use as a pulse oximeter sensor. The proposed change is for patient population and not for use as a pulse oximeter sensor. It is noted that the devices to which the sensors are attached have been cleared for use with the proposed patient population.

Technology and construction – The technology is identical to the predicates K143216– Xhale Assurance™ Alar / Nasal SpO_2 sensor. The basic design, fabrication, constructions and materials are identical to the predicate K143216 – Xhale Assurance™ Alar / Nasal SpO_2 sensor.
Discussion – The basic design, fabrication, constructions and materials are identical to the predicate K143216 – Xhale Assurance™ Alar / Nasal SpO_2 sensor.

Patient Population – The patient population is similar to the predicate K143216 – Xhale Assurance™ Alar / Nasal SpO_2 sensor.

Discussion – The patient population has been reduced from ≥30 kg to at least 4 years and older and weighing ≥15 kg. The reduction in patient weight does not impact clinical performance of the device. Please see Clinical Testing section for support of change in patient population.

Environment of Use – The environments of use are identical to the predicate K143216 – Xhale Assurance™ Alar / Nasal SpO_2 sensor**.**
Discussion – Both devices are used in the identical settings.

Non-Clinical Testing Summary –

Pulse Rate Accuracy, Inter-device reliability and accuracy, Skin Temperature – These specifications have not changed.
Discussion – The performance is identical to the predicate device, K143216 – Xhale Assurance™ Alar / Nasal SpO_2 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 reference K122996 – Xhale Assurance™ Alar / Nasal 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%.

We reviewed published anthropometric data to also support the fit of the subject device in the nostril. The data supported weight as a predictor of morphologic measurements. This data plus the acceptance of adult hypoxemic testing for patient as young as 4 years old were used to determine the new population.
Discussion – The clinical testing demonstrated that the performance is substantially equivalent to the predicate K143216 – Xhale Assurance™ Alar / Nasal SpO_2 sensor. ISO 80601-2-61 allows for an A_{RMS} range of up to ± 3% across the range of 70-100%. As the subject device is placed at the nasal alar, we included a weight limitation.

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.