O2 Concepts LLC
% Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, Nw
Buffalo, Minnesota 55313

Re: K182454
Trade/Device Name: O2 Concepts Oxlife Independence Model 301-0001
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable oxygen generator
Regulatory Class: Class II
Product Code: CAW
Dated: November 2, 2018
Received: November 5, 2018

Dear Mark Job:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 D. Courtney -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182454

Device Name
Oxlife Independence

Indications for Use *(Describe)*
The O2 Concepts Oxlife Independence is indicated on a prescription basis for the administration of supplemental oxygen. It is not intended for life support, nor does it provide any patient monitoring capabilities.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5. 510 k) Summary

I. Submitter

O2 Concepts LLC
199 Park Road Extension
Middlebury, CT 06762
Phone: 877-867-4008
Contact Person: Kate Forgione, Director of Quality
Date Prepared: December 17, 2018

II. Name of Device

Name of Device: O2 Concepts Oxlife Independence Model 301-0001

Common or Usual Name: Portable Oxygen Concentrator

CFR Regulation Number: 21 CFR 868.5440

Classification Panel: Anesthesiology

Regulatory Class: II

Product Code: CAW

III. Predicate Device:

Sequal Eclipse Portable Oxygen Concentrator (K013931)
This predicate has not been subject to a design related recall.
No reference devices were used in this submission.

IV. Device Description

The Oxlife Independence is a portable oxygen concentrator that enables patients requiring supplemental oxygen to be treated in a home environment, in an institutional environment or in a vehicle/mobile environment. The Oxlife Independence utilizes O2 Concepts' Dynamic Network Analysis (DNA) technology to provide equipment performance, location and usage data to O2 Concepts and its customers via cellular and GPS connection.

The device delivers 87%-95% pure oxygen to a patient through a standard single lumen nasal cannula. The Independence detects a patient breath and delivers a bolus of oxygen during the inhalation period in pulse mode or delivers a continuous flow of oxygen in continuous mode.

The Oxlife Independence can be set to deliver flowrates in pulse mode settings of 0.5 to 6.0 of 8ml – 96ml and in continuous mode of 0.5 to 3.0 liters per minute (LPM). Setting can be adjusted in increments of 0.5 for both modes.

Device standard power options include a 100-240VAC Power Supply, 10-15VDC Power Supply and rechargeable batteries.

V. Indications for Use

The O2 Concepts Oxlife Independence is indicated on a prescription basis for the administration of supplemental oxygen. It is not intended for life support, nor does it provide any patient monitoring capabilities.

Patient Population

Adult patients with chronic pulmonary diseases such as chronic bronchitis, emphysema, asthma, or lung cancer, those in the terminal stages of cancer or any patient requiring supplemental oxygen. It is a prescription device designed for indoor and outdoor use.

Environment of Use

Home, Travel or Institution

VI. Comparison of Technological Characteristics with the Predicate Device

Pressure Swing Absorption (PSA) is the technological principle for both the subject and predicate devices. It is based on molecular sieve/pressure swing absorption technology which draws in ambient air, pushes it through a sieve bed and then utilizes pressure swing absorption to convert the ambient air to pure oxygen.

Table 1 compares the key features of the proposed O2 Concepts Oxlife Independence with the identified predicate, the Sequal Eclipse.

TABLE 1 – COMPARISON OF PROPOSED DEVICE TO PREDICATE

Attribute	**Predicate Device:** **Sequal Eclipse K013931** 	**Proposed Device:** **O2 Concepts Oxlife Independence** 
Indications for Use	The Eclipse Oxygen System is intended for administration of supplemental oxygen. The Eclipse is not intended for life supporting or life sustaining applications nor does it provide any patient monitoring capabilities.	The O2 Concepts Oxlife Independence is indicated on a prescription basis for the administration of supplemental oxygen. It is not intended for life support, nor does it provide any patient monitoring capabilities.
Environments of Use	Travel, Home or Institution	Travel, Home or Institution
Prescription Use	Yes	Yes
Patient Population	Adult	Adult
Single Patient Multi Use	Yes	Yes
Patient Interface	Cannula port	Cannula port
Technology	Pressure Swing Adsorption with molecular sieve	Pressure Swing Adsorption with molecular sieve
Dimensions (HxWxD)	19.3” x 12.3” x 7.1”	20.29” x 10.85” x 9.45”
Weight	17.9 lbs.	16.7lbs.
Oxygen Concentration	87-95.6%	87-95%
Equivalent Flow Rates	Continuous 0.5 – 3.0LPM in 0.5 LPM increments Pulse Dose Settings 1-6	Continuous 0.5 – 3.0LPM in 0.5 LPM increments Pulse Dose Settings 0.5-6
Dose at Specified Flow	8 mL	8 mL
Filters	Air Inlet Filter	Air Intake Filter
User Interface	Buttons/LCD Display	Buttons/LCD Display
Electrical	100-240 VAC, 50/60 Hz 11.5-16V DC	100-240 VAC, 50/60 Hz 12-15V DC
Software	Embedded	Embedded
Acoustic Noise	48 dBA	56 dBA

Alarms	Unit Malfunction	Unauthorized battery
	Loss of Power	No external power High external power Low external power
	Low Battery	Low battery
	Low Oxygen Output	Low purity
	Flow Restricted	No Flow
	Power Cartridge Temperature	Over Temperature Invalid Motor Temperature Invalid Box Temperature
	No Inspiration in Pulse Mode	No Breath in Pulse Mode
Status Indicators	Battery/Power Condition Delivery Mode Flow Setting Pulse Dose Breath Indicator Alerts/Alarms	Battery/Power Condition Delivery Mode Flow Setting Pulse Dose Breath Indicator Alerts/Alarms History Log Diagnostics
Battery Duration	Approximately 2.4 hours at 2.0 Continuous	Approximately 2.5 hours at 2.0 Continuous
Operating Environment	Temperature 50°F to 104°F Humidity 10% to 95% @ 82.4° F	Temperature 50°F to 104°F Humidity 10% to 95% @ 82.4° F
Shipping/Storage Conditions	Temperature -4°F to 140°F Humidity Up to 95% non-condensing	Temperature -4°F to 140°F Humidity 0-95% non-condensing
Electrical Safety	AAMI IEC 60601-1-2:2007	IEC 60601-1 IEC 60601-1-2
Mechanical Safety	AAMI ANSI ES60601-1:2005	IEC 60601-1
Chemical Safety	N/A	N/A
Thermal Safety	AAMI ANSI ES60601-1:2005	IEC 60601-1
Type of Protection again electric shock	Type BF – Not for cardiac	Type BF – Not for cardiac
Biocompatibility	4 VOC's less than ambient Pass ISO 10993-5 Pass ISO 10993-10	4 VOC's less than ambient

Standards Met	AAMI ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 ANSI AAMI IEC 60601-1-2:2007/(R)2012 ANSI AAMI IEC 60601-1-8:2006 and A1:2012 ANSI AAMI HA60601-1-11:2015 ANSI AAMI IEC 62366-1:2015 ISO 80601-2-69 1st ed. ISO 8359:1996 ISO 10993-2, 2006 ISO 10993-5, 2014 ISO 10993-10, 2010 ISO 10993-12, 2012 ISO 18562-2, 2017 ISO 18562-3, 2017	IEC 60601-1 IEC 60601-1-2

Comparison Discussion

Indications for Use

The indications for use are equivalent when compared to the predicate device.

Patient Population

The patient populations are equivalent when compared to the predicate device. Adult patients with chronic pulmonary diseases such as chronic bronchitis, emphysema, asthma or lung cancer or those in the terminal stages of cancer, or any patient requiring supplemental oxygen.

Environment of Use

The environment of use is equivalent when compared to the predicate device. Both devices are used in the home, for travel or in an institution.

Principle of Operation & Technology

The essential design, components and principle operation of the Oxlife Independence based on molecular sieve/pressure swing absorption technology, to draw ambient air, push it through a sieve bed and then utilize pressure swing absorption to convert the ambient air to pure oxygen is equivalent to the predicate device.

The devices offer equivalent flow rates of oxygen and have equivalent alerts and alarms.

The difference between the device and the predicate is that the Oxlife Independence offers an optional technology, Dynamic Network Analysis (DNA), that providers can use to track device location, performance/usage data and alarms, via a cell and GPS module.

This technology does not change any performance characteristics of the device.

Both devices meet the requirements related to performance applicable to the portable oxygen concentrator and the differences noted in the comparison do not raise different questions of safety or effectiveness and therefore the subject device is substantially equivalent to the predicate device.

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

The biocompatibility evaluation for the subject device was conducted in accordance with the FDA Guidance Document, "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" as recognized by FDA.

Particulate Matter 2.5 micron (PM2.5 testing was completed and the POC emitted a mean PM 2.5 level less than the EPA PM2.5 level of 15 $\mu g/m^3$.

Inorganic gases (ozone, CO2, and CO) were evaluated with low levels detected of CO2; no level of CO and an ozone concentration less than the EPA allowed 0.050ppm.

Patient contact with the device is limited to:

- Handle
- Device Enclosure
- Battery
- Interface panel

The route of exposure to these materials would be through incidental contact with the patient's skin and does not contact the patient during normal device use. However, the oxygen that passes through the subject device per Annex A of ISO 10993-1:2009(E) is:

- Category: External communicating device
- Contact: Tissue
- Duration: C – Permanent (>30 days)

The POC is considered permanent contacting because the oxygen that passes through the device is inhaled by the patients through nasal tissue.

Electrical safety and electromagnetic compatibility (EMC)
Electrical safety and EMC testing was conducted on the O2 Concepts Oxlife Independence. The system complies with the following:

AAMI ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012
AAMI IEC 60601-1-2:2007/(R)2012
ANSI AAMI IEC 60601-1-8:2006 and A1:2012
ANSI AAMI HA60601-1-11:2015
ANSI AAMI IEC 62366-1:2015
ISO 80601-2-69 1st ed.
IEC 62304 Edition 1.1 2015-06

Verification and Validation Testing

Verification and Validation testing was conducted in accordance with ISO 80601-2-69 1st edition and documented which included device software, acoustic testing and packaging testing. The software for this device was considered a "moderate" level of concern, since a failure or latent flaw in the software could result in Minor Injury, either to a patient or to a user of the device. Mechanical and electrical safety testing was performed according to the performance standards listed above and internal test protocols to identify test methods.

The O2 Concepts Oxlife Independence was evaluated in accordance with ISO 80601-2-69 1st edition to assure it performs as intended and met user needs including the following:

Verification Testing – Testing of prototype devices to confirm that design outputs meet the design input requirements.
Validation Testing – Testing of production units to ensure that devices conform to user needs and intended uses.
Software Validation Testing – Testing of device software to ensure it meets the required specifications.
Usability Validation – Testing to ensure that users can be successfully operate the device using the supplied collateral.

Usability Study

Usability testing was conducted with 10 users and included appropriate tasks based on the intended patient population in an environment representative of the intended conditions of use. Testing found that the design of the device and the instructions for use were appropriate for the intended user population.

Animal Studies

Not applicable for this device

Clinical Studies

No clinical studies were performed.

VIII. Conclusions

As detailed, the indications for use, patient population, environment of use, technology and principles of operation and performance are substantially equivalent to the predicate. The identified differences between the subject device and the predicate device conclude that there are no new risks and thus the subject device can be determined to be substantially equivalent.