K132205

JUN 0 6 2014

Submitter:	Inova Labs, Inc. 3500 Comsouth Drive Austin, TX 78744 (512) 617-1700 (T) (512) 617-1692 (F)
Contact:	Ron Yarbrough Vice President of Regulatory Affairs and Quality Assurance (512) 617-1652 (T) (512) 617-1692 (F)
Summary Preparation Date:	25 April 2014
Device Name(s):	Activox DUO_2 Oxygen Concentrator System
Common Name:	Oxygen Concentrator System
Classification Number:	21 CFR 868.5440
Device Classification:	II
Product Code:	CAW
Predicate Device(s):	Respironics L4/Everflo (K061261) Inova Activox (K072688)

Product Description:
The Activox DUO_2 Oxygen Concentrator is designed to be primarily a stationary device for home/institutional use. The LifeChoice Activox POC is a portable device that provides additional functionality of the Activox DUO_2 Oxygen Concentrator System. The Activox DUO_2 Oxygen Concentrator base unit must be connected to the LifeChoice Activox POC a minimum of once every 45 days in order for the base unit to function as intended. The intent of this feature is to ensure the user at least periodically charges the battery powered LifeChoice Activox POC. While the Activox DUO_2 is connected, it will charge the internal battery for the LifeChoice Activox POC. The Activox DUO_2 can also charge the external battery (sold separately) for the LifeChoice Activox POC after the internal battery is charged.

Indications for Use:
The Activox DUO_2 Oxygen Concentrator System is used on a prescriptive basis by patients who are diagnosed as requiring supplemental oxygen. The oxygen concentrator will provide supplemental, high oxygen concentration to these patients. It is not life supporting nor life sustaining. It may be used continuously in a home or institutional/hospital setting.

Summary of Technological Characteristics:
The technical characteristics of the Activox DUO_2 Oxygen Concentrator System by Inova Labs are equivalent to those of the predicate devices. DUO_2 and the L4 / EverFlo devices operate on the principle of pressure swing adsorption (PSA) of atmospheric nitrogen onto zeolite materials to produce concentrated oxygen from air. The oxygen concentration for the subject DUO_2 device is 90-96% which is the same as the predicate EverFlo device. The flow rate for both subject and predicate devices are substantially equivalent up to 5 LPM continuous flow. The power supply for both subject and predicate devices meet global requirements. The Activox DUO_2 offers a portable oxygen concentrator (POC) connection for battery charging not present on the L4 / EverFlo predicate device.

Substantial Equivalence:

The Activox DUO_2 Oxygen Concentrator System shares the same indications for use, device operation, overall technical and functional capabilities and therefore is substantially equivalent to the predicate device(s). The subject device, Activox DUO_2 Oxygen Concentrator System has the following similarities to the previously cleared predicate devices: same intended use, same operating principle and same technology. Design verification tests were performed on the Activox DUO_2 Oxygen Concentrator System based on input from risk analysis and product requirements. Testing performed under design controls verified the design outputs meet the required acceptance criterion and determined the subject device is substantially equivalent to the predicate device. In summary, the subject device described in this submission K132205 is as safe and as effective as the predicate Respironics L4 / EverFlo device cleared in K061261 by comparison. Following is a summary of the substantial equivalence comparison table provided within K132205 (this submission).

Substantial Equivalence Comparison Summary Table for the Activox DUO_2 System

Characteristics	*Predicate #1 (Home Concentrator)*	*Predicate #2 (POC)*	*Subject Device[1] (POC and Home Concentrator)*	*Identical and/or Substantially Equivalent*
Company Name	Respironics, Inc.	Inova Labs, Inc.	Inova Labs, Inc.	N/A
Product Name	L4 / Ever Flo Oxygen Concentrator	LifeChoice Oxygen Concentrator	DUO Oxygen Concentrator System with Base Unit / Portable Component and Accessories	N/A
510(k) number	K061261	K072688	K132205	N/A
Pro Code	CAW	CAW	CAW	Yes
Classification	Class II	Class II	Class II	Yes
Regulation	21 CFR 868.5440	21 CFR 868.5440	21 CFR 868.5440	Yes
Intended Use	The Respironics L4 Oxygen Concentrator is intended to provide supplemental oxygen to persons requiring oxygen therapy. The device is not intended to be life supporting or life sustaining. The Respironics L4 Oxygen Concentrator is intended for use in the home or hospital / institutional environment.	The LifeChoice Oxygen Concentrator is a prescriptive device intended to provide supplemental, high oxygen concentration to patients. The LifeChoice is also portable and may be used continuously in a home, institution or travel environment.	The Activox DUO_2 oxygen concentrator system is used on a prescriptive basis by patients who are diagnosed as requiring supplemental oxygen. The oxygen concentrator will provide supplemental, high concentration oxygen to these patients. It is not life supporting nor life sustaining. It may be used continuously in a home or institutional/hospital setting.	Yes
Operation Principle	Operates on the principle of pressure swing adsorption (PSA) of	Operates on the principle of pressure swing adsorption (PSA) of	Operates on the principle of pressure swing adsorption (PSA) of atmospheric	Yes

Characteristics	*Predicate #1 (Home Concentrator)*	*Predicate #2 (POC)*	*Subject Device[1] (POC and Home Concentrator)*	*Identical and/or Substantially Equivalent*
	atmospheric nitrogen onto zeolite materials to produce concentrated oxygen from air.	atmospheric nitrogen onto zeolite materials to produce concentrated oxygen from air.	nitrogen onto zeolite materials to produce concentrated oxygen from air.	
Power On/Off Switch	Yes	Yes	Yes	Yes
Circuit Breaker	Yes	N/A	Yes	Yes
Humidifier Bottle	Yes	N/A	Yes	Yes
Flow Meter/Adjustable Knob [l/min]	Yes	N/A	Yes	Yes
Cabinet Air Filter	Yes	N/A	Yes	Yes
Oxygen Filter	Information not available	Yes	Yes	Yes
Power Cord	Yes	Yes	Yes	Yes
Power LED (Indicator Light)	Yes	Yes	Yes	Yes
Alarm Indicator LED	Yes	Yes	Yes	Yes
Audible Alarm	Yes	Yes	Yes	Yes
Low Oxygen Purity Detection	OPI model only	Yes	Yes	Yes
Runtime Counter	Information not available	Yes	Yes	Yes
Handle	Yes	Yes	Yes	Yes
Specifications	***(Home Unit)***	***(Portable)***	***Base Unit***	***N/A***
Dimensions W x H x D	35x58x24 cm	24x19x7.9 cm	36x57x34 cm	Yes
Weight	14 to 15 kg.	2.3 kg	16.5 kg	Yes
Flow	0.5 – 5 LPM Continuous	1 – 3 LPM PULSE-WAVE	0 – 5 LPM Continuous	Yes
O2 Concentration	90% - 96%	87% - 93%	90% - 96%	Yes
Alarm Conditions				
Power Failure Alarm	Yes	Yes	Yes	Yes
Low Flow Condition (via Pressure)	Yes	Yes	Yes	Yes
Low Oxygen Condition	Yes	Yes	Yes	Yes
Protection for over-heat and over-load	Information not available	Yes	Yes	Yes

Characteristics	*Predicate #1 (Home Concentrator)*	*Predicate #2 (POC)*	*Subject Device[1] (POC and Home Concentrator)*	*Identical and/or Substantially Equivalent*
Safety Valve on compressor outlet	Information not available	No (Unit has a high pressure alarm)	No (Unit has a high pressure alarm)	Yes
Environmental Conditions				
Operation temperature	13°C to 32°C	5°C to 40°C	10°C to 35°	Yes (Subject device has slightly greater operating temperature range)
Operational humidity range	15% - 95%, Non-cond.	20% - 95%, Non-cond.	15% - 95%, Non-cond.	Yes
Storage temperature	-34°C to 71°C	-20°C to 60°C	0°C to 60°C	Yes
Storage Humidity Range	15% - 95%, Non-cond.	20% - 95%, Non-cond.	15% - 95%, Non-cond.	Yes
Power				
Power supply global requirements 100 to 240 VAC 50-60 Hz	120 VAC / 230 VAC 60 / 50 Hz	120 VAC / 230 VAC 50 / 60 Hz	120 VAC / 60 Hz 230 VAC / 50 Hz	Yes
Average Power	Up to 350W (dependent on model)	Up to 120W	Up to 372W	Yes (within 6.3% based on the Home Concentrator predicate)

[1] ***NOTE**: The DUO_2 System is comprised of two components, the portable oxygen concentrator (LifeChoice Activox) and the (Home) Concentrator DUO_2 Base Unit. The LifeChoice Activox is an integral part included in the purchase of the base unit. The base unit is a new product added to the Inova Labs POC product line. The LifeChoice Activox component of the DUO_2 is an existing product offered by Inova Labs, previously cleared under 510(k) #K072688 and modified in K113317.*

N/A = Not Applicable

Summary of Non-clinical Testing:

Inova Labs utilized hardware testing based on IEC 60601-1, IEC 60601-1-2; electromagnetic testing based on IEC 60601-1-2; environmental (random vibration and shock) testing based on IEC 60608-2-64, IEC 60608-2-6, IEC 60608-2-27; software testing based on ISO 62304; packaging based on ISO 2248; and device standard ISO 8359 to establish a basis for the determination of equivalence. The Activox DUO_2 performance characteristics were established by referencing the known performance characteristics of the predicate device(s). Specifications for the Activox DUO_2 System were established to assure that the predicate systems and the Activox DUO_2 System performed in an equivalent manner. Performance specifications were set utilizing national and international standards for oxygen concentrators with respect to output, indications for use, safety features and electromagnetic interference where it was established as suitable for the environment of use.

All testing was conducted which established that the Activox DUO_2 System met or exceeded its design specifications and performed equally or better than the stated performance of the predicate device(s). Conclusions drawn from this non-clinical testing demonstrate that the subject device is as safe and as effective in comparison to the aforementioned predicate devices Respironics L4 / EverFlo cleared in K061261 and LifeChoice Activox cleared in K072688 and modified in K113317.

Safety and Effectiveness Information:
The review of the indications for use and the technical characteristics demonstrate that the Activox DUO_2 Oxygen Concentrator System is substantially equivalent to the predicate devices.

Conclusion:
The Activox DUO_2 Oxygen Concentrator System was found to be substantially equivalent to the predicate device(s). The Activox DUO_2 Oxygen Concentrator System shares the same indications for use, similar design features and functional features and thus is as safe and as effective in comparison to the 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

June 6, 2014

Inova Labs, Inc.
Ron Yarbrough
Vice President, Regulatory Affairs & Quality Control
3500 Comsouth Drive, Suite 100
Austin, TX 78744

Re: K132205
Trade/Device Name: Activox DUO2™ Oxygen Concentrator System
Regulation Number: 21 CFR 868.5440
Regulation Name: Oxygen Concentrator System
Regulatory Class: II
Product Code: CAW
Dated: May 02, 2014
Received: May 08, 2014

Dear Mr. Yarbrough:

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.

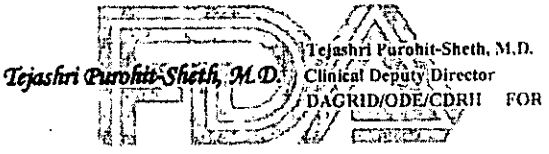
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



Erin I. Keith, M.S.
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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)*
K132205

Device Name
Activox DUO2 Oxygen Concentrator System

Indications for Use *(Describe)*
Activox DUO2 Oxygen Concentrator System is used on a prescriptive basis by adult patients who are diagnosed as requiring supplemental oxygen. The oxygen concentrator will provide supplemental, high concentration oxygen to these patients. It is not life supporting nor life sustaining. It may be used continuously in a home or institutional/hospital setting.

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)

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)*

FDA

Anya C. Harry -S
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