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

May 21, 2015

Air Liquide Healthcare
Ms. Angie Beyer
Compliance Specialist
2700 Post Oak Blvd., Suite 325
Houston, Texas 77056

Re: K143060
Trade/Device Name: Intelli-Ox
Regulation Number: Unclassified
Regulation Name: Unclassified
Regulatory Class: Unclassified
Product Code: ECX
Dated: April 20, 2015
Received: April 21, 2015

Dear Ms. Beyer:

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

Indications for Use

510(k) Number (if known):

Device Name: Intelli-Ox

Indications For Use:

The Intelli-Ox is an integrated portable oxygen delivery system intended to provide supplemental oxygen to adults. When administered by properly trained personnel for oxygen deficiency and resuscitation, the Intelli-Ox is for emergency use only. For all other medical applications, the device is Rx only.

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)

AIR LIQUIDE

510 (k) Summary
Intelli-Ox Portable Oxygen System
510(k) Number: K143060

Traditional 510(K): Premarket Notification: Intelli-Ox Portable Oxygen System

1. **APPLICANT'S/SUBMITTER'S INFORMATION**

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2. **DATE**

May 12, 2015

3. **DEVICE INFORMATION**

Trade/Proprietary Name:	Intelli-Ox
Common Name:	Portable Oxygen Delivery System
Device Name:	Cylinder, Compressed Gas, and Integrated Valve-Regulator
Classification Panel:	Anesthesiology
Classification Number:	Unclassified
Product Nomenclature:	Cylinder, Compressed Gas, and Integrated Valve-Regulator
Product Code(s):	ECX
Prior Submission :	No prior submission for the subject device.

AIR LIQUIDE

4. **DEVICE CLASSIFICATION**

Empty Compressed gas cylinders and compressed gas cylinder with valve assemblies are unclassified devices under product code ECX and reviewed by the Anesthesiology Branch, Division of Anesthesiology and Respiratory, General Hospital, Infection Control, and Dental Devices.

Individually, gas cylinder pressure regulators and gas pressure gauges are Class 1 devices and exempted from pre-market notification, but are part of the above mentioned assembly.

5. **PREDICATE DEVICE(s)**

The predicate device for the Intelli-Ox is the EZ-OX Plus, which was cleared under 510(k) K053117.

6. **DEVICE DESCRIPTION**

The Intelli-Ox portable oxygen system is a solution for supplying Oxygen USP using a device comprised of an integrated valve-regulator, flow meter and medical Oxygen aluminum cylinder with handle and shroud all integrated into a single unit. A range of user-selectable flow setting is available with the user being able to control the flow rate, including low flows that may be clinically appropriate for certain classes of patients. An additional DISS-1240 connection provides high flow oxygen delivery. When administered by properly trained personnel for oxygen deficiency and resuscitation, the Intelli-Ox is for emergency use only. For all other medical applications, the device is Rx only.

Key specifications include hose barb connection, protective shroud, carrying handle, easy to read digital content gauge, indexed flow meter, integrated valve-regulator and user instructions. This design allows medical personnel the ability to provide patient care and treatment sooner without delays caused by the need to mount a conventional regulator.

7. **INDICATIONS FOR USE**

The intended use for the modified device, as described in its labeling, has not changed as a result of the modification.

The Intelli-OX is an integrated portable oxygen delivery system intended to provide supplemental oxygen to adults. When administered by properly trained personnel for oxygen deficiency and resuscitation, the Intelli-Ox is for emergency use only. For all other medical applications, the device is Rx only.

8. **COMPARISON WITH PREDICATE DEVICE**

Very similar to the original EZ-OX Plus, the newly designed Intelli-Ox has been modified by replacing the analog gauge with a digital gauge. The gauge in both devices does not control the administration of flow, but rather is for information purposes. Both the Indications for Use and the Fundamental scientific technology of the proposed device are unchanged from the legally marketed device (predicate). A summary comparison of technological characteristics, including design and materials is provided in the table below:

Parameter	EZ-OX Plus	Intelli-Ox
Valve/Regulator		
Low Flow Settings	Yes (≥ .5L)	Yes (≥ .5L)
Flow Between Settings	No	No
Cylinder on/off	No	No
Filling Port	Active	Active
Contents Gauge	Active	Active
Filters	3	3
Pressure Design	3,000 psi (max)	3,000 psi (max)
Single stage piston style	Yes	Yes
Guard		
Hand Grip	1 grip	1 grip
Access Ports	Yes	Yes
Flow selector/ hose barb/ gauge aligned	Yes	Yes
Color	Green	Green
Height (guard and integrated valve-regulator)	7”	7”
Cylinder		
Cylinder Sizes	E	E
Weight (E) (product)	950 gr	950gr
Materials/construction	Aluminum	Aluminum

The technological characteristics of the EZ-OX Plus (predicate device) and the Intelli-Ox (modified device) are the same.

9. SUMMARY OF NON-CLINICAL TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

The Intelli-Ox system complies with the following industry and international standards that are applicable to medical gas regulators:

- ISO 14971: Medical Device Risk Management
- ISO 13485: Medical Device Quality Management System
- IEC 60513 ed. 2.0 (1994-01): Fundamental Aspects of Safety Standards for Medical Electrical Equipment
- United Nations Manual of tests and Criteria, 4th Edition revised with Amendment 2, Part III, Classification Procedures, Test Methods, and Criteria Relating to Class 3, Class 4 Division 5.1 and Class 9, Section 38.3, Lithium Batteries
- International Protection Rating (IP) of IP55
- IEC 61326-2-6-2 2nd Ed. 2012, EMC requirements, Medical Equipment
- ISO 21730 2nd Ed. 2007, Recommendations for Electromagnetic Compatiblity
- IEC 61000-6-4 2nd Ed. 2006-07, Electromagnetic Compatibility
- IEC 60601-1-2 Electrical Equipment Healthcare Application
- IEC 60601-1-2 Ed. 4.0, Medical Electrical Equipment
- ISO 10651-3 Electromagnetic Compatibility
- Title 21 of the U.S. Code of Federal Regulations (21 CFR) Parts 210 and 211

10. STATEMENT OF SUBSTANTIAL EQUIVALENCE

Based upon the performance testing and compliance with voluntary standards, the manufacturer believes that the Intelli-OX portable oxygen delivery system is substantially equivalent to the predicate device, and does not raise any new questions of safety and effectiveness.