DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 13, 2017

Air Liquide Healthcare America Corporation
Steve Miller
Director, Quality and Regulatory Affairs
12800 West Little York Road
Houston, Texas 77041-2280

Re: K161179
Trade/Device Name: Intelli-OX
Regulation Number: 21 CFR 868.2700
Regulation Name: Pressure Regulator
Regulatory Class: Class I
Product Code: ECX
Dated: February 13, 2017
Received: February 21, 2017

Dear Steve Miller:

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 yours,

Michael J. Ryan -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161179

Device Name
Intelli-OX

Indications for Use *(Describe)*
The Intelli-OX is an integrated portable oxygen delivery system intended to provide supplemental oxygen to adults. The device is MR Conditional and suitable for use during MR imaging for MRI systems up to 3.0 Tesla. 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510 (k) Summary
Intelli-Ox
510(k) Number: __K161179____

The following summary is provided in accordance with 21 CFR 807.92:

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

Air Liquide Healthcare America Corporation
12800 West Little York Road
Houston, TX 77041

Direct Phone:	800-624-8000
Internet:	www.us.airliquide.com
Establishment Registration No:	3003764448
Contact:	Steven Miller
Contact's Phone:	713-896-2280
Contact's Fax:	713-803-7427

2. **DATE**

April 20, 2016

3. **DEVICE INFORMATION**

Trade/Proprietary Name:	Intelli-Ox (E cylinders)
Common Name:	Portable Oxygen Delivery System
Device Name:	Cylinder, Compressed Gas, and Integrated Valve-Regulator
Classification Panel:	Anesthesiology
Classification Number:	Class 1
Regulation:	868.2700
Product Code(s):	ECX

Prior Submission: No prior submission for the subject device

4. DEVICE CLASSIFICATION

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

5. PREDICATE DEVICE(S)

The following device is the legally marketed device to which equivalence is being claimed:

- Intelli-Ox, K143060, Air Liquide Healthcare

6. DEVICE DESCRIPTION

The Intelli-OX portable oxygen delivery system that supplies Oxygen USP using a device comprised of an integrated valve-regulator, flow meter and medical 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 standard high flow oxygen delivery. When administered by properly trained personnel for oxygen deficiency and resuscitation, 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 content gauge, indexed flow meter, and integrated valve-regulator. 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. The device is MR Conditional and suitable for use during MR imaging for MRI systems up to 3.0 Tesla.

7. INDICATIONS FOR USE

The intended use for the proposed device, as described in its labeling, will include a statement that the device is MR Conditional and suitable for use during MR imaging for MRI systems up to 3.0 Tesla.

The Intelli-OX is an integrated portable oxygen delivery system intended to provide supplemental oxygen to adults. The device is MR Conditional and suitable for use during MR imaging for MRI systems up to 3.0 Tesla. 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. COMPARISION WITH PREDICATE DEVICE

The Intelli-OX with MR Conditional Indication is the same unit as the predicate device. The fundamental scientific technology of the proposed device is unchanged from the legally marketed predicate devices. The Intelli-OX with MR Conditional Indication adds a new indication for use. The new indication for use reflects the device being MR Conditional and suitable for use during MR imaging for MRI systems up to 3.0 Tesla. The device labeling for the Intelli-OX with MR Conditional Indication has been revised to reflect the additional indication for use. The change to the indications for use and device labeling does not raise any new questions of safety and effectiveness.

9. TESTING DATA

MRI performance testing was completed and documentation was provided to FDA in support of the substantial equivalence determination.

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

The Intelli-Ox systems are MR Conditional and comply with:

- ASTM F2052-15, "Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment"
- ISO TIR 10974, 2012, Clause 21, "Assessment of the Safety Magnetic Resonance Imaging for Patients with an Active Implantable Medical Device"

11. STATEMENT OF SUBSTANTIAL EQUIVALENCE

Based upon the MRI performance testing that is documented in this submission, the manufacturer believes that the proposed Intelli-Ox device is substantially equivalent to the predicate device, and does not raise any new questions of safety and effectiveness.