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

November 18, 2016

Essex Industries, Inc.
c/o Paul Dryden
Consultant
7700 Gravois
St. Louis, Missouri 63123

Re: K161472
Trade/Device Name: Walk-O2-Bout®
Regulation Number: 21 CFR 868.2700
Regulation Name: Pressure Regulator
Regulatory Class: Class I
Product Code: ECX
Dated: October 20, 2016
Received: October 21, 2016

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 and Part 809); 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 and Part 809), 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,

*Tejashri Purohit-Sheth, M.D.*

**Tejashri Purohit-Sheth, M.D.**
**Clinical Deputy Director**
**DAGRID/ODE/CDRH 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 on last page.*

510(k) Number *(if known)*

**K161472**

Device Name

**Walk-$O_2$-Bout®**

Indications for Use *(Describe)*

The Walk-$O_2$-Bout® is an integrated portable oxygen delivery system intended to provide supplemental oxygen to pediatrics and adults in hospital, sub-acute care, and pre-hospital / ground transport settings. It is offered in models that are MR-conditional (per ASTM F2052-15), and intended for use during MR imaging for static magnetic fields of 3.0 T or less. Compressed gas cylinders in service or in storage shall be stabilized or otherwise secured to prevent falling and rolling.

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)*

Essex Industries, Inc.
7700 Gravois
St. Louis, MO 63123

| | |
|---|---|
| **Official Contact:** | Russ Jacobsmeyer – Vice President of Engineering<br>Tel – 314.338.8723 |
| **Proprietary or Trade Name:** | Walk-$O_2$-Bout® |
| **Common/Usual Name:** | Cylinder, Compressed Gas, and Valve |
| **Classification Name/Code:** | ECX - Cylinder, Compressed Gas, and Valve<br>21 CFR 868.2700, Class I |
| **Predicate Device:** | K101792 – Linde – LIV Portable Oxygen System |

**Device Description:**
The **Walk-$O_2$-Bout®** regulator is designed to be installed on a medical grade aluminum cylinder having 0.750-16 UNF-2B threads; regulate high pressure oxygen from 300-2000 psig nominal; deliver a prescribed amount of oxygen; and be ignition fault resistant.

The device consists of:

- A threaded fill fitting per CGA 540. It shall allow the regulator installed on a cylinder to be refilled to its service pressure. It also allows for the pulling of a vacuum on the system.
- A pressure regulator section to reduce the pressure from 300-2000 psig to 50 psig nominal.
- Options of flow selector valves to control the flow between 0 and 25 L/min, at the regulated pressure.
- A vinyl dipped handle for ease of carrying.
- A DISS 1240 check valve to deliver 50 psig of oxygen high flow rates of oxygen to ventilators.

There are several models offered. In all cases the basic pressure regulator is identical for all models. The models are offered with the following options:

- Flow rate range of 0 - 4 L/min (Pediatric), 0 - 15 L/min and 0 – 25 L/min (adult)
- Check Valve
- Swivel or Fixed Barb Fitting
- Handle style
- MR Conditional

**Indications for Use:**
The Walk-O2-Bout® is an integrated portable oxygen delivery system intended to provide supplemental oxygen to pediatrics and adults in hospital, sub-acute care, and pre-hospital / ground transport settings. It is offered in models that are MR-conditional (per ASTM standard F2052-15), and intended for use during MR imaging for static magnetic fields of 3.0 T or less. Compressed gas cylinders in service or in storage shall be stabilized or otherwise secured to prevent falling and rolling.

**Patient Population:** Patients requiring supplement oxygen, Pediatrics and adults

**Environments of Use:** Hospital, sub-acute care, and pre-hospital / ground transport settings

**Contraindications:** None.

**Summary of substantial equivalence**
The proposed Walk-$O_2$-Bout® has been compared to the predicate K101792 – Linde – LIV Portable Oxygen System, see **Table 1**.

**Device Comparison**

| Description | Predicate Device K101792 | Subject Device WOB |
|---|---|---|
| **Device Name** | LIV | WALK-$O_2$-BOUT® |
| **Device Classification & Product code** | Class I / ECX 868.2700 | Class I / ECX 868.2700 |
| **Prescription Device:** | Yes | Yes |
| **Indications for Use** | The LIV is an integrated portable oxygen delivery system intended to provide supplemental oxygen to pediatrics and adults. The device is MR-conditional (per ASTM standard 2503-05*), and intended for use during MR imaging for MRI systems up to 3.0T. Rx only.<br><br>Compressed gas cylinders in service or in storage shall be stabilized or otherwise secured to prevent falling and rolling. | The Walk-$O_2$-Bout® is an integrated portable oxygen delivery system intended to provide supplemental oxygen to pediatrics and adults in hospital, sub-acute care, and pre-hospital / ground transport settings. It is offered in models that are MR-conditional (per ASTM F2052-15), and intended for use during MR imaging for static magnetic fields of 3.0 T or less.<br><br>Compressed gas cylinders in service or in storage shall be stabilized or otherwise secured to prevent falling and rolling. |
| **Environments of Use** | Hospital, sub-acute care, and pre-hospital / ground transport settings<br><br>Imaging suites | Hospital, sub-acute care, and pre-hospital / ground transport settings<br><br>Imaging suites |
| **Patient population** | Patient requiring supplemental oxygen<br><br>Models offered at different flow rates for use with patient populations as determined by the clinician | Patient requiring supplemental oxygen<br><br>Models offered at different flow rates for use with patient populations as determined by the clinician |
| **Flow selector and Flow Outlet control** | Yes | Yes |
| **Nominal pressure outlet** | 50 psig | 50 psig |
| **Cylinder On/Off** | Yes | Yes |
| **Filling Port** | Yes | Yes |
| **Contents Gauge** | Yes / active | Yes / active |
| **Excess Flow** | No | Yes |
| **Burst Disk** | Yes | Yes |
| **Single stage piston type** | Yes | Yes |
| **Hand grip** | Yes | Yes |
| **Oxygen cylinder size** | E | E |

| Description | Predicate Device K101792 | Subject Device WOB |
|---|---|---|
| **Access ports** | Yes | Yes |
| **MR Conditional** | 3.0 Tesla or less | 3.0 Tesla or less |
| **Maximum Pressure Inlet** | 2000 – 3000 psig | 2000 psig |
| **DISS 1240 fittings** | Yes | Yes |
| **Flow rates** | 0-25 L/min<br>Offered with difference flow rates | 0-4 lpm<br>0-15 lpm<br>0-25 L/min |
| **Flow accuracy** | ±10% | ±10% |
| **Operating Pressure range** | Up to 3000 psig | 300-2000 psig |
| **Outlet pressure range** | 48-65 psi | 48-65 psi |
| **Operating Temperature Range** | | -20°F to 130°F |
| **Standards** | ISO 10524-3<br>ASTM G173-03<br>CGA E-7<br>CGA 540<br>ASTM F2503-05* | ISO 10524-3<br>ASTM G175-03<br>CGA E-7<br>CGA G4.1<br>ASTM F2052-15* |
| **Materials of Construction** | Basic materials include non-magnetic materials to meet the ASTM F2052 requirements for MR conditional use.<br><br>Components are comprised on brass, aluminum, silicone, stainless steel | Basic materials include non-magnetic materials to meet the ASTM F2052 requirements for MR conditional use.<br><br>Components are comprised on brass, aluminum, silicone, stainless steel |
| **Biocompatibility** | Externally communicating, Tissue, Permanent Duration | Externally communicating, Tissue, Permanent Duration<br>VOC<br>$PM_{2.5}$ |

*Note ASTM F2503-05 is a device marking and labeling standard whereas ASTM F2052-15 is the Testing and Performance standard.

The proposed **Walk-$O_2$-Bout®** is viewed as substantially equivalent to the predicate device. In the table above, we have outlined the similarities and differences, if any, between the subject device and the predicate.

**Indications –**

- The **Walk-$O_2$-Bout®** is an integrated oxygen pressure regulator intended to provide supplemental oxygen to patients. It is available in non-MR and MR conditional styles depending upon their respective environment of use.
- **Discussion** – This is similar to the predicate – K101792 – Linde – LIV (Linde Integrated Valve), there are no differences except clarification of the environments of use. This difference does not raise different questions of safety and effectiveness.

**Patient Population –**

- It is intended for patient requiring supplemental oxygen, pediatric to adults.

- **Discussion** – The patient population is similar to the predicate – K101792 – Linde – LIV (Linde Integrated Valve).

**Environment of Use –**

- For use in professional healthcare settings – hospitals, ambulatory, imaging centers, pre-hospital.
- **Discussion** – The environments of use are similar to the predicate – K101792 – Linde – LIV (Linde Integrated Valve).

**Technology** –

- The principle of pressure regulating is based upon a single stage piston style with adjustable flow rates, flow gauge, burst disk, handle. The models and styles may vary with different flow rates, handles, oxygen fittings but in all cases the technology is similar.
- **Discussion** – This technology is similar to the predicate – K101792 – Linde – LIV (Linde Integrated Valve). There are no differences in technology, design, and model styles offered do not raise different questions of safety and effectiveness.

**Specifications –**

The performance specifications were evaluated and compared:

- Maximum inlet pressure
- Outlet pressure
- Flow rate ranges – 0-25 lpm available with different ranges for user preference
- Flow rate and Pressure accuracy
- Testing per ASTM F2052 for MR Conditional use
- Meeting applicable CGA standards
- **Discussion -** The subject device is similar to the predicate in all faucets of performance and specifications and any differences do not raise different questions of safety and effectiveness.

**Differences**

- As discussed in the above none of the differences raise different questions of safety and effectiveness.

**Non-clinical Testing Summary -**

We have performed a number of tests appropriate for the proposed device. These tests are listed in CGA E-7 as guidelines in design and manufacturing of high pressure valves. These tests include:

- Acceptance Test Procedure
- Low temperature
- High temperature
- Gas tightness (creep and leakage)
- Flow regulation (Flow capacity)
- Outlet Flow vs. inlet pressure
- Pressure regulation
- Static increment
- Pressure relief
- Mechanical resistance
- Endurance Inlet
- Fill fitting endurance

- Safety
- Drop
- Vibration and Shock
- Proof pressure
- Burst pressure
- Ignition (ASTM G175)
- MR Conditional Testing per ASTM F2052-15 (Note testing was done according to ASTM F2052-06).
- Biocompatibility

**Bench Testing -**

- The performance testing is based upon standards for material, construction, ignition, MRI compatibility, and accuracy. Direct comparative testing is not required as the specifications as well understood.
- **Discussion –** Based upon the testing and comparison to the standards and the available information on the predicate, we can find the subject device and the predicate substantially equivalent.

**Biocompatibility of Materials –**

- The materials were evaluated per ASTM G175-03 for ignition and for biocompatibility via VOC and $PM_{2.5}$. The testing demonstrated that the materials were safe for their intended use.
- **Discussion –** The materials were found to be compatible for their intended use and similar to the predicate.

**Clinical Testing Summary -**

There was no clinical testing.

**Substantial Equivalence Conclusion:** The sponsor has demonstrated through performance testing and non-clinical testing that the proposed device is substantially equivalent to the predicate.