DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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March 2, 2017

Essex Industries, Inc.
% Paul Dryden
Consultant
7700 Gravois
St. Louis, Missouri 63123

Re: K162811
Trade/Device Name: MR Conditional CGA 870
Regulation Number: 21 CFR 868.2700
Regulation Name: Pressure Regulator
Regulatory Class: Class I
Product Code: CAN
Dated: January 27, 2017
Received: January 31, 2017

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); 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,

Lori A. Wiggins -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)*
K162811

Device Name
MR Conditional CGA 870

Indications for Use *(Describe)*
The Essex MR Conditional CGA 870 pressure regulators are used with a portable oxygen delivery system intended to provide supplemental oxygen to 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 may be used during MR imaging for static magnetic fields of 3.0 T or less.

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

Official Contact: Russ Jacobsmeyer – Vice President of Engineering
Tel – 314.338.8723

Proprietary or Trade Name: Essex MR Conditional CGA 870

Common/Usual Name: Cylinder, Compressed Gas, and Valve

Classification Name/Code: CAN - Cylinder, Compressed Gas, and Valve
Class I, 21 CFR 868.2700

Predicate Device: Essex CGA 870 oxygen pressure regulator (Class 1, exempt)
Reference Device: K101792 – Linde – LIV Portable Oxygen System

Device Description:
The Essex MR Conditional CGA 870 pressure regulator is designed to be installed on a medical CGA 870 post valve cylinder, regulate high pressure oxygen from 500 to 2,000 psig nominal, deliver a specific amount of oxygen to an attached flow selector, and be ignition resistant.

The device consists of:

- A yoke style inlet fitting per CGA 870.
    - The regulator can be installed on any cylinder with a CGA 870 connection.
- A pressure regulator section is to reduce the pressure from 500-2,000 psig to 50 psig nominal.
- A flow selector valve to control the flow at the regulated pressure between 0 and 25 L/min.
- Made of materials which meet the MR Conditional requirements of ASTM F2052-15.

This is identical to our Class I, exempt model CGA 870 except for different materials to allow for the device to meet the ASTM F2052-15 - Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment.

Indications for Use:
The Essex MR Conditional CGA 870 pressure regulators are used with a portable oxygen delivery system intended to provide supplemental oxygen to 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 may be used during MR imaging for static magnetic fields of 3.0 T or less.

Environments of Use: Their environments of use include all healthcare settings including:

- Hospital, including intra-hospital transport
- Outpatient
- Imaging center (MRI Suite)
- Pre-hospital

Contraindications: None.

Summary of substantial equivalence

The proposed device has been compared to the predicate Essex CGA 870 oxygen pressure regulator (Class 1, exempt) for the technical characteristics, see **Table 1** and the reference device for environment of use, MR Conditional, and see **Table 2**.

Device Comparison

Table 1 – Comparison of Predicate Essex CGA 870 to the Subject Device – MR Conditional CGA 870

Description	**Predicate CGA 870 Device, Class I, exempt**	**Subject Device MR Conditional CGA 870**
Device Name	CGA 870	MR Conditional CGA 870
Device Classification & Product code	Class I / CAN	Class I / CAN
Prescription Device	Yes	Yes
Indications for Use	The Essex CGA 870 pressure regulator is a portable oxygen delivery system intended to provide supplemental oxygen too pediatrics and adults in hospital, sub-acute care, and pre-hospital / ground transport settings.	The Essex MR Conditional CGA 870 pressure regulators are used with a portable oxygen delivery system intended to provide supplemental oxygen to 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 may be used during MR imaging for static magnetic fields of 3.0 T or less.
Flow selector and Flow Outlet	Yes	Yes
Fixed pressure outlet	Yes ~ 50 psig	Yes ~ 50 psig
Cylinder On/Off	Yes	Yes
Filling Port	No When cylinder is empty the device is attached to a new cylinder	No When cylinder is empty the device is attached to a new cylinder
Contents Gauge	Yes / active	Yes / active
Excess Flow	No	No
Burst Disk	Burst Disk is located on the cylinder post valve.	Burst Disk is located on the cylinder post valve.
Single stage piston type	Yes	Yes
MR Conditional	N/A	3.0 Tesla or less
Pressure Inlet	2000 psig	2000 psig
Flow rates	0-25 L/min	0-25 L/min
Operating Pressure range	500-2000 psig	500-2000 psig
Operating Temperature Range	-20°F to 130°F	-20°F to 130°F

Description	Predicate CGA 870 Device, Class I, exempt	Subject Device MR Conditional CGA 870
Standards	ISO 10524-1 CGA E-4 CGA E-7 EN 738-1	ISO 10524-1 CGA E-4 CGA E-7 EN 738-1 ASTM F2052-15
Biocompatibility	Externally communicating, Tissue, Permanent duration VOC PM2.5	Externally communicating, Tissue, Permanent duration VOC PM2.5

Table 2 – Comparison of Reference Linde LIV (K101792) to the Subject Device – MR Conditional CG 870

Description	Reference Device Linde LIV - K101792	Subject Device MR Conditional CGA 870
Device Name	LIV	MR Conditional CGA 870
Device Classification & Product code	Unclassified/ECX	Class I / CAN
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 F2503-05*), and intended for use during MR imaging for MRI systems up to 3.0T. Compressed gas cylinders in service or in storage shall be stabilized or otherwise secured to prevent falling and rolling.	The Essex MR Conditional CGA 870 pressure regulators are used with a portable oxygen delivery system intended to provide supplemental oxygen to 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 may be used during MR imaging for static magnetic fields of 3.0 T or less.
Flow selector and Flow Outlet	Yes	Yes
Fixed pressure outlet	Yes ~ 50 psig	Yes ~ 50 psig
Cylinder On/Off	Yes	Yes
Filling Port	Yes	When cylinder is empty the device is attached to a new cylinder
Contents Gauge	Yes / active	Yes / active
Excess Flow	No	No
Burst Disk	Yes integral to the system	Burst Disk is located on the cylinder post valve.
Single stage piston type	Yes	Yes
Hand grip	Yes	No
Access ports	Yes	No
MR Conditional	3.0 Tesla	3.0 Tesla or less
Pressure Inlet	2000 psig	2000 psig

Description	Reference Device Linde LIV - K101792	Subject Device MR Conditional CGA 870
DISS 1240 fittings	Yes	No Not applicable
Flow rates	0-25 L/min	0-25 L/min
Operating Pressure range	Up to 3000 psig	500-2000 psig
Operating Temperature Range		-20°F to 130°F
Standards	ISO 10524-3 ASTM G173-03 CGA E-7 CGA 540 ASTM F2503-05*	ISO 10524-1 CGA E-4 CGA E-7 EN 738-1 ASTM F2052-15*
Biocompatibility	Externally communicating, Tissue, Permanent duration	Externally communicating, Tissue, Permanent duration VOC $PM_{2.5}$

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

The proposed MR Conditional CGA 870 is viewed as substantially equivalent to the predicate device for the performance, intended use and technical characteristics and the reference device for the addition of the MR conditional environment of use. In the tables above, we have outlined the similarities and differences, if any, between the subject device, the predicate and reference devices.

Indications –

- The MR Conditional CGA 870 is a standalone oxygen pressure regulator intended to provide supplemental oxygen.
- **Discussion** – The indications for the predicate and reference are similar with the predicate. One can find the indications for use to be similar and the differences do not raise any concerns of safety or effectiveness compared to the predicate or reference devices.

Patient Population –

- It is intended for adult patients requiring supplemental oxygen
- **Discussion** – The patient population is similar to the predicate and reference device. There are no differences that raise any concerns of safety or effectiveness compared to the predicate or reference devices.

Environment of Use –

- For use in all healthcare settings – hospitals, ambulatory, imaging centers, pre-hospital.
- **Discussion** – The environments of use are similar to the predicate and reference devices. The addition of MR Conditional use has been demonstrated to meet the standard which would not raise any new concerns of safety and effectiveness**.**

Technology –

- The principle of pressure regulating is based upon a single stage piston style with adjustable flow rates, flow gauge, burst disk and use of a separate cylinder.

- **Discussion** – This technology is identical to the predicate device and similar to the reference.

Differences
The only difference between the reference and the subject device is the change in materials to be MR Conditional. The difference between the reference and the subject device is that the predicate is an integrated regulator and the subject device is not. **Discussion** – These differences do not raise any new concerns of safety or effectiveness.

Non-clinical Testing Summary -

We have performed a number of tests appropriate for the proposed device. These tests include:

- **CGA E-4: Standard for Gas Pressure Regulators**
  - par. 4.1 Operating Temperature Range
  - par. 4.2.2.3 Resistance to Ignition (Oxygen Service)
  - par. 4.4 Gas Tightness
  - par. 4.5 Mechanical Resistance
  - par. 4.6 Endurance
  - par. 5.4 Pressure Relief Devices
  - par. 6.1 Pressure Regulation Coefficient, i
  - par. 6.2 Static Increment, SI
  - par. 6.3 Flow Regulation
  - par. 6.4 Flow Capacity
- **CGA E-7: American National Standard for Medical Gas Regulators and Flowmeters**
  - par. 5.4 Relief Valves
  - par. 5.6.1 Minimum Burst Strength
  - par. 5.6.2 Leakage
  - par. 5.7 Temperature for Storage and Operation
- **ISO 10524: Pressure Regulators and Pressure Regulators with Flow-Metering Devices for Medical Gas Systems**
  - par. 7.3 Pressure relief valve
  - par. 7.5 Resistance to ignition
  - par. 7.8 Gas tightness
  - par. 7.9.3 Mechanical resistance (high pressure section burst)
  - par. 7.9.4 Mechanical resistance (low pressure section burst)
  - par. 8.0 Environmental temperatures
- **EN 738-1: Pressure Regulators for use with Medical Gases**
  - par. 5.4.2.7 Performance, functional, and flow characteristics
  - par. 5.4.2.8 Relief valve
  - par. 5.4.2.9 Leakage
  - par. 5.4.2.10 Mechanical Strength
  - par. 5.4.2.11 Resistance to ignition
- MR Conditional Testing per ASTM F2052-15 (Note testing was done according to ASTM F2052-06 but there are no testing differences between the 2006 version and the 2015 version.
- Biocompatibility (VOC and $PM_{2.5}$)

Bench Testing -

- The performance testing is based upon standards for material, construction, ignition, MRI compatibility, and accuracy.

- **Discussion –** Based upon the testing and comparison to the standards, we can find the subject device and the predicate and reference devices to be substantially equivalent.

Biocompatibility of Materials –

- ISO 10993-1 would consider the materials in the gas pathway as – Externally communicating, Tissue / Dentin / Bone contact, Permanent Duration.
- The materials were evaluated per CGA E-4 for ignition and for biocompatibility via VOC and $PM_{2.5}$. The testing demonstrated that the materials were biocompatible for their intended use.
- **Discussion –** The materials were found to be compatible for their intended use and identical to the reference.

Animal Testing:

There was no animal testing.

Clinical Testing:

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 and reference devices.