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

April 17, 2015

Western/Scott Fetzer Co.
Mr. David C. Simo
Director of Quality and Regulatory
875 Bassett Road
Westlake, OH 44145-1142

Re: K142149
Trade/Device Name: OxyTote Infinity Series VIPR Systems and Praxair Grab 'n Go Opti Series VIPR systems
Regulation Number: Unclassified
Regulation Name: Cylinder, Compressed Gas, and Valve
Regulatory Class: Unclassified
Product Code: ECX
Dated: March 17, 2015
Received: March 20, 2015

Dear Mr. Simo:

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,

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): K142149

Device Name: OxyTOTE Infinity series VIPR systems and Praxair Grab 'n Go Opti series VIPR systems

Indications for Use:

For OxyTOTE Infinity:

> *"The OxyTOTE Infinity system is an integrated delivery system intended to provide supplemental oxygen, by Rx only, to patients. When administered by properly trained personnel for oxygen deficiency and resuscitation, the device is for emergency use only. For all other medical applications, the device is Rx only. The device is MR Conditional and suitable for use during MR imaging for MRI systems up to 3.0 Tesla and cannot be used directly in the MRI bore. The device is intended for limited duration use, such as would be necessary during patient transports."*

For Praxair Grab 'n Go Opti:

> *"The Grab 'n Go Opti system is an integrated delivery system intended to provide supplemental oxygen, by Rx only, to patients. When administered by properly trained personnel for oxygen deficiency and resuscitation, the device is for emergency use only. For all other medical applications, the device is Rx only. The device is MR Conditional and suitable for use during MR imaging for MRI systems up to 3.0 Tesla and cannot be used directly in the MRI bore. The device is intended for limited duration use, such as would be necessary during patient transports."*

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) SUMMARY
AS REQUIRED BY SECTION 807.92(c)

1. 510(k) Owner's Name, Address, Telephone Number, Fax Number, Contact Person

Western / Scott Fetzer Co
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Phone: (440) 871-2160
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Contact Person:

David C. Simo
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2. Date Prepared

April 17, 2015

3. Device Information

Trade/Proprietary Name:	OxyTOTE Infinity series VIPR systems and Praxair Grab 'n Go Opti series VIPR systems
Common Name:	Portable Oxygen Delivery System
Device Classification Name:	Cylinder, Compressed Gas, and Valve
Classification Product Code:	ECX

4. Predicate Device

The predicate device for the OxyTOTE Infinity and Praxair Grab 'n Go Opti series VIPR Systems is the EZ-OX Plus Generation II, which was cleared under 510(k) K131386. Western would like to advise that they were also the manufacturer of this device.

5. Device Description

The OxyTOTE Infinity and Praxair Grab 'n Go Opti series VIPR (Valve Integrated Pressure Regulator) Systems provide a package for those who need medical oxygen from portable cylinders. The oxygen regulator, analog pressure gauge, cylinder contents indicator and gas supply valve are combined, and permanently attached to the gas cylinder as one system. This design allows medical personnel the ability to provide patient care and treatment without the need to mount a conventional separate regulator.

The regulator reduces cylinder pressure and provides 10 user selectable flow rates (½, 1, 1½, 2, 3, 4, 6, 8, 15, 25 LPM) of USP oxygen that may be clinically appropriate for certain classes of patients. An additional DISS-1240 connection provides flow rates up to 100 LPM oxygen delivery. When administered by properly trained personnel for oxygen deficiency and resuscitation, the device is for emergency use only. For all other medical applications, the device is Rx only.

Key features include; hose barb connection, protective shroud, carrying handle, cylinder content gauge, indexed flow meter, shutoff valve, and AUX (DISS-1240) connection.

6. Device Function

The device is an integrated portable oxygen delivery system intended to provide supplemental oxygen to patients. This is a multiple use product that is used in healthcare applications (hospitals, clinics and ambulance use), where medical grade oxygen gas is required at prescribed flow rates or as determined by the emergency medical provider. When administered by properly trained personnel for oxygen deficiency and resuscitation, the device is for emergency use only. For all other medical applications, the device is Rx only.

In comparison to the predicate device, the OxyTOTE Infinity and Praxair Grab 'n Go Opti series VIPR systems incorporate the following additional features:

1. The fill valve includes a reverse flow check valve to prevent gas from exiting the fill port. The predicate device has a manual shutoff valve that requires a proprietary tool to actuate.
2. The fill valve is biased in an open position during cylinder evacuation process, and closes automatically when the device is disconnected from the fill rack. The valve on the predicate device must be manually opened during the evacuation process and manually closed before disconnecting from the fill rack.
3. The cylinder Pressure Relief Device (PRD) operates when a specific pressure has been reached. The predicate device PRD only operates when specific temperature and pressure requirements are met, meaning the PRD will not open if the cylinder is overfilled until exposed to an external heat source.
4. A Cylinder Contents Indicator (CCI) provides an indication of the cylinder contents in addition to the pressure gauge providing an assessment of cylinder content levels.
5. A high pressure shutoff valve which prevents gas from flowing into the pressure regulator. The predicate device is less redundant since it does not have a high pressure shutoff function resulting in more potential leak paths to be pressurized during transport and storage.

7. Design Description

The cylinder (Figure 1, item 13) is filled with Oxygen gas through the gas specific fill port (1) connection. The gas entering the fill port pushes open the check valve (2) allowing gas to flow through the valve body and into the cylinder (13). Once the cylinder is filled, the connection is detached from the fill port (1), and the fill port check valve (2) will automatically close to retain the pressure within the device. The gas pressure in the cylinder is indicated on the pressure gauge (12).

To deliver calibrated flow the practitioner opens the shutoff valve (3) by rotating the flow control knob (4) clockwise to the desired flow setting. Gas is then permitted to flow into the regulator (5) portion of the device where cylinder pressure (up to 3000 psig) is reduced to around 50 psig. This regulated gas goes downstream to feed the flow control (6) portion of the device where thee gas flows through an orifice (8) to provide a calibrated flow out the outlet barb (9). The gas flows through a nasal cannula or mask (not shown and not provided with the device) to the patient.

The flow control knob (7) can also be rotated to the AUX position, which opens the shutoff valve (3) and allows the gas to flow into the pressure regulator (5) portion of the device. This permits gas to be supplied through the AUX port connection (10) while preventing simultaneous flow from the outlet barb (9). The AUX port will provide flow up to 100 LPM when the demand valve is actuated by connecting fitting to the AUX outlet connection.

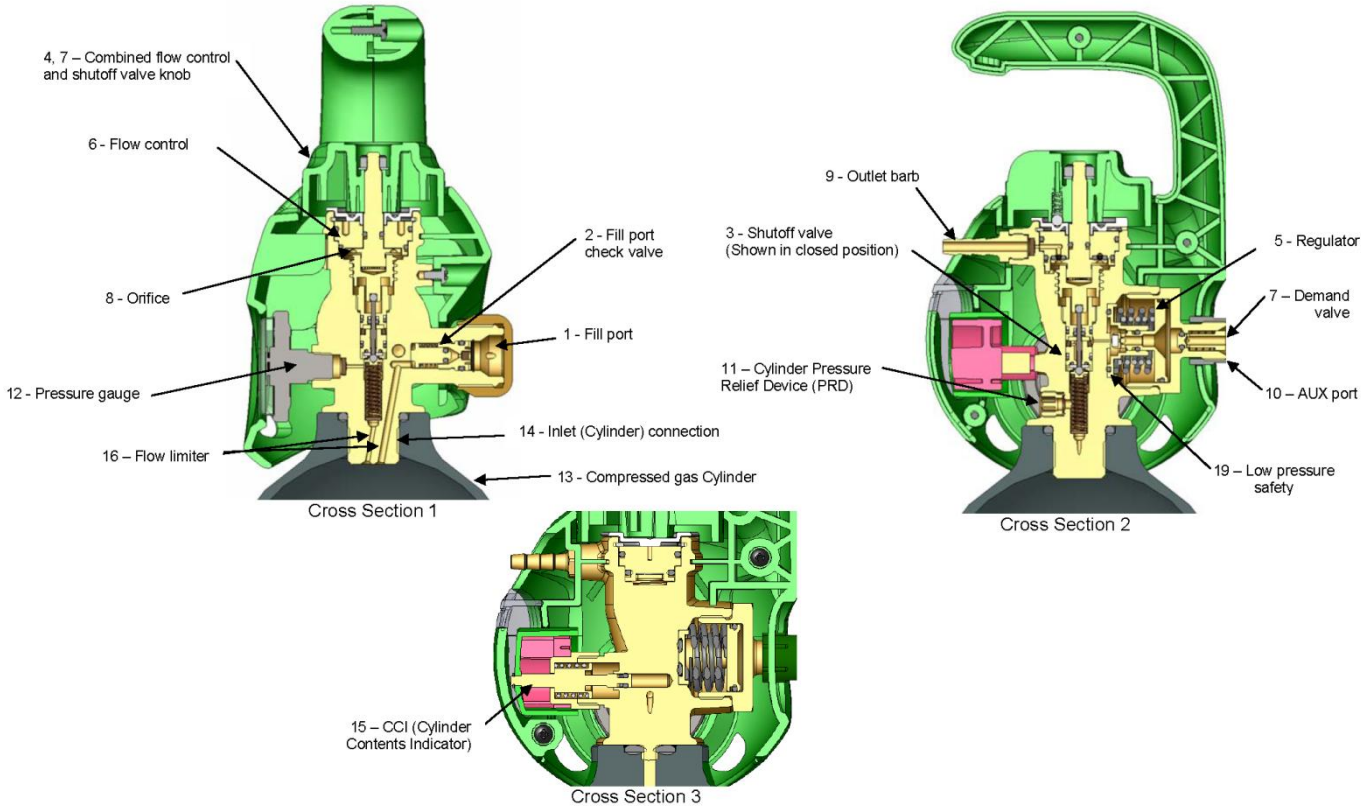

Figure 1 - OxyTOTE Infinity and Praxair Grab 'n Go Opti series VIPR Systems

8. Intended Use

For OxyTOTE Infinity:
"The OxyTOTE Infinity system is an integrated delivery system intended to provide supplemental oxygen, by Rx only, to patients. When administered by properly trained personnel for oxygen deficiency and resuscitation, the device is for emergency use only. For all other medical applications, the device is Rx only. The device is MR Conditional and suitable for use during MR imaging for MRI systems up to 3.0 Tesla and cannot be used directly in the MRI bore. The device is intended for limited duration use, such as would be necessary during patient transports."

For Praxair Grab 'n Go Opti:
"The Grab 'n Go Opti system is an integrated delivery system intended to provide supplemental oxygen, by Rx only, to patients. When administered by properly trained personnel for oxygen deficiency and resuscitation, the device is for emergency use only. For all other medical applications, the device is Rx only. The device is MR Conditional and suitable for use during MR imaging for MRI systems up to 3.0 Tesla and cannot be used directly in the MRI bore. The device is intended for limited duration use, such as would be necessary during patient transports."

9. Summary of Technological Characteristics

A summary comparison of technological characteristics, including design and materials is provided in the table below:

Feature	OxyTOTE Infinity and Praxair Grab 'n Go VIPR Systems	EZ-OX Plus Generation II (Predicate)	Explanation of Differences
510(k) Number	K142149	K131386	NA
Clearance Date	TBD	March 14, 2014	NA
Indications for Use	The (OxyTOTE Infinity / Praxair Grab 'n Go Opti) system is an integrated delivery system intended to provide supplemental oxygen, by Rx only, to patients. When administered by properly trained personnel for oxygen deficiency and resuscitation, the device is for emergency use only. For all other medical applications, the device is Rx only. The device is MR Conditional and suitable for use during MR imaging for MRI systems up to 3.0 Tesla and cannot be used directly in the MRI bore. The device is intended for limited duration use, such as would be necessary during patient transports.	The device is an integrated portable oxygen delivery system intended to provide supplemental oxygen to patients. When administered by properly trained personnel for oxygen deficiency and resuscitation, the device is for emergency use only. For all other medical applications, the device is Rx only.	The OxyTOTE Infinity / Praxair Grab 'n Go Opti statement articulates the MR Conditionality of the device, and states that the device is only intended for limited duration use. The predicate's statement contained neither.
Valve/Regulator			
Low Flow Settings	Yes (≥ 0.5L), 10 specific calibrated flow rates. (0.5, 1, 1.5, 2, 3, 4, 6, 8, 15, 25 SLPM Oxygen)	Yes (≥ 0.5L), 11 specific calibrated flow rates. (0.5, 1, 1.5, 2, 3, 4, 6, 8, 10, 15, 25 SLPM Oxygen)	The lack of a 10 LPM position is not a significant difference in performance.
Cylinder On/off	No	No	NA

Feature	OxyTOTE Infinity and Praxair Grab 'n Go VIPR Systems	EZ-OX Plus Generation II (Predicate)	Explanation of Differences
Filling Port Connection	CGA 540	CGA 540	NA
Auxiliary Port Connection	DISS 1240 100 LPM at > 600 PSIG	DISS 1240 40 LPM at > 290 PSIG	100 LPM targeted for Oxy-TOTE and Opti, 40 LPM targeted for predicate
Contents Gauge	Active	Active	NA
Cylinder Contents Indicator (CCI)	Yes	No	Red/Green visual indication of remaining gas pressure provides an assessment of cylinder content level.
Pressure Design	3,000 psi	3,000 psi	NA
Fill Valve	Automatic	Manual	A manual shutoff valve must be opened to evacuate the cylinder.
Residual Pressure Valve (RPV)	No	Yes	The RPV requires an additional step to be performed at the fill plant to vent the cylinders prior to filling.
Guard / Shroud			
Hand Grip	Yes	Yes	NA
Color	Green	Green	NA
Height (guard & integrated valve regulator)	5.88"	7"	NA
Cylinder			
Sizes	D and E	D and E	NA
Materials	Aluminum	Aluminum	NA
MRI Conditionality	Claimed: suitable for use during MR imaging for MRI systems up to 3.0 Tesla and cannot be used directly in the MRI bore.	Claimed: suitable for use during MR imaging for MRI systems up to 3.0 Tesla and cannot be used directly in the MRI bore.	NA

10. Performance Data (Non-clinical Testing)

Performance testing was completed and the device passed in accordance with the following standards:

- CGA E-18:2008 (first edition) : Medical Gas Valve Integrated Pressure Regulators
- ASTM G175-13: Standard Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Regulators Used for Medical and Emergency Applications
- ASTM F2052-06 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment.
- ASTM F2119-07 Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants.

Test results confirm that the OxyTOTE Infinity and Praxair Grab 'n Go Opti series VIPR systems meet its performance requirements.

11. Substantial Equivalence

Based upon the performance testing and subsequent passing results, the manufacturer believes that the OxyTOTE Infinity and Grab 'n Go Opti portable oxygen delivery systems are substantially equivalent to the predicate device, and do not raise any new questions of safety or effectiveness.