JUL 07 2014

510(k) Summary K132778
for the Praxair Grab 'n Go Plus / Grab 'n Go Digital

(per 21CFR 807.92 and *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm*)

1. SUBMITTER/510(K) HOLDER

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Date Prepared: September 3, 2013

2. DEVICE NAME

Trade Name: 1. Grab 'n Go Plus – Portable Medical Gas Delivery System (D, E cylinders)
2. Grab 'n Go Digital – Portable Medical Gas Delivery System (D, E cylinders)
Common Name: Medical Gas Delivery System
Device Name: Integrated Valve-Regulator and Compressed Gas Cylinder
Classification Panel: Anesthesiology
Classification Number: Unclassified
Product Code: ECX

3. PREDICATE DEVICES

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

- LIV (Linde Integrated Valve) Portable Oxygen System (Linde North America, Inc.), K101792

4. DEVICE DESCRIPTION

The Grab 'n Go Plus / Grab 'n Go Digital (collectively referred to as the Grab 'n Go system) integrated delivery system supplies oxygen using a device comprising an integrated valve-regulator with pressure gauge, flow meter and oxygen gas cylinder with protective shroud all integrated into a single unit. The device is able to provide a range of user selectable flow settings, including low and high flows that may be clinically appropriate for certain classes of patients. An additional DISS connection provides standard 50-PSI oxygen gas delivery.

The optional digital pressure gauge (Grab 'n Go Digital) provides both audible and visual low contents alerts and alarms as well as estimated time of use.

The system must only be used by trained medical personnel.

5. INDICATION FOR USE/INTENDED USE

The Grab 'n Go system is an integrated delivery system intended to provide supplemental oxygen, by Rx only, to neonates, pediatrics and adults. The device is MR-Conditional, and suitable for use during MR imaging for MRI systems up to 3.0 Tesla. The device is intended for limited duration use, such as would be necessary during patient transports.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICE

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

Parameter	Grab 'n Go Plus / Grab 'n Go Digital (Praxair Healthcare Services)	LIV (Linde Integrated Valve) (Linde North America, Inc.)
Regulatory Status	Proposed device	K101792
Indications for Use	The Grab 'n Go system is an integrated delivery system intended to provide supplemental oxygen, by Rx only, to neonates, pediatrics and adults. The device is MR-Conditional, and suitable for use during MR imaging for MRI systems up to 3.0 Tesla. The device is intended for limited duration use, such as would be necessary during patient transports.	The LIV is an integrated portable oxygen delivery system intended to provide supplemental oxygen to pediatric 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. Compressed gas cylinders in service or in storage shall be stabilized or otherwise secured to prevent falling and rolling.
Low Flow Setting	Yes	Yes
Flow Between Settings	No	No
One or Two Knob Operation	One	Two

Parameter	Grab 'n Go Plus / Grab 'n Go Digital (Praxair Healthcare Services)	LIV (Linde Integrated Valve) (Linde North America, Inc.)
DISS Connection	Yes	Yes
Filling Port	Yes	Yes
Contents Gauge	Active	Active
Contents Gauge Type	Bourdon-tube or Transducer, Digital	Bourdon-tube
Filters	4	3
Service Pressure Maximum	3335 PSI (max)	3000 PSI (max)
Regulator Style	Single stage piston	Single stage piston
MR Compatibility	Yes, up to 3.0 T	Yes, up to 3.0 T
Hand Grip	1 grip	2 grips
Access Ports	Yes	Yes
Flow Selector	Yes	Yes
Color	Green	Green
Height (valve-regulator and shroud)	7.5"	6.5"
Width	4.25"	4.75"
Cylinder Sizes	D, E	D, E
Medical Gases	Oxygen	Oxygen
Cylinder Material	Aluminum	Aluminum

The manufacturer believes that the technological characteristics of the Grab 'n Go system is substantially equivalent to those of the predicate device. Both the proposed and predicate devices are oxygen gas delivery systems comprised of an integrated valve-regulator with pressure gauge, flow meter and oxygen gas cylinder with protective shroud all integrated into a single unit. Differences of the Grab 'n Go system include the design and dimensions of the shroud, single knob operation, optional digital gauge and number of internal filters.

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

The Grab 'n Go system complies with the following industry and international standards that are applicable to medical gas regulators:

- ISO 13485:2003, "Medical devices -- Quality management systems -- Requirements for regulatory purposes"
- ISO 14971: 2007, "Medical devices -- Application of risk management to medical devices"
- IEC 60601-1:2012, "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance"
- IEC 60601-1-2:2007, "Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests"

- IEC 60601-1-8:2006, "Medical electrical equipment -- Part 1-8: General requirements for basic safety and essential performance -- Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems"
- IEC 60529:2001, "Degrees of protection provided by enclosures (IP Code)"
- IEC 60086-4:2007, "Primary batteries - Part 4: Safety of lithium batteries"
- CGA E-18:2008, "Medical Gas Valve Integrated Pressure Regulators"
- ISO 10524-3:2005/Amd 1:2013, "Pressure regulators for use with medical gases -- Part 3: Pressure regulators integrated with cylinder valves"
- ISO 9170-1:2008, "Terminal units for medical gases pipeline systems – Part 1: terminal units for use with compressed medical gases and vacuum"
- ISO 11117:2008 / Corr:2009, "Gas cylinders -- Valve protection caps and valve guards -- Design, construction and tests"
- ASTM G175 – 03(2011), "Standard Test methods for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Regulators Used for Medical and Emergency Applications"

The Grab 'n Go system is MR-conditional and complies with:

- ASTM F2052 – 06e1, "Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment"
- ASTM F2213 – 06(2011), "Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment"
- ASTM F2503 – 13, "Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment"
- ASTM F2119 – 01, "Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants"

8. SUMMARY OF CLINICAL TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

An end-user evaluation of the Grab 'n Go system was performed to validate the intended use of the device in the intended environment. Data shows that responses from end-users met the established acceptance criteria. End users were able to understand the user manual, properly use the device and understand the alarm functionality. Therefore, the Grab 'n Go system met the validation requirements.

9. STATEMENT OF SUBSTANTIAL EQUIVALENCE

The indications for use and overall design of the Grab 'n Go systems are identical to the predicate device. The proposed Grab 'n Go system complies with internationally recognized standards and meets all established safety and performance criteria. Therefore, the manufacturer believes that the Grab 'n Go system is substantially equivalent to the predicate device and the differences between the two products are minor, and raise no new issues of safety and effectiveness.

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

July 7, 2014

Praxair Healthcare Services
c/o Tina Wu, Ph.D., RAC
AptivSolutions
62 Forest Street, Suite 300
Marlborough, MA 01752

Re: K132778
Trade/Device Name: Grab 'n Go Plus I Grab 'n Go Digital
Regulation Number: Unclassified
Regulation Name: Medical Gas Delivery System
Regulatory Class: Unclassified
Product Code: ECX
Dated: June 2, 2014
Received: June 3, 2014

Dear Dr. Tina Wu:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Mary S. Brimer -S

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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)*
K132778

Device Name
Grab 'n Go Plus / Grab 'n Go Digital

Indications for Use *(Describe)*
The Grab 'n Go system is an integrated delivery system intended to provide supplemental oxygen, by Rx only, to neonates, pediatrics, and adults. The device is MR Conditional, and suitable for use during MR imaging for MRI systems up to 3.0 Tesla. The device is intended for limited duration use, such as would be necessary during patient transports.

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)*

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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