Class I Medical Device Recall: Praxair Inc., Grab 'n Go Vantage Portable Oxygen Cylinder Units

U.S. Food & Drug Administration

Recall Class: Class I

Date Recall Initiated: November 16, 2012

Product(s): Grab 'n Go Vantage Portable Oxygen Cylinder unit

Catalog Number:
OX-MAEGNGVNTG (US and Canada)
WESPRX-9500 (Global)

Range of manufacturing and distribution dates: Products were manufactured and distributed from June 17, 2009 to November 16, 2012.

Use: The Grab 'n Go Vantage Portable Oxygen Cylinder unit consists of an oxygen container and pressure regulator (valve). The pressure regulator (valve) is intended for medical purposes and is used to convert a medical gas pressure from a high variable pressure to a lower, more constant working pressure.

Recalling Firm:
Praxair Inc.
39 Old Ridgebury Road
Danbury, CT 06817-0001

Reason for Recall: Praxair Inc. has initiated a voluntary recall of its Grab 'n Go Vantage Portable Oxygen Cylinder unit because fires may occur inside the cylinder unit causing the wall of the unit to break and release oxygen. The fires are self extinguishing and may be caused by physical impact such as dropping or knocking over the cylinder unit. If a fire occurs, users may experience burns or a lack of oxygen (hypoxia). This product may cause serious adverse health consequences, including death.

Public Contact: Customers with questions can call Praxair, Inc. at 877-772-9247, Monday through Friday from 8am-5pm EST.

FDA District: New England District Office

FDA Comments: On November 26, 2012, Praxair, Inc. sent "Medical Device Correction" letters to customers and distributors describing the product, problem, and actions to be taken. Customers were also reminded of the following operating instructions:

- Store the Grab’n Go systems indoors in a safe area,
- Never store a system in an elevated location, and
- Handle systems safely and avoid jarring or dropping the system.

Customers were also instructed to send Grab’n Go Vantage Portable Oxygen Cylinder units to Praxair, Inc. for servicing and refilling after use in accordance with their normal processes.

Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to MedWatch: The FDA Safety Information and Adverse Event Reporting Program [1] either online, by regular mail or by FAX.

Additional Links:

1. Praxair Inc. Press Release [2] [3]
2. Grab’n Go Operating Instructions [4] [3]

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http://www.mdtmag.com/news/2013/01/class-i-medical-device-recall-praxair-inc-grab-n-go-vantage-portable-oxygen-cylinder-units

Links:
[1] http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm
[2] http://www.praxair.com/praxair.nsf/AllContent/C020A08D01705E8485257ADA0061CA3A?OpenDocument
[3] http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm
[4] http://www.praxair.com/GNGinstructions