U.S. Department
of Transportation

Pipeline and Hazardous Materials
Safety Administration

NOV 26 2008

1200 New Jersey Ave., SE
Washington, DC 20590

Mr. David Greene
DeVibiss Healthcare
100 DeVilbiss Drive
Somerset, PA 15501-2125

Ref. No. 08-0229

Dear Mr. Greene:

This responds to your letter dated August 25, 2008 regarding the applicability of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) to a device your company calls the iGo Portable Oxygen Concentrator (POC).

According to your letter the iGo Portable Oxygen Concentrator is a device that produces an oxygen enriched gas mixture by drawing in room air and extracting nitrogen. The device is light and capable of operating from an installed lithium ion battery pack. The device has a maximum operating pressure of 14 psia and is equipped with a pressure relief device designed to operate at 20 psia ± 3 psia. The lithium ion battery pack contains less than 8 grams equivalent lithium content and is a type proven to meet the requirements of each test in the UN Manual of Tests and Criteria. Though the lithium ion battery is excepted from the HMR, it must satisfy the requirements of § 173.21(c) which states that an electrical device is forbidden for transportation unless it is packaged in a manner to preclude it from creating sparks or generating a dangerous quantity of heat (for example, by the effective insulation of exposed terminals).

Based on the information provided, the iGo portable oxygen concentrator is not currently subject to the HMR because it meets the following criteria:

(1) The pressure of the oxygen in the device does not exceed 40.6 psia at 20°C;

(2) The lithium ion battery used to operate the device is excepted from the HMR;

(3) The portable oxygen concentrator contains no other materials subject to the HMR; and

(4) The battery pack is packaged in a manner to preclude it from creating sparks or generating a dangerous quantity of heat (for example, by the effective insulation of exposed terminals).

You should also note Federal Aviation Administration (FAA) approval is required before these electronic devices are used by passengers on board aircraft. The FAA published a final rule in the Federal Register regarding these devices on July 12, 2005 (70 FR 40156).

In addition, even with FAA approval the air carrier ultimately determines what may or may not be carried on its aircraft. We suggest that you check with the air carrier to ensure that the iGo portable oxygen concentrator may be carried.

I hope this satisfies your inquiry. If we can be of further assistance, please contact us.

Sincerely,

Charles E. Betts
Chief, Standards Development
Office of Hazardous Materials Standards

Leary
§ 173.185
Battery
08-0229

Drakeford, Carolyn <PHMSA>

From: INFOCNTR <PHMSA>
Sent: Thursday, September 18, 2008 4:44 PM
To: Drakeford, Carolyn <PHMSA>
Subject: FW: Request for Determination - Personal Oxygen Concentrator

From: Greene, Dave [mailto:Dave.Greene@DeVilbissHC.com]
Sent: Monday, August 25, 2008 11:06 AM
To: INFOCNTR <PHMSA>
Subject: Request for Determination - Personal Oxygen Concentrator

Attn: Mr. Edward Mazzullo
Director, Office of Hazardous Materials Standards
U.S. DOT/PHMSA (PHH-10)
1200 New Jersey Avenue, SE East Building, 2nd Floor43
Washington, DC 20590

Dear Mr. Mazzullo;
An HMIC Customer Service Representative has referred me to you in the matter described below.

DeVilbiss Healthcare is preparing to enter the market with a new Portable Oxygen Concentrator (POC) and is requesting amendment to SFAR 106 to include the iGo Portable Oxygen Concentrator in the list of approved POC's for aircraft use. Section 2 of SFAR 106 requires that PHMSA determine that the POC does not contain hazardous materials and that the requestor must provide documentation to the FDA to that effect. This e-mail is a request for such a determination and response relating that determination.

Background

DeVilbiss Healthcare is a manufacturer of therapeutic respiratory devices for use in the home and clinical settings. We have been a producer of oxygen concentrators for victims of Chronic Obstructive Pulmonary Disease (COPD) and other lung disorders since 1974. We have completed the development of a POC and are preparing for market entry.

The iGo Portable Oxygen Concentrator is a device that produces an oxygen enriched gas mixture (93% concentration of oxygen) by drawing in room air and extracting nitrogen, thus allowing oxygen to be delivered at a range of prescribed flows to patients with low oxygen saturation levels in the blood. The iGo Portable Oxygen Concentrator is light weight and can operate from an attached lithium-ion battery pack, features which allow the iGo Portable Oxygen Concentrator to be readily transported by the patient. It has two operating modes: continuous product flow at up to 3 LPM and pulse dosage mode at settings of 1 to 6. In pulse dosage mode, the concentrator delivers a bolus of oxygen at each inhalation in an amount equal to 14cc times the setting value. The iGo Portable Oxygen Concentrator is sized to fit easily under the seat of a commercial aircraft, permitting the user to travel by air with prescribed therapy.

Specifically, the following characteristics relate to the concentrator and its battery pack:

1. The operating pressure of the device is 14 psia (maximum), and a safety relief valve with a lift pressure of 20 (+/-3) psia is provided in the gas circuit.

2. The lithium ion battery pack contains less than 8 grams of lithium. The pack has passed IATA testing. The conclusion of the test sequence was that "The pack passes all the IATA

requirements as per the UN document ST/SG/AC.10/27/Add.2." The battery pack does not fall under Class 9 as per DOT 49 CFR Ch. I specifications (aggregate equivalent lithium content is less than 8 gms, approximately 7.92 grams).

3. The battery pack has no exposed terminals which could be the source of a short circuit. The safety features of the battery pack include a safety circuit to prevent over current generation, two electronic and one physical fuse and thermistors to detect excessive temperatures in the battery assembly and shut down operation of the battery.

4. The iGo Portable Oxygen Concentrator contains no other materials subject to the HMR, and

5. The battery pack is packaged in a manner to preclude it from creating sparks or generating a dangerous amount of heat or being subject to short-circuiting at exposed terminals.

If additional information is required from DeVilbiss Healthcare for the requested determination, please contact me at 724-413-4007 or e-mail me at Dave.Greene@DeVilbissHC.com.

Thank you for your assistance,

David Greene, PhD

Consultant to DeVilbiss Healthcare

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