U.S. Department
of Transportation

**Pipeline and Hazardous
Materials Safety
Administration**

1200 New Jersey Avenue, SE
Washington, D.C. 20590

JAN 02 2013

Mr. Andy Linn
VBOX Inc.
2340 East Co Rd J
White Bear Lake, MN 55110

Ref. No.: 12-0245

Dear Mr. Linn:

This responds to your October 24, 2012 email regarding the applicability of the Hazardous Materials Regulations (HMR; 49 CFR Parts 100-180) to a portable oxygen concentrator (POC) your company manufactures that is known by the trade name of the Trooper Oxygen Concentrator (Trooper™). You ask whether this device is regulated as a hazardous material under the HMR.

You state the Trooper™ is a device that separates oxygen from ambient air through a process called Vacuum Swing Absorption (VSA). The maximum operating pressure of the oxygen exerted within the device is less than 5 psig at 20°C (68°F). The device can be powered using AC or DC electricity. It is equipped with an AC power cord and a battery pack consisting of six 3.1 amp hour (Ah) lithium-ion cells equating to an equivalent lithium content of 0.93 grams per cell and 5.58 grams aggregate equivalent lithium content (66.96 watt hour (Wh)). The lithium ion cells and battery pack have been tested pursuant to Sub-section 38.3 of the United Nations Manual of Tests and Criteria. When offered for transportation the Trooper™ battery pack will be packaged in a manner to prevent short circuits and, when transported by aircraft passengers or crewmembers, the Trooper™ will be carried onboard rather than checked.

Based on the information provided in your letter, the Trooper™ POC is not subject to the HMR as a 2.2 non-flammable gas. The lithium-ion battery pack used to operate the device appears to conform to § 172.102(c)(1), Special Provision 188 for the transportation of small lithium cells and batteries and the POC contains no other hazardous materials. Therefore, the Trooper™ POC is not subject to any other requirements in the HMR.

Please note that notwithstanding the passenger exception in § 175.10(a)(18) of the HMR, Special Federal Aviation Regulation 106 (SFAR 106) "Rules for Use of Portable Oxygen Concentrator Systems on Board Aircraft" apply and are under the purview of the Federal Aviation Administration (FAA), not PHMSA. This response letter satisfies only one

requirement in the FAA approval process before a POC may be operated onboard an aircraft. You may contact Ms. DK Deaderick in FAA's Flight Standards Service at (202) 267-7480 for questions regarding FAA's approval process.

I hope this information is helpful. If you have further questions, please do not hesitate to contact this office.

Sincerely,

Robert Benedict
Chief, Standards Development Branch
Standards and Rulemaking Division

Winter
§ 173.168

Drakeford, Carolyn (PHMSA)

Portable Oxygen Concentrator
12-0245

From: INFOCNTR (PHMSA)
Sent: Thursday, October 25, 2012 1:58 PM
To: Drakeford, Carolyn (PHMSA)
Subject: RE: VBOX Trooper Portable Oxygen Concentrator (POC) - HMR;49 CFR Parts 171-180

Hi Carolyn,

We received the following request for a formal letter of interpretation.

Thanks,
Victoria

From: linn@vboxinc.com [mailto:linn@vboxinc.com]
Sent: Wednesday, October 24, 2012 8:55 AM
To: INFOCNTR (PHMSA)
Subject: VBOX Trooper Portable Oxygen Concentrator (POC) - HMR;49 CFR Parts 171-180

October 24, 2012

U.S. Department of Transportation
Pipeline and Hazardous Materials Safety Administration

Applicability of the Hazardous Materials Regulations to a portable oxygen concentrator (POC) (HMR; 49 CFR Parts 171-180)

Dear Sir or Madam:

Please accept this letter as a petition to receive a "Letter of Interpretation "regarding the applicability of the Hazardous Materials Regulations to a portable oxygen concentrator (POC) (HMR; 49 CFR Parts 171-180). The FAA requires a PHMSA letter of interpretation stating a POC does not contain hazardous materials and is not subject to the HMR to receive FAA clearance. As such, I have provided the following documents. These documents are considered "CONFIDENTIAL" at this time and should not be made available to the public.

1. (1) Trooper User Manual
2. (2) Certificate of Compliance-Battery Pack
3. (3) R1-768 Test Report-Battery Pack
4. (4) NC1000473 1 TRS-RTCA-DO-160E
5. (5) NC1000473 Report-EMC Immunity
6. (6) WC1000472 Report-60601-1-2
7. (7) NAMSA Biological Risk Assessment

Background:

VBOX is a manufacturer of medical oxygen concentrators. We are currently preparing for market introduction of our Trooper™ Oxygen System, a small, lightweight, battery powered POC device for patients with Obstructive

Pulmonary Disease (COPD) who require supplemental oxygen therapy. The Trooper™ is designed to address the portable oxygen requirements of patients with prescriptions up to 5 LPM in pulse flow mode operation. VBOX's objective is to provide an oxygen system that will substantially improve the quality of life of oxygen patients by increasing their mobility both inside and outside of their homes, including their ability to travel on aircraft.

VBOX's Trooper Oxygen System separates oxygen from ambient air through a process called Vacuum Swing Adsorption (VSA). The Trooper achieves superior performance though the VSA technology, a patented technology, patented pump and valve system, advanced molecular sieve and rechargeable batteries. It provides a patient with United States Pharmacopeia (USP) 87-94% medical grade oxygen.

The Trooper is scheduled for U.S. home care market introduction in spring 2012. It is an FDA 510(k) pre-market notification cleared device. Our 510(k) number is K121260.

The device can be briefly described as a 3.2 pound portable oxygen concentrator (POC) with battery. With two fully charged batteries the Trooper has duration-of-use of 7 hours at a setting of 2, and 20 breaths per minute. Batteries can be removed for a quick replacement with spare/extra batteries should the patient desire. In addition, the device can be powered by use of the AC power cord. The Trooper device has a maximum operating pressure of less than 5 psig at 20°C (68°F). The battery pack contains less than 5.58 g aggregate equivalent lithium content or 66.96 Wh per pack and each pack contains 6 cells. The Trooper™ Oxygen System does not contain any hazardous materials. A biological risk assessment was conducted by an independent third party and is provided in the attachment as item 7.

The device is intended for use by individuals requiring supplemental oxygen, by and on the order of a prescribing physician. The user will be ambulatory. The interface with the user will be through a standard single-lumen nasal cannula. Typically, most of the users will be diagnosed with chronic obstructive pulmonary disease (COPD).

If you have any further questions or require more information, please do not hesitate to contact me.

Sincerely,

Andy Linn

VBOX Inc.
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White Bear Lake, MN 55110

linn@vboxinc.com
651-207-5461 Direct