U.S. Department
of Transportation

**Pipeline and Hazardous
Materials Safety
Administration**

1200 New Jersey Avenue SE
Washington, DC 20590

SEP 2 0 2012

Richard W. Boerdner
Production Manager – POC
AirSep Corporation
401 Creekside Drive
Buffalo, New York 14228-2085

Ref. No. 12-0199

Dear Mr. Boerdner:

This responds to your September 5, 2012 letter regarding the applicability of the Hazardous Materials Regulations (HMR; 49 CFR Parts 100-180) to a portable oxygen concentrator your company manufactures and is known by the trade name FreeStyle 5. You ask whether this device is regulated as a hazardous material under the HMR.

You state the FreeStyle 5 is a device that separates oxygen from ambient air through a process called Pressure Swing Absorption (PSA). The maximum operating pressure of the oxygen exerted within the device is less than 200 kPa (gauge) at 20 °C. The device can be powered by multiple power sources, including AC or DC power and a rechargeable 4.8 Ah, 71.04 Wh, lithium ion battery pack. 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 and are packaged in a manner to prevent short circuits when offered for transportation or are carried onboard passenger-carrying aircraft.

Based on the information provided, the oxygen in the FreeStyle 5 is not subject to the HMR as a Division 2.2 non-flammable gas. Moreover, it is the opinion of this Office that the FreeStyle 5 device and the lithium ion batteries contained in the device appear to conform to 49 CFR 172.102(c)(1), Special provision 188 (SP 188), for the transportation of small lithium cells and batteries. Thus, provided the conditions in SP 188 continue to be met, the FreeStyle 5 is not subject to any other requirements in the HMR.

Although the exception in 49 CFR 175.10(a)(18) would apply to a passenger transporting a lithium battery-powered portable oxygen concentrator, the approval of the Federal Aviation Administration (FAA) is required before it may be operated onboard an aircraft.

I trust this satisfies your inquiry. Please contact us if we can be of further assistance.

Sincerely,

T. Glenn Foster

T. Glenn Foster
Chief, Regulatory Review and Reinvention Branch
Standards and Rulemaking Division

AirSep Corporation
401 Creekside Drive
Buffalo, New York 14228-2085
(716) 691-0202
Fax (716) 691-4141

Industrial & Medical Air Separation Equipment

Stevens
§175.10
§173.115.
Exceptions
12-0199

September 5, 2012

Mr. Charles Betts
U.S. DOT
PHMSA Office of Hazardous Materials Standards
Attention: PHH-10
East Building
1200 New Jersey Avenue, SE.
Washington, DC 20590-0001

Subject: Formal Letter of Interpretation

Dear, Mr. Betts

In accordance with 49 CFR 173.115, after review of this section of the CFR it is our interpretation that our FreeStyle 5 portable oxygen concentrator manufactured by AirSep Corporation in Buffalo New York is exempt as hazardous materials. However we would like your offices concurrence to our interpretation.

Our complete contact Information is as follows:

AirSep Corporation
401 Creekside Drive
Buffalo, New York 14228
Attn: Richard W. Boerdner – Production Manager - POC
(716) 691-0202 ext. 365
rboerdner@airsep.com

The device for which an exemption is being considered is a portable oxygen concentrator known by the trade name of FreeStyle 5. People who have a medical condition that requires them to receive supplemental oxygen therapy use this device as a source of oxygen. The FreeStyle 5 portable oxygen concentrator separates oxygen from ambient air through a process called Pressure Swing Adsorption (PSA). This portable oxygen concentrator uses oxygen conserving technology. The systems maximum operating pressure does not exceed 200 kPa gauge (29.0 psig/43.8 psia) at 20° C (68° F). The device uses multiple power sources, including AC or DC power and rechargeable lithium ion battery which is a 4.8 Ah, 71.04 Wh battery pack. The lithium ion cells and battery pack are compliant to the United Nations Manual of Tests and Criteria and is packaged in a manner to prevent short circuits when offered for transport or carried on board passenger aircraft.

AirSep Corporation requests your office concurrence that our FreeStyle 5 is exempt from section 175.10 paragraph A18 which allows a certificate holder to allow passengers to carry and operate such devices provided a number of conditions are met. AirSep Corporation is not a certificate holder however we do have procedures in place to ensure the safety and effectiveness of the FreeStyle 5. These include the requirements of the FDA's GMP (Good Manufacturing Practices), International standards IEC 60601-1 General requirements for safety for Medical equipment, and IEC 60601-1-2 for Electromagnetic compatibility requirements and tests for medical equipment. In addition the AirSep Quality Management System is approved as being compliant with the requirements of ISO9001:2008 and ISO 9000:13485 guideline with no exclusions.

I look forward to your review and input on exemption of this product. If you should need any more information please feel free to contact me.

Sincerely,

Richard W. Boerdner

Richard W. Boerdner
Production Manager - POC
AirSep Corporation