



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

1200 New Jersey Ave., S.E.
Washington, DC 20590

JUL 21 2008

Mr. Gilbert Roque, Jr.
Delphi Medical Systems
World Headquarters &
Customer Center
5725 Delphi Drive
Troy, Michigan 48098-2815

Ref. No. 08-0034

Dear Mr. Roque:

This responds to your letter dated February 5, 2008 asking whether Delphi Medical Systems' device "Portable Oxygen Concentrator" is exempt from the Hazardous Materials Regulations (HMR; 49 Parts 171-180), for purposes of transportation in commerce. You provided a description of the device, technical information, and a block diagram describing the operation of the device.

According to your letter, the Delphi Medical Systems' Portable Oxygen Concentrator (POC), Model RS-00400, uses molecular sieve/Pressure Swing Adsorption (PSA) technology to deliver concentrated oxygen. The POC delivers 90% oxygen +/- 3% to a patient through a standard single-lumen nasal cannula. The device can be operated by multiple power sources, including a 12 cell rechargeable lithium ion battery pack or powered by the 100-240VAC AC/DC power supply provided with the unit. The total lithium content of the battery pack is 7.92 grams and the lithium content of each cell is 0.66 grams. A series of chambers and valves allows pressurized air to enter the sieve bed assembly, effectively separating nitrogen from the air. When one chamber is receiving pressurized air, the other is purging nitrogen back into the air. The cycle is repeated continuously. The operating pressure of this device is "maximum pressure at "5" setting: 13 +/-1% psia @ 20°C."

On August 9, 2007, the Pipeline and Hazardous Materials Safety Administration (PHMSA) amended the HMR to tighten the safety standards for transportation of lithium batteries, including both primary (non-rechargeable) and secondary (rechargeable) lithium batteries (HM-224C & HM-224E; 72 FR 44929). A copy of the rulemaking is enclosed. Effective January 1, 2008, PHMSA revised and relocated the 8-gram exception for small lithium batteries formerly found under § 173.185(b)(2) of the HMR. New requirements applicable to the Delphi Medical Systems' Portable Oxygen Concentrator (POC), Model RS-00400 and external battery module, described in your letter, are provided in Special Provision 188 (§ 172.102).

In your letter, you indicate that the Delphi Medical Systems' Portable Oxygen Concentrator (POC), Model RS-00400, and external battery module meet the following criteria:

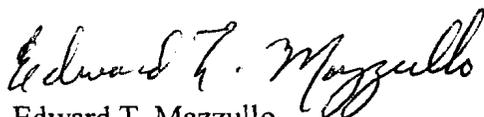
- (1) the pressure of the oxygen in the device does not exceed 40.6 psia at 20 °C;
- (2) the cells contain not more than 1.5 grams of lithium equivalent content;
- (3) the lithium ion batteries contain an aggregate equivalent lithium content of not more than 8g;
- (4) the device contains no other materials subject to the HMR; and
- (5) the batteries are fully contained in equipment and packaged in a manner to preclude sparks or the generation of a dangerous quantity of heat.

Based on the information above, the Delphi Medical Systems' Portable Oxygen Concentrator and external battery module meet Special Provision 188. Provided they continue to meet the requirements established by Special Provision 188, you are not otherwise subject to the HMR.

You should also note that Federal Aviation Administration (FAA) approval is required before these electronic devices may be 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). A copy of the rulemaking is enclosed.

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

Sincerely,



Edward T. Mazzullo
Director, Office of Hazardous
Materials Standards

Enclosures

DELPHI

Engrum
§ 173.220 (d)
§ 175.10(a) (1)
Battery
08-0034

February 5, 2008

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

Dear Mr. Mazzullo:

We would like to request a formal letter of interpretation that our Portable Oxygen Concentrator, Model RS-00400 manufactured by Delphi Medical Systems is exempt as hazardous materials according to the rules of 49 CFR Parts 100-180.

This device is a portable oxygen concentrator that is intended to deliver concentrated oxygen for adult patients requiring supplemental oxygen. We also intend to obtain FAA approval to use this device on-board an aircraft to expand the mobility of patients using this device.

This product has obtained FDA Clearance on January 3, 2008 and is manufactured according to FDA's Quality System Regulation Part 820 and Quality Management System according to ISO 13485.

I have attached the device description, technical information, and the block diagram of this device to help guide you on understanding the operation of the device.

I look forward to answering your questions and I can be reached at:

Delphi Medical Systems
5725 Delphi Drive
Troy, MI 48098
Attn: Gilbert Roque Jr. -- Sr. Regulatory Affairs Engineer
(248) 813-2373
Gilbert.c.roque.jr@delphi.com

Sincerely,


Gilbert Roque Jr.
Sr. Regulatory Affairs Engineer

G.R.

cc:

Device Description

FDA Clearance (K073232)

The Delphi POC delivers 90% oxygen +/- 3% to a patient through a standard single-lumen nasal cannula. Ambient air is drawn by the compressor in the system and filtered before entering the molecular sieve beds, which adsorb nitrogen allowing oxygen to pass and be stored in an accumulator. Embedded software is used to control the valves, sensors, and system functions to ultimately deliver oxygen to the patient and monitor system alarms and performance.

The Delphi POC operates on a demand flow basis during the inhalation part of the breathing cycle. It operates by detecting a patient breath and delivering a precise bolus of oxygen, thru a final filter, to the patient during the inhalation period.

The Delphi POC can be prescribed to deliver flowrates between 1-5 LPM with increments of 0.5 LPM to a patient. The device can be operated by a rechargeable battery or powered by the 100-240VAC AC/DC power supply provided with the unit.

The basic design of the Delphi POC is equivalent to other approved oxygen concentrators and is substantially equivalent in the principles of operation to the predicate device noted in the submission.

Technological Characteristics:

The Delphi Portable Oxygen Concentrator (POC) uses molecular sieve / Pressure Swing Adsorption (PSA) technology to deliver concentrated oxygen. A series of chambers and valves allows pressurized air to enter the sieve bed assembly, effectively separating nitrogen from the air. When one chamber is receiving pressurized air, the other is purging nitrogen back into the air. The cycle is repeated continuously. The concentrated oxygen created at each cycle is stored in a chamber to be delivered to a patient when a breath is detected.

The technological characteristics of the Delphi Portable Oxygen Concentrator are substantially equivalent to the predicate device noted in the submission and these technologies are well established for portable oxygen concentrators.

Technical Information

Rechargeable Lithium Ion Battery Pack

Number of Cells: 12
Cell Lithium content: 0.66 grams
Cell Capacity: 2200mAh
Total Pack Capacity: 6.6Ah
Total Pack Lithium content: 7.92 grams

ELC¹

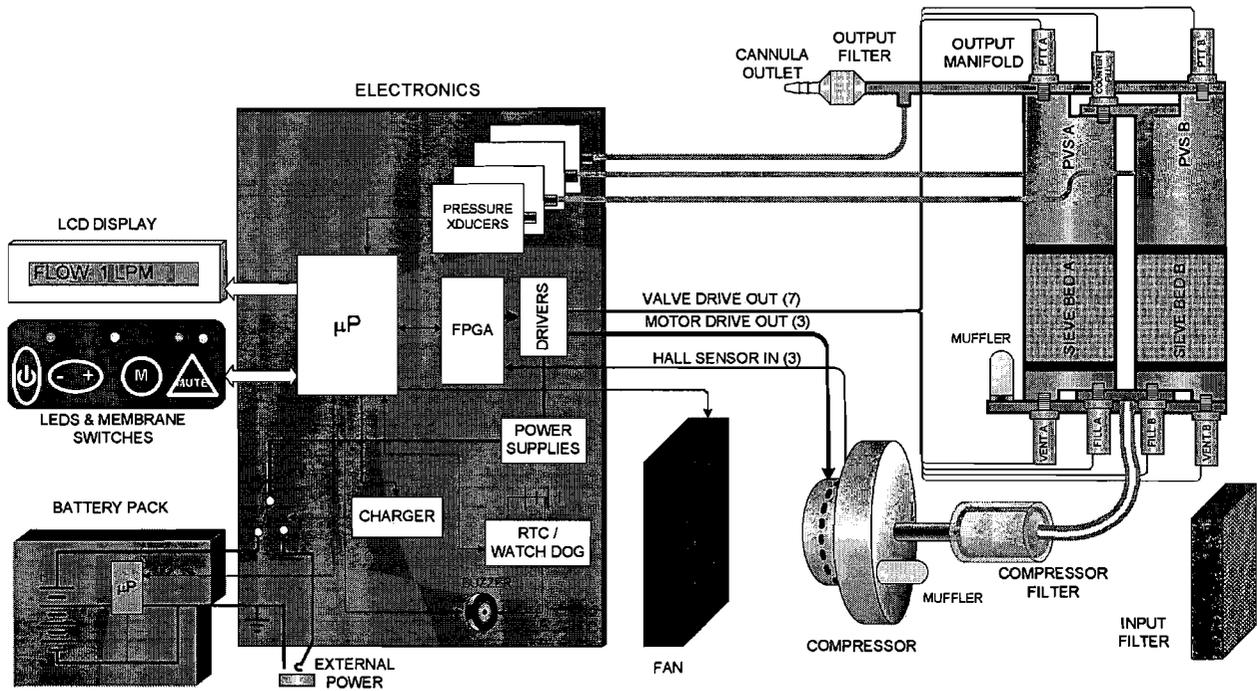
Coin Cell Battery

Panasonic Model BR1225

Maximum Pressure

Maximum pressure at "5" setting: 13 +/-1 % PSIA @ 20°C

Block Diagram



Accessories

Description	Catalog Number	Part Number
Portable Oxygen Concentrator	RS-00400	DM-01001123
Rechargeable Battery	RS-00402	DM-01001119
AC/DC Power Supply	RS-00403	DM-01001223
Patient Filter	RS-00404	DM-01001191
Input Filter	RS-00405	DM-01001964
Carry Case	RS-00406	DM-01001823