K073242

DELPHI
Medical Systems
5725 Delphi Drive Troy, MI 48098-2815 USA

Section V 510(k) Summary (As required by section 807.92(c))

JAN - 3 2008

Submitter:	Delphi Medical Systems 5725 Delphi Drive Troy MI 48098
Contact:	Gilbert Roque Jr., Sr. Regulatory Affairs Engineer
Telephone: **Fax:**	(248) 813-2373 (248) 813-5008
Date Prepared:	July 2007

DEVICE NAME AND CLASSIFICATIONS

Type of Submission:	Traditional 510(k)
Proprietary Name:	Delphi Portable Oxygen Concentrator Model RS-00400
Common Name:	Portable Oxygen Concentrator
Classification Name:	Portable Oxygen Generator
Product Code:	CAW
Medical Specialty / Panel:	Anesthesiology
Device Classification:	Class II
Regulation Number:	21 CFR 868.5440
Predicate Device:	Airsep Corporation, LifeStyle Oxygen Concentrator, 510(k) # K020324

Intended Use:

The Delphi Portable Oxygen Concentrator is intended to provide supplemental oxygen in a home, institution, or travel environments.

Device Description:

The Delphi Portable Oxygen Concentrator is lightweight and can deliver $\geq$ 87% oxygen to a patient through a standard single-lumen nasal cannula. The device detects a patient breath and operates by delivering a bolus of oxygen during the inhalation period.

The device can be set to deliver flowrates between 1-5 LPM with increments of 0.5 LPM to a patient. The device can be operated when powered by the 100-240VAC AC/DC power supply provided with the unit and designed to operate with a DC automotive adaptor. In addition, the device contains a rechargeable battery allowing it to be carried by a patient while traveling.

Indications for Use:

The POC is a prescription only device and not intended for life-supporting or life-sustaining. The users of the Delphi Portable Oxygen Concentrator are adults requiring oxygen therapy to treat conditions such as COPD. The POC is designed to enable its users to be more mobile in their daily activities both indoors and outdoors

Technological Characteristics:

The Delphi Portable Oxygen Concentrator (POC) uses Pressure Swing Adsorption 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 the device detects a patient breath.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 3 2008

Delphi Medical Systems
C/O Mr. Jeff D. Rongero
Senior Project Engineer
Underwriters Laboratories, Incorporated
12 Laboratory Drive
Research Triangle, North Carolina 27709

Re: K073242
Trade/Device Name: Portable Oxygen Concentrator
Regulation Number: 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: December 17, 2007
Received: December 19, 2007

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

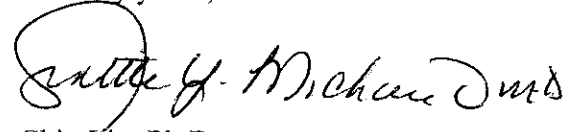
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu-Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DELPHI
Medical Systems
5725 Delphi Drive Troy, MI 48098-2815 USA

Section IV: Indications for Use Statement

Applicant: Delphi Medical Systems

510(k) Number: _____

Device Name: Portable Oxygen Concentrator

Indications for Use:

The Portable Oxygen Concentrator is intended to provide supplemental oxygen in a home, institutional, or travel environment.

Prescription Use Only: __X__ Over-the-Counter Use: _____

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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