



MAY 21 2009

**510(K) SUMMARY FOR
THE INVACARE TRANSPORTABLE OXYGEN CONCENTRATOR (TPOC)**

This summary of 510(k) safety and effectiveness information is being supplied in accordance with the requirements of the SMDA of 1990 and 21 CFR 807.92

The assigned 510(k) number is 16083751

Date: December 11, 2008

Submitted by: Invacare Corporation
Registration No. 1525712
One Invacare Way
Elyria, Ohio 44035-4190

Telephone: 440-326-6356
Fax: 440-326-3458

Contact Person: Mr. Carroll Martin

Trade Name: TPOC

Model: TPOC100

Common Name: Oxygen Concentrator

Classification Name: Generator, Oxygen, Portable per 21 CFR 868.5440

Legally Marketed Predicate Device(s): Invacare Flyer Oxygen Concentrator; K0719028, Dec 12, 2007.

Device Description: The Invacare TPOC is to be used by patients with respiratory disorders who require supplemental oxygen. The device can be used in the home, an institution, vehicle and various mobile and outdoor environments. The device is not intended to sustain or support life. The device is typically used with a nasal cannula to direct oxygen from the device to the patient.

When set for Continuous Flow Mode, the TPOC can deliver up to 3 LPM continuous flow in 0.5 LPM increments. While in Pulse Delivery Mode, when the demand for oxygen is detected, the oxygen is delivered through pulsed flow with pulse flow settings of 1 through 5. The oxygen concentration level of the output gas ranges from 87% to 95.6% in all modes.

The modified TPOC contains an integrated oxygen sensor to provide added monitoring of the output gas purity, as well as additional patient warnings and alarms based on those levels. The oxygen sensor process uses a heated Zirconia element as the method of measurement. This is the exact same sensor process used in previously cleared oxygen concentrators such as the Invacare Platinum 5 Oxygen Concentrator, K020386.

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One Invacare Way PO Box 4028 Elyria, OH 44036-2125 USA
440-329-6000 Fax 440-366-1803 www.invacare.com



With the addition of continuous flow, the TPOC is now capable of supporting two features commonly available with continuous flow concentrators; use with a humidifier bottle for humidification and use in conjunction with PAP, Bi-Level and other such devices as an oxygen bleed-in. The use of this equipment is only during continuous flow mode, as indicated in the User's Manual.

Along with a removable Lithium battery pack, standard power options include switching power supplies operating from AC power outlet (120 VAC/ 60 Hertz nominal) and from accessory DC outlets typically found in a mobile vehicle type environment (12 VDC nominal).

The Invacare TPOC uses a molecular sieve and pressure swing adsorption methodology to produce the oxygen gas output. Ambient air enters the device, is filtered and then compressed. This compressed air is then directed toward one of two nitrogen adsorbing sieve beds. Concentrated oxygen exits the opposite end of the active sieve bed and is directed into an oxygen reservoir where it is delivered to the patient in specific volumes during the inhalation portion of a detected breath in pulse mode. In continuous flow mode, the operation is the same with the exception that the oxygen is delivered continuously, without the need for breath detection.

The basic technology of the Invacare TPOC is equivalent to its predicate device.

Intended Use: The Invacare TPOC is intended to be used by patients with respiratory disorders who require supplemental oxygen. It supplies a high concentration of supplemental oxygen and is used with a nasal cannula to channel oxygen from the concentrator to the patient. The Invacare TPOC can be used in a home, institution, vehicle, and various mobile environments. The Invacare TPOC does not nor is it intended to sustain or support life.

Substantial Equivalence:

Features	Invacare TPOC100	Invacare Flyer
510(k) Number	TBD	K0719028
Date Cleared	TBD	12/12/2007
Intended Use	The Invacare TPOC is intended to be used by patients with respiratory disorders who require supplemental oxygen. It supplies a high concentration of supplemental oxygen and is used with a nasal cannula to channel oxygen from the concentrator to the patient. The Invacare TPOC can be used in a home, institution, vehicle and various mobile environments. The Invacare TPOC does not nor is it intended to sustain or support life.	The Invacare Flyer is intended to be used by patients with respiratory disorders who require supplemental oxygen. It supplies a high concentration of supplemental oxygen and is used with a nasal cannula to channel oxygen from the concentrator to the patient. The Invacare Flyer can be used in a home, institution, vehicle and various mobile environments. The Invacare Flyer does not nor is it intended to sustain or support life.
Method by which Oxygen is Released	Molecular sieve (mechanical)	Molecular sieve (mechanical)

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Process by which Oxygen is Released	Pressure swing adsorption	Pressure swing adsorption
Sieve Bed Material	Synthetic zeolite	Synthetic zeolite
Software/ Hardware	Analog and digital electronics with microprocessor	Analog and digital electronics with microprocessor
Flow Control	Microprocessor controlled valves	Microprocessor controlled valves
Weight	≤ 18.0 lbs. (without battery module or cart)	≤ 7.0 lbs. (with internal battery)
Oxygen Purity	87% minimum at all flow rates	87% minimum at all flow rates
Oxygen Sensor	Yes	No
Flow Rates	Continuous flow rates of 0.5 - 3.0 LPM (0.5 LPM resolution) Pulse Flow – 1, 2, 3, 4, 5	No Continuous flow rate Pulse Flow – 1, 2, 3, 4, 5
Power Options	AC power supply 100-240 V, 50/60 Hz; DC power supply 11-16 V	AC power supply 100-240 V, 50/60 Hz; DC power supply 11-16 V
Battery	Li-ion, 16.8 Volt, 15.6 Ah	Li-ion, 16.8 Volt, 5.2 Ah

Performance Testing: The performance testing conducted as a result of the modifications to the Invacare Flyer, as required by the risk analysis, was performed and the results demonstrated that the predetermined acceptance criteria were met.

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440-329-6000 Fax: 440-366-1803 www.invacare.com



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Carroll L. Martin, RAC
Regulatory Manager
Invacare Corporation
One Invacare Way
P.O. Box 4028
Elyria, Ohio 44036-2125

MAY 21 2009

Re: K083751

Trade/Device Name: Invacare TPOC Portable Oxygen Concentrator
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: April 30, 2009
Received: May 4, 2009

Dear Mr. Martin:

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 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.

Page 2- Mr. Martin

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k 083751

Device Name: Invacare TPOC Portable Oxygen Concentrator

Indications for Use: The Invacare TPOC Portable Oxygen Concentrator is intended to be used by patients with respiratory disorders who require supplemental oxygen. It supplies a high concentration of supplemental oxygen and is used with a nasal cannula to channel oxygen from the concentrator to the patient. The Invacare TPOC Portable Oxygen Concentrator can be used in a home, institution, vehicle, and various mobile environments. The Invacare TPOC Portable Oxygen Concentrator does not nor is it intended to sustain or support life.

Prescription Use
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

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

L Schultz Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: k 083751