JUL - 2 2002

K020388

510(k) SUMMARY

Invacare Corporation's
Model Platinum 5 Oxygen Concentrator

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared.

Invacare Corporation
One Invacare Way
Elyria, Ohio 44036
Phone: (440) 329-6000
Facsimile: (440) 365-4558

Contact Person:
Edward A. Kroll
Director, Regulatory Affairs

Date Prepared: February 4, 2002

Name of Device and Name/Address of Sponsor
Invacare Platinum 5 Oxygen Concentrator

Invacare Corporation
One Invacare Way
Elyria, Ohio 44036
Phone: (440) 329-6000
Facsimile: (440) 365-4558

Common or Usual Name
Oxygen Concentrator

Classification Name
Portable Oxygen Generator

Predicate Devices
Sunrise Medical Model DeVilbiss 5 Oxygen Concentrator (K991722)

Intended Use
The intended function and use of the Invacare Model Platinum Oxygen Concentrator is to provide supplemental oxygen to patients with respiratory disorders, by separating nitrogen from room air, by way of a molecular sieve. It is not intended to sustain or support life.

Technological Characteristics and Substantial Equivalence

A. Device Description

The Invacare Model Platinum 5 Oxygen Concentrator is an electromechanical, prescription device designed for use in the home, by patients that require supplemental oxygen. Its intended function and use is to provide supplemental oxygen to patients with respiratory disorders, by separating nitrogen from room air, by way of a molecular sieve. It is not intended to sustain or support life.

Oxygen is delivered to the user by means of standard oxygen supply tubing and a standard nasal cannula, which are not supplied with the device. A standard humidifier bottle may be used, if desired.

The front panel of the device contains the controls and indicators. These include a standard barb fitting for attaching the oxygen tubing, the adjustable flow meter, a power light indicator, an elapsed time meter, and a standard on/off rocker type power switch.

B. Substantial Equivalence

The Invacare Model Platinum Oxygen Concentrator is substantially equivalent to the Sunrise Medical Model DeVilbiss 5 Liter Oxygen Concentrator (K990711).

Performance Data

The Invacare Model Platinum Oxygen Concentrator was tested in accordance with the electrical, mechanical and environmental performance requirements for home use respiratory devices set forth in the Anesthesiology and Respiratory Devices Branch's November 1993 document entitled "Reviewer Guidance for Pre-market Notification Submissions", published by the Anesthesiology and Respiratory Devices Branch. In all instances the device met the required performance criteria and functioned as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 2 2002

Mr. Edward A. Kroll
Invacare Corp.
One Invacare Way
P.O. Box 4028
Elyria, OH 44036

Re: K020386
Invacare Platinum 5 Oxygen Concentrator
Regulation Number: 868.5440
Regulation Name: Generator, Oxygen, Portable
Regulatory Class: II (two)
Product Code: CAW
Dated: May 16, 2002
Received: May 17, 2002

Dear Mr. Kroll:

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.

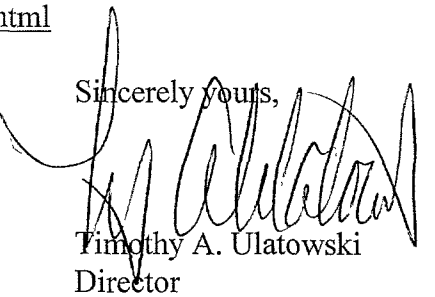
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): ~~FBD~~ K020386

Device Name: *Invacare Platinum 5 Oxygen Concentrator*

Indications For Use:
The intended function and use of the Invacare Model Platinum Oxygen Concentrator is to provide supplemental oxygen to patients with respiratory disorders, by separating nitrogen from room air, by way of a molecular sieve. It is not intended to sustain or support life.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K020386

(Optional Format 1-2-96)