JUL 2 3 2002

K021685

510(k) SUMMARY

Invacare Corporation's
Model Venture HomeFill II With Oxygen Conserver

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: May 21, 2002

Name of Device and Name/Address of Sponsor
Invacare Model Venture HomeFill II with Oxygen Conserver

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
Invacare Corporation Model HomeFill II Complete Home Oxygen System (K003939).

Intended Use
The intended function and use of the Invacare Model Venture HomeFill II with oxygen conserver is to provide supplemental oxygen to patients in the home and to supply pressurized oxygen to fill gas cylinders for the patient's personal ambulatory use. It is not intended to sustain or support life.

Technological Characteristics and Substantial Equivalence

A. Device Description

The Invacare Venture Home Fill II with oxygen conserver is an electromechanical, prescription device designed for use in the home, by patients that require supplemental oxygen. It consists primarily of a 5 liter per minute (lpm) oxygen concentrator, a compressor module, and a portable oxygen cylinder with specially adapted cylinder fitting that includes an oxygen conserver. The oxygen conserver delivers oxygen to the user at the beginning of each breath instead of on a continuous basis.

The concentrator provides continuous flow of oxygen at concentrations of 87% to 96%, at flow rates of 0 to 5lpm. The compressor fills the cylinder with oxygen concentrations of 90% to 96%, and the cylinder regulator allows flow rates of 0 to 6 lpm. The oxygen supplied by the oxygen concentrator is supplemental and is not considered to be life supporting or life sustaining. The system is not sold or labeled as sterile.

B. Substantial Equivalence

The Invacare Model Venture HomeFill II with oxygen conserver is substantially equivalent to the Invacare Model HomeFill II Complete home Oxygen System (K003939)

Performance Data

A number of mechanical and electrical tests were conducted on the Invacare Model HomeFill II with oxygen conserver and the oxygen conserver to demonstrate that the device performs as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 3 2002

Mr. Edward A. Kroll
Director, Regulatory Affairs
Invacare Corporation
One Invacare Way
Elyria, Ohio 44036-2125

Re: K021685
Trade/Device Name: Invacare Model Venture HomeFill II with Oxygen Conserver
Regulation Number: 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: May 21, 2002
Received: May 22, 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) 594-4646. 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): ~~TBD~~ K021685

Device Name: *Invacare Model Venture HomeFill II with Oxygen Conserver*

Indications For Use:

The intended function and use of the Invacare Model Venture HomeFill II with oxygen conserver is to provide supplemental oxygen to patients in the home and to supply pressurized oxygen to fill gas cylinders for the patient's personal ambulatory use. 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 K021685

(Optional Format 1-2-96)