MAR 2 1 2001

K003939

510(k) SUMMARY

Invacare Corporation's
Venture Model IOH 200 HomeFill II Oxygen Compressor

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: December 19, 2000

Name of Device and Name/Address of Sponsor
Venture IOH 200 Home Fill II Complete Home Oxygen System

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 Model IOH 100 Complete Home Oxygen System (K983627)

Intended Use
The intended function and use of the Invacare Model IOH 200 Complete Home Oxygen System is to provide supplemental oxygen to patients and to supply pressurized oxygen to fill gas cylinders for the patient's personal ambulatory use.

Technological Characteristics and Substantial Equivalence

A. Device Description

The Invacare Venture IOH 200 HomeFill II Oxygen Device 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 and to supply pressurized oxygen to fill gas cylinders for the patient's personal ambulatory use.

The device consists primarily of a 5 liter per minute (lpm) oxygen concentrator, a compressor module, and a portable oxygen cylinder with specially adapted cylinder fitting. 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 IOH 200 Home Fill II Complete Home Oxygen System is substantially equivalent to the Invacare Model Venture IOH 100 Complete Home Oxygen System which was granted marketing clearance by FDA on October 22, 1999 under 510(k) Accession Number K983627.

Performance Data

The Invacare Model Venture IOH 200 Complete Home Oxygen System 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 Premarket 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

MAR 21 2001

Mr. Edward A. Kroll
Invacare Corporation
One Invacare Way
P.O. Box 4028
Elyria, OH 44036-2125

Re: K003939
Invacare Model Venture IOH 200 Complete Home Oxygen System
Regulatory Class: II (two)
Product Code: 73 CAW
Dated: December 19, 2000
Received: December 21, 2000

Dear Mr. Kroll:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

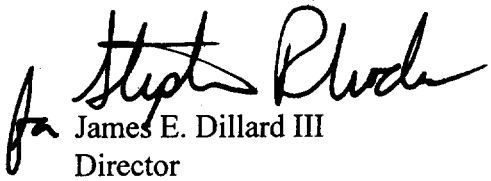
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 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"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): ~~TBD~~ K003939

Device Name: *Invacare Model Venture IOH 200 Complete Home Oxygen System*

Indications For Use:

The intended use of the Invacare Model Venture IOH 200 Complete Home Oxygen System is to provide supplemental oxygen to patients and to supply pressurized oxygen to fill gas cylinders for the patients personal ambulatory use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003939

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

(Optional Format 1-2-96)