OCT 27 1999

K992643

510(k) SUMMARY

Invacare Corporation's
MODEL IRC 1001 AEROSOL COMPRESSOR

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

Invacare Corporation
899 Cleveland Street
Elyria, Ohio 44035
Phone: (440) 329-6000
Facsimile: (440) 365-4558

Contact Person:

Edward A. Kroll
Director, TQM and Regulatory Affairs

Date Prepared: August 2, 1999

Name of Device and Name/Address of Sponsor

Invacare Corporation
899 Cleveland Street
Elyria, Ohio 44035
Phone: (440) 329-6000
Facsimile: (440) 365-4558

Common or Usual Name

Nebulizer

Classification Name

Nebulizer

Predicate Devices

Intended Use

The intended use of the Invacare Model IRC 1001 Aerosol Compressor is to provide compressed air to a nebulizer for the generation of aerosolized medications, based on a physicians' prescription.

Technological Characteristics and Substantial Equivalence

A. Device Description

This product is an electrically powered device designed for use in the treatment of respiratory disorders, such as asthma, in a household environment. Its' intended use is to provide compressed air to a nebulizer for the generation of aerosolized medications, based on a physicians' prescription. Nebulizers are used to convert liquid medication to aerosol form for delivery to a patient through inhalation. The device is comprised of three major components: (1) an enclosure; (2) a compressor; and (3) wiring components

The enclosure is made of a flame retardant material which provides mechanical protection from the environmental effects and impact loads to the device Air is drawn through the polypropylene filter to remove dust particles. The power switch is located on the rear of the unit between the two shrouds.

The oil-free, small piston diaphragm compressor is the primary performance component of the Model IRC 1001 Aerosol Compressor, and provides the compressed air to the nebulizer. The compressor is kept cool during operation by an integral thermoplastic fan. The main wiring components are the power cord, and the power switch. Power to the compressor is controlled by actuation of the power switch when the unit is connected to line voltage.

The IRC 1001 Aerosol Compressor is portable, weighing 3.5 pounds. It has a nominal nebulizer operating pressure of 10 psig and nebulization rate of 5.5 -6.0 lpm. It includes one of two different disposable nebulizer packages. These are the Medic-Aid Ltd. "Side Stream" Nebulizer (Invacare Model MS 2100) and the Allegiance "Misty-Neb" Nebulizer (Invacare Model Number MS 2200). Each nebulizer package includes a mouthpiece, a nebulizer, a connector tube and flexible air tubing.

The nebulization particle size varies slightly depending on which of the above nebulizers is used. When used with the Sidestream nebulizer, mass median diameter is 3.0 μm. When used with the Misty-Neb nebulizer, mass median diameter is 2.01μm (Average $\pm$ 0.12 std. dev.). To operate the Model IRC 1001 Aerosol Compressor, one end of the air tubing is secured to the compressor air outlet while the nebulizer is fitted to the other end of the tubing. The patient then adds the liquid medication according to the physician's prescription and plugs the power cord into the wall outlet.

The clean nebulizer mouthpiece is inserted into the nebulizer and the unit is turned on to start the compressor. After passing through the compressor, the air expands and the resulting high pressure causes liquid in its path to break into droplets of microscopic size. These droplets are projected on an air current for disposition into the respiratory tract.

B. Substantial Equivalence

The IRC 1001 Aerosol Compressor is substantially equivalent to Invacare Corporations' Model IRC 1199 "Passport" Aerosol Compressor (K914251, January 24, 1992), and Medic-Aid Ltd. Model "Freeway Lite" Aerosol Compressor (K934749, July 25, 1994).

Performance Data

The Model IRC 1001 Aerosol Compressor 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 March 1993 document entitled "Reviewer Guidance for Premarket Notification Submissions". In all instances the device met the required performance criteria and functioned as intended. Additionally, this device meets the requirements specified in Underwriters Laboratory (UL) UL 544 Standard for Medical and Dental Equipment and UL 1431 Standard for Personal Hygiene and Healthcare Appliances.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 1999

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

Re: K992643
Model IRC 1001 Aerosol Compressor
Regulatory Class: II (two)
Product Code: 73 CAF
Dated: August 2, 1999
Received: August 6, 1999

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,

Joanna Hilwa, Reviewer for

Wolf Sapirstein, M.D.
Acting Director
Division of Cardiovascular,
  Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
  Radiological Health

Enclosure

510(k) Number (if known): *TBD*

Device Name: Model IRC 1001 Aerosol Compressor

Indications For Use: The Invacare Model IRC 1001 Aerosol Compressor is a prescription device designed for use in the treatment of respiratory disorders, such as asthma, in a household environment. Its intended use is to provide compressed air to a nebulizer for the generation of aerosolized medications, based on a physician's prescription. Nebulizers are used to convert liquid medication to aerosol form for delivery to a patient through inhalation.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K992643

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

(Optional Format 1-2-96)