K973468

510(k) SUMMARY

Invacare Corporation's
MODEL IRC 1199 ULTRASONIC NEBULIZER

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) 366-9724

DEC - 8 1997

Contact Person: Edward A. Kroll
Director, TQM and Regulatory Affairs

Date Prepared: September 8. 1997

Name of Device and Name/Address of Sponsor

Invacare Corporation
899 Cleveland Street
Elyria, Ohio 44035
Phone: (440) 329-6000
Facsimile: (440) 366-9724

Common or Usual Name

Nebulizer

Classification Name

Nebulizer

Predicate Devices

Medox Model Champion Ultrasonic Nebulizer (K954327 December 1995)
DeVilbiss Model 5500 Ultrasonic Nebulizer (K946095 August 24, 1995)

Intended Use

The intended use of the Invacare Model IRC 1199 Scout Nebulizer is to convert liquid medication to aerosol form, and deliver it to the patient through inhalation.

Technological Characteristics and Substantial Equivalence

A. Device Description

The Invacare Ultrasonic Nebulizer is a portable, light weight device designed for use in the home. Its' intended function and use is to convert liquid medication to aerosol form, and deliver it to the patient through inhalation. The conversion from liquid to aerosol form is achieved using ultrasound technology. Ultrasonic energy is transmitted through the conducting chamber to the medication cup, which contains the medication. The high intensity sound waves break the medication into fine particles suitable for inhalation. Room air drawn in by a fan, propels the nebulized medication to the mouthpiece for the patient to inhale.

B. Substantial Equivalence

The Scout Untrasonic Nebulizer submission is substantially equivalent to other legally marketed ultrasonic nebulizers intended for home use. Specifically, the Scout Nebulizer is substantially equivalent to the Medox Corporations' Model "Champion" Compact Nebulizer (K954327 December 19, 1995), and DeVilbiss Health Care Inc. Model 5500 Ultrasonic Nebulizer (K946095, August 24, 1995).

Each of these devices are portable, hand held, ultrasonic nebulizers with the same intended function and use. They consist of the same basic materials, are of similar construction, and each device is operable using an AC power adapter, or optional battery pack power source. Additionally, each device delivers medication upon demand by the patient, and uses ultrasound technology as the means for converting the liquid medication to aerosol form.

Performance Data

The Model IRC 1199 Scout Ultrasonic Nebulizer 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 1992 document entitled "Draft Reviewer Guidance for Home Use Respiratory Devices" In all instances the Scout 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

DEC - 8 1997

Mr. Edward A. Kroll
Invacare Corporation
899 Cleveland Street
P.O. Box 4028
Elyria, Ohio 44036-2125

Re: K973468
Model IRC 1199 "Scout", Nebulizer
Regulatory Class: II (two)
Product Code: 73 CAF
Dated: September 10, 1997
Received: September 12, 1997

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 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/dsmamain.html".

Sincerely yours,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): *K973468*

Device Name: *Invacare Model IRC 1199 Scout Nebulizer*

lications For Use:

Prescription device only.
Used for the delivery of aerosol medication for treatment of various respiratory conditions, such as asthma, on patients from adolescence through adults. Intended for indoor and outdoor use (50°F - 104°F, 15%-95% non condensing humidity)

(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)

M. Pugh

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K973468

(Optional Format 1-2-96)