K982242

JAN 27 1999

510(k) SUMMARY

Invacare Corporation's
Revised CPAP 10/9/98

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

Invacare Corporation
One Invacare Way
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Elyria, Ohio 44036-2125
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Contact Person: Edward A. Kroll
Director, TQM and Regulatory Affairs

Date Prepared: June 24, 1998

Name of Device and Name/Address of Sponsor
Invacare Corporation
One Invacare Way
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Common or Usual Name

CPAP

Classification Name

Ventilator, Noncontinuous

Predicate Devices
The Invacare CPAP is substantially equivalent to the Resmed Sullivan V CPAP System (K930656, 3/15/94) and the Respironics Solo CPAP System (K961626, 7/18/96).

Intended Use
The intended function and use is of the Invacare CPAP is to treat Obstructive Sleep Apnea (OSA) in the home, in adults by delivering continuous positive airway pressure.

Contraindications
The Invacare nasal CPAP system is for the treatment of Obstructive Sleep Apnea (OSA) in adults.

CONTRAINDICATIONS
Nasal CPAP therapy should be used under the supervision of a licensed physician. The following conditions contraindicate the use of Nasal CPAP for some patients:

1. Existing respiratory failure of insufficiency resulting in potential risk of rebreathing.
2. Pneumothorax or pneumomediastinum.
3. Bullous lung disease.
4. Untreated cardiac failure or hypotension.
5. Massive epistaxis or previous history of massive epistaxis (nose bleed).
6. Pneumoencephalus, recent trauma or surgery that may have produced cranionasopharyngeal fistula.
7. Acute sinusitis, otitis media or perforated ear drum.

The clinician should assess on a case by case basis the relative risks and benefits of nasal CPAP therapy in such a subject. When assessing the relative risks and benefits, the clinician should understand that the Invacare CPAP system can deliver pressures up to 18 cmH_2O. Also in the unlikely event of certain fault conditions, a maximum static pressure of 27cmH_2O is possible. If such a pressure could present risk to particular patients, then this device MUST NOT be used.

Technological Characteristics and Substantial Equivalence

A. <u>Device Description</u>

The Invacare CPAP is an electromechanical device that produces Continuous Positive Airway Pressure. Its' intended function and use is to treat Obstructive Sleep Apnea (OSA) in the home, by delivering continuous positive airway pressure to patients with OSA.

It consists basically of a blower motor and a microprocessor based control system. Air enters the device through an inlet filter which traps dust and airborne particles. The filtered air is then directed to the blower motor where it is pressurized, and then delivered to an outlet nozzle located on the front of the unit. The nozzle accepts standard, smooth, flexible, 22mm diameter tubing.

Pressurized air is delivered to the patient through a standard nasal mask with an exhaust port. The microprocessor controls the pressure delivered by controlling the speed of the motor. Pressure is adjustable from 3 to 18 cm H^2O, and is preset by the Clinician during set up in the home. The amount of pressure selected in based upon the Physician's prescription.

Pressurized air is delivered to the patient through a standard nasal mask with an exhaust port. The microprocessor controls the pressure delivered by controlling the speed of the motor. Pressure is adjustable from 3 to 18 cm H^2O, and is preset by the Clinician during set up in the home. The amount of pressure selected in based upon the Physician's prescription.

The CPAP controls and displays include a 5 digit numerical LED display (each digit made of 7 segments) three additional standard LED indicators, a large control button, and two sections: the patient controls and displays, and the therapist's setup controls and displays. In normal operating condition, only the patient interface is available. The therapist must open the top cover of the device to reveal the additional two small buttons and operate the set-up controls.

The patient interface consists of the "Invacare" control button, the 5-digit numerical display, and three LED indicators. The meaning of the symbols associated with the three LED indicators are, "standby," "delay," and "pressure." The five digit numerical display, displays the pressure being provided by the unit. The "Invacare" control button is a push button toggle switch which places the unit in normal, therapy (if desired), or standby modes. In therapy mode, airway pressure starts at a rate that is less than the prescribed pressure, and gradually increases to full prescribed pressure. This mode is used when patients find full prescribed pressure to be uncomfortable during initial use, and prefer a gradual increase. In standby mode, the unit is on, but, there is no power to the blower motor.

As stated above, the clinical set up interface is located under a cover which is fastened to the outer housing. Removing the cover exposes the clinical interface controls which include the patient interface items described above and two additional buttons. The two additional buttons are labeled with symbols indicating "up" and "down." The symbols under the associated with the three LED indicators under the cover are, "time," "delay," and "pressure." The up and down buttons are used by the clinician to set the prescribed pressure and program the therapy mode if desired. Additionally, the clinician can also determine patient compliance with the prescribed use of the device, by viewing the hour and compliance meters. The hours and compliance meters monitor the hours of device use and the pressure delivered.

A. Substantial Equivalence

The Invacare CPAP covered by this submission is substantially equivalent to other legally marketed CPAP devices intended for home use. Specifically, the Invacare CPAP is substantially equivalent to **the Resmed Corporations' Model "Sullivan" CPAP device (K930656, March 15, 1994), and Respironics Model "Solo" CPAP system (K961626, 7/18/96).** The Invacare CPAP has the same intended use, principle of operation and technological characteristics as the two previously cleared devices.

The Invacare CPAP and its predicate devices are all electromechanical devices that produce Continuous Positive Airway Pressure. All have the same intended function and use which is to treat Obstructive Sleep Apnea (OSA), by delivering continuous positive airway pressure to patients with OSA. They consist of the same basic materials, are of similar construction, and the same technological characteristics.

Each of these devices consist basically of a blower motor and microprocessor control system. Technology is similar in that all function by taking in room air through an inlet filter, directing it to a blower motor where it is pressurized, and channeling it to an outlet nozzle, for delivery to the patient through a standard mask and tubing arrangement. Performance characteristics for operating pressure, pressure adjustment, power requirements and maintenance are also similar. Finally all of these devices vary operating pressure by controlling motor speed.

Performance Data

The Invacare CPAP 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" In all instances the Invacare CPAP 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

JAN 27 1999

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

Re: K982242
Invacare Nasal CPAP System
Regulatory Class: II (two)
Product Code: 73 BZD
Dated: January 14, 1999
Received: January 19, 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,

Thomas J. Callahan

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): *TBD* K982242

Device Name: *Invacare CPAP*

Indications For Use: *To treat Obstructive Sleep Apnea (OSA) in adults by delivering continuous positive airway pressure.*

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark Kramer

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices **OR**

510(k) Number _____

Prescription Use ✓
(Per 21 CFR 801.109)

Over-The-Counter Use ___

(Optional Format 1-2-96)