MAR 2 5 2004

510(k) SUMMARY OF SAFETY & EFFECTIVENESS

Invacare Polaris EX Heated Humidifier

Submitter's Information:

Invacare Corporation
One Invacare Way
Elyria, Ohio 44036
Phone: (440) 329-6000
Facsimile: (440) 365-4558

Contact Person:

Janice Brownlee
Director, Regulatory Affairs

Name of Device: Invacare Polaris EX Heated Humidifier

Common or Usual Name: Heated Humidifier

Classification Name: Humidifier, Respiratory Gas, (Direct Patient Interface)

Predicate Device(s): Respironics REMstar Heated Humidifier (K012633, 2/28/02).

Intended Use

The Invacare Polaris EX Heated Humidifier is an accessory for the Invacare Polaris EX CPAP, a prescription device for use in the home, that is used by an adult (>30 kg) who has been diagnosed with Obstructive Sleep Apnea (OSA). The intended function and use of the heated humidifier is to provide moisture to the patient circuit in order to improve patient comfort.

Device Description

The Invacare Polaris EX Heated Humidifier is an accessory for the Invacare Polaris EX CPAP, a prescription device for use in the home, that is used by an adult (>30 kg) who has been diagnosed with Obstructive Sleep Apnea (OSA).

The intended function and use of the heated humidifier is to provide moisture to the patient circuit in order to improve patient comfort. The addition of heated humidification relieves the drying and irritating effects on the patient airways, which may result from the use of a CPAP system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 5 2004

Invacare Corporation
Ms. Janice Brownlee
Director, Regulatory Affairs
One Invacare Way
P.O. Box 4028
Elyria, Ohio 44036-2125

Re: K031176
Trade/Device Name: Invacare Polaris EX Heated Humidifier, Model ISP4000
Regulation Number: 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT
Dated: March 16, 2004
Received: March 23, 2004

Dear Ms. Brownlee:

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), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,

Chiu Lin, Ph.D.
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): K031176

Device Name: Invacare Polaris EX Heated Humidifier

Indications For Use:
The Invacare Polaris EX Heated Humidifier is an accessory for the Invacare Polaris EX CPAP, a prescription device for use in the home, that is used by an adult (>30 kg) who has been diagnosed with Obstructive Sleep Apnea (OSA).

The intended function and use of the heated humidifier is to provide moisture to the patient circuit in order to improve patient comfort.

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K031176

(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)

(Optional Format 1-2-96)