FEB 1 1 2003

K022642

510(k) SUMMARY
(Revised December 16, 2002)

Invacare Corporation's
Model Twilight Nasal Mask

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:
Rae Ann Farrow
Manager, Regulatory Compliance

Date Prepared: August 7, 2002

Name of Device and Name/Address of Sponsor
Invacare Model Twilight Nasal Mask

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

Common or Usual Name
CPAP Mask

Classification Name
Ventilator, Non-continuous

Predicate Devices
Resmed Corporation Mirage Nasal Mask **(K982530)**, and the Sleepnet Corporation Model IQ™ Nasal Mask **(K993269)**.

Intended Use

The Invacare Model Twilight Nasal CPAP Mask is intended to be used with positive airway pressure devices such as CPAP, to provide 3-20 cmH_2O for the treatment of adult obstructive sleep apnea. The mask is to be used on adult patients (>30 kg) for whom positive airway pressure therapy has been prescribed. The mask is intended for single patient use.

Technological Characteristics and Substantial Equivalence

A. Device Description

The Twilight nasal mask is a prescription device intended for use with Continuous Positive Airway Pressure (CPAP), and Bi-Level devices. It is intended to provide a single patient use interface for the delivery of CPAP or Bi-Level therapy to adult patients (>30Kg). It is designed for use with CPAP and Bi-Level delivery systems having pressure ranges from 3-20 cmH_2O.

The Twilight nasal mask consists of a mask that fits over the nose of the patient and a headgear to hold the mask in place. The mask has a removable molded silicone cushion that seals around the patient's nose. A standard and a large cushion are designed for use with the same mask. This also allows for replacement of a worn or damaged cushion without the need to replace the entire mask. The cushion mounts into a rigid polycarbonate shell by means of a flanged area that fits snugly between the wall of the mask shell and an inner retaining ring that is permanently mounted into the shell.

The mask includes an opening that accepts a standard, flexible, 22cm OD breathing tube. The breathing tube is connected to the output of the CPAP/Bi-Level delivery device, and to the input of the Invacare Twilight Nasal Mask. The mask is then placed over the users' nose and mouth. The flexible tube provides a transition between the more rigid output tube of the delivery device, and the mask, thus allowing freedom of movement while maintaining patient circuit integrity.

B. Substantial Equivalence

The Invacare Model Twilight Nasal Mask covered by this submission is substantially equivalent to the other devices currently being marketed in the United States that have been granted marketing clearance by FDA. Specifically, the Twilight Mask is substantially equivalent to the **Resmed Corporation Mirage Nasal Mask (K982530)**, and the **Sleepnet Corporation Model IQ™ Nasal Mask (K993269).**

Performance Data

A number tests were conducted on the Invacare Model Twilight Nasal Mask. In all cases the mask performed as designed and intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 2003

Ms. Rae Ann Farrow
Manager, Regulatory Compliance
Invacare Corporation
One Invacare Way
Elyria, Ohio 44036

Re: K022642
Trade/Device Name: Invacare's Model ISP9600 Twilight Nasal Mask
Regulation Number: 868.5905
Regulation Name: Non-continuous Ventilator
Regulatory Class: II
Product Code: BZD
Dated: November 12, 2002
Received: November 14, 2002

Dear Ms. Farrow:

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.

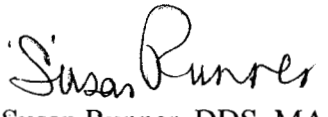
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

10(k) Number (if known): *K022642*

Device Name: *Invacare's Model ISP9600 Twilight Nasal Mask*

Indications For Use:

The Invacare Model Twilight Nasal CPAP Mask is intended to be used with positive airway pressure devices such as CPAP, to provide 3-20 cmH_2O for the treatment of adult obstructive sleep apnea. The mask is to be used on adult patients (>30 kg) for whom positive airway pressure therapy has been prescribed. The mask is intended for single patient use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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

510(k) Number: K022642

(Optional Format 1-2-96)