SEP - 5 2006

510(K) SUMMARY FOR INVACARE CORPORATION'S TWILIGHT II NASAL MASK

This summary of 510(k) safety and effectiveness information is being supplied in accordance with the requirements of the SMDA of 1990 and 21 CFR 807.92

The assigned 510(k) number is K061874.

Date: August 31, 2006

Submitted by: Invacare Corporation
One Invacare Way
Elyria, Ohio 44035-4190

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Fax: 440-326-3607

Contact Person: Janice Brownlee, Director, Regulatory Affairs and Quality Systems

Trade Name: Twilight II Nasal Mask (Note: to distinguish this modification from the original mask in the marketplace, it will be marketed as the Twilight II, though the test reports may have referred to it as the Twilight Mask)

Common Name: CPAP Mask

Classification Name: Non-continuous ventilator (IPPB) accessory 21CFR 868.5905

Legally Marketed Predicate Device(s): ISP9600 Twilight Nasal Mask: K022642, February 11, 2003
ResMed Mirage Activa Nasal Mask; K030798, April 9, 2003

Device Description:
The Invacare Twilight II Nasal Mask is a prescription device intended for use with positive airway pressure devices. It is intended to provide single or multiple patient use/reuse for the delivery of respiratory therapy to adult patients (>30 Kg) with obstructive sleep apnea in a sleep lab or home care setting. It is designed for use with positive airway pressure devices having pressure ranges from 3-20 cmH_2O.

The Invacare Twilight II Nasal mask consists of a mask that fits over the nose of the patient and headgear to hold the mask in place. The mask has a removable molded silicone cushion that seals around the patient's nose. A small, 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, 22mm (outside diameter) breathing tube. The breathing tube is connected to the output of the positive airway pressure device and to the input of the Invacare Twilight II Nasal Mask. The mask is then placed over the user's nose. The flexible tube provides a transition between the more rigid output tube of the delivery device and the mask, thus allowing fr3eedom of movement while maintaining patient circuit integrity.

The Invacare Twilight II Nasal Mask can be reused on multiple patients by disinfecting the mask according to provided instructions. Following cleaning with Enzol® enzymatic cleaning detergent, the mask is disinfected u sing a Cidex® OPA solution or STERRAD Disinfection System. Testing has shown the mask can be disinfected 30 times without loss of effectiveness.

Intended Use: The Invacare Model Twilight II Nasal Mask is intended to be used with positive airway pressure devices such as CPAP, for the treatment of adult obstructive sleep apnea. There is a port on the mask swivel to allow for pressure measurement. 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 or multiple patient re-use.

Substantial Equivalence: The Invacare Twilight II Nasal Mask is similar in design, intended use, safety and performance specifications as the Invacare Twilight Nasal Mask, cleared under 510(k) accession number K022642 on February 11, 2003 and the ResMed Mirage Activa Nasal Mask, cleared under 510(k) accession number K030798 on April 9, 2003.

Performance Testing: This mask has been tested to meet the requirements of AAMI TIR12 for high-level disinfection. Other performance standards used are the same as those used in the submission for the Twilight Nasal Mask, K022642.

Performance Data: This device is similar to the predicate devices and incorporates features from both. The only difference as compared to both predicate devices is the disinfection process, which will allow multiple users. The performance data shows the Invacare Twilight II Nasal Mask performs in a manner that is substantially equivalent to the predicate devices.

INVACARE CORPORATION
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 2006

Ms. Janice Brownlee
Director, Regulatory Affairs and Quality Systems
Invacare Corporation
One Invacare Way
Elyria, Ohio 44035-4190

Re: K061874
Trade/Device Name: Invacare Twilight II Nasal Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontiuous Ventilator
Regulatory Class: II
Product Code: BZD
Dated: August 24, 2006
Received: August 25, 2006

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.

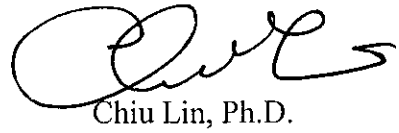
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

Indications for Use

510(k) Number (if known): K061874

Device Name: Invacare Twilight II Nasal Mask

Indications for Use: The Invacare Model Twilight II Nasal Mask is intended to be used with positive airway pressure devices such as CPAP, for the treatment of adult obstructive sleep apnea. There is a port on the mask swivel to allow for pressure measurement. 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 or multiple patient re-use.

Prescription Use ___✔___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

...ion Sign-Off)
...sion of Anesthesiology, General Hospital,
...ction Control, Dental Devices
...) Number: K061874