APR 3 0 2007

510(K) SUMMARY FOR INVACARE'S TWILIGHT FULL FACE 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 k 070321.

Date: February 1, 2007

Submitted by: Invacare Corporation
Registration No. 1525712
One Invacare Way
Elyria, Ohio 44035-4190

Telephone: 440-326-6356
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Contact Person: Mr. Carroll Martin

Trade Name: Twilight Full Face Mask

Common Name: Mask

Classification Name: Ventilator, non-continuous (respirator) per 21 CFR 868.5905

Legally Marketed Predicate Device(s): ResMed Mirage Full Face Mask Series 2; K023244 November 27, 2002
Respironics Spectrum 2 Reusable Full Face Mask, Model 1004884; K002465, September 8, 2000

Device Description: The Twilight full Face Mask consists of a mask that fits over the nose and mouth of a 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 and mouth. The cushion mounts to a rigid clear plastic frame. The frame has built in exhalation ports, a full swivel for locating the pressure device hose, a tubing swivel to allow for twisting of the hose, and a built in anti-asphyxia valve to allow the inner volume of the mask to be open to the outer atmosphere when there is no pressure being supplied by the flow generator device. Mounted to the frame is an adjustable forehead support for resting against the patient's forehead. The headgear has quick release clips and hook and loop adjustment on the straps.

Intended Use: The Invacare Twilight Full Face Mask is intended to be used with positive airway pressure (PAP) devices, such as CPAP and Bi-Level, which provide 4-20 cmH_2O for the treatment of adult obstructive sleep apnea. There is a port on the mask 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:

Specification	Twilight Full Face Mask	ResMed Mirage Full Face Mask Series 2	Respironics Spectrum 2 Reusable Full Face Mask, Model 1004884
510(k) Number	TBD	K023244	K002465
Date Cleared	TBD	November 27, 2002	September 8, 2000
Intended Use	The Invacare Twilight Full Face Mask is intended to be used with positive airway pressure (PAP) devices, such as CPAP and Bi-Level, which provide 4-20 cmH_2O for the treatment of adult obstructive sleep apnea. There is a port on the mask 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.	The Ultra Mirage Full Face Mask is intended for multi-patient use for adult patients (>30 kg) prescribed continuous positive airway pressure (CPAP) or bi-level therapy in hospital, clinic, and/or home environments.	The ComfortFull 2 Reusable Full face Mask and Headgear are intended for use by adults as an interface with Respironics CPAP or bi-level devices. The mask covers the nose and mouth. An exhalation port is built into the ComfortFull 2 mask so that a separate exhalation port is not required. Before using this mask, the home care provider should verify device pressure(s). This mask is not suitable for providing life support ventilation.
Patient Use	Adults >30Kg	Adults >30Kg	Adults
Single/Multiple Patient Use	Multiple-patient	Multiple-patient	Multiple-patient
Input Device Range	4-20 cmH_2O	4-20 cmH_2O	3-40 cmH_2O
Mask Frame Material	Polycarbonate	Polycarbonate	Polycarbonate
Nasal Cushion Material	Silicone	Silicone	Silicone
Anti-asphyxia Valve	Yes - silicone	Yes - silicone	Yes - silicone
Hose Connection Input	For Ø22mm hose	For Ø22mm hose	For Ø22mm hose
Exhalation Ports	5	6	44
Swivel Connections	360° Rotation	360° Rotation	360° Rotation
Ports	1 port	2 ports	1 port
Exhaust Flow	23 LPM @ 4 cmH_2O 53 LPM @ 20 cmH_2O	22 LPM @ 4 cmH_2O 54 LPM @ 20 cmH_2O	Below 5 cmH_2O, unknown ~ 43 LPM @ 20 cmH_2O
Pressure Drop at patient connection	< 0.3 cmH_2O @ 50 LPM < 1.0 cmH_2O @ 100 LPM	Unknown	Unknown
Internal volume (Dead space)	Dead space varies according to cushion sizes but is less than 303ml	Dead space varies according to cushion sizes but is less than 258mL	Dead space varies according to cushion sizes and is between 274mL and 428mL

As the chart above shows, the Invacare Full Face Mask incorporates features from both predicate devices. All of the above devices have the same intended use for the same patient population, are made of similar materials, have exhalation ports to prevent re-breathing of exhaled gases, have an anti-

asphyxia valve to guard against possible suffocation if the PAP unit shuts down while the patient is wearing the mask and ports in the mask frame to allow for pressure measurement devices.

Performance Testing: The Invacare Twilght Full Face Mask has been tested in accordance with the following:

ISO 17510-2:2003:	Sleep apnoea breathing therapy – Part 2: Masks and application accessories
ISO 5356-1:2004:	Anaesthethic and respiratory equipment – Conical connectors – Part1: Cones and sockets
ISO 13485:2003:	Medical devices - Quality management systems – Requirements for regulatory purposes
ISO 14971:2000: (Amendment 2003)	Medical devices – Application of risk management to Medical Devices
EN 980:2003:	Graphical symbols for use in the labeling of medical devices
EN 1041:1998:	Information supplied by the manufacturer with medical devices

Performance Data: The performance data found in this submission shows that the Invacare Full Face Mask performs as intended and in a manner that is substantially equivalent to the predicate devices.

Conclusion: The data presented in this submission shows that the Invacare Twilight Full Face Mask performs as intended and in a manner that is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Carroll Martin
Regulatory Specialist
Invacare Corporation
One Invacare Way
Elyria, Ohio 44035-4190

APR 30 2007

Re: K070321
Trade/Device Name: Twilight Full Face Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: February 1, 2007
Received: February 5, 2007

Dear Mr. Martin:

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.

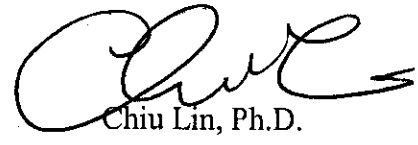
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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): K070321

Device Name: Twilight Full Face Mask

Indications for Use: The Invacare Twilight Full Face Mask is intended to be used with positive airway pressure (PAP) devices, such as CPAP and Bi-Level, which provide 4-20 cmH_2O for the treatment of adult obstructive sleep apnea. There is a port on the mask 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)

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

510(k) Number: K070321