K062224

510(k) SUMMARY

Special 510(k) – RespCare Hybrid AV Mask

Submitter's Name:	RespCare Inc.
Submitter's Address:	6601 Lyons Road, Suites B1-B4 Coconut Creek, Fl 33073, USA
Telephone Number:	(561) 208-3778
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Contact Person:	Frank Pelc
Date:	August 1, 2006
Proprietary Name:	RespCare Hybrid AV Mask
Common/Usual Name:	Face Mask
Classification:	Class II, CFR 868.5905, BZD
Classification Name:	Accessory to Noncontinuous Ventilator
Predicate Device:	K052227, RespCare Face Mask

AUG 17 2006

Device Description

The RespCare Hybrid AV Mask is a patient interface accessory to a positive pressure ventilator intended for treatment of respiratory insufficiencies and obstructive sleep apnea. The device delivers positive airway pressure from a CPAP or bi-level device to the patient's oral and nasal passages. Connection to the ventilator device is made by a standard 22 mm fitting. The mask is held in place on the face by headgear worn around the head. The device includes anti-asphyxia valve and oxygen entrainment port features.

Comparison to Predicate Devices

Modifications relate to providing a mask for use with systems that incorporate built-in exhalation devices. The exhalation ports are removed from the mask shell. Also, the optional male coupling adaptor is eliminated, as a female coupling is appropriate for connecting to a separate exhalation device. Labeling changes relate only to the above changes. The instructions specify that the Hybrid AV must be used with a separate exhalation device, and specify that the mask connects to a male hose fitting.

Other than these differences, the Hybrid AV Mask is essentially similar to the predicate device.

Substantial Equivalence

The information provided in this Special 510(k) demonstrates that the proposed device is substantially equivalent to the identified predicate device. The intended use and indications of the modified device are the same as the intended uses and indications as the predicate device. The modified device uses the same fundamental scientific technology as the predicate device. Changes to the design do not raise new issues of safety and effectiveness, and safety and effectiveness are verified using the same methods as reviewed in the K052227 clearance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 17 2006

Mr. Frank Pelc
Director, Regulatory Affairs
Pespcare, Incorporated
6601 Lyons Road, Suites B1-B4
Coconut Creek, Florida 33073

Re: K062224
Trade/Device Name: RespCare Hybrid AV Mask
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: August 1, 2006
Received: August 3, 2006

Dear Mr. Pelc:

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 (301) 443-6597 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):

Device Name: RespCare Hybrid AV Mask

Indications for Use:
The RespCare Hybrid AV Mask is intended for use by adults (> 30 kg) as a patient interface for CPAP or Bi-Level positive-pressure ventilation devices for treatment of respiratory insufficiencies and obstructive sleep apnea.

(Applies to the standard version):
For homecare applications, the Hybrid AV Mask may be reused multiple times by a single patient. For institutional applications (i.e. hospital or other clinical settings), this interface may be reused multiple times by multiple patients.

(Applies to the Disposable version):
The Hybrid AV Disposable Mask is a single patient, single use interface.

Prescription Use __X___ 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)

...Sign-Off)
...ion of Anesthesiology, General Hospital,
...ion Control, Dental Devices
...) Number: K062224