K062019

AUG 17 2006

510(k) SUMMARY

Submitter's Name:	RespCare Inc.
Submitter's Address:	6601 Lyons Road, Suites B1-B4 Coconut Creek, Fl 33073, USA
Telephone Number:	(561) 208-3778
Fax Number:	(954) 727-8479
Contact Person:	Frank Pelc
Date:	July 14, 2006
Proprietary Name:	RespCare Hybrid NE Mask
Common/Usual Name:	Face Mask
Classification:	Class II, CFR 868.5895, CBK
Classification Name:	Accessory to Continuous Ventilator
Predicate Devices:	K030515 – Hans Rudolph 7500 Vmask K023135 – Respironics Image3 SE

Device Description
A specialized interface for Non-Invasive Ventilation. It will be modeled after the RespCare Face Mask (K052227), with intentional exhalation features removed for use with ventilators equipped with an active safety valve.

Comparison to Predicate Devices
The RespCare Hybrid NE Mask is essentially similar to the legally marketed predicate interfaces listed above in function, intended use, materials, and features. The essential difference between the RespCare face mask and the predicate devices is the shape of the interface.

Both the proposed device and the predicates are intended to be used as a patient interface for non-invasive ventilation devices. Each are designed to be suitable for use with ventilators equipped with an active safety valve. Each deliver non-invasive ventilation to the patient's oral and nasal passages and provide a seal against the face as it is held in place with a headgear worn around the head. Each provide accessory ports for pressure monitoring or supplemental oxygen, and connect to the ventilator device via a standard 22 mm fitting.

Substantial Equivalence
The RespCare Hybrid NE Mask is equivalent to the predicate devices in intended use, environment of use, patient population, and frequency of use. Its basic method of operation and design is also equivalent to the predicates, as described in the comparison above. Materials information and functional testing relative to the intended use of the RespCare Hybrid NE Mask show that it is as safe and effective as the predicate devices.

As such, it is RespCare's conclusion that the RespCare Hybrid NE Mask 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

AUG 17 2006

Mr. Frank Pelc
Director, Regulatory Affairs and Quality Compliance
Innomed Technologies, Incorporated /RespCare, Incorporated
6601 Lyons Road, Suites B1-B4
Coconut Creek, Florida 33073

Re: K062019
Trade/Device Name: Hybrid NE Mask
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: July 14, 2006
Received: July 17, 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

SECTION 7: INDICATIONS FOR USE

510(k) Number (if known): K062019

Device Name: Hybrid NE Mask

Indications for Use:

The Hybrid NE Mask is intended to provide a patient interface for application of noninvasive ventilation. The mask is to be used as an accessory to ventilators that have adequate alarms and safety systems for ventilator failure, and which are intended to administer positive pressure ventilation. The mask will be offered in a disposable version and a multi-use version. It is intended for use on adult patients (>30 kg), who are appropriate candidates for noninvasive ventilation.

(Applies to the standard version):
For homecare applications, the Hybrid NE 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 RespCare Hybrid NE Mask Disposable 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)
of Anesthesiology, General Hospital,
ion Control, Dental Devices
Number: K062019