SECTION 9: 510(K) SUMMARY

K071149

1. ***Summary Preparation Date***: April 7, 2007

2. ***Manufacturer/Applicant Information***:

Name: Hans Rudolph, Inc.

Company Headquarters and Manufacturing Location:

7205 Central

Kansas City, MO 64114

FDA Establishment Registration Number: 1922553

Contact Name: Kevin Rudolph, Vice President

Phone Number: 816-363-5522

Fax Number: 816-822-1414

E-Mail: kevin@rudolphkc.com

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3. ***Device Names and Designations:***

Proprietary Name	6500 Series V2masks™ (Non-vented)	6600 Series V2masks™ (Vented)	6700 Series V2masks™ (Non-vented)
Model Numbers and Sizes	6520 Large 6530 Medium 6540 Small 6550 Extra Small 6560 Petit	6620 Large 6630 Medium 6640 Small 6650 Extra Small 6660 Petit	6720 Large 6730 Medium 6740 Small 6750 Extra Small 6760 Petit
Common/Usual Name	Face Mask	Face Mask	Face Mask
Classification Name	Continuous Ventilator Accessory	Noncontinuous Ventilator (IPPB) Accessory	Noncontinuous Ventilator (IPPB) Accessory
Classification Panel	Anesthesiology	Anesthesiology	Anesthesiology
Classification Code	CBK	BZD	BZD
Regulation Number	CFR 21 Part 868.5895	CFR 21 Part 868.5905	CFR 21 Part 868.5905
Regulatory Class	2	2	2

4. ***Performance Standards and Special Controls:*** There are currently no performance standards or special control requirements for these devices.

5. ***Substantial Equivalency***: The V2masks™ are substantially equivalent to the following predicates:

6500 Series V2masks™ Predicates	6600 and 6700 Series V2masks™ Predicates
Respironics Image3 SE Disposable Full-Face Mask (K023135)	Respironics Image3 Disposable Full-Face Mask (K002465)
ResMed Mirage Non-Vented Full Face Mask Series 2 (K023244, K023284, and K023306)	ResMed Hospital Full Face Mask (K041362)
Hans Rudolph 7500 Series Reusable Oro-Nasal NIV Mask (K030515)	Hans Rudolph 7600 Series Multi-Patient Multi-Use Oro-Nasal CPAP/NIPPV Masks (K030822 and K020759)

The V2masks™ possess the same intended use, indications for use, and intended patient population as these predicate devices. No new questions regarding safety or effectiveness are raised.

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Among the evidence presented in the 510(k) to support the equivalency of the V2masks™ to the predicates is: (a.) device description and hazard analysis, (b.) laboratory studies comparing the performance of the V2masks™ to the predicates and (c.) laboratory performance verification and validation data.

6. ***Intended Use, Indications for Use, & Environment***:

6500 Series V2masks™

Intended Use: The 6500 Series V2masks™ are disposable, single-patient-use, adult oro-nasal masks intended to provide a patient interface for application of noninvasive ventilation. The masks are to be used as an accessory to continuous ventilators which have adequate alarms and safety systems for ventilator failure.

Indications for Use & Environment: The Masks are specifically indicated for use on adult patients (> 30 kilograms weight) to administer positive pressure ventilation for treatment of respiratory failure or respiratory insufficiency. They are intended for use on patients who are appropriate candidates for noninvasive ventilation, in the home, hospital, or other clinical settings by individuals that have received at least minimal instruction or training on the use of the masks as well as the device and system to which the masks are intended to connect.

6600 Series V2masks™

Intended Use: The 6600 Series V2masks™ are disposable, single-patient-use, adult oro-nasal CPAP and noninvasive positive pressure ventilation (NIPPV) masks which incorporate passive, continuous flow exhaust ports into the mask itself. They are intended for use with certain CPAP machines for treatment of obstructive sleep apnea, and for use with other similar ventilators that use this exhaust port configuration providing a minimum of 3 cm H_20 pressure measured at the mask.

Indications for Use & Environment: The Masks are specifically indicated for use on adult patients (> 30 kilograms weight) for treatment of Obstructive Sleep Apnea or any other conditions requiring CPAP or noninvasive ventilatory support (at pressures >3.0 cm H_20 at the mask) in homes, hospitals, or other clinical settings by individuals that have received at least minimal instruction or training on the use of the masks as well as the device and system to which the masks are intended to connect.

6700 Series V2masks™

Intended Use: The 6700 Series V2masks™ are disposable, single-patient-use, adult oro-nasal CPAP/NIPPV masks without any passive, continuous flow exhaust port built into the mask. They are intended for use with certain CPAP machines for treatment of obstructive sleep apnea, and for use with other similar ventilators that incorporate the patient vent into the patient circuit instead of the mask. These masks provide a minimum of 3 cm H_20 pressure measured at the mask.

Indications for Use & Environment: The Masks are specifically indicated for use on adult patients (> 30 kilograms weight) for treatment of Obstructive Sleep Apnea or any other conditions requiring CPAP or non-invasive ventilatory support (at pressures >3.0 cm H_20 at the mask) in homes, hospitals, or other clinical settings by individuals that have received at least minimal instruction or training on the use of the masks as well as the device and system to which the masks are intended to connect.

Contraindications

The V2masks™ may not be suitable for use on patients with the following conditions:

1. open wounds that are prone to infection
2. hemodynamic or cardiorespiratory instability
3. unconsciousness
4. claustrophobia, anxiety, or other discomfort with oro-nasal mask
5. facial or nasopharyngeal deformity, beard, or other inability to fit mask & seal properly
6. excessive reflux, GI blood, or nasal secretions
7. impaired cough reflex, hiatal hernia, or inability to swallow or clear secretions
8. upper airway obstruction or facial trauma
9. barotrauma
10. recent facial, esophageal, or gastric surgery
11. patients unable to remove mask
12. patients under medication with a drug that may cause vomiting
13. patients requiring immediate intubation

Complications

The V2masks™ are non-invasive devices. The surface which is applied directly to the patient's skin is soft, pliable and biocompatible material. The masks are safe in both construction and use. This has been confirmed by the performance of Verification and Validation Testing, Biocompatibility Confirmation, Hazard Analyses, and Comparative Testing (all are included as a part of this 510(k) submittal).

Following are some possible minor to moderate complications for the V2masks™:

1. infection due to improper use over open wounds
2. skin irritation after prolonged use caused by rubbing of the mask
3. nasal or dental pain or deformity
4. drying of pharyngeal and nasal mucosa
5. eye irritation or conjunctivitis
6. gastric distention and abdominal pain or flatulence from ingested air
7. some slight discomfort after prolonged use
8. decreased secretion clearance especially during upper respiratory tract infections
9. aspiration of secretions

7. ***General Device Description***: The Disposable Single-Patient-Use Oro-Nasal V2mask™ devices consist of the following basic components:

1. Mounting Head Gear
2. Face Piece
3. Swivel Port Assembly

The Face Piece and the Swivel Port Assembly are cleanable and are disposable after 7 days of single-patient treatment. However, they are not reusable after this time.

The Mounting Head Gear is also cleanable and disposable but not reusable after multiple uses. The Mounting Head Gear which comes in two sizes has straps which are adjustable in both length and tension. It holds the Face Piece against the patient's face to prevent any gas leakage.

The Elbow of the Swivel Port Assembly for the 6600 Series V2masks™ incorporate a series of vent holes to provide a continuous air leak to flush out the dead space CO_2 and prevent it from being rebreathed by the patient during CPAP or noninvasive positive pressure ventilation (NIPPV) therapy using the required single-limb patient circuit.

The Face Piece for all sizes of the 6500 and 6700 Series V2masks™ are nonvented. They do not incorporate vent holes in the Elbow. However, the 6500 Series requires the incorporation of a an active exhalation valve into the expiratory limb of the patient circuit used with the continuous ventilation device providing the noninvasive ventilation. The 6700 requires the incorporation of an exhaust valve into the single-limb patient circuit of the CPAP or NIPPV device. This provides the required air flow to flush out the dead space CO_2 and prevent it from being rebreathed.

The Swivel Port Assembly for the 6600 Series and the 6700 Series V2masks™ consists of the following pieces:

1. Mask Adapter
2. Elbow with Ant--Asphyxia Valve (AAV)
3. 22 mm OD Swivel Port

The AAV functions as a safety mechanism which allows the patient to breathe fresh air if the NIPPV or CPAP output ceases. It allows a minimum IPAP, EPAP or CPAP pressure of 3 cm H_20.

The 6500 Series V2mask™ Swivel Port Assembly consists of the same pieces except the Elbow does not incorporate an AAV. The safety mechanism provided by an AAV is already provided by the continuous ventilator which would recognize an AAV in the mask as a patient circuit leak.

8. ***Device Materials Biocompatibility***: All mask materials have successfully undergone biocompatibility testing at nationally-recognized biological testing laboratories. The mask Face Piece, which contacts the patient's skin, is constructed of injection grade thermoplastic elastomer (TPE). The anti-asphyxia valve, which comes into contact with the patient's breathed gases, is constructed of latex-free silicone rubber. The rest of the mask components (the Swivel Port Assembly), which comes into contact with the patient's breathed gases, is constructed of acrylic-based multipolymer compound. The mask Head Gear materials consist of nylon, polyester straps, and polycarbonate clips.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 1 2008

Mr. Kevin Rudolph
Vice President
Hans Rudolph, Incorporated
7205 Central
Kansas City, Missouri 64114

Re: K071149
Trade/Device Name: Hans Rudolph, Inc., 6500 Series V2masks ™
Hans Rudolph, Inc., 6600 Series V2masks ™
Hans Rudolph, Inc., 6700 Series V2masks ™
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II
Product Code: BZD
Dated: January 28, 2008
Received: January 30, 2008

Dear Mr. Rudolph:

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) 276-0115. 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 STATEMENT

510(k) Number (if known): _____

Device Name: Hans Rudolph, Inc., 6500 Series V2masks™

Indications For Use:

The 6500 Series V2masks are disposable, single-patient-use, adult oro-nasal masks intended to provide a patient interface for application of noninvasive ventilation. The masks are to be used as an accessory to continuous ventilators which have adequate alarms and safety systems for ventilator failure.

The masks are specifically indicated for use on adult patients (> 30 kilograms weight) to administer positive pressure ventilation for treatment of respiratory failure or respiratory insufficiency. They are intended for use on patients who are appropriate candidates for noninvasive ventilation, in the home, hospital, or other clinical settings by individuals that have received at least minimal instruction or training on the use of the masks as well as the device and system to which the masks are intended to connect.

Prescription Use __X__ AND/OR Over-The-Counter Use ___
(Per 21 CFR 801.109 Subpart D) (21 CFR 807 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: K071149

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: Hans Rudolph, Inc., 6600 Series V2masks™

Indications For Use:

The 6600 Series V2masks are disposable, single-patient-use, adult oro-nasal CPAP/NIPPV masks which incorporate passive, continuous flow exhaust ports into the mask itself. They are intended for use with certain CPAP machines for treatment of obstructive sleep apnea, and for use with other similar ventilators that use this exhaust port configuration providing a minimum of 3 cm H_20 pressure measured at the mask.

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Prescription Use __X__ AND/OR Over-The-Counter Use ____
(Per 21 CFR 801.109 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K071149

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: Hans Rudolph, Inc., 6700 Series V2masks™

Indications For Use:

The 6700 Series V2masks are disposable, single-patient-use, adult oro-nasal CPAP/NIPPV masks without any passive, continuous flow exhaust port built into the mask. They are intended for use with certain CPAP machines for treatment of obstructive sleep apnea, and for use with other similar ventilators that incorporate the patient vent into the patient circuit instead of the mask. These masks provide a minimum of 3 cm H_20 pressure measured at the mask.

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