AUG 1 3 2002

K020759

SECTION 14: 510(K) SUMMARY

1. ***Summary Preparation Date***: August 7, 2001

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 and Title Official Correspondent: Kevin Rudolph, Vice President
Phone Number: 816-363-5522
Fax Number: 816-822-1414

3. ***Proprietary Name***: 7600 Series Reusable Full-Face CPAP/NIPPV Masks

Model Numbers & Sizes:
a. 7620 Large
b. 7630 Medium
c. 7640 Small
d. 7650 Extra Small
e. 7660 Petite
Common/Usual Name: Face Mask
Classification Name: Noncontinuous Ventilator (IPPB) Accessory
Classification Panel: Anesthesiology
Classification Code Based on Full-Face Mask Predicates: BZD

4. ***BZD Device Identification***: (21 CFR Part 868.5905): A noncontinuous ventilator (intermittent positive pressure breathing-IPPB) is a device intended to deliver intermittently an aerosol to a patient's lungs or to assist a patient's breathing. [The device which is the subject of this 510(k) submittal is an accessory to such a device (FDA product code BZD) and also to other blower-operated ventilation devices with product codes MNT, MNS, and CBK.]

5. ***Regulatory Status***: Noncontinuous ventilators and their accessories (FDA product code BZD) have been classified by the FDA as class II. Ventilation devices MNT, MNS and CBK have also been classified by the FDA as class II. There are currently no performance standards or special control requirements for any of these devices.

6. ***Substantial Equivalence***: The Hans Rudolph 7600 Series Reusable Full-Face CPAP/NIPPV Masks are substantially equivalent to the ResMed Sullivan7 Mirage™ Full Face Mask (K982530), Respironics Spectrum™ Disposable Full Face Masks (K936047), and the Respironics Spectrum™ Reusable Full Face Masks (K961915).

The characteristics of the Hans Rudolph 7600 Series Reusable Full-Face CPAP/NIPPV Masks are similar to those of the predicates mentioned above. The few minor differences in technological characteristics do not raise any new questions regarding safety or effectiveness.

Hans Rudolph has created a Design Control Procedure system which is in accordance with ISO 9001, EN 46001, and the FDA Quality System Requirements detailed in 21 CFR 820. It has complied with these Design Control Procedures for all of the verification and validation (V & V) data generated to support the equivalency of this device.

Among the V & V data generated to support the equivalency of the Hans Rudolph 7600 Series Reusable Full-Face CPAP/NIPPV Masks to the predicates is: (a.) risk assessment and reduction analysis, (b.) laboratory studies comparing the performance of the 7600 Series Masks with predicates, (c.) human factors studies, and (d.) laboratory performance verification and validation.

7. ***General Device Description***: The 7600 Series Reusable Full-Face CPAP/NIPPV Masks consists of the following components:

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

The Face Piece and the Swivel Port Assembly are both sterilizable and reusable. The Mounting Head Gear is disposable after multiple uses.

The Mounting Head Gear is adjustable in both its size and tension and holds the Face Piece against the patient's face to prevent any gas leakage. The size range of adjustment have been determined by a Mask Human Factors Study. The Mounting Head Gear also holds both the Face Piece and the Swivel Port Assembly onto the patient's head and is capable of adjusting to varying head sizes as determined by the Mask Human Factors Study.

The physical properties and dimensional ranges of the Face Piece (Mask) sizes listed under section #3 above have been determined by a Mask Human Factors Study.

All Face Piece sizes incorporate a series of vent holes in the area of the nose to provide a continuous air leak to flush out the dead space CO_2 and prevent it from being rebreathed by the patient. The incorporation of these holes do not interfere with the other performance requirements of the 7600 Series Mask. The vent holes also function to allow the patient to exhale normally regardless as to whether he or she is connected to single or dual level CPAP system or an MNT, MNS or CBK ventilator and regardless of the make or model of the CPAP or MNT, MNS or CBK ventilator blower device being used.

The Swivel Port Assembly consists of the following pieces:

1. Mask Adapter
2. Elbow with Anti-Asphyxia Valve
3. 22 mm Swivel Port

The 22 mm Swivel Port is sized to connect to all standard CPAP or MNT, MNS or CBK ventilator blower tubing types. The Elbow provides 360° of swivel rotation both at the Mask Adapter and at the 22 mm Swivel Port. The Anti-Asphxyia Valve is detachable from the Elbow for cleaning, sterilization and replacement.

The Anti-Asphxyia Valve functions as a safety mechanism which allows the patient to breathe fresh air if the CPAP or MNT, MNS, or CBK ventilator blower output ceases.

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

Intended Use: The Hans Rudolph 7600 Vmask Series is a reuseable, single patient multi –use, adult Full-Face CPAP/NPPV mask which incorporates a passive, continuous flow exhaust port at the patient connection. It is 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 H2O pressure measured at the mask.

Environment of Use: The Hans Rudolph 7600 Series Reusable Full-Face CPAP/NIPPV Masks are for use in homes, hospitals, and other clinical settings by individuals that have received at least minimal instruction or training on the use of the device and system to which the masks are intended to connect.

Indications for Use: The Hans Rudolph 7600 Series Reusable Full-Face CPAP/NIPPV Masks are 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 $\geq$ 3.0 cm H_2O at the mask in homes, hospitals, and other clinical settings.

Contraindications: The masks will not remain sterile between repeated single-patient uses and should not be placed over open wounds that are prone to infection. Cleaning, disinfection, and sterilization procedures are included as part of the Instructions for Use.

The Hans Rudolph 7600 Series Reusable Full-Face CPAP/NIPPV Masks may not be suitable for use on patients with the following conditions:

1. a minimum pressure < 3 cm H_2O at mask
2. open wounds that are prone to infection
3. hemodynamic or cardiorespiratory instability
4. unconsciousness
5. claustrophobia, anxiety, or other discomfort with full-face mask
6. facial or nasopharyngeal deformity, beard, or other inability to fit mask & seal properly
7. excessive reflux, GI blood, or other secretions
8. impaired cough reflex, hiatal hernia, or inability to swallow or clear secretions
9. upper airway obstruction or facial trauma
10. barotrauma
11. need for ventilation or ventilatory support more than 12 hours per day

12. recent facial, esophageal, or gastric surgery
13. patients unable to remove mask
14. patients under medication with a drug that may cause vomiting
15. patients requiring immediate intubation

Complications: The Hans Rudolph 7600 Series Reusable Full-Face CPAP/NIPPV Masks are non-invasive devices. The silicone surface which is applied directly to the patient's skin is soft, pliable and a biocompatible material. The masks are safe in both construction and use. This has been confirmed by the performance of Verification and Validation Testing, Biocompatibility Testing, Risk Assessment Analysis, and Comparative Testing.

Following are some possible minor to moderate complications:

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

9. ***Device Materials***: The mask Face Piece, which contacts the patient's skin, is constructed of silicone rubber (latex-free). This material has successfully undergone biocompatibility testing at a nationally recognized biological testing laboratory. The mask Head Gear materials consist of nylon and polyester straps and polycarbonate clips. All other components which are not in contact with the patient's skin are constructed of polysulfone material. All mask components other than the Head Gear are capable of both glutaraldehyde and steam sterilization.

10. ***Comparison Table***: The table that follows describes the important characteristics of the 7600 Series Reusable Full-Face CPAP/NIPPV Masks and three claimed predicates: ResMed Sullivan7 Mirage™ Full Face Masks (K982530), Respironics Spectrum™ Reusable Full Face Masks (K961915), and Respironics Spectrum™ Disposable Full Face Masks (K936047) **[Characteristics of the Respironics disposable mask are mostly identical to the Respironics reusable mask, exceptions for the disposable mask are indicated in brackets]**. The similarities and differences between the 7600 Series Reusable Full-Face CPAP/NIPPV Masks and its predicates are shown in the "Similar/Different" column. **The differences are always shown at the bottom section of each "Similar/Different" cell and are shown in bold type.**

		Predicate devices		7600 Series Reusable Full-Face CPAP/NIPPV Masks
#	Characteristic	ResMed Sullivan7 Mirage™ Full Face Mask	Respironics Spectrum™ Reusable and Disposable Full Face Mask [Disposable Exceptions]	Similar/Different
1	intended use	adult patient interface accessory for use with CPAP, bilevel, or ventilation support systems	connect adult or pediatric patients to CPAP, BiPAP, or ventilation support system designed to augment the patient's ability to breathe on a spontaneous basis	connect adult patients to single and dual level CPAP devices and to non-invasively connect adult patients to blower-operated respiratory support ventilators
2	indications	obstructive sleep apnea (OSA), respiratory insufficiency, and/or respiratory failure	respiratory failure, respiratory insufficiency, and/or obstructive sleep apnea	obstructive sleep apnea or any other conditions requiring CPAP or non-invasive ventilatory support
3	environment	hospitals, homes, and clinical settings	hospital, homes, and institutions	homes, hospitals, and other clinical settings
4	personnel education and training	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	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	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
5	reuse	single patient multi-use	single patient multi-use [disposable]	single patient multi-use
6	safety mechanisms	anti-suffocation valve to guard against loss of flow source; mask quick-release feature to guard against aspiration or suffocation; mask vent holes to prevent CO_2 buildup	entrainment valve to guard against loss of flow source; mask quick-release feature to guard against aspiration or suffocation	safety breathe-out valve to guard against loss of flow source; mask pull-string release feature to guard against aspiration or suffocation; mask vent holes to prevent CO_2 buildup
7	anti-suffocation valve threshold	3.0 cm H_2O minimum	3.0 cm H_2O minimum	3.0 cm H_2O minimum

		Predicate devices		7600 Series Reusable Full-Face CPAP/NIPPV Masks
#	Characteristic	ResMed Sullivan7 Mirage™ Full Face Mask	Respironics Spectrum™ Reusable and Disposable Full Face Mask [Disposable Exceptions]	Similar/Different
8	fastening means	headgear straps	headgear straps	mounting head gear straps
9	mask sizes	three sizes (small, medium & large) fit a range of adult patients	four sizes (petite, small, medium & large) fit a range of adult patients	five sizes (petite, extra small, small, medium, & large) fit a range of adult patients **Model 7600 series has one more size than Respironics and two more sizes than ResMed to ensure a good fit**
10	mask material in contact with face	silicone rubber; soft, comfortable, latex-free	silicone rubber [vinyl]; comfortable	soft biocompatible silicone rubber (latex-free) **Spectrum™ Disposable uses vinyl**
11	cleaning instructions	yes	yes [no]	yes **Respironics Disposable has none**
12	validated disinfection instructions	instructions exist (not known if these are validated)	such instructions found only for exhalation valve (validation status unknown) [no]	 **Model 7600 series has validated disinfection instructions for all reusable mask components**
13	validated sterilization instructions	none known to exist	validated instructions found only for exhalation valve component [no]	 **Model 7600 series has validated sterilization instructions for all reusable mask components**
14	sterility at shipment	provided clean, non-sterile	provided clean, non-sterile	provided clean, non-sterile

		Predicate devices		7600 Series Reusable Full-Face CPAP/NIPPV Masks
#	Characteristic	ResMed Sullivan7 Mirage™ Full Face Mask	Respironics Spectrum™ Reusable and Disposable Full Face Mask [Disposable Exceptions]	Similar/Different
15	contraindications listed in labeling	a minimum pressure < 3 cm H_2O at the mask; impaired cardiac sphincter function; excessive reflux; impaired cough reflex; hiatus hernia; insufficient arousability; insufficient capability to remove mask; uncooperative, obtunded, or unresponsive patients	a minimum pressure < 3 cm H_2O at the mask; uncooperative, obtunded, or unresponsive patients; impaired cardiac sphincter function; excessive reflux; impaired cough reflex; hiatal hernia; patients unable to remove mask; patients under medication with a drug that may cause vomiting	min P < 3 cm H_2O at mask; open wounds that are prone to infection; hemodynamic or cardiorespiratory instability; unconsciousness; claustrophobia, anxiety, or other discomfort with full-face mask; facial or nasopharyngeal deformity, beard, or other inability to fit mask & seal properly; excessive reflux, GI blood, or other secretions; impaired cough reflex, hiatal hernia, or inability to swallow or clear secretions; upper airway obstruction or facial trauma; barotrauma; need for ventilation or ventilatory support more than 12 hours per day; recent facial, esophageal, or gastric surgery; patients unable to remove mask; patients under medication with a drug that may cause vomiting; patients requiring immediate intubation **more contraindications are recognized and these should also apply to predicates**
16	complications listed in labeling	infection due to improper use over open wounds; skin irritation after prolonged use caused by rubbing of the mask; some slight discomfort after prolonged use; aspiration of secretions; allergic reaction; stomach distention	infection due to improper use over open wounds; skin irritation after prolonged use caused by rubbing of the mask; some slight discomfort after prolonged use; aspiration of secretions; allergic reaction; stomach distention; belching	infection due to improper use over open wounds; skin irritation after prolonged use caused by rubbing of the mask; nasal or dental pain or deformity; drying of pharyngeal and nasal mucosa; eye irritation or conjunctivitis; gastric distention and abdominal pain or flatulence from ingested air; some slight discomfort after prolonged use; decreased secretion clearance especially during upper respiratory tract infections; aspiration of secretions **more details are given on complications and these should also apply to predicates**

		Predicate devices		7600 Series Reusable Full-Face CPAP/NIPPV Masks
#	Characteristic	ResMed Sullivan7 Mirage™ Full Face Mask	Respironics Spectrum™ Reusable and Disposable Full Face Mask [Disposable Exceptions]	Similar/Different
17	assemblies	headgear; mask (includes mask cushion, cushion clip, port cap, mask frame, mask port, port cap, & air vent); and valve (includes valve frame, valve membrane, valve clip, valve elbow, tab, swivel, & swivel clip)	headgear; full face mask (includes face mask, adjustable forehead tab, entrainment valve, quick release tab, quick release cord, and pressure pick-off port cap); and exhalation valve	mounting head gear; face piece with vent holes; and swivel port assembly (includes mask adapter, elbow with anti-asphxyia valve, and 22 mm swivel port)
18	material of mask shell & other pieces not in contact with face (excludes anti-suffocation valve)	transparent polycarbonate or acrylic	transparent polycarbonate or acrylic	**transparent polysulfone**
19	service life	unknown	unknown	**2 years**
20	maximum operating pressure	ResMed Sullivan7 VPAP7 series flow generators are rated at 25 cm H_2O maximum operating pressure. The Mirage™ Reusable Full Face Mask is used as a patient connection means.	Respironics Esprit ventilator is rated at 35 cm H_2O maximum operating pressure. The Spectrum Reusable Masks are used as patient connection means. [Respironics Vision is rated at 40 cm H_2O maximum operating pressure. The Spectrum Disposable Masks are used as patient connection means.]	Model 7600 is capable of meeting all its specifications while operating at a maximum pressure of 40 cm H_2O
21	carbon dioxide rebreathing	built-in air leak provided by series of holes in mask near nose flushes CO_2 out of mask	continuous air leak from exhalation valve helps to flush CO_2 out of mask	built-in air leak provided by series of holes in mask near nose flushes CO_2 out of mask

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 2002

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

Re: K020759
Trade/Device Name: 7600 Series Reusable Full-Face CPAP/NIPPV Masks
Regulation Number: 868.5905
Regulation Name: Accessory to Non-Continuous Ventilator
Regulatory Class: II
Product Code: BZD
Dated: June 12, 2002
Received: June 14, 2002

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646 . Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

Patricia Cucciardi for

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 5: INDICATIONS FOR USE STATEMENT

510(k) Number (if known) K020759

Device Name: Hans Rudolph 7600 Series Reusable Full-Face CPAP/NIPPV Masks

Indications For Use:

The Hans Rudolph 7600 Vmask series is a reusable, single patient multi-use, adult Full-Face CPAP/NIPPV mask which incorporates a passive, continuous flow exhaust port at the patient connection. It is 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 cmH20 pressure measured at the mask.

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 $\geq$ 3.0 cm H_2O at the mask) in homes, hospitals, and 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.

(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: K020759

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)