K030822

JUN - 3 2003

SECTION 10: 510(K) SUMMARY

1. ***Summary Preparation Date***: February 5, 2003

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

3. ***Proprietary Name***: 7600 Series Multi-Patient Multi-Use Oro-Nasal CPAP/NPPV 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 Multi-Patient Multi-Use Oro-Nasal CPAP/NPPV Masks are substantially equivalent to the Hans Rudolph 7600 Series Reusable (Single-Patient Multi-Use) Oro-Nasal CPAP/NPPV Masks (K020759).

These masks are identical in design, material and construction. The only difference between the two devices is that the labeling of the Multi-Patient Multi-Use Mask has been modified to

include mask use on multiple patients after proper cleaning and sterilization or disinfection has been performed.

The 510(k) includes verification data for both the recommended sterilization and disinfection processes.

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

Intended Use: The Hans Rudolph 7600 Vmask series are reusable, multi-patient multi-use, adult Oro-Nasal CPAP/NPPV masks which incorporate a passive, continuous flow exhaust port at the patient connection. 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_2O 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 $\geq$ 3.0 cm H_2O 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 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 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 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

8. ***General Device Description:*** 7600 Series Multi-Patient Multi-Use Oro-Nasal CPAP/NPPV 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 by multiple patients. The Mounting Head Gear is disposable after multiple uses by a single patient only.

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.

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 ventilation device tubing types. The Elbow provides 360° of swivel rotation both at the Mask Adapter and at the 22 mm Swivel Port. The Anti-Asphyxia Valve is detachable from the Elbow for cleaning, sterilization and replacement.

The Anti-Asphyxia Valve functions as a safety mechanism which allows the patient to breathe fresh air if the CPAP or ventilation device output ceases.

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 3 2003

Mr. Kevin Rudolph
Vice President
Hans Rudolph, Incorporated
7200 Wyandotte
Kansas City, Missouri 64114

Re: K030822
Trade/Device Name: 7600 Series Multi-Patient Multi-Use Oro-Nasal CPAP/NPPV Masks
Regulation Number: 21 CFR 868.5905
Regulation Name: Non-Continuous Ventilator
Regulatory Class: II
Product Code: 73 BZD
Dated: March 12, 2003
Received: March 14, 2003

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 (301) 594-4646. 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/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (if known) K030822

Device Name: Hans Rudolph 7600 Series Multi-Patient Multi-Use Oro-Nasal CPAP/NPPV Masks

Indications For Use:

The Hans Rudolph 7600 Vmask series are reusable, multi-patient multi-use, adult Oro-Nasal CPAP/NPPV masks which incorporate a passive, continuous flow exhaust port at the patient connection. 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_2O pressure measured at the mask.

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(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: K030822

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)