510(k) Summary

Lakeview Sleep Center, Nasal Comfort Freedom

The assigned 510(k) number is: K130686

510(k) Owner: Lakeview Sleep Center
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OCT 16 2013

Contact Person: Andy Black

Date Prepared: October 15, 2013

Device Name and Classification

Classification Name:	Accessory to Noncontinuous Ventilator (IPPB)
Common/Usual Name:	Vented Nasal Mask
Proprietary Name:	Nasal Comfort Freedom
Device Classification:	Class II
Regulation Number	21 CFR Ref. § 868.5905
Product Code:	BZD

Device Description

The Nasal Comfort Freedom is a medical device that is capable of connection to a positive pressure source, and provides a conduit for delivery of an air flow to a patient's nose. The device is a single-patient re-use device supplied non-sterile by prescription.

The Nasal Comfort Freedom interfaces with the patient by way of nasal pillows assembled into a breathing chamber. The nasal pillows and breathing chamber are soft and flexible to conform to the patient's nose. A rotating elbow is connected to the breathing chamber and incorporates a passive vent for exhaled gases to escape the device. The elbow is permanently connected at its distal end to a rotating connector. The Rotating Connector provides a means by which air supply may be connected and disconnected from the breathing mask via two

clips incorporated into the Tubing Connector. The supplied tubing uses a standard conical fitting for connection to currently marketed 22mm fittings for use with CPAP ventilators and accessories.

The Nasal Comfort Freedom is secured to the patient during use by way of a disposable adhesive strip that is fitted over the bridge of the patient's nose. The adhesive on the underside of the Nose Strip provides attachment to the patient's skin, while the outward facing layer of the strip features the loop side of a hook-and-loop fabric. The Breathing Chamber of the mask incorporates two hook fabric strips to be mated with the loop fabric of the Nose Strip. The patient may fit the nasal pillows into the nostrils, and then secure the hook strips over the loop strip on the nose to provide a snug fit of the device. Following each use, the Nose Strip may be removed and discarded by the patient.

Indications for Use

The Nasal Comfort Freedom provides a conduit such that airflow from a positive pressure source is directed to a patient's nose. The device is intended for adult patients (>66 lb/30kg) for whom positive airway pressure has been prescribed. The device is single-patient re-use, and is intended for use in a clinical or home-use environment.

Substantial Equivalence Claim

Based on comparison of device features, materials, intended use and performance, the Lakeview Sleep Center, Nasal Comfort Freedom is substantially equivalent to the commercially available predicate devices ResMed Swift FX approved by the FDA under 510k number K090244, and Respironics GoLife Nasal Mask approved by the FDA under 510k number K102502. Table 1 shows a summary of the technological characteristics of the Nasal Comfort Freedom compared to the predicate devices.

Differences in the Indications For Use statement of the Nasal Comfort Freedom and its predicate devices do not affect the safety and effectiveness of the device when used as labeled. The Nasal Comfort Freedom is indicated as a conduit for airflow from a positive pressure source, where the positive pressure air source is a CPAP or bi-level system specified by the Indications For Use of the predicate devices. Also the Nasal Comfort Freedom is single patient-reuse in both hospital and home use environments, where the predicate devices are multi-patient use in the hospital setting; therefore, the indications of the Nasal Comfort Freedom are more restrictive, and do not introduce additional risk to the patient compared to the predicate devices.

The technology incorporated into the Nasal Comfort Freedom is substantially equivalent to the technology for the predicate devices. All devices use a similar design structure that connects a positive air pressure source (CPAP machine) to a patient's nose by way of tubing, a breathing chamber with passive venting, and nasal pillows that insert into the patient's nostrils. All devices use equivalent or similar materials, with the prevalent air path materials consisting of Polycarbonate and Silicone.

The sizes of the components of the Nasal Comfort Freedom are equivalent to those of the predicate devices. The devices feature a 15mm ID connection tube intended for connection to tubing compatible with a CPAP machine. The Nasal Comfort Freedom has equivalent venting design, equivalent nasal pillow diameters, and has slightly less dead space than does the Swift FX.

The Nasal Comfort Freedom differs from the predicate devices in the method by which the device is fixed to the patient. The predicate devices use straps that are connected to the breathing chamber and fitted around the patient's head. The Nasal Comfort Freedom utilizes straps connected to the breathing chamber that are able to be attached to an adhesive strip applied to the patient's nose. The attachment method includes connection points to the chamber that are in an equivalent location as are those of the predicate devices, and comparative test data indicates that the Nasal Comfort Freedom has greater resistance to displacement from the patient than does the attachment mechanism of the predicate Swift FX. The adhesive strips are disposable, and may be available in various sizes for conformity to a variety of patient sizes.

Table 1. Summary of technological characteristics compared to predicate devices

Attribute	ResMed Swift FX	Respironics GoLife	Lakeview Sleep Center Nasal Comfort Freedom
A. Intended Use			
A.1 Indications for Use Statement	The Swift FX channels airflow noninvasively to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bilevel system. The Swift FX is: * to be used by adult patients (> 66 lb/30 kg) for whom positive airway pressure has been prescribed * intended for single-patient re-use in the home environment and multipatient re-use in the hospital / institutional environment.	The GoLife Nasal Mask is intended to provide an interface for Continuous Positive Airway Pressure (CPAP) or bi-level therapy. This mask is intended for single-patient reuse in the home and multi-patient, multi-use in the hospital/institutional environment. This mask is to be used on patients greater than 66 lbs / 30 kg.	The Nasal Comfort Freedom provides a conduit such that airflow from a positive pressure source is directed to a patient's nose. The device is intended for adult patients (>66 lb/30kg) for whom positive airway pressure has been prescribed. The device is single-patient re-use, and is intended for use in a clinical or home-use environment.
A.2 Labeling	Equivalent in content	Label not available	Equivalent in content
A.3 Target Population	Adult patients (>66 lbs)	Adult patients (>66 lbs)	Adult patients (>66 lbs)
B. Technology			
B.1 Patient contacting materials	Unknown	Hytrel, Silicone, Ethylene octane copolymer, Polycarbonate, Urethane	Silicone, Polycarbonate, Polyolefin, Polyethylene, Nylon, 3M 7331 adhesive
B.2 Design	The ResMed Swift FX is a nasal pillow style mask featuring a chamber, rotating elbow, tubing with connectors for adaptation to CPAP machines, nasal pillows, and strap headgear.	The Respironics GoLife is a nasal pillow style mask featuring a chamber, rotating elbow, tubing with connectors for adaptation to CPAP machines, nasal pillows, and strap headgear.	The Nasal Comfort Freedom is a nasal pillow style mask featuring a chamber, rotating elbow, tubing with connectors for adaptation to CPAP machines, nasal pillows, and straps for connection to patient's nose.
B.3 Length of connector tubing	12 inches	Unknown	12 inches
B.4 Diameter	Connector tubing ID = 15mm Minimum airway diameter 6mm as measured	Connector tubing ID = 15mm	Connector tubing ID = 15mm Minimum airway diameter 7mm
B.5 Exhaust	Passive, 38 holes, 0.027" diameter ~ 0.022 sq in exhaust area	Passive, dimensions unknown	Passive, 36 holes, 0.031" +/- 0.003" diameter ~ min 0.022 sq in exhaust area
B.6 Dead Space	103 mL (per IFU)	< 27mL (per IFU)	90 mL
B.7 Operating Pressure	4 - 20 cm H_2O	Unknown	5-20 cm H_2O
B.6 Sterilization	None	None	None

Attribute	ResMed Swift FX	Respironics GoLife	Lakeview Sleep Center Nasal Comfort Freedom
C. Performance Specifications			
C.1 Resistance to Flow	0.45 cmH_2O at 50 L/min (as measured)	0.5 cm H_2O at 50 L/min (per IFU)	0.46 cmH_2O at 50 L/min (as measured)
C.2 Exhaust Flow	Size XS: 2.8L/min at 3cm H_2O 8.5L/min at 10cm H_2O 28.3L/min at 20cm H_2O 39.6L/min at 30cm H_2O 53.8L/min at 40cm H_2O Size L: 11.3L/min at 3cm H_2O 25.5L/min at 10cm H_2O 56.6L/min at 20cm H_2O 73.6L/min at 30cm H_2O 90.6L/min at 40cm H_2O	Unknown	5.1L/min at 3cm H_2O 21.0L/min at 10cm H_2O 44.7L/min at 20cm H_2O 63.4L/min at 30cm H_2O 82.7L/min at 40cm H_2O
C.3 Inspiratory and Expiratory Resistance	Resistance to flow = 8.90cmH_2O	Unknown	Resistance to flow = 4.72cmH_2O
C.4 CO_2 Rebreathing	Normal Conditions: 38.42% at 5cmH2O 30.53% at 10cmH2O Single Fault Condition 1: 30.92% at 5cmH2O 32.68% at 10cmH2O Single Fault Condition 2: 46.58% at 5&10cmH2O	Unknown	Normal Conditions: 8.86% at 5cmH2O 7.34% at 10cmH2O Single Fault Condition 1: 11.95% at 5cmH2O 16.86% at 10cmH2O Single Fault Condition 2: 23.91% at 5&10cmH2O
C.5 Patient Disengagement	Superior Peel Max Load = 3.8N Displacement = 4.2mm Laterial Shear Max Load = 20.0N Displacment = 25.0mm	Unknown	Superior Peel Max Load = 12.6 Displacement at Swift FX max load= 4.1mm Lateral Shear Max Load = 46.0 N Displacement at Swift FX max load= 2.5 mm
C.6 Conical Fittings	Meets ISO 5356-1:2004	Meets ISO 5356-1:2004	Meets ISO 5356-1:2004

Summary of Testing

The Nasal Comfort Freedom has been tested in accordance with applicable standards. A summary of non-clinical tests performed to support the claim of substantial equivalence is below.

1. Conical Fitting Testing, ISO 5356-1:2004, Anesthetic and Respiratory Equipment
    a. Drop Test
    b. Engagement
    c. Disengagement
    d. Leakage
2. Resistance to Flow
3. Exhaust Flow
4. Inspiratory and Expiratory Resistance
5. Dead Space Volume
6. CO2 Rebreathing
7. Patient Disengagement
8. Biocompatibility Testing, ISO 10993-1:2009, Biological Evaluation of Medical Devices

The non-clinical tests performed were intended to assess the characteristics of airflow through the device, measured pressures within the device and at the patient interface, determine the ability of the device to exhaust exhaled gases from the patient, compare the ability of the device to remain affixed to the patient, and evaluate the materials from which the device is constructed.

The results of performance testing of the Nasal Comfort Freedom demonstrate that it is substantially equivalent to the performance, safety, and effectiveness of the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 16, 2013

Lakeview Sleep Center
C/O Mr. Andy Black
Senior Engineer
Medical Murray, Incorporated
400 North Rand Road
NORTH BARRINGTON IL 60010

Re: K130686
Trade/Device Name: Nasal Comfort Freedom
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: September 3, 2013
Received: September 17, 2013

Dear Mr. Black:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

FOR

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K130686

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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)

Anya C. Harry -S

Digitally signed by Anya C. Harry -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anya C. Harry -S, 0.9.2342.19200300.100.1.1=0011315590
Date: 2013.10.11 17:59:00 -04'00'