DEC 1 2005

K051964

510(k) Summary

Submitter Information:

Comedica, Inc.
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Dallas, TX 75214

Contact:

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Date Prepared:

November 28, 2005

Device Name & Classification:

Common Name: Noncontinuous Ventilator
Trade Name(s): PowerNeb™
Classification Name: Intermittent Positive Pressure Breathing Device
Class II device per 21 CFR 868.5905
Panel: DCRND, Anesthesiology, Defibrillator Device Group
Product Code: NHJ

Predicate Device:

The PowerNeb® Noncontinuous Ventilator is substantially equivalent to the following devices:

Bird (IPV) Noncontinuous Ventilator, marketed by Percussionaire Corp. under K895485 and the EZ Pap, marketed by DHD Healthcare Corp. under K991300. Comparative pre-set percussive frequency is equivalent to the Vortran PercussiveNEB, marketed under K003684 (which was found to be substantially equivalent to the Bird IPV). A comparison of these devices is provided below.

PowerNeb® (Proposed Device)	**IPV® (K895485)**	**EzPAP®(K991300)**
Indications: • Mobilization of endobronchial secretions • Lung expansion therapy • Treatment and prevention of atelectasis	Indications: • Mobilization of endobronchial secretions • Treatment and prevention of atelectasis	Indications: • Mobilization of endobronchial secretions • Treatment and prevention of atelectasis
Creates a positive expiratory pressure	Creates a positive expiratory pressure	Creates a positive expiratory pressure
Increases patient Functional Residual Capacity (FRC)	Increases patient Functional Residual Capacity (FRC)	Increases patient Functional Residual Capacity (FRC)
Creates a positive inspiratory pressure.	Creates a positive inspiratory pressure.	Creates a positive inspiratory pressure.
Selector ring adjustable in percussive mode (CHFO™) to provide peak pressures ≤ 30 cmH2O.[1]	Working pressure adjustable in percussive mode (IPV®) to provide peak pressures from 0 to > 80 cmH2O.	No percussive mode.
Provides a clinician controlled flow in static flow mode (CPEP™) for positive airway pressures of 0-20 cmH2O.	No static flow mode.	Provides a clinician controlled flow in static flow mode (EzPAP®) for positive airway pressures of 0-20 cmH2O.
Nebulization is standard feature.	Nebulization is standard feature.	Nebulization must be added.
Can provide a percussive or static lung inflation component.	Provides percussive component only.	Provides static component only.
Percussive frequency rate pre-set at 100 – 300 bpm.[2]	Clinician controlled percussive frequency rate at 100 – 300 bpm.[3]	No percussive frequency.
Disposable, single-patient use interface circuit.	Non-disposable, re-usable interface circuit.	Disposable, single-patient use device.

[1] In recent years an abundance of evidence has emerged to suggest that peak alveolar pressures of 30 cmH2O and less are safer than those higher than 30. E.g. see attached article, *New England Journal of Medicine,* May 4, 2000. 342(18):1301-1308.
[2] PercussiveNEB™ (K003684), which used IPV as a predicate, is also preset.
[3] IPV® has just announced a model with pre-set frequency. Literature is not available at this writing.

Description:

The PowerNeb is a pneumatic, single-patient use device used to enhance secretion clearance, deliver aerosol, and recruit lung volumes. PowerNeb uses a fixed venture against a user-set orifice to create a continuous high frequency oscillation (CHFO) waveform at 180-220 breaths per minute (BPM). The PowerNeb can also deliver a continuous expiratory pressure (CPEP) when switched to CPEP mode.

This device is pneumatic in operation and does not incorporate any electronic parts or software. This device is non-sterile, and is not intended to be sterilized by the user. The PowerNeb is packaged with a a small-volume nebulizer/mouthpiece, and a disposable manometer, each of which has been previously 510k cleared.

Intended Use:

PowerNeb® is indicated for mobilization of secretions, lung expansion therapy, the treatment and prevention of pulmonary atelectasis, and also has the ability to provide supplemental oxygen when used with compressed oxygen.

Performance Testing

Performance testing includes comparative testing against the predicate devices, as well as testing of particle sizes from the small-volume nebulizer both with and without the PowerNeb, to determine any effects of the PowerNeb on the nebulizer's performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 2005

Comedica, Incorporated
C/O Ms. Krista Oakes
Principal
Amica Solutions
2300 McDermott Road, Suite 200-207
Plano, Texas 75025

Re: K051964
Trade/Device Name: PowerNeb™
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: NHJ
Dated: October 25, 2005
Received: October 26, 2005

Dear. Ms. Oakes:

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

Indications for Use

510(k) # (if known): K051964

Device Name: PowerNeb ™

Indications for Use:

PowerNeb® is indicated for mobilization of secretions, lung expansion therapy, the treatment and prevention of pulmonary atelectasis, and also has the ability to provide supplemental oxygen when used with compressed oxygen.

Prescription Use __x____ AND/OR Over-the-Counter Use _____
(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)

[signature]

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

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