K124032

510(k) Summary

APR 2 5 2013

Date Prepared	26-Mar-13
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Official Contact:	Hejie Wang - RA / QA Specialist
Proprietary or Trade Name:	MetaNeb® or MetaNeb® 4
Common/Usual Name:	Noncontinuous ventilator (IPPB)
Classification Code/Name:	NHJ – non-continuous ventilator (IPPB) 21 CFR 868.5905 Class 2
Predicate Devices:	K051964 – PowerNeb® CoMedica K895485 – IPV – Percussionaire Corp

Device Description:

The MetaNeb® System is a therapeutic device that uses a systematic approach to enhance normal mucus clearance and resolve or prevent patchy atelectasis.

The system has three modes:

- Aerosol—for the delivery of aerosol only. In this mode CHFO and CPEP are not available.
- CHFO (Continuous High Frequency Oscillation)—a pneumatic form of chest physiotherapy that delivers medicated aerosol while oscillating the airways with continuous pulses of positive pressure.
- CPEP (Continuous Positive Expiratory Pressure)—supplies medicated aerosol combined with continuous positive pressure to help hold open and expand the airways.

There are three major components to The MetaNeb® System:

- Circuit - includes a mouthpiece, handset, nebulizer, tubing, and filter/tri-connector. It is a single patient use, disposable that is intended for multiple treatment sessions.
- Controller - contains the controls to select the three different modes. It also has a manometer to monitor pressure. Power is supplied by a hose connected to a 50 psi oxygen source.
- Stand - lets The MetaNeb® System be easily moved from room to room.

Indications for Use:

The MetaNeb® System 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.

Patient Population:

Adult and Child > 2 years old

Environment of Use:

Hospitals, sub-acute facilities, physician offices, and clinics.

Predicate Device Comparison:

The MetaNeb® system is viewed as substantially equivalent to the predicate devices because:

Indications –
The proposed indications for use 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 are identical to the predicates
Discussion: The indications for use are identical to the predicates CoMedica PowerNeb (K51964) and Bird IPV (K895485).

Technology –
The design of the MetaNeb® system as a pneumatically operated system with different modes of operation: CPEP, CHFO, and aerosol only are identical to the predicates in design and basic function and performance.
Discussion: The design of MetaNeb® is substantially equivalent to the predicates CoMedica PowerNeb (K51964) and Bird IPV (K895485).

The MetaNeb® offers some convenient features for the user that are different than the predicates. These are Aerosol Only mode vs. the Comedica PowerNeb (K051964) which requires the user to set the CPEP to minimum flow to deliver aerosol only. While the predicate IPV (K895485) has use an in-line nebulizer but does not have an aerosol only setting. These differences do not raise any new safety or efficacy concerns relative to the predicates.

Materials –
The materials in the gas and fluid pathway are considered external communicating, tissue contacting, prolonged duration have been tested per ISO 10993-1.
Discussion: All associated materials in the gas or fluid pathway have been tested per ISO 10993-1 and where applicable VOC and $PM_{2.5}$ testing was performed. The results demonstrate the materials to be safe for the intended use.

Environment of Use –
The proposed environments of use are hospital and sub-acute facilities which are identical to the predicates, noting that the Bird IPV is also intended for the home environment.
Discussion: The intended environments of use are identical to the predicates CoMedica PowerNeb (K51964) and Bird IPV (K895485).

Patient Population –
The MetaNeb® is intended for patients that require therapy mobilization of secretions, lung expansion therapy, the treatment and prevention of pulmonary atelectasis.
Discussion: It is noted that the Bird IPV indicates that it is used with neonates to adults and the patient population for the MetaNeb® system could be > 2 years old. This is considered equivalent to the predicates CoMedica PowerNeb (K51964) and Bird IPV (K895485).

Differences –
There are no differences between the predicate and the proposed device which would raise any new safety or risks and thus can be found to be substantially equivalent.

Table 1 – Substantial Equivalence Comparative Table

	MetaNeb®	**PowerNeb CoMedica - K051964**	**IPV Bird - K895485**
CFR Classification	868.5905 NHJ	868.5905 NHJ	868.5905 NHJ
Classification name	Device, positive pressure breathing, intermittent (IPPB)	Device, positive pressure breathing, intermittent (IPPB)	Device, positive pressure breathing, intermittent (IPPB)
Indications for Use	Indicated for mobilization of secretions, lung expansion therapy, treatment and prevention of pulmonary atelectasis, ability to provide supplemental oxygen when used with compressed oxygen.	Indicated for mobilization of secretions, lung expansion therapy, treatment and prevention of pulmonary atelectasis, ability to provide supplemental oxygen when used with compressed oxygen.	Indicated for the mobilization and raising of endobronchial secretions, bronchodilation, reducing mucosal edema, resolution of diffuse patchy atelectasis in all patient populations.
Environments of Use	Hospital, sub-acute facilities	Hospital, sub-acute facilities	Hospital, sub-acute facilities, homecare
Patient Population	Adult Child > 2 years old	All patients that require therapy mobilization of secretions, lung expansion therapy, the treatment and prevention of pulmonary atelectasis.	All patient populations

	MetaNeb®	**PowerNeb CoMedica - K051964**	**IPV Bird - K895485**
Contraindications	-Untreated tension pneumothorax -Untrained or unskilled operator -History of pneumothorax -Pulmonary air leak -Recent pneumonectomy -Pulmonary hemorrhage -Myocardial infarction -Vomiting	-Untreated tension pneumothorax -Untrained or unskilled operator -History of pneumothorax -Pulmonary air leak -Recent pneumonectomy -Pulmonary hemorrhage -Myocardial infarction -Vomiting	-Untreated tension pneumothorax -Lack of adequate, skilled supervision
Mode of Operation	Pneumatic system using a fixed venturi patient circuit combined with medicated aerosol to deliver continuous high frequency oscillation therapy at 2 pre-set frequencies and amplitude. Can deliver continuous expiratory pressure (CPEP) combined with medicated aerosol.	Pneumatic system using a fixed venturi patient circuit combined with medicated aerosol to deliver continuous high frequency oscillation therapy at 1 pre-set frequency and amplitude Can deliver continuous expiratory pressure (CPEP) combined with medicated aerosol.	Pneumatic system using a variable (sliding) venturi patient circuit combined with medicated aerosol to deliver continuous high frequency oscillation therapy at multiple user settable frequencies and amplitudes. Equivalent CPEP function not available.
Modes	CPEP CHFO Aerosol Only	CPEP CHFO Can allow in-line aerosol treatments	CHFO Can allow in-line aerosol treatments
CPEP Continuous Positive Expiratory Pressure	Controlled static flow with positive pressures $\leq$ 30 cm H_2O	Controlled static flow with positive pressures $\leq$ 20 cm H_2O	No static flow mode

	MetaNeb®	**PowerNeb CoMedica - K051964**	**IPV Bird - K895485**
CHFO Continuous High Frequency Oscillations	Controlled continuous flow with frequencies up to 300 beats per minute and peak positive pressures ≤ 30 cmH_2O	Controlled continuous flow with frequencies up to 300 beats per minute and peak positive pressures ≤ 30 cmH_2O	Controlled Intrapulmonary Percussive Ventilation (IPV) frequencies up to 300 beats per minute and peak positive pressures ≤ 80 cmH_2O
Aerosol Only	Controlled continuous constant flow to in-line nebulizer delivering medicated aerosol only.	Equivalent Aerosol Only function by setting CPEP to minimum flow with in-line nebulizer	Can use in-line nebulizer
Patient Circuit	Disposable circuit referred to as "hand-set" includes connection for in-line nebulizer Draw in room air mix with medicated aerosol and gas from controller	Disposable circuit referred to as "hand-set" includes connection for in-line nebulizer Draw in room air mix with medicated aerosol and gas from controller	Reusable circuit includes connection for in-line nebulizer Draw in room air mix with medicated aerosol and gas from controller
Patient Circuit settings	Expiratory resistance adjustment	Expiratory resistance adjustment	Not available
Patient Interface	Mouthpiece Face mask Insert into ventilator circuit	Mouthpiece Face mask	Mouthpiece Insert into ventilator circuit
Controller	Pneumatic and air or oxygen	Pneumatic and air or oxygen	Pneumatic and air or oxygen
Controller settings	On/off Mode selection Frequency selection for CHFO mode Pressure adjustment for CPEP mode Pressure manometer Connection for patient circuit	On/off Mode selection Pressure adjustment for CPEP mode Connection for patient circuit	On/off Pressure and frequency adjustment for CHFO mode Pressure manometer Connection for patient circuit

	MetaNeb®	**PowerNeb** **CoMedica - K051964**	**IPV** **Bird - K895485**
Ventilator connection	Placed in-line in the inspiratory limb of the ventilator circuit with a standard "T" adapter. Ventilator set to pressure mode only	Not available	Placed in-line in the ventilator circuit with a IPV cone adapter Ventilator set to pressure mode only
Performance Testing **CPEP Mode @ Max Flow** Peak Pressure (cmH_2O): Total Respirable Dose (0.5-5 um) (Report 12-0058) **CHFO Mode @ MetaNeb "High"** Peak Pressure (cmH_2O): Frequency (BPM) Total Respirable Dose (0.5-5 um) (Report 12-0058) **CHFO Mode @ MetaNeb "High" with Ventilator Connection** Peak Pressure (cmH_2O): Frequency (BPM) Total Respirable Dose (0.5-5 um) (Report 12-0061)	 27.8 to 29.9 Albuterol 735.5 – 890.6 Ipratrompium 149.2 - 187 Cromolyn 2567.6 – 3046.6 21.1 to 25.4 226 Albuterol 139.2 – 200.2 Ipratrompium 27- 54.6 Cromolyn 673.1 – 948.1 Albuterol 421.6 – 572.4 Ipratrompium 124.5 – 204.6 Cromolyn 1367.9 – 1903.9 20.5 to 44.1 226 to 231 Albuterol 95.8 ± 13.1 Ipratrompium 110.8 ± 8.6 Cromolyn 73.4 ± 15.4	 32.6 to 35.1 Albuterol 631.5 – 818.8 Ipratrompium 137.1 – 155.1 Cromolyn 2362.1 – 2695.2 9.7 to 10.3 222 to 235 Albuterol 171.3 – 202.1 Ipratrompium 30.5 – 48.3 Cromolyn 805.4 – 1002.7	 This mode is not available on IPV 25.3 to 27.0 214 to 235 Albuterol 243.7 – 349.5 Ipratrompium 90 – 112.7 Cromolyn 900.1 – 1196.1 19.8 to 44.4 226 to 235 Albuterol 91.1 ± 10.6 Ipratrompium 97.1 ± 3.4 Cromolyn 88 ± 9.2

	MetaNeb®	PowerNeb Comedica - K051964	IPV Bird - K895485
Materials	Materials have been evaluated under the following Direct contact Indirect contact gas pathway VOC $PM_{2.5}$ CO Ozone	Many materials are identical to the MetaNeb® Cleared under K051964	No data – Cleared under K895485

Non-clinical Testing Summary -

We performed comparative a series of non-clinical bench testing to demonstrate that the MetaNeb® is equivalent to the predicates. These tests included:

- Comparative Particle Characterization testing via Cascade Impactor
  - Adult flow rates
  - Pediatric flow rates
  - In various controller modes (Aerosol, CHFO, CPEP)
- Cleaning validation
- Simulated Life Cycle testing
- Environmental and Mechanical testing
- Comparative Performance Testing as compared to the predicate in simulated breathing and ventilator condition

The other tests can be found in the identified Sections of this submission.

- Cleaning validation
- Environmental and Mechanical testing

The comparative testing demonstrates that the proposed device is substantially equivalent to the predicate devices.

Biocompatibility of Materials –

The MetaNeb® system has been evaluated for biocompatibility. There are several levels of patient contact and methods of testing that had to be utilized. The following is a summary of the system and our approach to evaluating biocompatibility.

The system can be viewed as having 3 levels of biocompatibility:

- Controller, which is a pneumatic system
  - Address via VOC, CO, Ozone and $PM_{2.5}$ testing
- Patient circuit before the nebulizer (Group 2 reference)
  - Indirect, external communicating, tissue / mucosal, prolonged duration (> 24 hr < 30 days)
  - Cytotoxicity, Sensitization, Irritation / Intracutaneous reactivity
- Patient circuit components and materials after the nebulizer (Group 1)
  - Indirect, external communicating, tissue / mucosal, permanent duration (> 30 days) per FDA internal memo and historical guidance
  - Cytotoxicity, Sensitization, Genotoxicity, Implantation

Discussion –
All materials were tested according to ISO 10993-1 for the appropriate level of patient contact and duration and found to pass the applicable ISO 10993-1 test requirements.

Substantial Equivalence Conclusion -

The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate have been found to substantially equivalent.

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

April 25, 2013

Mr. Paul Dryden
Consultant
Hill-Rom Services Pte, Limited
1 Yishun Avenue 7
Singapore 768923

Re: K124032
Trade/Device Name: MetaNeb®
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: NHJ
Dated: March 26, 2013
Received: March 27, 2013

Dear Ms. Wang:

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,

Kwame O. Ulmer -S for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
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Enclosure

Indications for Use Statement

510(k) Number: K124032

Device Name: MetaNeb®

Indications for Use:

The MetaNeb® System 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.

Patient population – Adult and Children > 2 years old

Environments of use – Hospitals, sub-acute facilities, physician offices, and clinics.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Amy K Levelle -S
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for L.S.

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

510(k) Number: K124032