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 PM2.5 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

<table>
<thead>
<tr>
<th>CFR Classification</th>
<th>MetaNeb®</th>
<th>PowerNeb CoMedica - K051964</th>
<th>IPV Bird - K895485</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classification name</td>
<td>Device, positive pressure breathing, intermittent (IPPB)</td>
<td>Device, positive pressure breathing, intermittent (IPPB)</td>
<td>Device, positive pressure breathing, intermittent (IPPB)</td>
</tr>
<tr>
<td>Indications for Use</td>
<td>Indicated for mobilization of secretions, lung expansion therapy, treatment and prevention of pulmonary atelectasis, ability to provide supplemental oxygen when used with compressed oxygen.</td>
<td>Indicated for mobilization of secretions, lung expansion therapy, treatment and prevention of pulmonary atelectasis, ability to provide supplemental oxygen when used with compressed oxygen.</td>
<td>Indicated for the mobilization and raising of endobronchial secretions, bronchodilation, reducing mucosal edema, resolution of diffuse patchy atelectasis in all patient populations.</td>
</tr>
<tr>
<td>Environments of Use</td>
<td>Hospital, sub-acute facilities</td>
<td>Hospital, sub-acute facilities</td>
<td>Hospital, sub-acute facilities, homecare</td>
</tr>
<tr>
<td>Patient Population</td>
<td>Adult Child &gt; 2 years old</td>
<td>All patients that require therapy mobilization of secretions, lung expansion therapy, the treatment and prevention of pulmonary atelectasis.</td>
<td>All patient populations</td>
</tr>
<tr>
<td>Contraindications</td>
<td>MetaNeb®</td>
<td>PowerNeb CoMedica - K051964</td>
<td>IPV Bird - K895485</td>
</tr>
<tr>
<td>-------------------</td>
<td>----------</td>
<td>-----------------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td>- Untreated tension pneumothorax</td>
<td>- Untreated tension pneumothorax</td>
<td>- Untreated tension pneumothorax</td>
<td></td>
</tr>
<tr>
<td>- Untrained or unskilled operator</td>
<td>- Untrained or unskilled operator</td>
<td>- Lack of adequate, skilled supervision</td>
<td></td>
</tr>
<tr>
<td>- History of pneumothorax</td>
<td>- History of pneumothorax</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Pulmonary air leak</td>
<td>- Pulmonary air leak</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Recent pneumonectomy</td>
<td>- Recent pneumonectomy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Pulmonary hemorrhage</td>
<td>- Pulmonary hemorrhage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Myocardial infarction</td>
<td>- Myocardial infarction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Vomiting</td>
<td>- Vomiting</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mode of Operation</th>
<th>MetaNeb®</th>
<th>PowerNeb CoMedica - K051964</th>
<th>IPV Bird - K895485</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>Can deliver continuous expiratory pressure (CPEP) combined with medicated aerosol.</td>
<td>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.</td>
<td>Equivalent CPEP function not available.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Modes</th>
<th>MetaNeb®</th>
<th>PowerNeb CoMedica - K051964</th>
<th>IPV Bird - K895485</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPEP</td>
<td>CPEP</td>
<td>CPEP</td>
<td></td>
</tr>
<tr>
<td>CHFO</td>
<td>CHFO</td>
<td>No static flow mode</td>
<td></td>
</tr>
<tr>
<td>Aerosol Only</td>
<td>Can allow in-line aerosol treatments</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CPEP Continuous Positive Expiratory Pressure</th>
<th>MetaNeb®</th>
<th>PowerNeb CoMedica - K051964</th>
<th>IPV Bird - K895485</th>
</tr>
</thead>
<tbody>
<tr>
<td>Controlled static flow with positive pressures ≤ 30 cm H₂O</td>
<td>Controlled static flow with positive pressures ≤ 20 cm H₂O</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Page 33 of 311
<table>
<thead>
<tr>
<th>CHFO Continuous High Frequency Oscillations</th>
<th>MetaNeb®</th>
<th>PowerNeb CoMedica - K051964</th>
<th>IPV Bird - K895485</th>
</tr>
</thead>
<tbody>
<tr>
<td>Controlled continuous flow with frequencies up to 300 beats per minute and peak positive pressures ≤ 30 cmH₂O</td>
<td>Controlled continuous flow with frequencies up to 300 beats per minute and peak positive pressures ≤ 30 cmH₂O</td>
<td>Controlled Intrapulmonary Percussive Ventilation (IPV) frequencies up to 300 beats per minute and peak positive pressures ≤ 80 cmH₂O</td>
<td></td>
</tr>
<tr>
<td>Aerosol Only</td>
<td>Controlled continuous constant flow to in-line nebulizer delivering medicated aerosol only.</td>
<td>Equivalent Aerosol Only function by setting CPEP to minimum flow with in-line nebulizer</td>
<td>Can use in-line nebulizer</td>
</tr>
<tr>
<td>Patient Circuit</td>
<td>Disposable circuit referred to as &quot;hand-set&quot; includes connection for in-line nebulizer</td>
<td>Disposable circuit referred to as &quot;hand-set&quot; includes connection for in-line nebulizer</td>
<td>Reusable circuit includes connection for in-line nebulizer</td>
</tr>
<tr>
<td></td>
<td>Draw in room air mix with medicated aerosol and gas from controller</td>
<td>Draw in room air mix with medicated aerosol and gas from controller</td>
<td>Draw in room air mix with medicated aerosol and gas from controller</td>
</tr>
<tr>
<td>Patient Circuit settings</td>
<td>Expiratory resistance adjustment</td>
<td>Expiratory resistance adjustment</td>
<td>Not available</td>
</tr>
<tr>
<td>Patient Interface</td>
<td>Mouthpiece</td>
<td>Mouthpiece</td>
<td>Mouthpiece</td>
</tr>
<tr>
<td></td>
<td>Face mask</td>
<td>Face mask</td>
<td>Insert into ventilator circuit</td>
</tr>
<tr>
<td>Controller</td>
<td>Pneumatic and air or oxygen</td>
<td>Pneumatic and air or oxygen</td>
<td>Pneumatic and air or oxygen</td>
</tr>
<tr>
<td>Controller settings</td>
<td>On/off Mode selection</td>
<td>On/off Mode selection</td>
<td>On/off</td>
</tr>
<tr>
<td></td>
<td>Frequency selection for CHFO mode</td>
<td>Pressure adjustment for CPEP mode</td>
<td>Pressure and frequency adjustment for CHFO mode</td>
</tr>
<tr>
<td></td>
<td>Pressure adjustment for CPEP mode</td>
<td>Pressure manometer</td>
<td>Pressure manometer</td>
</tr>
<tr>
<td></td>
<td>Connection for patient circuit</td>
<td>Connection for patient circuit</td>
<td>Connection for patient circuit</td>
</tr>
</tbody>
</table>
### Ventilator connection

<table>
<thead>
<tr>
<th>MetaNeb®</th>
<th>PowerNeb CoMedica - K051964</th>
<th>IPV Bird - K895485</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placed in-line in the inspiratory limb of the ventilator circuit with a standard &quot;T&quot; adapter. Ventilator set to pressure mode only</td>
<td>Not available</td>
<td>Placed in-line in the ventilator circuit with a IPV cone adapter Ventilator set to pressure mode only</td>
</tr>
</tbody>
</table>

### Performance Testing

#### CPEP Mode @ Max Flow

Peak Pressure (cmH₂O): 27.8 to 29.9
- Albuterol: 735.5 - 890.6
- Ipratrompium: 149.2 - 187
- Cromolyn: 2567.6 - 3046.6
- Total Respirable Dose: 735.5 - 890.6

Peak Pressure (cmH₂O): 32.6 to 35.1
- Albuterol: 631.5 - 818.8
- Ipratrompium: 137.1 - 155.1
- Cromolyn: 2362.1 - 2695.2

This mode is not available on IPV

#### CHFO Mode @ MetaNeb “High”

Peak Pressure (cmH₂O): 21.1 to 25.4
- Albuterol: 226
- Ipratrompium: 139.2 - 200.2
- Cromolyn: 673.1 - 948.1
- Total Respirable Dose: 226

Peak Pressure (cmH₂O): 9.7 to 10.3
- Albuterol: 222 to 235
- Ipratrompium: 171.3 - 202.1
- Cromolyn: 805.4 - 1002.7

Frequency (BPM): 214 to 235

#### CHFO Mode @ MetaNeb “High” with Ventilator Connection

Peak Pressure (cmH₂O): 20.5 to 44.1
- Albuterol: 226 to 231
- Ipratrompium: 95.8 ± 13.1
- Cromolyn: 73.4 ± 15.4
- Total Respirable Dose: 139.2

Peak Pressure (cmH₂O): 19.8 to 44.4
- Albuterol: 226 to 235
- Ipratrompium: 91.1 ± 10.6
- Cromolyn: 88 ± 9.2
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.

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.
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" (21 CFR 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 Q. Ulmer -S

Anthony D. Watson, B.S., M.S., M.B.A.
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 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 or Over-the-counter use (Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Amy K Levelle, S
2013-04-25 10:34:25
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K124032

Page 28 of 311