DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 17, 2016

Hill-Rom Services Pte Ltd
c/o Paul Dryden
Consultant for Hill-Rom
1 Yishun Ave 7
Singapore 768923

Re: K151689
Trade/Device Name: MetaNeb® 4 System
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: NHJ
Dated: February 12, 2016
Received: February 16, 2016

Dear Mr. Dryden,

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Tejashri Purohit-Sheth, M.D.

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Clinical Deputy Director
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Enclosure

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

510(k) Number *(if known)*

K151689

Device Name

MetaNeb® 4 System

Indications for Use *(Describe)*

The MetaNeb® 4 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 – 5 years old and above whom can follow verbal instructions.

Environment of Use – Hospitals, sub-acute and nursing facilities, physician offices, clinics, and home settings

Type of Use *(Select one or both, as applicable)*

XX Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Date Prepared	15-Mar-16

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Official Contact: Huifang Zhu - RA / QA Specialist

Proprietary or Trade Name: MetaNeb® 4 System

Common/Usual Name: Noncontinuous ventilator (IPPB)

Classification Code/Name: NHJ – non-continuous ventilator (IPPB)
21 CFR 868.5905
Class II

Predicate Devices: K124032 – Hill-Rom – MetaNeb®
K051964 – CoMedica – PowerNeb®
K895485 – Percussionaire Corp (Bird) – IPV

Device Description:
The MetaNeb® 4 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® 4 System:

- Circuit - includes a mouthpiece, handset, nebulizer, tubing, and filter/tri-connector. It is a single patient use, assembly 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 air or oxygen source, e.g., wall source, cylinder or portable medical air compressor.
- Stand – to move the MetaNeb® 4 System from room to room.

The MetaNeb® 4 System incorporates 2 changes vs. the predicate MetaNeb®, K124032. The changes are listed in **Table 1.**

	Predicate MetaNeb® - K124031	Difference / Modification for Proposed Device
Environment of use	Hospitals sub-acute facilities physician offices clinics	Expanding to include nursing facility and home setting
Power sources	Air source from facility supply, e.g., cylinder or wall source	Adding portable medical air compressor as an additional air source.

Table 1 – Differences / Modifications between proposed MetaNeb® 4 System and Predicate MetaNeb® (K124032)

Indications for Use:
The MetaNeb® 4 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 – 5 years old and above whom can follow verbal instructions

Environment of Use – Hospitals, sub-acute and nursing facilities, physician offices, clinics, and home settings

Predicate Device Comparison:
The MetaNeb® 4 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 predicate Hill-Rom MetaNeb® system (K124032).

Patient Population –
The patient population is similar to the predicate MetaNeb®, K124032 but the lower age has changed to 5 years and above who can follow verbal instructions.
Discussion: The difference in patient population relates to the ability to use a mouthpiece in a home setting.

Environment of Use –
The addition of the environments of use to include nursing care facilities and home care settings is identical to the predicate Bird IPV (K895485).

Discussion: The expansion in the intended environments of use is substantially equivalent to the predicate Bird IPV (K895485). We have evaluated the risks associated with home use and performed a usability study that supports that the device may be used within this environment.

Technology –
The design of the MetaNeb® 4 System as a pneumatically operated system with different modes of operation: CPEP, CHFO, and aerosol only are identical to the predicate in design and basic function and performance.
Discussion: The design of MetaNeb® is identical to the predicate MetaNeb® (K124032).

Performance –
The basic performance features and parameters are identical to the predicate MetaNeb® (K124032).
Discussion: The proposed changes do not alter the performance specifications of the proposed MetaNeb® 4 System and the predicate MetaNeb® (K124032).

Non-clinical Comparative Performance

Materials –
The materials in the gas and fluid pathway are considered as having 2 types of patient contact:

- External communicating, tissue contacting, permanent duration and
- Surface contact, mucosal contact, permanent duration for the mouthpiece

The materials are unchanged and identical to the predicate submission MetaNeb®, K124032.
Discussion: All associated materials in the gas or fluid pathway are identical to the predicate Hill-Rom MetaNeb® (K124032). We did perform additional $PM_{2.5}$ testing even though the controller is identical to the predicate MetaNeb® (K124032).

Bench Testing -
We performed a series of non-clinical bench tests to demonstrate that the modified MetaNeb® 4 System is equivalent to the predicates. These tests included:

- Compatibility testing of portable air compressors to performance specifications
- Performance comparison of air source, portable compressor vs. wall source
- Biocompatibility – Controller
    - Material Certification
    - $PM_{2.5}$ testing for the controller – reconfirmation only
- Usability – home environment

The comparative testing demonstrates that the proposed modifications are substantially equivalent to the predicate devices.

Table 2 – Substantial Equivalence Comparative Table

	Proposed MetaNeb® 4 System	**MetaNeb® Hill-Rom - K124032**	**PowerNeb Comedica - K051964**	**IPV Bird - K895485**
Intended 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 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
Indications for Use	The MetaNeb® 4 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.	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.	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	Use of Percussaire® IPV® is indicated for the mobilization and raising of endobronchial secretions, bronchodilation, reducing mucosal edema, and the resolution of diffuse patchy atelectasis in all patient populations.

	Proposed **MetaNeb® 4 System**	**MetaNeb®** **Hill-Rom - K124032**	**PowerNeb** **Comedica - K051964**	**IPV** **Bird - K895485**
Environments of Use	Hospital, sub-acute facilities Nursing care, Homecare	Hospital, sub-acute facilities	Hospital, sub-acute facilities	Hospital, sub-acute facilities Homecare
Patient Population	5 years old and above whom can follow verbal instructions	Adult Children > 2 years old	All patients that require therapy mobilization of secretions, lung expansion therapy, the treatment and prevention of pulmonary atelectasis.	All patient populations
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 -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 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.

	Proposed MetaNeb® 4 System	**MetaNeb® Hill-Rom - K124032**	**PowerNeb Comedica - K051964**	**IPV Bird - K895485**
Modes	CPEP CHFO Aerosol Only	CPEP CHFO Aerosol Only	CPEP CHFO	CHFO
CPEP Continuous Positive Expiratory Pressure	Controlled static flow with positive pressures $\leq$ 30 cm H_2O	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[1,2]
CHFO Continuous High Frequency Oscillations	Controlled continuous flow with frequencies up to 300 beats per minute and peak positive pressures $\leq$ 30 cmH_2O	Controlled continuous flow with frequencies up to 300 beats per minute and peak positive pressures $\leq$ 30 cmH_2O	Controlled continuous flow with frequencies up to 300 beats per minute and peak positive pressures $\leq$ 30 cmH_2O	Controlled Intrapulmonary Percussive Ventilation (IPV) frequencies up to 300 beats per minute and peak positive pressures $\leq$ 80 cmH_2O
Aerosol Only	Controlled continuous constant flow to in-line nebulizer delivering medicated 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 “handset” includes connection for in-line nebulizer Draw in room air mix with medicated aerosol and gas from controller No in-line filter (Home) In-line filter (Acute care)	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 In-line filter (Acute care)	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 $\leq$ 30 cm H_2O	Expiratory resistance adjustment $\leq$ 30 cm H_2O	Expiratory resistance adjustment $\leq$ 30 cm H_2O	Not applicable but the IPV can provide pressures $\leq$ 80 cmH_2O

	Proposed MetaNeb® 4 System	**MetaNeb® Hill-Rom - K124032**	**PowerNeb Comedica - K051964**	**IPV Bird - K895485**
Patient Interface	Mouthpiece Insert into ventilator circuit	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	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 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
Ventilator connection	Placed in-line in the inspiratory limb of the ventilator circuit with a standard “T” adapter. Only for acute care environment	Placed in-line in the inspiratory limb of the ventilator circuit with a standard “T” adapter. Only for acute care environment	Not available	Placed in-line in the ventilator circuit with a IPV cone adapter

Table 3 compares the performance specifications of the proposed MetaNeb® 4 System to the predicates for Peak Pressure under various therapy mode conditions. We should note that the test set-up parameters are identical to those used when comparing the MetaNeb® in submission K124032.

The results demonstrate substantial equivalence of the maximum peak pressure of the MetaNeb® 4 System as compared to the identified predicates.

Table 3 – Substantial Equivalence Comparative Performance – Expiratory Pressures

Therapy Mode	Proposed MetaNeb® 4 System with Standard Patient Circuit	MetaNeb® Hill-Rom – K124032 With original Patient Circuit	PowerNeb Comedica - K051964	IPV Bird - K895485[1,2]
CPEP Mode @ High Flow Peak Pressure (cmH_2O)	10.7 to 29.9	10.7 to 29.9	18.9 to 35.4	This mode is not available on IPV
CPEP Mode @ Medium Flow Peak Pressure (cmH_2O)	7.7 to 14.6	7.7 to 14.6	9.4 to 18.3	
CPEP Mode @ Low Flow Peak Pressure (cmH_2O)	0.2 to 2.0	0.2 to 2.0	0.2 to 1.2	
CHFO Mode @ High Flow Peak Pressure (cmH_2O)	11.2 to 25.4	11.2 to 25.4		10.1 to 26.7
CHFO Mode @ Low Flow Peak Pressure (cmH_2O)	8.7 to 20.3 From K124032 data	8.7 to 20.3 From K124032 data		11 to 23

[1] Note: When IPV is tested at comparable setting the differences in peak pressure is < 5 cmH_2O.
[2] Note: IPV is capable of a maximum peak pressure of 80 cmH_2O

Usability -

We performed a usability study with 2 user groups: caregivers and lay users. The study evaluated the ability of each group to perform critical tasks related to setting the MetaNeb® 4 System up and performing simulated treatments, 100% of the participants completed all the tasks successfully without use errors that could have lead to unacceptable risk of harm.

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.