

510(k) Summary

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Date prepared: 8-Oct-13
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Official Contact: Erik Lausund
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Proprietary or Trade Name: Seattle-PAP

Common/Usual Name: Bubble CPAP System

Classification Name/Code: BZD - Noncontinuous ventilator (IPPB)
CFR 868.5905, Class II

Device: Seattle-PAP

Predicate Devices: K100011 – Fisher & Paykel – Bubble CPAP System

OCT 11 2013

Device Description:

Seattle-PAP is a bubble continuous positive airway pressure (CPAP) device. Seattle-PAP is installed at the end of an expiratory limb, distal to the patient, in a continuous gas flow breathing system. Seattle-PAP is intended to assist spontaneous breathing in neonates and infants, up to weights of 10 kg.

Seattle-PAP is comprised of two key elements; a water container and a tube inserted into the water. The Water Reservoir contains the water and has a Lid permanently attached to help prevent splashing and spillages. The Lid has an integrated Water Level Adjustment Port, so a clinician can adjust the water level in the Reservoir, if necessary, without disconnecting the breathing circuit.

The tube is comprised of a Funnel-Swivel that is permanently attached to Bubble Tube. The Funnel-Swivel helps prevent spillages when filling the Water Reservoir initially and can rotate to help reduce tension that may build up in the expiratory limb of the breathing circuit. The expiratory end of the patient's breathing circuit, distal to the patient, is inserted into the center of the Funnel-Swivel. A Bubble Tube Lock mechanism is used to ensure the depth of the tube in the water does not change unintentionally.

The gas bubbling out of the end of the Tube creates air pressure oscillations in the breathing circuit. These pressure oscillations do not adversely affect the performance of the Seattle-PAP device, i.e. the ability to deliver the desired CPAP pressure accurately.

Indications for Use:

The Seattle-PAP is intended to provide continuous positive airway pressure (CPAP) to spontaneously breathing neonates and infants, up to weights of 10 kg, requiring respiratory

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support due to conditions associated with prematurity, such as Respiratory Distress Syndrome, or other conditions where CPAP is required or desired and prescribed by a physician.

It is for use only by trained medical personnel in hospital clinical environment, such as the Neonatal Intensive Care Unit (NICU) and Pediatric Intensive Care Unit (PICU).

Patient Population:

Neonates and infants up to weights of 10 kg

Environment of Use:

Hospital clinical environment, such as the Neonatal Intensive Care Unit (NICU) and Pediatric Intensive Care Unit (PICU).

Contraindications

- Non-spontaneous breathing patient
- Congenital abnormalities or malfunctions where positive pressure therapies are contraindicated (e.g., diaphragmatic hernia and tracheo-oesophageal fistula)

Predicate Device Comparison:

Table 1 – Comparison to Predicates with Similar Technology and Indications for Use

	Proposed device	Predicate
510(k)		K100011
Manufacturer		Fisher & Paykel
Device Name	Seattle-PAP	Bubble CPAP
Product Code	BZD	BZD
CFR	868.5905	868.5905
Indications for Use	<p>The Seattle-PAP is intended to provide continuous positive airway pressure (CPAP) to spontaneously breathing neonates and infants, up to weights of 10 kg, requiring respiratory support due to conditions associated with prematurity, such as Respiratory Distress Syndrome, or other conditions where CPAP is required or desired and prescribed by a physician.</p> <p>It is for use only by trained medical personnel in hospital clinical environment, such as the Neonatal Intensive Care Unit (NICU) and Pediatric Intensive Care Unit (PICU).</p>	<p>Intended to provide continuous positive airway pressure (CPAP) to spontaneously breathing neonates and infants, up to weights of 10 kg, requiring respiratory support due to conditions associated with prematurity, such as Respiratory Distress Syndrome, or other conditions where CPAP is required or desired and prescribed by a physician.</p>

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	Proposed device Seattle-PAP	Predicate K100011 Fisher & Paykel - Bubble CPAP
Environment of Use	Hospital clinical environment, NICU and PICU	Hospital clinical environment, NICU and PICU
Patient population	Neonates and infants, up to weights of 10 kg	Neonates and infants, up to weights of 10 kg
Prescriptive	Yes, for use by trained medical personnel	Yes, for use by trained medical personnel
Principle of Operation	Expiratory limb of a breathing circuit connected to a column that is submerged in water. The water column acts to provide pressure when exhaling, CPAP. The column is adjustable.	Expiratory limb of a breathing circuit connected to a column that is submerged in water. The water column acts to provide pressure when exhaling, CPAP. The column is adjustable.
Pressure Oscillations	Pressure oscillations are created as gas exits the Bubble Tube.	Pressure oscillations are created as gas exits the Bubble Tube.
Placed in expiratory limb of breathing circuit	Yes	Yes
Single use, disposable	Yes	Yes
Pressure range	4.5 to 10 cm H ₂ O	3 to 10 cm H ₂ O
Accuracy As measured during comparative testing	Specified as +/- 1 cm H ₂ O Tested accuracy = -0.21 to +0.17 H ₂ O	Not specified in available documentation. Tested accuracy -0.09 to +0.52 H ₂ O
Gas flow range	4 to 12 Lpm	4 to 15 Lpm
Material biocompatibility	All materials are out of direct or indirect gas pathway	All materials are out of direct or indirect gas pathway
Non-clinical Performance Testing	Environmental conditions, storage, operational, aging and endurance testing Mechanical Drop test Accuracy Reproducibility of MAP Repeatability of performance	Accuracy Reproducibility of MAP
Standards	None under section 514	None under section 514

Based upon the above comparative table it is our view that there are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate device.

The data presented in the comparative table above indicate no significant differences between the intended device and the predicate device that affect the safety or effectiveness of the respective devices.

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The Seattle Children's Hospital Seattle-PAP is viewed as substantially equivalent to the predicate devices because:

Indications –

- The intended use to provide continuous positive airway pressure (CPAP) to spontaneously breathing neonates and infants, up to weights of 10 kg, requiring respiratory support due to conditions associated with prematurity, such as Respiratory Distress Syndrome, or other conditions where CPAP is required or desired and prescribed by a physician is identical to the predicate.
- **Discussion** – The indications for use are identical to the predicate Fisher & Paykel – Bubble CPAP (K100011)

Technology and Mode of Operation –

- The concept of a tube / column submerged in water to create CPAP is identical to the predicate Fisher & Paykel – Bubble CPAP (K100011)
- The ability to adjust the pressure by changing the column depth in water is identical to the predicate.
- Creates pressure oscillations in the expiratory limb of the breathing circuit from the gas bubbling out the end of the tube under water.
- The performance specifications are almost identical to the predicate.
- **Discussion** – The technology and mode operation are identical to the predicate Fisher & Paykel – Bubble CPAP (K100011)

Environment of Use –

- Identical to predicate – Fisher & Paykel – Bubble CPAP (K100011)
- **Discussion** – The environments of use are identical to the predicate's.

Differences –

No differences between the predicate and the proposed device would raise any new safety or risk concerns, thus the two devices can be found to be substantially equivalent.

Non-clinical Testing Summary -

We have performed a number of tests appropriate for the proposed device. These tests include:

- Repeatability and Accuracy of Mean Airway Pressure (MAP)
- Reproducibility of Mean Airway Pressure (MAP)
- Accuracy to control MAP
- Comparison of MAP control Seattle-PAP vs. Predicate Fisher & Paykel (K100011)
- Adjustability of device from 4.5 to 10 cm H₂O
- Measured MAP at various flow rates 4 -12 Lpm
- Endurance testing for 180 hours and performance
- Storage – high temperature
- Operational – high temperature
- Storage – low temperature
- Operational – low temperature

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- High Humidity – operational / storage
- Age testing
- Vibration – sinusoidal
- Vibration – random
- Shock
- **Discussion** – The performance testing, post-conditioning and comparative testing all demonstrated that the Seattle-PAP met its performance specifications and was substantially equivalent to the predicate K100011.

Biocompatibility of Materials –

- Materials are typical of the predicate
 - The device is downstream of the patient, on the expiratory limb. The device is not in the direct or indirect gas pathway.
- **Discussion** – No ISO 10993 testing is required.

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 be substantially equivalent to the predicate.



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

October 11, 2013

Seattle Children's Hospital
C/O Mr. Paul Dryden
Regulatory Consultant
1900 Ninth Avenue
SEATTLE WA 98101

Re: K131502
Trade/Device Name: Seattle-PAP
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: September 9, 2013
Received: September 11, 2013

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.

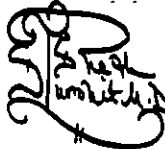
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 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,



Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID

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 Statement

510(k) Number: _____ (To be assigned)

Device Name: Seattle-PAP

Indications for Use:

The Seattle-PAP is intended to provide continuous positive airway pressure (CPAP) to spontaneously breathing neonates and infants, up to weights of 10 kg, requiring respiratory support due to conditions associated with prematurity, such as Respiratory Distress Syndrome, or other conditions where CPAP is required or desired and prescribed by a physician.

It is for use only by trained medical personnel in hospital clinical environment, such as the Neonatal Intensive Care Unit (NICU) and Pediatric Intensive Care Unit (PICU).

Prescription Use XX
(Part 21 CFR 801 Subpart D)

or

Over-the-counter use ___
(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)

K131502

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,
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