Non-Confidential Summary of Safety and Effectiveness
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6-May-08

Pulmodyne
2055 Executive Dr.
Indianapolis, IN 46241

Tel – (317) 246-5505

Official Contact: Tami Lefevers, Quality Manager

Proprietary or Trade Name: Pulmodyne CHF Flow Generator

Common/Usual Name: CPAP flow generator

Classification Name: Breathing Attachment Positive End Expiratory Pressure
BYE – 868.5965

Predicate Devices: Caradyne – Whisperflow – K982283

Device Description:

The Pulmodyne CHF Flow Generator is a venturi type oxygen / air mixture delivery device which provides CPAP pressure at high flows to a spontaneously breathing patient. It can deliver up to 150 Lpm flow at a FiO₂ between 28- 100%. It utilizes standard in-line PEEP valves to set the prescribed pressure and interfaces with the patient via a face mask or ET tube. The Pulmodyne CHF Flow Generator incorporates several components:

- Flow generator (two styles - fixed flow and variable flow)
- Patient interface - mask
- PEEP valve
- Circuit / tubing and connectors
- Air entrainment filter

The Pulmodyne CHF Flow Generator is multi-patient, reusable and can be cleaned while the other components: circuit, mask, entrainment filter, and PEEP valve are disposable, single patient use.

Indications for Use: To provide CPAP to spontaneously breathing adult patients in the hospital and pre-hospital (EMS) environment.

Patient Population: Adults

Environment of Use: Hospital, sub-acute institution, or pre-hospital (EMS)
Contraindications: There are several conditions where therapeutic CPAP is contraindicated:

Patients who have:
- Facial lacerations
- Laryngeal trauma
- Recent tracheal or esophageal anastomosis
- Gastrointestinal bleeding or ileus
- Recent gastric surgery
- Basilar skull fracture
- Patients at high risk of vomiting
- Emphysematous Bulla - when an area of the lung may be brittle and present a risk of bursting
- Hypovolaemia - low blood volume

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Variable / Adjustable</th>
<th>Whisper flow</th>
<th>Proposed</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>WF 8500</td>
<td>Pulmodyne CHF</td>
</tr>
<tr>
<td></td>
<td></td>
<td>K982283</td>
<td>Flow Generator</td>
</tr>
</tbody>
</table>

Use

- Intended for delivery of CPAP: Yes
- Used with PEEP valves, CPAP mask and circuit tubing: Yes
- Environment – Hospital, sub-acute and pre-hospital (EMS): Yes

Design

- Works by a venturi method to create a vacuum to provide high flows: Yes
- Has oxygen inlet fitting which attach to wall oxygen source standard CGA or DISS fitting: Yes
- Has an On / Off valve: Yes
- Can adjust oxygen flow through the venturi port: Yes
- Has an air entrainment port with 22 mm ID inlet: Yes
### Attribute Summary Table

<table>
<thead>
<tr>
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<th>Whisper flow WF 8500</th>
<th>Proposed Pulmodyne CHF K982283 Flow Generator</th>
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</thead>
<tbody>
<tr>
<td>Air entrainment port with particulate filter</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Has a valve which adjusts the flow to the venturi nozzle</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Outlet port (22 mm)</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Option for an in-line oxygen analyzer</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Circuit is standard 22 mm tubing</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Can have a humidifier placed in-line</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Connects to patient interface - mask or ET tube</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Utilizes a standard PEEP valve to establish the circuit pressure</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Patient can entrain room air should oxygen flow fail</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>One-way valve to prevent rebreathing, if no gas flow</td>
<td>Yes in mask</td>
<td>Yes in elbow</td>
</tr>
<tr>
<td>Flow generator can be cleaned and is reusable</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Other components - circuit, mask</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>PEEP valve, entrainment filter are Disposable, single patient use</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Accessories required -</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CPAP mask</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Particulate filter at air entrainment port</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>22 mm tubing</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Head strap for mask</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Various connectors</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>PEEP valves</td>
<td>Yes</td>
<td>Yes</td>
</tr>
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<td>WF 8500 Pulmodyne CHF K982283 Flow Generator</td>
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Performance Standards / Specifications

- Oxygen input pressure 60 psi: Yes
- Output flow range up to 140 Lpm: Yes
- Fittings - 22 and 30 mm: Yes
- Range of Oxygen (FiO₂): 28-100%

Materials

- Generator - Stainless steel and PVC: Yes
- CPAP mask - PVC and silicone: Yes
- Circuit tubing and connectors - PE: Yes

Conclusion:

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.
Pulmodyne
C/O Mr. Paul E. Dryden
President
ProMedic, Incorporated
24301 Woodsage Drive
Bonita Springs, Florida 34134-2958

Re: K080256
   Trade/Device Name: Pulmodyne CHF Flow Generator
   Regulation Number: 21 CFR 868.5965
   Regulation Name: Positive End Expiratory Pressure Breathing Attachment
   Regulatory Class: II
   Product Code: BYE
   Dated: May 6, 2008
   Received: May 7, 2008

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.

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) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

Enclosure
510(k) Number: K080256 (To be assigned)

Device Name: Pulmodyne CHF Flow Generator

Indications for Use:

To provide CPAP to spontaneously breathing adult patients in the hospital and pre-hospital (EMS) environment.

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)

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

510(k) Number: K080256