K080256

MAY - 9 2008

Non-Confidential Summary of Safety and Effectiveness

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 FiO_2 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 were 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

Attribute	Variable / Adjustable	
	Whisper flow WF 8500 K982283	**Proposed Pulmodyne CHF Flow Generator**
Use		
Intended for delivery of CPAP	Yes	Yes
Used with PEEP valves, CPAP mask and circuit tubing	Yes	Yes
Environment – Hospital, sub-acute and pre-hospital (EMS)	Yes	Yes
Design		
Works by a venturi method to create a vacuum to provide high flows	Yes	Yes
Has oxygen inlet fitting which attach to wall oxygen source standard CGA or DISS fitting	Yes	Yes
Has an On / Off valve	Yes	Yes
Can adjust oxygen flow through the venturi port	Yes	Yes
Has an air entrainment port with 22 mm ID inlet	Yes	Yes

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

Attribute	Variable / Adjustable	
	Whisper flow WF 8500 K982283	**Proposed Pulmodyne CHF Flow Generator**
Performance Standards / Specifications		
Oxygen input pressure 60 psi	Yes	Yes
Output flow range up to 140 Lpm	Yes	Yes
Fittings - 22 and 30 mm	Yes	Yes
Range of Oxygen (FiO_2)	28-100%	28-100%
Materials		
Generator - Stainless steel and PVC	Yes	Yes
CPAP mask - PVC and silicone	Yes	Yes
Circuit tubing and connectors – PE	Yes	Yes

Conclusion:

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 9 2008

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 Atachment
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.

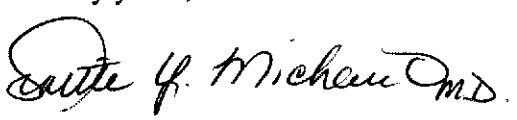
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Indications for Use Statement

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 (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)

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

510(k) Number: K080256