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K 982283

caradyne™

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Non-Confidential Summary of Safety and Effectiveness

June 25, 1998

Caradyne, Ltd.
Parkmore Business Park
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Galway, Ireland

Tel - 011-353-91-709010
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Official Contact:	John O'Dea, Ph.D., General Manager
Proprietary or Trade Name:	Whisperflow Oxygen Flow Generators and accessories
Common/Usual Name:	CPAP generator
Classification Name:	Breathing Attachment, Positive End Expiratory Pressure
Device:	Whisperflow Oxygen Flow Generators and accessories
Predicate Devices:	Vital Signs - Downs Flow Generators - K811393, K831503
	Vital Signs CPAP mask - K801883
	EMS Mask - K871851

Device Description:

The Whisperflow Oxygen 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 140 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.

Indicated Use --	To provide CPAP to a spontaneously breathing adult patient.
Environment of Use --	Hospital and pre-hospital.
Patient population --	Spontaneously breathing adult patients.

Comparison to Predicate Devices:

Attribute	**Variable / Adjustable**		
	Whisperflow	**Vital Signs**	
	WF 8500	**Model 9250 K821503**	**Vital Flow100**
Use			
Intended for delivering of CPAP	Yes	Yes	Yes

Attribute	Variable / Adjustable		
	Whisperflow WF 8500	Vital Signs Model 9250 K821503	Vital Flow100
Used with PEEP valves, CPAP mask and circuit tubing	Yes	Yes	Yes
Environment Hospital / pre-hospital (EMS)	Yes	Yes	Yes
Design			
Works by a venturi method to create a vacuum to provide high flows	Yes	Yes	Yes
Has oxygen inlet fitting which attached to wall oxygen source standard CGA or DISS fitting	Yes	Yes	Yes
Has an On / Off valve	Yes	Yes	Yes
Can adjust oxygen flow	Yes	Yes	Yes
Has an air entrainment port with 22 mm ID inlet	Yes	Yes	Yes
Air entrainment port can have a standard particulate / bacterial filter attached	Yes	Yes	Yes
Has a valve which adjusts the flow to the venturi nozzle	Yes	No	Yes
Outlet port (22 mm)	Yes	Yes	Yes
Recommend an in-line oxygen analyzer	Yes	Yes	Yes
Recommend an in-line safety valve PEEP valve	Yes	Yes	Yes
Circuit is standard 22 mm tubing	Yes	Yes	Yes
Can have a humidifier placed in-line	Yes	Yes	Yes
Connects to patient interface - mask or ET tube	Yes	Yes	Yes
Utilizes a standard PEEP valve to establish the circuit pressure	Yes	Yes	Yes
Patient can entrain room air should oxygen flow fail	Yes	Yes	Yes

Attribute	Variable / Adjustable		
	Whisperflow WF 8500	Vital Signs Model 9250 K821503	Vital Flow100
Mask has a one-way valve to prevent rebreathing, if no oxygen flow	Yes	Yes	Yes
Flow generator can be EO gas sterilized	Yes	Yes	Yes
Accessories required -			
CPAP mask	Yes	Yes	Yes
Particulate filter at air entrainment port	Yes	Yes	Yes
22 mm tubing	Yes	Yes	Yes
Head strap for mask	Yes	Yes	Yes
Various connectors	Yes	Yes	Yes
PEEP valves	Yes	Yes	Yes
Performance Standards / Specifications			
Oxygen input pressure 60 psi	Yes	Yes	Yes
Output flow range up to 140 Lpm	Yes	Yes	Yes
Fittings 22 mm	Yes	Yes	Yes
Range of Oxygen (FiO_2)	28-100%	33-100%	33-100%
Materials			
Whisperflow generator - Stainless steel, PVC	Yes	Yes	Yes
CPAP mask - PVC and silicone	Yes	Yes	Yes

Attribute	Fixed Flow Whisperflow WF 8530	 Vital Signs Model 9200 K811393
Use		
Intended for delivering of CPAP	Yes	Yes
Used with PEEP valves, CPAP mask and circuit tubing	Yes	Yes
Environment Hospital / 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 attached to wall oxygen source standard CGA or DISS fitting	Yes	Yes
Has an air entrainment port with 22 mm ID inlet	Yes	Yes
Air entrainment port can have a standard particulate / bacterial filter attached	Yes	Yes
Outlet port which is 22 mm	Yes	Yes
Recommend an in-line oxygen analyzer	Yes	Yes
Recommend an in-line safety valve PEEP valve	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
Mask has a one-way valve to prevent rebreathing if no oxygen flow	Yes	Yes

Attribute	Fixed Flow Whisperflow WF 8530	 Vital Signs Model 9200 K811393
Flow generator can be EO gas sterilized	Yes	Yes
Accessories required -		
CPAP mask	Yes	Yes
Particulate filter for air entrainment port	Yes	Yes
22 mm tubing	Yes	Yes
Head strap for mask	Yes	Yes
Various connectors	Yes	Yes
PEEP valves	Yes	Yes
Performance Standards / Specifications		
Oxygen input pressure 60 psi	Yes	Yes
Output flow range up to 140 Lpm dependent		
of PEEP pressure	Yes	Yes
Fittings 22 mm	Yes	Yes
Oxygen (FiO_2) %	28%	33%
Materials		
Whisperflow generator - Stainless steel, PVC	Yes	Yes
CPAP mask - PVC and silicone	Yes	Yes

Differences between Other Legally Marketed Predicate Devices

The differences between the Whisperflow generators and CPAP mask and the predicates are:

1. CPAP mask is a ribbed cushion design versus an air cushion design.
2. The Whisperflow generators have a wider range of FiO_2 which may help in weaning patients from the ventilator.

There are no other significant differences between the intended device and the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 9 1999

Mr. Paul E. Dryden
Caradyne, Ltd.
c/o Promedic, Inc.
6329 W. Waterview Court
McCordsville, IN 46055

Re: K982283
Whisperflow Oxygen Flow Generator - Adjustable Model WF 85
Regulatory Class: II (two)
Product Code: 73 BYE
Dated: January 26, 1999
Received: January 27, 1999

Dear Mr. Dryden:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Pursuant to the Notice of February 6, 1996 regarding listing of Indications for Use on a separate sheet, the following is per that request.

510(k) Number: K982283 (To be assigned)

Device Name: Whisperflow Oxygen Flow Generator system

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Luke Modos

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K982283

Luke Modos 9-21-98

Prescription Use ✓ **or** **Over-the-counter use** __
(Per CFR 801.109)