K992101

JAN - 6 2000

Premarket Notification 510(k)
Section 2 - Certification and Summaries

Criterion 40

Non-Confidential Summary of Safety and Effectiveness

page 1 of 4
January 4, 2000

Caradyne, Ltd.
Parkmore Business Park
Parkmore West
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Official Contact: John O'Dea, Ph.D. - General Manager

Proprietary or Trade Name: Criterion 40

Common/Usual Name: Airway Pressure Monitor

Classification Name: Airway Pressure Monitor (includes gauges and / or alarm)

Device: Criterion 40

Predicate Devices: Monaghan, Ltd. CM 5000 Airway Pressure Monitor - K871083

The Criterion 40 is a microprocessor controlled device that measures and monitor patient airway pressure, produces continuous positive airway pressure. It measures low and high pressures and advises the user if the pressure fall outside the user-set ranges. It operates on AC / DC power and provides digital and graphically readouts of the pressure - real-time and peak pressures. It connects into the patient circuit with the use of a pressure tubing with integral in-line filter and a connector.

Indicated Use -- Is intended to measure airway pressure when used with positive pressure devices. The device alarms when the airway pressure falls outside of the user selected high and low alarm limits and displays peak pressure and real-time airway pressures. It may be used with positive pressure devices which do not include pressure measurement capabilities, e.g. resuscitation bags or basic ventilators, or as an independent backup pressure monitor for devices with pressure measurement capability. The device has been designed for stationary and intra-institution transport only.

Premarket Notification 510(k) Criterion 40

Section 2 - Certification and Summaries

Non-Confidential Summary of Safety and Effectiveness

January 4, 2000

Environment of Use -- Hospital, sub-acute institutions, home care

	[redacted]	[redacted] (New Device)
[redacted]	For use with positive pressure devices as a standalone or backup device to measure and monitor high and low airway pressures	Standalone accessory to supplement patient monitoring during ventilation (positive) to notify of undesirably low and / or high pressures.
[redacted]	Yes	Yes
[redacted]	Any patient utilizing positive pressure devices and the clinician desires to have pressure monitoring.	Any patient utilizing positive pressure devices and the clinician desires to have pressure monitoring.
[redacted]	Hospital, Sub-acute Institutions, Home Care	Hospital, Sub-acute Institutions, Home Care
	Limited to stationary and intra-institution transport only	Limited to stationary and intra-institution transport only
[redacted]		
Weights (lb.)	approx. 2 lb.	approx. 1 lb.
Size (W x H x D)	6.5" x 3.4" x 5"	7.5" x 6" x 4"
Controls	Microprocessor controlled, solid-state pressure transducer, AC / DC adaptable	Solid-state pressure transducer, DC adaptable
Power specifications	120 V AC, 60 Hz, 20 W or 230 V AC, 50 Hz, 60 mA, 12 V DC	9 V DC
Output	Digital readout of pressures	Analog readout of pressures
Materials which interface with patient	PVC, K-resin for the pressure tubing and airway connector tee	PVC, K-resin for the pressure tubing and airway connector tee
Patient interface	Airway adapter placed in the circuit or connection to a face mask	Airway adapter placed in the circuit or connection to a face mask
Display of information	Low pressure alarm setting High pressure alarm setting Status of alarm silence and time remaining Peak pressure Real-time pressure Power source and status Audible and visual alarm	Low pressure alarm setting High pressure alarm setting Inadvertent off - audible Pressure gauge shows values (peak and real-time read upon visual observation) Power status alarm Audible alarm
[redacted]		
Low pressure alarm range	1 - 20 cm H_2O 1 cm H_2O resolution	2 - 50 cm H_2O resolution not specified

Premarket Notification 510(k) Criterion 40

Section 2 - Certification and Summaries

Non-Confidential Summary of Safety and Effectiveness

page 3 of 4

January 4, 2000

[redacted]	[redacted] (New Device)	[redacted]
High pressure alarm range	5 - 99 cm H_2O 1 cm H_2O resolution	2 - 100 cm H_2O resolution not specified
Peak pressure	Displayed as value	Determined by visual observation
Real-time pressure	Displayed as bar graph	Determined by visual observation only
Alarm delay	Yes - 1 - 20 seconds	Yes - 2 - 60 seconds
AC / DC operation	120 V AC / 230 V AC and 12 V DC	9 V DC no AC capabilities
Accuracy of pressure alarm	+/- (1 + 3% of reading) rounded up to nearest cm H_2O	+/- 3 cm H_2O
Accuracy of display - Peak and Pressure bar graph	+/- (1 + 3% of reading) rounded up to nearest 0.5 cm H_2O	Not specified
Alarms	Low pressure High pressure Loss of power Low battery	Low pressure High pressure Inadvertent off Low battery
Operating temperature / humidity	5 °C to 45 °C, 15 - 95% RH	16 °C - 34 °C, 20 - 90% RH
Storage temperatures	-40 °C to 60 °C @ 95% RH	not specified
Battery life	up to 24 hours for backup and transport use but primary power supply is AC	up to 2 months
Zero calibration	Yes	Yes
[redacted]		
Pressure tubing with in-line filter and airway connector	Yes	Yes
Pole mount	Yes	Yes
AC power supply	Yes	Not applicable
[redacted]		
IEC 601-1-2	Yes	CSA C22.2 No. 125 Risk Class 2
UL 260 / IEC 601-1	Yes	Yes
FDA PMN requirements November, 1993	Yes	Not Known
[redacted]	None	None
[redacted]	Comparable	Comparable

Non-Confidential Summary of Safety and Effectiveness
page 4 of 4
January 4, 2000

[redacted]

The Criterion 40 Airway Pressure Monitor is viewed as substantially equivalent to the following predicate device - Monaghan CM 5000 Airway Pressure Monitor (APM) cleared under K871083 and other modifications under K873953, K925673, and K931394.

The differences between the Criterion 40 and the predicate device are minimal. There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices. They are viewed as substantially equivalent to the predicate devices since they:

1. Have the same intended uses
   1.1 Intended for the measurement and monitoring patient airway pressure
   1.2 Provide high and low alarms

2. Have the same environments for use
   2.1 Used in hospitals, sub-acute institutions, home care settings
   2.2 The device has been designed for stationary and intra-institution transport only.

3. Are similar in design
   3.1 Utilize the same design and functional features

4. They employ the same technology
   4.1 Utilize a pressure transducer
   4.2 Utilized tubing to interface with patient circuit

5. Are made of identical materials
   5.1 Utilize similar materials for the monitor and accessories

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 6 2000

Caradyne, Ltd.
c/o Mr. Paul E. Dryden
ProMedic, Inc.
6329 W. Waterview Court
McCordsville, IN 46055-9501

Re: K992101
Criterion 40 - Airway Pressure Monitor
Regulatory Class: II (two)
Product Code: 73 CAP
Dated: October 8, 1999
Received: October 12, 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,

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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[redacted]

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: K992101 (To be assigned)

Device Name: Criterion 40 Airway Pressure Monitor

Intended Use : Is intended to measure airway pressure when used with positive pressure devices. The device alarms when the airway pressure falls outside of the user selected high and low alarm limits and displays peak pressure and real-time airway pressures. It may be used with positive pressure devices which do not include pressure measurement capabilities, e.g. resuscitation bags or basic ventilators, or as an independent backup pressure monitor for devcies with pressure measurement capability. Environment of use is hospital, home, and sub-acute institutions. The device has been designed for stationary and intra-institution transport only.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K992101

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