DEC 8 1998

MEDICAL ELECTRONIC DEVICES CORP.

K983459

POCD Pulsed Oxygen Conserving Device
510(k) Summary

Submitter's Name, Address, Telephone Number, and Contact Person

Submitter
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Date Prepared

September 15, 1998.

Name of Device

Trade Name: Pulsed Oxygen Conserving Device or POCD

Common name: Oxygen Conserver

Classification name: Ventilator, Non-Continuous (Respirator)
21CFR 868.5905

Predicate Devices

(1) CHAD Therapeutics, Inc. Oxymatic-24 (K884562)
(2) CHAD Therapeutics, Inc. Oxymatic Electronic Oxygen Conserver (K852650)
(3) Airsep Corporation Impulse (K962766)

Intended Use

The POCD Pulsed Oxygen Conserving Device is indicated for use to conserve oxygen for patients prescribed 1 to 4 liters per minute of supplemental oxygen and use nasal cannulas and USP bottled oxygen.

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Technological Characteristics and Substantial Equivalence

The Pulsed Oxygen Conserving Device or "POCD" is intended to be used as an accessory to an oxygen supply system to reduce or conserve the amount of oxygen used by the patient. The POCD is a battery operated electronic device that is microprocessor controlled and contains a capacitive breath sensor and a normally closed valve. When installed between the oxygen supply and patient's nasal cannula, the device detects the patient's inhalation opens the valve according to the device's breath skipping algorithm and delivers a preset bolus of oxygen to the patient. The valve closes and conserves the oxygen that would have been wasted during the end of inhalation and during exhalation.

The POCD is intended to be used with USP bottled oxygen and nasal cannulas and is installed as shown in Figure 1.

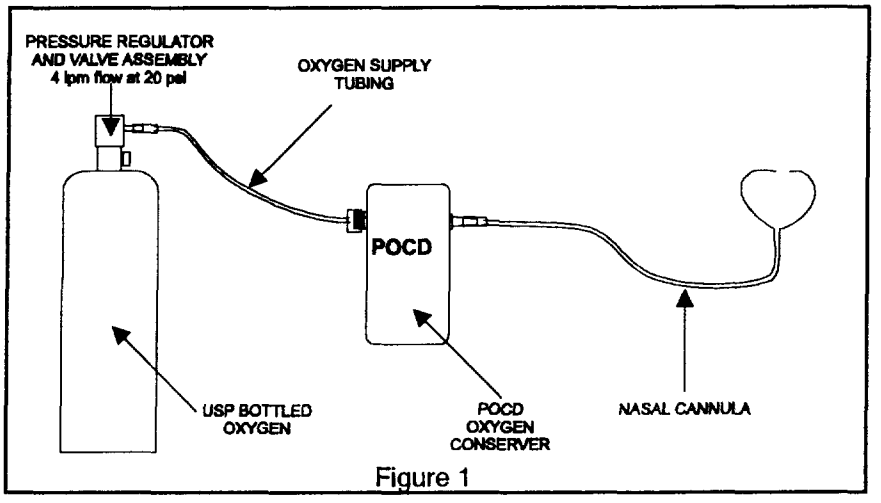


Figure 1

The front panel of the POCD has a selector switch and a battery status light. When the selector switch is set to the "Bat" position the battery status light will illuminate to give the user an indication of the condition of the battery in the device. I n addition to providing battery status information to the user while in the "Bat" setting, the POCD will indicate a low battery condition by flashing the battery status light Red if the unit is in any of the operational settings; "4", "3", "2", or "1", and the battery voltage falls below 1.10V.

When the selector switch is set to "4", "3", "2", or "1" the device operates as follows:

> The capacitive pressure transducer changes its capacitance in response to the negative pressure produced by the user's inhalation effort. This change in capacitance is converted into a change in voltage and is amplified. When this amplified voltage exceeds the reference voltage of the comparator, the comparator's output changes state. This change is input into the microprocessor. The microprocessor then opens the valve for a preset time period to deliver 35 ml of oxygen or indexes a counter in the breath skipping algorithm.

The breath skipping algorithm, a clinically proven method of maintaining equivalent blood oxygen saturation versus prescribed *continuous oxygen flow rates* and used in all three of the predicate devices, works by delivering a bolus of oxygen to the user according to the following schedule:

Selector Switch Setting	Equivalent Continuous Flow Prescription	POCD Breath Skipping Algorithm
4	4 lpm	Delivery on almost every breath (99%)
3	3 lpm	Delivery on 3 out of 4 breaths (75%)
2	2 lpm	Delivery on every other breath (50%)
1	1 lpm	Delivery on 1 out of 4 breaths (25%)

The POCD contains an alarm package which is designed to alert the user in the event of disconnection or restriction of the cannula or unit malfunction. The POCD will produce an audible alarm tone to alert the user if it has not detected sufficient negative pressure to cause the comparator output to change states within 30 seconds. The POCD will also produce an intermittent audible tone if the device's continuous self check routine has detected a malfunction in the microprocessor or software control code.

The POCD is substantially equivalent in intended use and principal of operation to other oxygen conserving devices including the CHAD Therapeutics Oxymatic-24 (K884562), CHAD Therapeutics Oxymatic Electronic Oxygen Conserver (K852650), and the Airsep Impulse (K962766). These predicate devices, like the POCD, are electronic products that use a breath sensor and normally closed valve. Additionally, the predicate devices, like the POCD, use a breath skipping algorithm to conserve oxygen while maintaining patient oxygen saturation levels equivalent to 1 to 4 liter per minute continuous oxygen flow delivery.

Performance Data

Extensive functional testing of the POCD has been performed. In addition, testing of the device has been performed under various environmental conditions, including impact/drop testing, storage temperature testing, electromagnetic interference testing, electrostatic discharge testing and surface temperature testing. Power supply testing was also performed; these tests included battery life testing and low power indicator testing. The functional, environmental and power supply testing performed on the device demonstrated that it meets its performance objectives and complies with applicable FDA guidelines.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 6 2002

Mr. Thomas Wenzel
Medical Electronic Devices Corp.
2807 Oregon Court D6
Torrance, CA 90503

Re: K983459
Pulsed Oxygen Conserving Device
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II (two)
Product Code: 73 NFB

Dear Mr. Wenzel:

This letter corrects our substantially equivalent letter of December 8, 1998, regarding the Pulsed Oxygen Conserving Machine. Our letter identified the product code as 73 BZD. This is in error; the correct product code is 73 NFB as indicated above.

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.

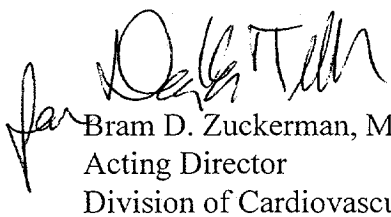
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Medical Electronic Devices Corp.
Pulsed Oxygen Conserving Device
Indications for Use Statement

510(k) Reference Number:

This is an initial submission; no number has yet been assigned.

Statement of Indications for Use:

The POCD Pulsed Oxygen Conserving Device is indicated for use to conserve oxygen for patients prescribed 1 to 4 liters per minute of supplemental oxygen and use nasal cannulas and USP bottled oxygen.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark Kramer

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K983459

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)