K992935

JUN 2 0 2000

Demand Oxygen Conserving Device
510(k) Summary

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

Submitter
Barry A. Schwartz
Contemporary Products, Inc.
530 Riverside Industrial Pkwy.
Portland, ME 04103
Telephone: 207-797-4647
Facsimile: 207-797-9411
FDA Establishment No.: 1223412

Contact Person
Barry A. Schwartz
Contemporary Products, Inc.
530 Riverside Industrial Pkwy.
Portland, ME 04103
Telephone: 207-797-4647
Facsimile: 207-797-9411

Date Prepared

August 27, 1999

Name of Device

Trade Name: OCD2001

Common Name: Oxygen Conserver

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

Predicate Devices

1. Medical Electronic Devices Corp. DOCD (K983601)
2. Invacare IPD Oxygen Conserving Device (K953852)
3. Chad Therapeutics, Inc. Oxymatic Electronic Oxygen Conserver (K852650)

Intended Use

The OCD2001 is indicated for use to conserve oxygen for patients prescribed 1/2 to 6 liters per minute of supplemental oxygen and use nasal cannulas and USP bottled oxygen.

Technological Characteristics and Substantial Equivalence

The OCD2001 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 OCD2001 is a battery operated electronic device that is microprocessor controlled and contains a 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 flow rate set on the device and delivers a preset bolus of oxygen to the patient as determined by the device flow rate algorithm. The valve closes and conserves the oxygen that would have been wasted during the end of inhalation and during exhalation.

The OCD2001 is intended to be used with USP bottled oxygen and nasal cannulas and is installed as shown in Figure 1.

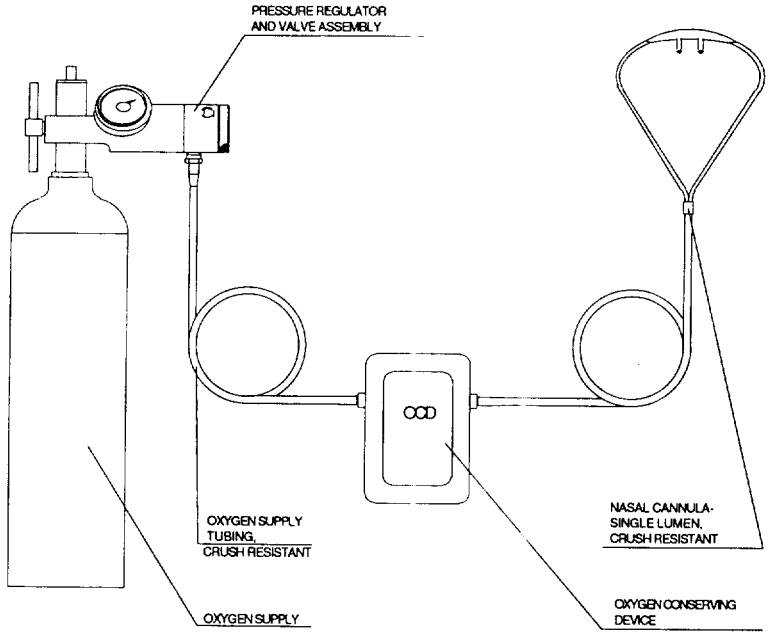


FIGURE 1

The top panel of the OCD2001 has a selector switch, battery status light and flow fault/apnea light. The battery LED winks every four (4) seconds when about 3 hours remain in the batteries and once every second when about 30 minutes remain. An audible alarm "chirp" accompanies the LED blinking. It

then lights steady if batteries can no longer properly power the unit informing the patient that the unit has shut down.

When the selector switch is set to "ON" the device operates as follows:

The sensing diaphragm closes its circuit in response to .5cm negative pressure produced by the user's inhalation effort. This circuit closing is input into the microprocessor. The microprocessor then opens the valve to allow the appropriate bolus of oxygen to flow (based upon the chart that follows) and then waits for the next negative pressure.

Chart 1

Liter Flow Setting	Bolus Size
1/2 lpm	5 ml
1 lpm	10 ml
2 lpm	20 ml
3 lpm	30 ml
4 lpm	40 ml
5 lpm	50 ml
6 lpm	60 ml

The OCD2001 contains an alarm package that is designed to alert the user in the event of disconnection of the cannula or unit malfunction. The OCD2001 will produce an audible alarm tone to alert the user if it has not detected sufficient negative pressure to close the circuit on the sensing diaphragm with in 30 seconds. The OCD2001 will cause the flow/apnea light to light a steady red if the microprocessor should fail.

The OCD2001 is substantially equivalent in intended use and principal of operation to other oxygen conserving devices including the Invacare IPD Oxygen Conserving Device (K953852) and the Chad Therapeutics Oxymatic Electronic Oxygen Conserver (K852650). These predicate devices, like the OCD2001, are electronic products that use a breath sensor and normally closed valve. Additionally, the Invacare IPD Oxygen Conserving Device, like the OCD2001 opens the valve and delivers the oxygen to the patient on every detected inhalation.

Performance Data

Extensive functional testing of the OCD2001 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. Barry A. Schwartz
President
Contemporary Products, Inc.
530 Riverside Industrial Pkwy.
Portland, ME 04103

Re: K992935
OCD2001
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II (two)
Product Code: 73 NFB

Dear Mr. Schwartz:

This letter corrects our substantially equivalent letter of June 20, 2000, regarding the OCD2001. 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.

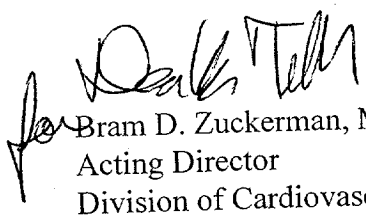
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Contemporary Products, Inc.
Demand 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 OCD2001 Demand Oxygen Conserving Device is indicated for use to conserve oxygen for patients prescribed 1/2 to 6 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)

for Mark N Melkerson

(Division Sign-Off)
Division of Cardiovascular, Respiratory and Neurological Devices

510(k) Number: K992935

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

(Optional Format 1-2-96)