K023420

MED Corporation

OCT 2 5 2002

Special 510(K)

510(K) Summary

Medical Electronic Devices Corporation

Modified Medical Electronic Devices Corporation
POCD Pulsed Oxygen Conserving Device

October 2, 2002

Submitter Information:

Medical Electronic Devices Corporation
2807 Oregon Court, D6
Torrance, California 90503

Submitter's Name: Thomas Wenzel
Phone: (310) 618-0306

Device Name:

Proprietary Name: Medical Electronic Devices Corporation $POCD_{EB}$

Common Name: Oxygen Conserver

Classification Name: Noncontinuous Ventilator

Predicate Device Equivalence:

Substantial equivalence is claimed to the Medical Electronic Devices Corporation unmodified POCD, cleared for commercial distribution per K983459 and the CHAD Therapeutics OXYMATIC Model 311.

Device Description:

The Medical Electronic Devices Corp. $POCD_{EB}$ 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 $POCD_{EB}$ is a battery operated electronic device that is microprocessor controlled and contains a breath sensor and normally closed valve. It delivers boluses of oxygen every breath that is equivalent to 1 to 4 liters per minute constant flow, depending on the flow setting.

Intended Use:

The Medical Electronic Devices Corp. $POCD_{EB}$ is intended for to conserve oxygen for patients prescribed 1 to 4 liters per minute of supplemental oxygen and use nasal cannulas and USP bottled oxygen.

Comparison of Technological Characteristics:

The $POCD_{EB}$ has the same technological characteristics as the predicate device, i.e. the POCD. The hardware portion of the device is identical to the POCD except for labeling. The software has been modified to deliver a bolus of oxygen on every breath, rather than skipping breaths at lower flow rates. This dosing algorithm is identical to the algorithm used in the predicate device CHAD Therapeutics OXYMATIC Model 311.

Summary of Testing:

Appropriate performance, mechanical, electrical, electromagnetic and environmental testing was performed to demonstrate that the $POCD_{EB}$ would perform as intended.

Conclusions:

Based on the above, we concluded that the $POCD_{EB}$ is substantially equivalent to currently marketed devices and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 25 2002

Mr. Thomas Wenzel
President
Medical Electronic Devices Corporation
2807 Oregon Court, D6
Torrance, California 90503

Re: K023420
Trade/Device Name: Pulsed Oxygen Conserving Device
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II
Product Code: 73 NFB
Dated: October 10, 2002
Received: October 11, 2002

Dear Mr. Wenzel:

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) 594-4646. 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,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

MED Corporation

Medical Electronic Devices Corporation
$POCD_{EB}$ Premarket Notification

Indications for Use Statement

K023420

Device Name:

Modified Medical Electronic Devices Corp. POCD Pulsed Oxygen Conserving Device (i.e. $POCD_{EB}$)

Indications for Use:

The modified Medical Electronic Devices Corp. POCD Pulsed Oxygen Conserving Device is intended for use in the same manner as the unmodified device, i.e., 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)

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

510(k) Number: K023420

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Medical Electronic Devices Corporation
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