K013472

NOV 2 8 2001

SPECIAL 510(k)

510(k) SUMMARY

Chad Therapeutics, Inc.

Modified Chad Total O_2™ Delivery System

September 18, 2001

Submitter Information:

Chad Therapeutics, Inc.
21622 Plummer Street
Chatsworth, CA 91311

Submitter's Name: Kevin McCulloh
Phone: (818) 882-0883

Device Name:

Proprietary name: **Total O_2™**

Common Name: Chad **Total O_2™** Delivery System

Classification Name: Portable Oxygen Generator

Predicate Device Equivalence:

Substantial equivalence is claimed to the Chad Therapeutics Unmodified Chad **Total O_2** Delivery System, cleared for commercial distribution per K971889.

Device Description:

The Chad **Total O_2** Delivery System addresses several needs of patients and homecare providers. The **Total O_2** Delivery System has been designed to reduce the need for bulk storage and transport of liquid oxygen as well as the storage and transport of high-pressure oxygen tanks. The **Total O_2** Delivery System is comprised of conventional pressure adsorption technology which supplies low pressure oxygen to a nasal cannula and/or an integral pressure intensifier which compresses a small portion of the gas to pressures up to 2015 psig in an oxygen gas cylinder for ambulatory use.

The **Total O_2** Delivery System has a unique cylinder fill mechanism, which allows it to be easily, and safely connected to the patient's **Total O_2** oxygen cylinder. The unique cylinder fill mechanism ensures that **Total O_2** oxygen cylinders can only be filled through the unique fill port with the **Total O_2** Delivery System. The **Total O_2** oxygen cylinders will be offered in two versions:

1. The original **Total O_2** cylinders with built in pressure reducer.

2. The **Total O_2** Post Valve cylinders with the same unique fill port as the original **Total O_2**, no built in pressure reducer but with a unique post valve outlet. The valve incorporates an internal mechanism to prevent filling the cylinders through the unique post valve connection port. Furthermore the **Total O_2** post valve oxygen cylinders can only dispense the oxygen in the cylinder through the unique post valve port.

Intended Use:

The intended use of the Chad **Total O_2** Delivery System is to supply low-pressure supplemental oxygen to patients in the home, health care facility or hospital and to supply pressurized oxygen to fill oxygen cylinders for patient's ambulatory use.

The oxygen supplied by the **Total O_2** Delivery System is supplemental and is not considered to be life supporting and not intended to be used with or for any life support applications or in the presence of flammable anesthetics. Geriatric, pediatric or other patients unable to communicate discomfort may require additional monitoring, as with the case with oxygen concentrators currently in use. The device is not sold sterile or intended to be sterilized.

Indications for use:

The modified Chad **Total O_2** Delivery System is intended for use in the same manner as the unmodified device:

The **Total O_2** Delivery System is indicated for Supplemental Medical Oxygen for treatment of Respiratory Diseases.

Comparison of Technological Characteristics:

The modified Chad **Total O_2** Delivery System has the same technological characteristics as the predicate device.
The software portion of the device is identical to the predicate device.
The hardware portions of the device is identical except for the following; the **Total O_2** oxygen cylinders have been modified to allow for the use of two versions:

1. The original **Total O_2** cylinders with built in pressure reducer.

2. The **Total O_2** post valve cylinders with the same unique fill port as the original **Total O_2**, no built in pressure reducer but with a unique post valve outlet incorporating a mechanism to prevent filling the cylinders through the unique post valve connection port. The Chad **Total O_2** post valve cylinders could only be filled through the unique fill port and dispense through the unique post valve port. The unique post valve would incorporate an index pin in accordance with the CGA V-1 number 13 position to prevent CGA-870 regulators, conserving devices, etc. from attaching to the unique post valve.

Summary of Testing:

Performance, mechanical, electrical, electromagnetic compatibility and environmental testing was conducted to demonstrate that the Chad **Total O_2** Delivery System would perform as intended.

Conclusions:

Based on the above, we concluded that the Chad Therapeutics modified Chad **Total O_2** Delivery System is substantially equivalent to the unmodified Chad **Total O_2** Delivery System 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

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Mr. Kevin McCulloh
Vice President, Engineering
Chad Therapeutics, Inc.
21622 Plummer Street
Chatsworth, CA 91311

Re: K013472
Chad Total O_2™ Delivery System
Regulation Number: 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II (two)
Product Code: 73 CAW
Dated: September 18, 2001
Received: October 18, 2001

Dear Mr. McCulloh:

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,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (If Known): K013472

Device Name: Modified Chad Total O_2™ Delivery System

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Division of Cardiovascular & Respiratory Devices
510(k) Number K013472