CHAD THERAPEUTICS
The Ambulatory O_2 Specialists!

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MAY 11 2004

K033364

510(k)

510(k) SUMMARY

Chad Therapeutics, Inc.

Chad Therapeutics Sage

October 17, 2003

Submitter Information:

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

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

Device Name:

Proprietary names: Chad Therapeutics Sage

Common Name: Therapeutic Device

Classification Name: Non-continuous ventilator

Predicate Device Equivalence:

Substantial equivalence is claimed to the Chad Therapeutics 400 Series conservers cleared for commercial distribution per K000890, K003455, K010389 and the DeVilbiss PulseDose conserving device cleared for commercial distribution per K961126.

Device Description:

The Chad Therapeutics Sage is a microprocessor-controlled device, which is a combination of a low-pressure regulator and a therapeutic oxygen device, designed for use with ambulatory oxygen systems. It delivers boluses of oxygen that is equivalent to 1 to 6 liters per minute, depending on the flow rate setting and whether the user is at rest or active.

Intended Use:

The Chad Therapeutics Sage is intended for prescription use only, to be used as part of a portable therapeutic oxygen system for patients that require supplemental oxygen while at rest or during activity.

Comparison of Technological Characteristics:

The device has many similar technological characteristics as the predicate devices, except that the Sage has both a rest and activity setting and incorporates a motion sensor to detect user activity to switch the device automatically from an at rest to an active flow setting.

Summary of Testing:

Performance, mechanical, electrical, electromagnetic compatibility, magnetic fields immunity, magnetic fields emissions, quasi-static electric fields and environmental testing was conducted to demonstrate that the Sage would perform as intended.

Conclusions:

Based on the above, we concluded that the Chad Therapeutics Sage is substantially equivalent to legally marketed predicate 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

MAY 11 2004

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

Re: K033364
Trade Name: Chad Therapeutics Sage
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: NFB
Dated: April 23, 2004
Received: April 26, 2004

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), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,

for Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033364

Device Name: Chad Therapeutics Sage

Indications For Use:

The Chad Therapeutics Sage is intended for prescription use only, to be used as part of a portable therapeutic oxygen system for patients that require supplemental oxygen while at rest or during activity.

Prescription Use ___✓___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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: K033364