

CHAD THERAPEUTICS, INC.
21622 PLUMMER STREET
CHATSWORTH, CA 91311

JUL 5 2002

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K020475



510(k)

510(k) SUMMARY

Chad Therapeutics, Inc.

Chad Therapeutics OXYPNEUMATIC CYPRESS Model 511

February 11, 2002

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
OXYPNEUMATIC CYPRESS Model 511

Common Name: Oxygen conserver

Classification Name: Non-continuous ventilator

Predicate Device Equivalence:

Substantial equivalence is claimed to the Victor Medical Products O2n Demand II cleared for commercial distribution per K992659, the Western Medica OPC Oxygen Conserving Device cleared for commercial distribution per K010747 and the Precision Medical PM 1800 Conserving Device cleared for commercial distribution per K001412.

Device Description:

The Chad Therapeutics OXYPNEUMATIC CYPRESS Model 511 is a pneumatic-controlled device, which is a combination of a low-pressure regulator and an oxygen conserver, 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.

Intended Use:

The Chad Therapeutics, Inc. OXYPNEUMATIC CYPRESS Model 511 is intended for prescription use only, to be used as part of a portable oxygen delivery system for patients that require supplemental oxygen in their home and for ambulatory use.

Comparison of Technological Characteristics:

The OXYPNEUMATIC CYPRESS Model 511 has the same technological characteristics as the predicate devices.

Summary of Testing:

Performance, mechanical and environmental testing was conducted to demonstrate that the OXYPNEUMATIC CYPRESS Model 511 would perform as intended.

Conclusions:

Based on the above, we concluded that the Chad Therapeutics OXYPNEUMATIC CYPRESS Model 511 is substantially equivalent to legally marketed predicate devices and is safe and effective for its intended use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 5 2002

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

Re: K020475

Trade/Device Name: Chad Therapeutics OXYPNEUMATIC CYPRESS,
Model 511
Regulation Number: 868.5905
Regulation Name: Non-continuous Ventilator
Regulatory Class: II
Product Code: NFB
Dated: May 10, 2002
Received: May 14, 2002

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,


for 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

510 (k) Number (If Known): K020475

Device Name: Chad Therapeutics OXYPNEUMATIC CYPRESS Model 511.

Indications for Use:

The Chad Therapeutics OXYPNEUMATIC CYPRESS Model 511 is intended for prescription use only, to be used as part of a portable oxygen delivery system for patients that require supplemental oxygen in their home and for ambulatory use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Susan Purno
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020475