DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Kevin Jorczak
Vice President
Remcore, Incorporated
14 Bond Street
Boston, Massachusetts 02118

OCT 25 2006

Re: K060265
Trade/Device Name: Remcore Remote Control Oxygen Delivery System
Regulation Number: 21 CFR 868.2700
Regulation Name: Pressure Regulator
Regulatory Class: I
Product Code: CAN
Dated: October 3, 2006
Received: October 6, 2006

Dear Mr. Jorczak:

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.

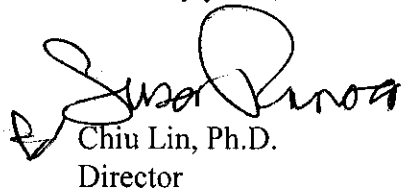
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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): K060265

Device Name: Remcore Remote Control Oxygen Delivery System

Indications for Use:

The Remcore Remote Control Oxygen Delivery system is an adjunct to the use of supplemental oxygen prescribed by a physician for a patient whose lung disease limits his or her ability to adequately supply the body with oxygen. The amount of supplemental oxygen needed to continuously provide the oxygen saturation prescribed will vary with different degrees of exertion. Current oxygen delivery systems do not allow a patient to alter the flow rate of oxygen when the patient is not next to the oxygen source. The Remcore Remote Control Oxygen Delivery System allows a patient to change the flow rate, as prescribed by the physician, in accordance with the activity of the patient. For example, a patient might require 2 liters/minute of supplemental oxygen at rest, but 5 liters/minute to climb the stairs. The Remcore system will allow the patient sitting downstairs to remotely increase the oxygen flow rate to 5 liters/minute, regardless of where in the house the oxygen tank or concentrator is located, and after arriving upstairs to remotely return the oxygen flow rate to 2 liters/minute.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

n of Anesthesiology, General Hospital,
ion Control, Dental Devices

Number: K060265