DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 2004

Clear Medical, Inc.
c/o Wayne Pong
Quality Team Leader
1776 136th Place NE
Bellevue, WA 98005

Re: K012600 - Supplemental Validation Submission
Trade/Device Name: See Enclosed List
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: NLF
Dated: August 8, 2001
Received: August 13, 2001

Dear Mr. Pong:

The above-referenced premarket notification (510(k)) was cleared by the Office of Device Evaluation (ODE) on July 3, 2002. We have received your supplemental validation data as required for reprocessed single-use devices by the Medical Device User Fee and Modernization Act of 2002. After reviewing your supplemental validation data, we have determined the devices listed in the enclosure accompanying this letter are 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 these devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (PMA) they 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 devices 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 devices comply 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 applicable 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.

The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in classification for your devices and thus, permits you to legally market the devices. This letter will allow you to continue marketing the devices listed in the enclosure accompanying this letter.

If you desire specific advice for your devices 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

Statement of Indications for Use

510(K) NUMBER (IF KNOWN): K012600

DEVICE NAME: ClearMedical/Nellcor Oxisensor II O_2 Transducer, Part No. D-25 / D-25L

INDICATIONS FOR USE:

The adult Oxisensor, model D-25 and D-25L, is indicated for single patient use when continuous noninvasive arterial oxygen saturation and pulse rate monitoring are required for patients weighing more than 30 kg.

(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)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012680

[redacted]

K012600 – Trade/Device Name List

Clear Medical/Nellcor Oxisensor II, O2 Transducer, Model D-25
Clear Medical/Nellcor Oxisensor II, O2 Transducer, Model D-25L

JUL 3 2002

510(k) Summary K012600

Submitter's name and Address:	ClearMedical, Inc. 1776 – 136th Place NE Bellevue, WA 98005 Ph (425) 401-1414 Fax (425) 401-1515
FDA Registration Number:	3017110
Contact Person:	Richard Radford Director of Research and Product Development
Date Summary Prepared:	August 8, 2001
Trade or Proprietary Name:	ClearMedical/Nellcor Oxisensor II, Adult O_2 Transducer, Parts D-25/D-25L
Common Name:	Oxisensor
Classification:	Oximeter (per 21 CFR 870.2700) / DQA

Equivalent Device

The reprocessed ClearMedical/Nellcor Oxisensor II, Adult O_2Transducer, Parts D-25/D-25L, is substantially equivalent to the Nellcor Oxisensor II™ Parts D-25/D-25L. This determination has been reached based on an evaluation and analysis of the predicate device's technical and promotional labeling and specific bench and non-invasive clinical testing. For all established indicators of substantial equivalence the ClearMedical devices demonstrated equality in safety and performance.

Device Description

The ClearMedical/Nellcor Oxisensor is an accessory device to an oximeter monitoring system. The oximeter system is designed for the determination of functional oxygen saturation and pulse rate. The oxisensor is designed as a transducer for the transmission of electrical signals from the oximeter to the patient and the return of patient modified signals back to the oximeter for analysis and display of patient information.

510(k) Summary (Cont'd)

The sensor contains three optical components: two light emitting diodes (LEDs) that serve as light sources and one photodiode that acts as a light detector. Both the LEDs and photodiode are contained within a laminated envelope with an adhesive bandage for attachment to a patient. Attached to the laminated envelope is a sensor cable, which terminates in a connector element that connects to the oximeter.

Intended Use of the Oxisensor

The reprocessed ClearMedical/Nellcor D-25/ D-25L Oxisensor is intended as a single patient use transducer/accessory sensor to a Nellcor Oximeter system. The role of the sensor is the acquisition of patient data which is used by the oximeter in the determination of functional oxygen saturation and pulse rate of adult patients. The D-25/D-25L oxisensor is used in conjunction with the Nellcor oximeter in a hospital environment where non-invasive monitoring of pulse oxygen hemoglobin saturation (SpO_2) and pulse rate (PR) are required for patients with potentially abnormal pulmonary/circulatory function.

Technological Characteristics of ClearMedical/Nellcor Oxisensor Compared with the Nellcor Oxisensor

The predicate device and the ClearMedical/Nellcor sensor contain three optical components: two light emitting diodes (LEDs) that serve as light sources and one photodiode that acts as a light detector. Both the LEDs and photodiode are contained within a laminated envelope with an adhesive bandage for attachment to a patient, which serves to align the optical sensors and retain the sensor to a patient digit. Attached to the laminated envelope is a sensor cable, which terminates in a molded PVC connector element that connects to the oximeter. In form, the predicate device and the ClearMedical/Nellcor Oxisensor are substantially equivalent.

Other technological indicators of substantial equivalence were identified and included functionality in optical sensitivity of the optical diodes, continuity of sensor circuitry, comparative non-invasive Co-Oximetry and Oximetry data, infection control methodology, fit/attachment and connector function.

Summary of the ClearMedical/Nellcor Oxisensor Performance

Based on an assessment of bench tests, and clinical and/or non-clinical performance data, we believe that in all relevant safety and performance indicators the ClearMedical/Nellcor Oxisensor demonstrates substantial equivalence to the Nellcor Oxisensor predicate device.