K012715

AUG - 1 2003

510K Summary of Safety & Effectiveness

Submitter:	Hygia Health Services, Inc. 434 Industrial Lane Birmingham, Alabama 35211 Phone: (205) 314-3920 Fax: (205) 314-3959
Contact:	Mrs. Tracy Wood Comas Chief Operating Officer Phone: (205) 314-3920 Fax: (205) 314-3959 Email: tracy.comas@hygia.net
Date:	August 1, 2003
Trade or Proprietary Name:	Hygia Health Services Reprocessed D-25 and N-25 Nellcor Oxisensors
Common Name:	Pulse Oximeter sensor, oxygen transducer
Classification:	21CFR 870-2700 - Oximeter DQA
Equivalent Device:	Corresponding Mallinckrodt, Inc., Nellcor Oxisensors legally marketed under various 510(k) premarket notifications.
Device Description:	The Hygia Health Services Oxisensors are non-invasive probes used to provide continuous SpO2 monitoring and pulse rate. The probes contain a dual wavelength light emitting diode (LED), and an optical photodiode sensor which are housed in a pad which attaches to the patient using adhesive material. The LED emits red and infrared light in alternate pulses, governed by the Oximeter instrument. The photodiode sensor responds to the light and generates a current that is interpreted by the Oximeter instrument. The Oximeter instrument interprets the different amounts of each light type (red and infrared) from the output of the photodiode and interprets the information and displays a reading. The sensor operates without any type of tissue penetration, electrical contact, or heat transfer to the patient. The sensors use optical means to determine the light absorption of functional arterial hemoglobin.

510K Summary of Safety & Effectiveness (cont'd)

Indications for Use:	The sensor is indicated for use as a non-invasive method to provide continuous SpO2 monitoring and pulse rate.
Technological Characteristics:	The predicate device and the Hygia Health Services reprocessed device contain dual wavelength LED and a photodiode. The LED and photodiode are encased in a pad which attaches to the patient using adhesive material. The sensors are connected to a cable and they terminate in a pin connector. Biocompatibility and performance/functional testing demonstrate that the devices are equivalent and are safe and effective for their intended use.
Testing:	Functional testing, cleaning validation, and biocompatibility testing demonstrates that the reprocessed devices perform as intended and are safe and effective.
Conclusion:	Based on the assessment of functional testing, cleaning validation, and biocompatibility testing performed, Hygia Health Services concludes that the Hygia Health Services reprocessed pulse Oximeter sensors are substantially equivalent to the Mallinckrodt, Inc., Nellcor predicate sensors.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 4 - 2004

Hygia Health Services, Inc.
c/o Tracy Wood Comas
434 Industrial Lane
Birmingham, AL 35211

Re: K012715
Trade/Device Name: Hygia Health Services Reprocessed Pulse Oximeter Sensors (Models D-25 and N-25)
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: NLF, DQA
Dated: May 27, 2004
Received: May 28, 2004

Dear Ms. Comas:

The above-referenced premarket notification (510(k)) was cleared by the Office of Device Evaluation (ODE) on August 1, 2003. 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 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 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 device to a legally marketed predicate device results in a classification for your device and thus, permits you to legally market the device. This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification, including the supplemental validation data you submitted.

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,

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

Applicant: Hygia Health Services, Inc.

510(k) Number: K012715

Device Name: Hygia Health Services Reprocessed D-25 and N-25 Nellcor Oxisensors

Indications For Use:

The Hygia Health Services Reprocessed Nellcor Oxisensor is used as a non-invasive method to provide continuous SpO2 monitoring and pulse rate.

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K012715

X PRESCRIPTION DEVICE