MAY 2 8 2008

K080424

510K Summary

Submitter:	Hygia Health Services, Inc. 434 Industrial Lane Birmingham, Alabama 35211 Phone: (205) 314-3920 Fax: (205) 314-3959
Contact:	Jerome James Director of R&D Phone: (205) 314-3920 Fax: (205) 314-3959 Email: jerry.james@hygia.net
Date:	February 12, 2008
Trade or Proprietary Name:	Hygia Health Services Reprocessed Sensors
Common Name:	Oximeter, Reprocessed
Classification:	21 CFR 870-2700-Oximeter NLF
Equivalent Device:	Corresponding Masimo LNCS Pulse Oximeter Sensors legally marketed under various 510(k) premarket notifications and Hygia reprocessed Nellcor Pulse Oximeter sensors Masimo 510(k) K041815 Masimo 510(k) K051212 Hygia Health Service's 510(k) K041867
Device Description:	The Hygia Health Services reprocessed pulse Oximeter sensors are non-invasive sensors used to provide continuous SpO2 monitoring and pulse rate. The sensors 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

510K Summary of Safety & Effectiveness (Con't)

	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.
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 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. Clinical Testing demonstrated that the reprocessed devices used with the Masimo Radical SET pulse oximeter perform as intended and are safe and effective.
Conclusion:	Based on the assessment of clinical testing, non-clinical 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 Masimo LNCS predicate sensors.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 2008

Mr. Jerome James
Director of R&D
Hygia Health Services, Incorporated
434 Industrial Lane
Birmingham, Alabama 35211

Re: K080424
Trade/Device Name: Hygia Health Services Reprocessed Sensors [Adult Pulse Oximeter Sensor (HHS-1859); Adult-N Pulse Oximeter Sensor (HHS-1862); Pediatric Pulse Oximeter Sensor (HHS-1860); Infant Pulse Oximeter Sensor (HHS-1861)]
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: NLF
Dated: April 28, 2008
Received: April 29, 2008

Dear Mr. James:

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) 276-0115. 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

Applicant:	Hygia Health Services, Inc.
510 (k):	K
Device Name:	Hygia Health Services Reprocessed Sensors
Indications for Use:	The Hygia Health Services Reprocessed Masimo LNCS Pulse Oximeter sensors are used as a non-invasive method to provide continuous SpO_2 monitoring and pulse rate monitoring. This device is intended for prescription use.

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

510(k) Number: K080424

List of Models

Sensor Model	Intended Oximeter	Hygia Catalog #
Adult Pulse Oximeter sensor	Masimo Radical SET	HHS 1859
Adult-N Pulse Oximeter Sensor	Masimo Radical SET	HHS-1862
Pediatric Pulse Oximeter Sensor	Masimo Radical SET	HHS-1860
Infant Pulse Oximeter Sensor	Masimo Radical SET	HHS-1861