

SEP 10 2004

K041867

510K Summary of Safety & Effectiveness

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Date: July 7, 2004

Trade or
Proprietary Name: Hygia Health Services Reprocessed Sensors

Common Name: Oximeter, Reprocessed

Classification: 21 CFR 870-2700-Oximeter
NLF

Equivalent Device: Corresponding Mallinckrodt, Inc., Nellcor OxiMAX and
Oxisensors legally marketed under various 510(k) premarket
notifications

Hygia Health Service's 510(k) 012715
Nellcor Puritan Bennett, Inc. 510(k) K012891
Nellcor Puritan Bennett, Inc. 510(k) K863784

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

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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.

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.



SEP - 6 2006

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Tracy Wood Comas
Chief Operating Officer
Hygia Health Services, Incorporated
434 Industrial Lane
Birmingham, Alabama 35211

Re: K041867

Trade/Device Name: Hygia Health Services Reprocessed Sensors
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: NLF
Dated: July 7, 2004
Received: July 19, 2004

Dear Ms. Wood Comas:

This letter corrects our substantially equivalent letter of July 19, 2004.

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 (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 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 continue 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/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

List of Models: Hygia Health Services Reprocessed Sensors

Nellcor Oxisensor II
D-20
I-20
Nellcor OxiMax
MAX-A with event history
MAX-AL with event history
MAX-N with event history
MAX-P with event history
MAX-I with event history
MAX-A with event history disabled
MAX-AL with event history disabled
MAX-N with event history disabled
MAX-P with event history disabled
MAX-I with event history disabled