



SEP - 6 2006

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Heather Crawford
Director, Regulatory Affairs
Vanguard Medical Concepts, Incorporated
5307 Great Oak Drive
Lakeland, Florida 33815

Re: K012344

Trade/Device Name: Vanguard Reprocessed Pulse Oximeter Sensors
(Models D-25, D-25L, N-25, D-20 and I-20)

Regulation Number: 21 CFR 870.2700

Regulation Name: Oximeter

Regulatory Class: II

Product Code: NLF, DQA

Dated: May 19, 2004

Received: May 21, 2004

Dear Ms. Crawford:

This letter corrects our substantially equivalent letter of August 4, 2006.

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.

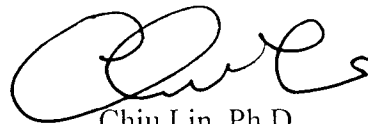
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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: Vanguard Reprocessed Pulse Oximeter Sensors

Nellcor Oxisensor II
D-20
D-25L
D-25
N-25
I-20

510(k) Summary of Safety & Effectiveness, Continued

Device Description Oximeter sensors are used with compatible pulse oximeters to noninvasively continually monitor oxygen saturation and pulse rate. The primary components of the sensors are light-emitting diodes (red and infrared LED) and a photosensor. These components are embedded within a taping system to wrap the sensor around a patient's finger, foot or hand so that the LED and photosensor are directly opposite each other. As light is emitted and received across the vascular bed, the rates of absorption at the two wavelengths vary depending upon the ratios of oxygenated and deoxygenated hemoglobin within the blood. The pulse oximeter detects the changes in absorption and utilizes an algorithm to calculate the corresponding pulse rate (beats/minute) and percent arterial oxygen saturation.

Vanguard receives previously used oximeter sensors from healthcare facilities; cleans, reworks, (replaces the tape [all patient-contacting materials]), inspects, tests, repackages and sterilizes the devices; and returns them to the healthcare facility.

Technological Characteristics The Vanguard reprocessed oximeter sensors are essentially identical to the currently marketed OEM sensors. No changes are made to the currently marketed device's specifications and they possess the same technological characteristics. Biocompatibility and performance/functional testing demonstrate that the devices are equivalent and continue to be safe and effective for their intended use.

Test Data Sterilization validations, and functional/performance and biocompatibility testing demonstrates that the reprocessed devices perform as intended and are safe and effective.

Conclusion Based on the information provided herein and the 510(k) "Substantial Equivalence" Decision Making Process Chart, we conclude that the Vanguard reprocessed pulse oximeter sensors are substantially equivalent to the predicate devices, Mallinckrodt, Inc., Nellcor Oxisensor® II Sensors, under the Federal Food, Drug and Cosmetic Act.

Indications for Use

510(k) Number: K012344

Device Name: Vanguard Reprocessed Pulse Oximeter Sensors

Indications for Use:

The sensor is indicated for use in continuous noninvasive arterial oxygen saturation and pulse rate monitoring.

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


Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)



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

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