OCT - 7 2010

510K Summary

K101280

Submitter:	Midwestern Reprocessing Center, LLC 3995 Fashion Square Blvd. Suite 11 Saginaw, MI 48603 Phone: (989) 583-4623 Fax: (989) 583-4633
Contact:	Jerome James Consultant Phone: (205) 314-3920 Fax: (205) 314-3959 Email: jerry.james@hygia.net
Date:	May 3, 2010
Trade or Proprietary Name:	Midwestern Reprocessing Center Reprocessed Sensors
Common Name:	Oximeter, Reprocessed
Classification:	21 CFR 870-2700-Oximeter NLF
Equivalent Device:	Corresponding Masimo LNCS, Nellcor OxiMax, and Nellcor Oxisensor II Pulse Oximeter Sensors and Hygia Health Services Reprocessed Pulse Oximeter Sensors legally marketed under various 510(k) premarket notifications. Masimo 510(k) K041815 Masimo 510(k) K051212 Hygia Health Services 510(k) K080424 Hygia Health Services 510(k) K041867 Nellcor Puritan Bennett, Inc. 510(k) K012891 Nellcor Puritan Bennett, Inc. 510(k) K863784 Hygia Health Services 510(k) K012715
Device Description:	The Midwestern Reprocessing Center 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,

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

	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.
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 devices and the MRC 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 to their predicate devices
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 its compatible 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, Midwestern Reprocessing Center concludes that the Midwestern Reprocessing Center reprocessed pulse Oximeter sensors are substantially equivalent to their predicate devices..

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Midwest Reprocessing Center LLC
C/O Mr. Jerome James
Hygia Health Services, Incorporated
434 Industrial Lane
Birmingham, Alabama 35211

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Re: K101280
Trade/Device Name: MRC Reprocessed Sensors
Regulation Number: 21 CFR 870.2700
Regulation Name: Reprocessed Oximeter
Regulatory Class: II
Product Code: NLF
Dated: September 29, 2010
Received: October 1, 2010

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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

K101280

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Applicant: Midwestern Reprocessing Center, LLC (MRC)

510 (k): K

Device Name: MRC Reprocessed Sensors

Indications for Use: The MRC Reprocessed Pulse Oximeter sensors are used as a non-invasive method to provide continuous SpO_2 monitoring and pulse rate monitoring.

These devices are intended for prescription use.

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

510(k) Number: K101280