JUL 29 2008

K081238

SECTION 5: 510(k) SUMMARY

Submitter:

Ascent Healthcare Solutions
10232 South 51st Street
Phoenix, Arizona 85044

Contact:

Katie Bray
Regulatory Affairs Manager
(480) 763-5300 (o)
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kbray@ascenths.com

Date of preparation: April 29, 2008

Name of device: *Trade/Proprietary Name:* Reprocessed Pulse Oximeter Sensors

Classification Name: Oximeter, Reprocessed

Predicate Device	510(k) Title	Manufacturer
K060143	LNCS and SPO2.COM Sensors	Masimo Corporation
K041815	LNCS Oximetry Sensors	Masimo Corporation

Device description: The devices are reprocessed Low Noise Cabled Sensors (LNCS)® Series - Adult, Pediatric, and Infant S_pO_2 adhesive sensors. The sensors are disposable devices used for continuous noninvasive arterial oxygen saturation and pulse rate monitoring.

Indications for Use: Reprocessed Pulse Oximeter Sensors are indicated for use in continuous noninvasive arterial oxygen saturation and pulse rate monitoring.

Technological characteristics: The design, materials, and intended use of Reprocessed Pulse Oximeter Sensors are identical to the predicate devices. The mechanism of action of Reprocessed Pulse Oximeter Sensors is identical to the predicate devices in that the same standard mechanical design and size and equivalent materials are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation. In addition, Ascent Healthcare Solutions' reprocessing of Pulse Oximeter Sensors includes removal of adherent visible soil and decontamination. Each individual Pulse Oximeter Sensor is tested for appropriate function of its components prior to packaging and labeling operations.

Performance data: Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of Reprocessed Pulse Oximeter Sensors. This included the following tests:

- Biocompatibility
- Validation of reprocessing
- Function test(s)
- Packaging Validation

Performance testing demonstrates that Reprocessed Pulse Oximeter Sensors perform as originally intended.

Conclusion:

Ascent Healthcare Solutions concludes that the modified devices (Reprocessed Pulse Oximeter Sensors) are safe, effective, and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 29 2008

Ms. Katie Bray
Regulatory Affairs Manager
Ascent Healthcare Solutions
10232 South 51st Street
Phoenix, Arizona 85044

Re: K081238
Trade/Device Name: Reprocessed Masimo Pulse Oximeter Sensors
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: NLF
Dated: April 29, 2008
Received: May 1, 2008

Dear Ms. Bray:

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.

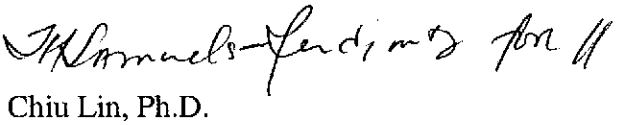
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: Reprocessed Masimo Pulse Oximeter Sensors

Indications For Use:
This sensor is indicated for use in continuous noninvasive arterial oxygen saturation and pulse rate monitoring.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K081238