K093306

510(k) Summary

MAR - 4 2010

Submitter: Nonin Medical, Inc.

Contact Person:
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13700 1st Ave. North
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Date Prepared: October 22, 2009

Trade Name: Oximeter Sensor

Classification Name: and Number: Class II, 21 CFR 870.2700

Product Code: 74 DQA

Predicate Device(s): Nonin's 7000 sensor as cleared in the following 510(K) submissions: Model 7500 (K07128 cleared on July 12, 2007), Model LS1-9R LifeSense (K063752 cleared on May 4, 2007), Model 9600 (K023044 cleared on July 23, 2003), Model 2500A (K050056 cleared on June 21, 2005), and Model 2500 (K002690 cleared on October 11, 2000).

Device Description: The 6500MA (wrap-around model) and 6500SA (interlocking model) are fingertip single-patient use disposable, transmittance sensors. They are comprised of a lamination of two foams (patient contact side and external side) with the optical components and a malleable wire within the lamination. The optical components are identical to the currently marketed Model 7000 single-patient use disposable sensor. The sensors are compatible with all Nonin-branded pulse oximeters.

Intended Use: Nonin's Models 6500MA and 6500SA Single-Patient Use Disposable Pulse Oximeter Sensors are indicated for non-invasive spot-checking and/or continuous monitoring of adult and pediatric patients who are well or poorly perfused, weighing greater than 60 pounds (30 kilograms). It is intended for use in environments including operating room, surgical recovery, critical care, emergency room, long-term care, home use and mobile environments.

Functional and Safety Testing:

Nonin's Model 6500 sensor series have successfully undergone both bench and clinical testing in order to demonstrate that it meets the requirements of ISO 9919:2005 Clause 50 Accuracy of Operating Data, Clause 102 section 102.2 Labeling, and IEC 60601-1:1998 (ISO 10993-1:2003) Clause 48 Biocompatibility.

Substantial Equivalence:

	Predicate Device Model 7000 Sensor Series	Subject Device Model 6500 Sensor Series
Patient Population:	Adult/Pediatric (weighing > 30 kilograms)	Same
Sensor Application Site:	Fingers	Same
Patient Use/Reuse:	Disposable	Same
Sterility:	Non-sterile	Same
Measurement Technique:	Fingertip transmittance sensor	Same
SpO2 Accuracy (Arms) (70-100%):	±3 digits	±2 digits
SpO2 Low Perfusion Accuracy (Arms) (70-100%):	±3 digits	±2 digits
Pulse Rate Accuracy (Arms) (18-300 BPM):	±3 digits	Same
Low Perfusion Pulse Rate Accuracy (Arms) (40-240 BPM):	±3 digits	Same
Red: Infrared:	660 nm @ 0.8 mW maximum average power 910 nm @ 1.2 mW maximum average power	Same
Operating: Storage/Transportation:	0º to +40º C (32º F to 104º F) -30º to +50º C (-22º F to 122º F)	Same -30º to +70º C (-22º F to 158º F)
Operating: Storage/Transportation:	10 to 90% non-condensing 10 to 95% non-condensing	Same
Sensor Housing:	Microfoam	Polyurethane, cross-linked polyester foam, polyethylene/polyurethane, polyester with adhesive

Conclusion:

Nonin's Model 6500 sensor series is substantially equivalent to Nonin's Model 7000 sensors when used with Nonin-branded Pulse Oximeters monitors.

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

Ms. Lori Roth
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Nonin Medical, Incorporated
13700 1st Avenue North
Plymouth, Minnesota 55441

MAR - 4 2010

Re: K093306
Trade/Device Name: Model 6500 Sensor Series
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: February 1, 2010
Received: February 4, 2010

Dear Ms. Roth:

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 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 Statement

510(k) Number (if known) K093306

Device Name Nonin Medical, Inc. Model 6500 Sensor Series

Indications for Use

Nonin's Models 6500MA and 6500SA Single-Patient Use Disposable Pulse Oximeter Sensors are indicated for non-invasive spot-checking and/or continuous monitoring of adult and pediatric patients who are well or poorly perfused, weighing greater than 60 pounds (30 kilograms). It is intended for use in environments including operating room, surgical recovery, critical care, emergency room, long-term care, home use and mobile environments.

Prescription Use ____X_____
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultheiss

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

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