K093853

510(k) Summary

Submitter:	Nonin Medical, Inc.
Contact Person:	Lori M. Roth Clinical/Regulatory Specialist Nonin Medical, Inc. 13700 1st Ave. North Plymouth, MN 55441-5443
Date Prepared:	December 15, 2009, revised April 21, 2010, revised June 2, 2010
Trade Name:	Model 6000CX and 7000X Sensor Series
Classification Name: and Number:	Class II, 21 CFR 870.2700
Product Code:	74 DQA
Predicate Device(s):	Nonin's 7000X 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 6000CX are single-patient use disposable, cloth transmittance sensors. They are comprised of woven cloth material (like a Band-Aid) that allows the sensor to be applied to the patient's appendices with the ability to stretch the sensor material for improved position and comfort. The optical components are identical to the currently marketed Model 7000X single-patient use disposable sensor. The modification that was made to the currently marketed 7000X sensor series is a transparent envelope was added to the sensor optics to improve sensor performance. The sensors are compatible with all Nonin-branded pulse oximeters.
Intended Use:	Nonin's Models 6000CA and 7000A Single-Patient Use Disposable Pulse Oximeter Sensors are indicated for non-invasive spot-checking and/or continuous monitoring of adult pediatric patients who are well or poorly perfused, weighing greater than 60 pounds (30 kilograms). It is intended for use

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	in environments including operating room, surgical recovery, critical care, emergency room, long-term care, home use and mobile environments. Nonin's Models 6000CP and 7000P Single-Patient Use Disposable Pulse Oximeter Sensors are indicated for non-invasive spot-checking and/or continuous monitoring of pediatric patients who are well or poorly perfused, weighing greater than 22 pounds (>10 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. Nonin's Models 6000CI and 7000I Single-Patient Use Disposable Pulse Oximeter Sensors are indicated for non-invasive spot-checking and/or continuous monitoring of infant patients who are well or poorly perfused, weighing greater than 4 pounds (>2 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. Nonin's Models 6000CN and 7000N Single-Patient Use Disposable Pulse Oximeter Sensors are indicated for non-invasive spot-checking and/or continuous monitoring of neonate/adult patients who are well or poorly perfused, weighing less than 4 pounds (<2 kilograms) or adults weighing greater than 66 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 6000CX and 7000X 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.
Sensor Comparison Table	A sensor comparison summary table is on page 3 of this summary.
Conclusion:	Nonin's Model 6000CX and 7000X sensor series are substantially equivalent to Nonin's currently marketed Model

7000X sensors when used with Nonin-branded Pulse Oximeters monitors.

Sensor Comparison Chart		
Product	7000X Sensor (Predicate Device)	6000CX and 7000X Sensors (Subject Devices)
Indications for Use:	Nonin's Model 7000A oximeter sensor is designed as a Single-Patient Use Disposable sensor for monitoring patients weighing more than 30 kilograms. It is intended for use where little motion is expected or cross-contamination is a concern. The NONIN Model 7000P Pediatric Flexi-Form II Pulse Oximeter Sensor is designed as a single patient use sensor for monitoring pediatric patients weighing 10 to 40 kilograms. It is intended for use where moderate sensor motion is expected or cross-contamination is a concern The NONIN Model 7000I Infant Flexi-Form II Pulse Oximeter Sensor is designed for monitoring infant patients (weighing 2 to 20 kilograms) as a single patient use sensor. It is intended for use where moderate sensor motion is expected or cross-contamination is a concern. The NONIN Model 7000N Neonatal Flexi-Form II Pulse Oximeter Sensor is designed as a single patient use sensor for monitoring neonatal patients weighing 2-10 kilograms. It is intended for use where moderate sensor motion is expected or cross-contamination is a concern.	Nonin's Models 6000CA and 7000A Single-Patient Use Disposable Pulse Oximeter Sensors are indicated for non-invasive spot-checking and/or continuous monitoring of adult 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. Nonin's Models 6000CP and 7000P Single-Patient Use Disposable Pulse Oximeter Sensors are indicated for non-invasive spot-checking and/or continuous monitoring of pediatric patients who are well or poorly perfused, weighing greater than 22 pounds (>10 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. Nonin's Models 6000CI and 7000I Single-Patient Use Disposable Pulse Oximeter Sensors are indicated for non-invasive spot-checking and/or continuous monitoring of infant patients who are well or poorly perfused, weighing greater than 4 pounds (>2 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. Nonin's Models 6000CN and 7000N Single-Patient Use Disposable Pulse Oximeter Sensors are indicated for non-invasive spot-checking and/or continuous monitoring of neonate/adult patients who are well or poorly perfused, weighing less than 4 pounds (<2 kilograms) or adults weighing greater than 66 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.
Sensor Application Site:	Fingers/Foot	Same
Patient Use/Reuse:	Single-Use Disposable	Same
Sterility:	Non-sterile	Same
Measurement Technique:	Transmittance sensor	Same
Red: Infrared:	660 nm @ 0.8 mW maximum average power 910 nm @ 1.2 mW maximum average power	Same for all previously listed models
Operating: Storage/Transportation:	0° to +40° C (32° F to 104° F) -30° to +50° C (-22° F to 122° F)	-5° to +40° C (23° F to 104° F) -30° to +70° C (-22F° to 158° F) for all previously listed models
Operating: Storage/Transportation:	10 to 90% non-condensing 10 to 95% non-condensing	Same for all previously listed models
Sensor Optic Housing:	Microfoam	7000X Same 6000CX Cloth

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 RN, BSN
Clinical / Regulatory Specialist
Nonin Medical, Incorporated
13700 1st Avenue North
Plymouth, Minnesota 55441-5443

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Re: K093853
Trade/Device Name: Model 6000CX and 7000X Sensor Series
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: April 21, 2010
Received: May 6, 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. 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 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) _____

Device Name Nonin Medical, Inc. Model 6000CX and 7000X Sensor Series

Indications for Use

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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)

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

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