K113215

MAY 14 2012

Attachment 3
510(k) Summary

Submitter:	Nonin Medical, Inc.
Contact Person:	Brodie Pedersen Senior Regulatory Engineer Nonin Medical, Inc. 13700 1st Ave. North Plymouth, MN 55441-5443
Phone:	763-553-9968
Fax:	763-553-7807
Date Prepared:	October 31, 2011
Trade Name:	EQUANOX Advance Neonatal/Pediatric Sensor 8004CB Series for use with Model 7600 Regional Oximeter System with EQUANOX Technology
Classification Name and Number:	Oximeter Class II, 21 CFR 870.2700
Product Code:	MUD
Predicate Device(s):	Nonin's Model 8004CB Series Oximeter Sensor used with the Model 7600 Equanox Advance Regional Oximeter System is substantially equivalent to the Model 8004CA Oximetry Sensor cleared with the Model 7600 Regional Oximeter System cleared by the FDA in K102715 on 12/17/2010, and the FORE-SIGHT® Oximeter MC-2000 Series Cerebral Oximeter manufactured by CAS Medical Systems Inc. that was cleared by the FDA under K094030 on 12/23/10.

Indications for Use:

Model 8004CB (Adhesive Version)

The 8004CB Single-Patient use, Non-Sterile, Disposable Regional Oximetry Sensor is intended for use as an absolute real-time adjunct monitor of hemoglobin oxygen saturation of blood underneath the sensor at cerebral and somatic sites. The sensor is for spot-checking and continuous monitoring of neonate, infant, and pediatric patients weighing less than 88 pounds (40 kilograms). The sensor may be repositioned or replaced with another 8004CB sensor without baseline re-establishment. It is intended for use in environments including the operating room, surgical recovery, critical care, emergency room, long term care and mobile environments.

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Indications for Use continued:

Model 8004CB-NA (Non-Adhesive Version)

The 8004CB-NA Non-Adhesive, Single-Patient use, Non-Sterile, Disposable Regional Oximetry Sensor is intended for use as an absolute real-time adjunct monitor of hemoglobin oxygen saturation of blood underneath the sensor at cerebral and somatic sites. The sensor is for spot-checking and continuous monitoring of neonate, infant, and pediatric patients weighing less than 88 pounds (40 kilograms). The sensor may be repositioned or replaced with another 8004CB-NA sensor without baseline re-establishment. It is intended for use in environments including the operating room, surgical recovery, critical care, emergency room, long term care and mobile environments.

Model 7600 Regional Oximeter System

Nonin's non-invasive Model 7600 4- Channel Regional Oximeter System is intended for use as an absolute real-time adjunct monitor of hemoglobin oxygen saturation of blood underneath the sensor at cerebral and somatic sites. It is intended for spot-checking or continuous monitoring of adult, or neonate, infant and pediatric patients. It is intended for use in environments including the operating room, surgical recovery, critical care, emergency room, long-term care and mobile environments.

Device Description:

Nonin's® EQUANOX Advance Neonatal/Pediatric Sensor 8004CB Series for use with the Model 7600 4-Channel Regional Oximeter System continuously monitors and records the mixed arterial/venous blood oxygen levels (rSO_2) through non-invasive near-infrared spectroscopy of tissue under the sensors.

The 7600 system is comprised of three subsystems; sensor, patient oximetry device (pod) and display unit. The sensor allows light absorption measurements at various wavelengths in the near-infrared spectrum (approximately 700 to 900 nanometers). The sensor is sized appropriately for the patient population.

The sensors plug into the patient oximetry device (pod) which controls the light emitted from the sensor LEDs and measures the light returning via the sensor photodiodes. From these measurements, the 7600PA pod determines specific absorption values and calculates the rSO_2 value. The pod then communicates the rSO_2 readings and other data to the display unit. Up to 4 pods with attached sensors may be used with a single 7600 display unit

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The 7600 display unit displays real-time regional oximetry data. It is a battery-backed, mains-powered device equipped with audio and visual alarm indicators. Real-time data and playback output is accomplished through a Bluetooth transceiver module or serial RS-232 connection.

Technological Characteristics and Performance:

EQUANOX Advance Neonatal/Pediatric Sensor 8004CB Series is equivalent in construction to Nonin's previously cleared 8004CA regional oximeter sensor. The performance of the EQUANOX Advance Neonatal/Pediatric Sensor 8004CB Series, for use on patient's weighing less than 88pounds (40 kg), accuracy specifications are absolute rSO_2 accuracy (Arms*): 45% to 95% rSO_2 ±5.9%. Based on the measured regional hemoglobin saturation value (rSO_2) of cerebral sensors calibrated to arterial / venous hemoglobin oxygen ($SavO_2$) value, determined from venous and arterial blood samples from 44 subjects ranging in age from 4 days to 10 years. The model used for blood in the brain is 70% venous and 30% arterial. The venous blood was drawn from the right jugular bulb. The accuracy of the sensors in comparison to the blood gas analyzer samples measured over the rSO_2 range of 45 – 95%. Accuracy data is calculated using the root-mean-squared (Arms value) for all subjects, per ISO 9919:2005, Medical Electrical Equipment—Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.

Functional and Safety Testing:

Nonin's EQUANOX Advance Neonatal/Pediatric Sensor 8004CB Series used with the Model 7600 Regional Oximeter System was developed following the risk management processes defined by ISO 14971:2007 Medical Devices – Application of Risk Management to Medical Devices. The EQUANOX Advance Neonatal/Pediatric Sensor 8004CB Series has successfully undergone laboratory safety and performance testing in accordance with ISO 9919:2005, Medical Electrical Equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use, IEC 60601-1:1995 Medical electrical equipment – part 1: General requirements for safety and IEC 60601-1-2:2007 General requirements for basic safety and essential performance – Collateral standards: Electromagnetic compatibility – requirements and tests.
Evaluation of materials was performed in accordance with ISO 10993-1:2009, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process.

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A prospective controlled multisite study involving a diverse ethnic pediatric population ranging in age from 4 days to 10 years used $SavO_2$ values to simultaneously validate the rSO_2 values measured by the Model 7600 4-Channel Regional Oximeter System with the EQUANOX Advance Neonatal/Pediatric Sensor 8004CB Series.

Performance testing and clinical testing were successfully completed in order to ensure that it has appropriate performance, functional features and is substantially equivalent to the predicate device.

Conclusion:

Nonin's EQUANOX Advance Neonatal/Pediatric Sensor 8004CB Series used with the Model 7600 Regional Oximeter System is substantially equivalent to the Model 7600 4-Channel Regional Oximeter with Equanox Technology and Bluetooth wireless Technology K102715 cleared 12/17/2010 including regional sensors 8004CA and 8000CA. It is equivalent to the FORE-SIGHT® Oximeter MC-2000 Series Cerebral Oximeter manufactured by CAS Medical Systems Inc. that was cleared by the FDA under K094030 on 12/23/10.

The conclusion drawn is that the revised indications for use and labeling are substantially equivalent to the predicate device and do not raise new questions of safety and effectiveness.

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

MAY 14 2012

Nonin Medical, Inc.
c/o Mr. Brodie C. Pedersen
Senior Regulatory Engineer
13700 1st Avenue North
Plymouth, MN 55441

Re: K113215
Trade/Device Name: EQUANOX Advance Neonatal/Pediatric Sensor 8004CB Series for use with Model 7600 Regional Oximeter System with EQUANOX Technology
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: MUD
Dated: April 10, 2012
Received: April 11, 2012

Dear Mr. Pedersen:

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

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,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1. Indications for Use Statement

510(K) Number: K113215

Device Name:

Nonin Medical, Inc. EQUANOX Advance™ Neonatal/Pediatric Sensor 8004CB Series for use with the Model 7600 4 Channel Regional Oximeter System with Equanox™ Technology

Indications for Use:

Model 8004CB (Adhesive Version)

The 8004CB Single-Patient use, Non-Sterile, Disposable Regional Oximetry Sensor is intended for use as an absolute real-time adjunct monitor of hemoglobin oxygen saturation of blood underneath the sensor at cerebral and somatic sites. The sensor is for spot-checking and continuous monitoring of neonate, infant, and pediatric patients weighing less than 88 pounds (40 kilograms).. The sensor may be repositioned or replaced with another 8004CB sensor without baseline re-establishment. It is intended for use in environments including the operating room, surgical recovery, critical care, emergency room, long term care and mobile environments.

Model 8004CB-NA (Non-Adhesive Version)

The 8004CB-NA Non-Adhesive, Single-Patient use, Non-Sterile, Disposable Regional Oximetry Sensor is intended for use as an absolute real-time adjunct monitor of hemoglobin oxygen saturation of blood underneath the sensor at cerebral and somatic sites. The sensor is for spot-checking and continuous monitoring of neonate, infant, and pediatric patients weighing less than 88 pounds (40 kilograms). The sensor may be repositioned or replaced with another 8004CB-NA sensor without baseline re-establishment. It is intended for use in environments including the operating room, surgical recovery, critical care, emergency room, long term care and mobile environments.

Model 7600 Regional Oximeter System

Nonin's non-invasive Model 7600 4- Channel Regional Oximeter System is intended for use as an absolute real-time adjunct monitor of hemoglobin oxygen saturation of blood underneath the sensor at cerebral and somatic sites. It is intended for spot-checking or continuous monitoring of adult, or neonate, infant and pediatric patients. It is intended for use in environments including the operating room, surgical recovery, critical care, emergency room, long-term care and mobile environments.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 Ophthalmic, Neurological and Ear, Nose and Throat Devices

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