K131021

NONIN

2. "510(k) Summary" as required by section 807.92(c)

Submitter:	Nonin Medical, Inc.
	13700 1st Ave. North Plymouth, MN 55441-5443
Phone:	763-553-9968
Fax:	763-553-7807
Contact Person:	Brodie Pedersen Senior Regulatory Engineer
Date Prepared:	May 13, 2013
Trade Name:	Model 3230
Classification Name and Number:	Pulse Oximeter Class II, 21 CFR 870.2700
Product Code:	DQA
Predicate Device(s):	Nonin's Model 3230 finger pulse oximeter is substantially equivalent to the Onyx Vantage 9590 cleared by the FDA under K112843 on 4/19/2012, and Model 9560 Onyx II Finger Pulse Oximeter and cleared by the FDA under K081285 on 6/5/2008. As shown in the table below, these devices represent the same technical characteristics as the subject device utilizing the same materials, power source and communication technology. The display of the Model 3230 is a color LCD providing the same information to the user as the predicate LED display.

SEP 11 2013

CATEGORY	Identical/ Different	3230 BLE	ONYX® II 9560	ONYX® VANTAGE 9590
INDICATIONS FOR USE	Similar	The Nonin® Model 3230 Finger Pulse Oximeter is a small, lightweight, portable device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate of patients who are well or poorly perfused. It is intended for spot-checking of patients with digits between 0.8 – 2.5 cm (0.3 – 1.0 inch) thick.	The Nonin Onyx II Model 9560 Finger Pulse Oximeter is a small, lightweight, portable, wireless device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate of patients who are well or poorly perfused. It is intended for spot-checking of adult and pediatric patients on fingers (other than the thumb) between 0.3 – 1.0 inch (0.8 – 2.5 cm) thick. The device's intended use environments include hospitals, clinics, long-term care facilities, skilled nursing facilities, emergency medical services and home healthcare services	The Nonin® Onyx Vantage 9590 Finger Pulse Oximeter is a small, lightweight, portable device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate of patients who are well or poorly perfused. It is intended for spot-checking of adult and pediatric patients on digits (fingers, thumb, toes) that are between 0.3 – 1.0 inch (0.8 – 2.5 cm) thick. The device's intendec use environments include hospitals, clinics, long-term care facilities, skilled nursing facilities, emergency medical services, and home healthcare services.
SYSTEM CONFIGURATIONS				
Parts and Accessories				
Batteries	Identical for all	LR03 AAA (2)	LR03 AAA (2)	LR03 AAA (2)
Operator's instructions	Different	Paper	CD	CD
OVERALL SPECIFICATIONS				
SpO2 Range	Identical for all	0% to 100% SpO2	0% to 100% SpO2	0% to 100% SpO2
Pulse Rate Range	Identical for all	18-321 BPM	18-321 BPM	18-321 BPM
Accuracy				
SpO2	Identical for all	±2 digits (± 1 Arms)	±2 digits (± 1 Arms)	±2 digits (± 1 Arms)
Low Perfusion SpO2	Identical for all	±2 digits (± 1 Arms)	±2 digits (± 1 Arms)	±2 digits (± 1 Arms)
Pulse Rate	Identical for all	20 to 250 BPM ±3 digits	20 to 250 BPM ±3 digits	20 to 250 BPM ±3 digits
Low Perfusion Pulse Rate	Identical for all	40 to 240 BPM ±3 digits	40 to 240 BPM ±3 digits	40 to 240 BPM ±3 digits
Displays				

CATEGORY	Identical/ Different	3230 BLE	ONYX® II 9560	ONYX® VANTAGE 9590
7-Segment 3-Digit Displays	Similar	Multi-pixel 3-Digit Displays	7-Segment 3-Digit Displays (LEDs)	7-Segment 3-Digit Displays (LEDs)
Pulse Strength Tricolor	Different	LCD, readings or dashes give two levels of pulse quality indication	Three LED's, Red, Yellow and Green give three levels of pulse quality indication	Three LED's, Red, Yellow and Green give three levels of pulse quality indication
Connectivity				
	Different	Bluetooth SMART	Saber Bluetooth Module	N/A
Package	Different	Box	Clamshell	Clamshell

Indications for Use:

Model 3230

The Model 3230 Finger Pulse oximeter is a small, lightweight portable device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate of patients who are well or poorly perfused. It is intended for spot checking of adult and pediatric patients on digits between 0.3 – 1.0 inch (0.8 – 2.5 cm) thick.

Device Description:

Model 3230 Bluetooth® Smart Pulse oximeter is a small, lightweight, portable, digit pulse oximeter that displays numerical values for functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate by measuring the absorption of red and infrared (IR) light passing through perfused tissue. Changes in the absorption caused by the pulsation of blood in the vascular bed are used to determine oxygen saturation and pulse rate. Light emitting diodes (LEDs) are contained within the device along with the photo detector, which is on the opposite side of the probe from the LEDs. The SpO2 and pulse rate are displayed on the LCD display contained within the device. A color LCD provides a visual indication of the pulse signal, while blinking at the corresponding pulse rate. The display will indicate if poor pulse quality that may affect the readings. All associated electronics and the microcontrollers are within the sensor, which is activated by placing on a patient's digit. This simple operation activates the internal circuitry automatically upon application. The device is intended for spot-checking adult and pediatric patients who are well or poorly perfused.

Testing:

Nonin's Model 3230 Pulse Oximeter is supported by both laboratory and clinical hypoxia accuracy testing in order to ensure that it has appropriate performance and functional features to fully comply with recognized standards and is substantially equivalent to the predicate device.

Functional and Safety Testing:

Laboratory testing included: software verification, safety testing for electrical, mechanical, biocompatibility analysis, ingress protection, electromagnetic compatibility, device performance, usability evaluation, wireless Bluetooth certification and mechanical durability have been performed to demonstrate equivalency with the predicates. As shown in the table below the device met the relevant requirements of the applicable recognized standards.

Test	Reference	Result
Electrical Safety	IEC 60601-1	Pass
Temperature and Humidity	IEC 60601-1 IEC 60601-1-11	Pass
Cleaning	IEC 60601-1	Pass
Electromagnetic Immunity and Emissions	IEC 60601-1-2	Pass
Bluetooth Wireless certification	FCC wireless certification Grant	Pass
Performance	ISO 80601-2-61 IEC 60601-1 IEC 60601-1-6	Pass
Ingress Protection	ISO 80601-2-61 IEC 60601-1-11	Pass
Mechanical Durability	ISO 80601-2-61	Pass
Atmospheric Pressure	IEC 60601-1	Pass
Usability	IEC 60601-1-6 IEC 60601-1-11	Pass

Clinical Testing:

HYPOXIA: Clinical testing included induced laboratory hypoxia testing on healthy volunteers and Usability / Human Factors Stucy was performed to get real user feedback from both naïve and experienced pulse oximeter users.

Clinical hypoxia accuracy testing conducted during induced hypoxia studies on 14 healthy, nonsmoking, light-to-dark-skinned subjects in an independent research laboratory. The measured arterial hemoglobin saturation value (SpO2) of the device was compared to arterial hemoglobin oxygen (SaO2) value, determined from blood samples with a laboratory co-oximeter. The accuracy of the device is in comparison to

the co-oximeter samples measured over the SpO2 range of 70-100%. Accuracy data was calculated using the root-mean-squared (Arms value) for all subjects, per ISO 80601-2-61 and ISO 9919, Standard Specification for Pulse Oximeters for Accuracy in a non-motion environment demonstrated a specified accuracy of ±2%. There were no reported adverse effects during these investigations.

The purpose of this study was to verify SpO_2 performance accuracy of the Nonin Medical pulse oximeter system on the finger and thumb in stationary (non-motion) conditions over the range of 70 to 100 percent SaO_2. Accuracy of device on the toes was also verified. These aims were achieved by comparing SpO_2 measurements with those of arterial blood samples assessed by CO-oximetry. The study was designed in accordance with ISO 80601-2-61 and ISO 9919. The goal, in its entirety, was to show the SpO_2 accuracy performance for the devices. It was expected that the Accuracy Root Mean Square (A_{rms}) performance of the above pulse oximetry systems will meet a specification of ±3% for the range of 70 – 100% SaO_2.

Methods: Subjects were connected to a breathing circuit, in which the gas flow delivery was adjusted for subject comfort. This gas circuit provided a gas mixture of medical grade oxygen and nitrogen. The program was run in manual mode, in which the gas mixture was changed by the controller. The program was used to induce hypoxia in a stair-stepped manner which allowed each subject to settle at his or her SpO_2 level (e.g. plateau). At each plateau, arterial blood sampling was performed. After drawing a waste sample to clear the arterial line, an arterial sample was drawn. The beginning and end of each draw was noted on the data collection system. This series of waste draw, and arterial draws was repeated multiple times for each plateau. At the end of each plateau, the arterial line was flushed with sterile saline. Subsequently, the program was adjusted to allow the subject to reach a new level of SpO_2 and the process was repeated. Samples were run on four (4) CO-oximeters. The SpO_2 values at each draw were paired with the average of the two OSM (Radiometer) CO-oximeters.

This study enrolled subjects who were provided IRB-approved informed consent as documented on an informed consent form. Subjects needed to be healthy, non-smoking, competent adults, between eighteen and forty-five (18—45) years of age. Good health was evidenced by satisfactory completion of a health assessment form.

Conclusions: The oximeter in a non-motion environment demonstrated a specified accuracy of ±2% over the specified range. The oximeter, in a non-motion environment demonstrated a specified accuracy of ±3% on the toe.

USABILITY: The testing performed for this Usability / Human Factors Study was to get real user feedback from both naïve and experienced pulse oximeter users.

The primary objective of this study was to collect data to demonstrate the usability of the Model 3230 Oximeter in the intended patient population for simulated home use and identify any potential impediments to use. The usability components tested in this study included effectiveness, symbol comprehension and operator satisfaction. Effectiveness and symbol comprehension were the primary objectives. Operator satisfaction, time to first reading, and time to shut off were secondary objectives.

Effectiveness was assessed by determining the rates of proper placement, proper device assembly, and proper device disassembly.

Methods: Prior to using the device, users were given a Quick Start Guide and Instructions for Use (IFU) that included instructions and diagrams for placement and use of the device. The user was then instructed to perform specific tasks with the device. These tasks simulated home use and include assembly, use, and disassembly of the device After use, the user was asked to complete a questionnaire regarding the various aspects of using the Model 3230 Oximeter, symbol comprehension, and to provide feedback to improve device use or instructions for use.

Usability validation was conducted with 27 subjects. Subjects needed to be healthy competent adults. There were no reported adverse effects during these investigations.

Conclusion: The Model 3230 has been found to be safe and effective for the intended users, uses and use environments.

Conclusion:

Nonin's Model 3230 is substantially equivalent to the Onyx Vantage 9590 cleared by the FDA under K112843 on 4/19/2012, and the Model 9560 Onyx II Finger Pulse Oximeter and cleared by the FDA under K081285 on 6/5/2008 both manufactured by Nonin Medical, Inc. The positive results of testing, lead to the conclusion 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 Center – WO66-G609
Silver Spring, MD 20993-0002

September 11, 2013

Nonin Medical, Incorporated
Mr. Brodie C. Pedersen
Senior Regulatory Engineer
13700 1st Avenue North
PLYMOUTH MN 55441-5443

Re: K131021
Trade/Device Name: Model 3230
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: August 9, 2013
Received: August 12, 2013

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 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 contact 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. 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

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1. Indications for Use Statement

510(K) Number: K131021

Device Name:

Nonin Medical, Inc. Model 3230

Indications for Use:

Model 3230

The Model 3230 Finger Pulse oximeter is a small, lightweight portable device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate of patients who are well or poorly perfused. It is intended for spot checking of adult and pediatric patients on digits between 0.3 – 1.0 inch (0.8 – 2.5 cm) thick.

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)

Lester W. Schultheis Jr
2013.09.10 15:59:13 -04'00'

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

510(k) Number: K131021