NONIN MEDICAL

JUL 07 2014

2. 510(k) Summary

Submitter:	Nonin Medical, Inc. 13700 1st Ave. North Plymouth, MN 55441-5443
Phone: **Fax:**	763-553-9968 763-553-7807
Contact Person:	Brodie Pedersen Senior Regulatory Engineer
Date Prepared:	June 19, 2014
Trade Name:	Model 3231
Classification Name and Number:	Pulse Oximeter Class II, 21 CFR 870.2700
Product Code:	DQA
Predicate Device(s):	Nonin's Model 3231 finger pulse oximeter is substantially equivalent to the Model 3230 Finger Pulse oximeter cleared by the FDA under K131021 on 9/11/2013.
Indications for Use:	**Model 3231** The Nonin® Model 3231 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 with digits between 0.8 – 2.5 cm (0.3 – 1.0 inch) thick.
Device Description:	Model 3231 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 there is poor pulse quality that may affect the readings. All associated electronics and the microcontroller 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.

The modification of the Model 3230 to the Model 3231, include the removal of Bluetooth LE 4.0 and the addition USB 2.0 for serial communication. This modification includes moving from batteries to the USB 2.0 to power the Model 3231. The oximeter circuitry, software and electro optical elements of the Model 3231 are identical to the Model 3230. There are no technological characteristic changes to the device that affect the measurement or display of SpO2 or pulse rate to the user.

Technological Characteristics Comparison:

Characteristic	Identical/ Different	Model 3230	Model 3231
INDICATIONS FOR USE	Identical except Model Number	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 adult and pediatric patients with digits between 0.8 – 2.5 cm (0.3 – 1.0 inch) thick.	The Nonin® Model 3231 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 with digits between 0.8 – 2.5 cm (0.3 – 1.0 inch) thick.
SYSTEM CONFIGURATIONS			
Parts and Accessories			
Power input	Different	LR03 AAA batteries(2)	USB 2.0
Operator's instructions	Identical	Paper	Paper
OVERALL SPECIFICATIONS			
SpO2 Range	Identical	0% to 100% SpO2	0% to 100% SpO2
Pulse Rate Range	Identical	18-321 BPM	18-321 BPM
Accuracy			
Decades	Identical	Decade Oxygen Saturation (Arms) 70 – 80% ±2 80 – 90% ±2 90 – 100% ±2 70 – 100% ±2	Decade Oxygen Saturation (Arms) 70 – 80% ±2 80 – 90% ±2 90 – 100% ±2 70 – 100% ±2

Characteristic	Identical/ Different	Model 3230	Model 3231
SpO2	Identical	±2 digits (± 1 Arms)	±2 digits (± 1 Arms)
Low Perfusion SpO2	Identical	±2 digits (± 1 Arms)	±2 digits (± 1 Arms)
Pulse Rate	Identical	20 to 250 BPM ±3 digits	20 to 250 BPM ±3 digits
Low Perfusion Pulse Rate	Identical	40 to 240 BPM ±3 digits	40 to 240 BPM ±3 digits
Displays			
7-Segment 3-Digit Displays	Identical	Multi-pixel 3-Digit Displays	Multi-pixel 3-Digit Displays
Pulse Strength	Identical	LCD, readings or dashes give two levels of pulse quality indication	LCD, readings or dashes give two levels of pulse quality indication
Connectivity			
	Different	Bluetooth SMART	USB 2.0
Package	Identical	Box	Box

Testing:

Nonin's Model 3231 Pulse Oximeter is supported by predicate 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 guidance documents and is substantially equivalent to the predicate device except these features specific to the modifications.

Functional and Safety Testing:

Laboratory testing included: software verification, safety testing for electrical, mechanical, biocompatibility analysis, ingress protection, electromagnetic compatibility, device performance, usability evaluation, 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 and guidance.

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
USB 2.0 certification	USB 2.0	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

Conclusion:

Nonin's Model 3231 is substantially equivalent to the Model 3230 Bluetooth® Smart Pulse oximeter cleared by the FDA under K131021 on 9/11/2013, manufactured by Nonin Medical, Inc. The concurrent shared design elements and positive results of testing, lead to the conclusion that the 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

July 7, 2014

Nonin Medical, Inc.
Mr. Brodie Pedersen
Senior Regulatory Engineer
13700 1st Ave. North
Plymouth, MN 55441-5443

Re: K140785
Trade/Device Name: Nonin Model 3231 Finger Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: April 22, 2014
Received: April 23, 2014

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,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NONIN MEDICAL

1. Indications for Use Statement

510(K) Number: K140785

Device Name:

Nonin Medical, Inc. Model 3231

Indications for Use:

Model 3231

The Nonin® Model 3231 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 with digits between 0.8 – 2.5 cm (0.3 – 1.0 inch) 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)

Todd D. Courtney -S
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