DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 23, 2016

Nonin Medical, Inc.
Kim Aves
Principal Regulatory Affairs Specialist
13700 1st Avenue North
Plymouth, Minnesota 55441

Re: K160231
Trade/Device Name: Model X-100C CO-Met™ Oximetry System
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: November 28, 2016
Received: December 1, 2016

Dear Kim Aves:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Tejashri Purohit-Sheth, M.D.

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Clinical Deputy Director
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160231

Device Name
Model X-100C CO-Met™ Oximetry System

Indications for Use *(Describe)*

Model X-100C

Nonin's Model X-100C CO-Met™ Oximetry System is indicated for noninvasive measuring of functional oxygen saturation of arterial hemoglobin (%SpO2), carboxyhemoglobin saturation (%COHb), methemoglobin saturation (%MetHb), and pulse rate of adult and pediatric patients (>66 lbs / 30 kg) using the Model 8300AA sensor. The measurements may be multiple spot-checks to observe change and/or continuous monitoring. The X-100C system is indicated for use by trained personnel in clinical and non-clinical settings, including Emergency Medical Service (EMS), hospitals, medical facilities, and mobile environments. This device is not meant for sole use in clinical decision making; it must be used in conjunction with additional methods of assessing clinical signs and symptoms.

Model 8300AA

The Model 8300AA reusable finger clip sensor is intended for noninvasive measuring of functional oxygen saturation of arterial hemoglobin (%SpO2), carboxyhemoglobin saturation (%COHb), methemoglobin saturation (%MetHb), and pulse rate of adult and pediatric patients (> 66 lbs / 30 kg). The measurements may be multiple spot-checks to observe change and/or continuous monitoring. It is intended for use in Emergency Medical Service (EMS), hospitals, medical facilities, and mobile environments. This device is not meant for sole use in clinical decision making; it must be used in conjunction with additional methods of assessing clinical signs and symptoms.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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5. "510(k) Summary" as required by section 807.92(c)

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Date Prepared: January 29, 2016; Revised December 22, 2016

Trade Names: Model X-100C CO-Met™ Oximetry System

Common Name: Oximeter

Classification Name: Oximeter

Regulation Number: Class II, 21 CFR 870.2700 (Oximeter)

Product Code, Panel: DQA, Anesthesiology

Predicate Device(s): **Masimo Rainbow SET Radical 7 Pulse CO-Oximeter, K061204**

Device Description: The Masimo Rainbow SET® Radical 7 Pulse CO-Oximeter (Radical 7) with Rainbow technology allows for noninvasive monitoring of arterial oxygen saturation (%SpO2), pulse rate, carboxyhemoglobin saturation (%SpCO), and/or methemoglobin saturation (%SpMet). The Radical 7 features an LCD display that continuously displays numeric values for %SPO2 and pulse rate. Other information displayed by the Radical 7 include: %SpCO and/or %SpMet, Low Signal IQ (Low SIQ), Perfusion Index (PI), alarm status, alarm silence, battery life, sensor status, trends, and pleth waveform. The Radical 7 has output interfaces including SatShare connection to multi-parameter monitors, Nurse Call analog output, and RS-232 serial output.

The Radical 7 is intended to be used with Masimo LNOP series of oximetry sensors, LNCS series of oximetry sensors, and patient cables. The Radical 7 is also intended to be used with Masimo Rainbow (SpCO/SpMet) sensors and Rainbow patient cables, cleared under K061204 (July 27, 2006.)

Radical 7 Indications for Use (as cleared under K061204)

The Masimo SET® Radical 7 Pulse CO-Oximeter and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SP02), pulse rate (measured by an SP0 2 sensor), carboxyhemoglobin (measured by an SpCO/SpMet sensor), and/or methemoglobin saturation (measured by an SpCO/SpMet sensor). The Masimo SET® Radical 7 Pulse CO-Oximeter and accessories are indicated for use with adult, pediatric, and neonatal patients during both

no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments. In addition, the Masimo SET® Radical 7 Pulse CO-Oximeter and accessories is indicated to provide the continuous noninvasive monitoring data obtained from the Masimo SET® Radical 7 Pulse CO-Oximeter and accessories of functional oxygen saturation of arterial hemoglobin ($Sp0_2$) and pulse rate (measured by an $Sp0_2$ sensor) to multi-parameter devices for the display of those devices.

Device Description: The Model X-100C CO-Met Oximetry System displays (COHb), methemoglobin (MetHb), pulse oxygen saturation (SpO2), and pulse rate (PR) data transmitted from one channel of data through a direct connection of the signal processor to the monitor. The monitor receives, displays, provide alarm management, and storage of COHb, MetHb, SpO2, and PR. The device is capable of running on battery power or on AC power via an external power supply. The device is equipped with patient alarms to alert the user to abnormal conditions and shall provide real time data output of COHb, MetHb, SpO2, and PR.

Intended Use:

Model X-100C

Nonin's Model X-100C CO-Met™ Oximetry System is indicated for noninvasive measuring of functional oxygen saturation of arterial hemoglobin (%SpO_2), carboxyhemoglobin saturation (%COHb), methemoglobin saturation (%MetHb), and pulse rate of adult and pediatric patients (>66 lbs / 30 kg) using the Model 8300AA sensor. The measurements may be multiple spot-checks to observe change and/or continuous monitoring. The X-100C system is indicated for use by trained personnel in clinical and non-clinical settings, including Emergency Medical Service (EMS), hospitals, medical facilities, and mobile environments. This device is not meant for sole use in clinical decision making; it must be used in conjunction with additional methods of assessing clinical signs and symptoms.

Model 8300AA

The Model 8300AA reusable finger clip sensor is intended for noninvasive measuring of functional oxygen saturation of arterial hemoglobin (%SpO_2), carboxyhemoglobin saturation (%COHb), methemoglobin saturation (%MetHb), and pulse rate of adult and pediatric patients (> 66 lbs / 30 kg). The measurements may be multiple spot-checks to observe change and/or continuous monitoring. It is intended for use in Emergency Medical Service (EMS), hospitals, medical facilities, and mobile environments. This device is not meant for sole use in clinical decision making; it must be used in conjunction with additional methods of assessing clinical signs and symptoms.

Comparison of Intended Use (Indications for Use)

Radical 7	X-100C	Comment
Continuous monitoring	Multiple spot-checks to observe change and/or continuous monitoring	Multiple spot-checks to observe change is a form of monitoring.
Adult, pediatric and neonatal patients	Adult and pediatric	Nonin is not seeking clearance for X-100C in the neonate population. The Radical 7 applied part labeling indicates neonate use for SpO_2 and pulse rate only.
Intended use does not specify patient size, weight or age	Nonin specifies patient population based on weight (>66 lbs./30kg)	The X-100C clarifies the use population regarding appropriate fit of the applied part, to ensure accuracy of measurements.
Does not specify user qualifications	For use by trained personnel	The X-100C is meant to be used by trained healthcare professionals to ensure proper use of the device and understanding of the display values. The X-100C is meant to be used in conjunction with additional methods of assessing clinical signs and symptoms.
Motion and no motion conditions	Nonin is not seeking motion claims for any parameters	The Radical 7 labeling indicates motion and no motion specific to SpO_2 and pulse rate only. The X-100C is meant to be used in conjunction with additional methods of assessing clinical signs and symptoms.
Poorly perfused patients	Nonin is not seeking low perfusion claims	The Radical 7 labeling indicates poor perfusion specific to SpO_2 and pulse rate only. The X-100C is meant to be used in conjunction with additional methods of assessing clinical signs and symptoms.
Hospitals, hospital-type facilities, mobile, and home environments.	Emergency Medical Service (EMS), hospitals, medical facilities, and mobile environments.	The X-100C is intended for use by trained healthcare professionals, not the lay or home user who are not trained in the proper use of the device and/or understanding of the display values.

Testing:

The Nonin Model X-100C and 8300AA sensors are supported by electrical and mechanical safety, electromagnetic compatibility, device performance, and clinical testing to ensure appropriate functionality and to demonstrate substantial equivalence to the predicate devices. The devices were tested with the Model X-100 system. **Table 1** summarizes the technological characteristics of the proposed device and the predicate device.

Table 1

CATEGORY	Identical/Similar/ Different	Model X-100C System (Subject)	Radical-7™ K061204 (Predicate)
Standalone • AC Power Requirements • Power consumption • Fuses	Different	100-240 VAC, 50-60 Hz	100-240 VAC, 47-63 Hz 55 VA 1 Amp, Fast Acting, Metric, (5x20mm), 250V
Batteries • Type • Capacity • Charging Time	Different	7.2 volt Li-ion battery pack, 2.4 Ah when charged 6 hours[1] 2.5 hours	NiMH (Handheld and docking station) 4 hours[2] (Handheld) 10 hours[3] (Docking station) 3 hours (Handheld) 6 hours (Docking station)
Environmental			
Operating Temperature	Similar	32 ºF to 104 ºF (0 ºC to 40 ºC)	41 ºF to 104 ºF (5 ºC to 40 ºC)
Storage/Transport Temperature	Similar	-22 ºF to 158 ºF (-30 ºC to 70 ºC)	-40 ºF to 158 ºF (-40 ºC to 70 ºC)
Operating Humidity	Similar	15% to 93%, noncondensing	5% to 95%, noncondensing
Storage/Transport Humidity	Different	Up to 93%, noncondensing	Not specified
Operating Altitude	Different	0 to 4,000 meters (0 to 13,124 feet)	-304 to 5,486 meters (-1,000 to 18,000 feet)
Physical Characteristics			
Dimensions	Different	X-100MM • 305 mm W x 180 mm H x 130 mm D (12.0” W x 7.2” H x 5.0” D) X-100SPMM • 21.4 mm H x 21.7 mm W x 72.7 mm L (including strain relief) with 0.75 m cable (0.84” H x 0.85” W x 3.1” L (including strain relief) with 2.5 ft cable)	Handheld • 8.9” x 3.3’ x 2.1” (22.6 cm x 8.4 cm x 5.3 cm) Standalone • 3.5” x 10.5” x 7.7” (8.9 cm x 26.7 cm x 19.6 cm)

[1] Fully charged battery and screen at default brightness

[2] Fully charged battery with the backlight at minimum and Power save mode on

[3] Fully charged battery with the backlight at minimum and Power save mode on

CATEGORY	Identical/Similar/ Different	Model X-100C System (Subject)	Radical-7™ K061204 (Predicate)
Weight	Different	X-100MM • Approximately 900 grams (2 pounds) X-100SPMM • 40 grams (1.4 ounces)	Handheld: 1.3 lbs. (0.59 kg) Docking station (RDS-1, RDS-2, RDS-3): • 2.5 lbs. (1.14 kg) Docking station (RDS-1B) • 4.11 lbs. (1.86 kg) Standalone (RDS-1, RDS-2, RDS-3) • 3.8 lbs. (1.73 kg) Standalone (RDS-1B) • 5.4 lbs. (2.45 kg)
Trending	Different	Not specified	72 hours of trending at 2 second resolution, up to 18 days of trending at 10 second resolution, output to serial printer or other serial devices.
SpO_2 Averaging	Similar	6 seconds	2, 4, 8, 10, 12, 14, or 16 seconds[4]
Display/Indicators	Similar	%SpO_2, %COHb, %MetHb, pulse rate, pleth waveform, alarm status, status messages, , sensor fault, poor signal indicator, signal processor communication error, visual alarm indicator, alarm silence, Bluetooth, battery indicator and date and time.	%SpO_2, %SpCO, %SpMet, pulserate, pleth waveform, alarm status, trends, status messages,battery status, visual alarm indicator, Signal IQ, perfusion index, pleth variability index, APOD and FastSat.
Display Update Rate	Similar	2-5 seconds, typically < 2 seconds	1 second
Response Time	Similar	<10 second delay	< 20 second delay
Display color	Similar	Black	Blue
Display Type	Identical	Backlit LCD	Backlit LCD
Pixels	Similar	800 x 600	480 x 160 dots
Output Interface	Similar	Bluetooth Serial RS-232 Nurse Call/Analog Output	SatShare (RDS-1) Serial RS-232 (RDS-1, RDS-1B, RDS-3) Nurse Call/Analog Output (RDS-1, RDS-1B, RDS-3) Phillips Vuelink, Spacelabs Universal Flexport, RadNet, RadLink (RDS-1, RDS-1B, RDS-3)
Compliance			
EMC Compliance	Identical	IEC 60601-1-2, Class B	EN60601-1-2, Class B
Equipment Classification	Similar	IEC 60601-1 /CAN/CSA-C22.2 No. 601.1 / UL 60601-1,	IEC 60601-1 / UL 60601-1
Type of Protection	Similar	Internally powered (on batterypower). Class II with AC	Class 1 (on AC power), Internally powered (on battery power)
Degree of Protection	Similar	Patient Cable: Type BF-Applied Part	Patient Cable: Type BF-Applied Part SatShare Cable: Type BF-Applied Part
Mode of Operation	Identical	Continuous	Continuous
Enclosure Degree of Ingress Protection	Different	IP32	Not Specified

[4] With FastSat the averaging time is dependent on the input signal. For the 2 and 4 second settings the averaging time may range from 2-4 and 4-6 seconds respectively.

Functional, Electrical and Mechanical Safety Testing: The results of the testing demonstrate equivalency with the predicate devices and compliance to recognized standards. Table 2 summarizes test results for the proposed devices, which met the relevant requirements of the applicable recognized standards.

Table 2

Test	Reference	Result
Electrical Safety	IEC 60601-1	Pass
Temperature and Humidity	IEC 60601-1 EN 1789	Pass
Atmospheric Pressure (Altitude)	IEC 60601-1	Pass
Electromagnetic Immunity and Emissions	IEC 60601-1-2	Pass
Performance	ISO 80601-2-61 IEC 60601-1 IEC 60601-1-6 IEC 60601-1-12 IEC 62304 ANSI/AAMI EC13 ISO 14155	Pass
Ingress Protection	ISO 80601-2-61	Pass
Diaphoretic related ingress	Internal performance characterization	Pass
Mechanical Durability	IEC 60601-1 ISO 80601-2-61 ISTA 2A ASTM D-4169	Pass
Biocompatibility	ISO 10993-1 ISO 10993-5 ISO 10993-10	Biocompatible per Cytotoxicity Sensitization and Irritation

Accuracy (clinical) testing:

COHb Accuracy Testing

COHb accuracy testing was conducted at an independent research laboratory on healthy, male and female, non-smoking, light to dark-skinned subjects that were 18 years of age and older.

The measured carboxyhemoglobin value (%COHb) of the sensors was compared to simultaneous arterial blood samples as assessed by co-oximetry. The accuracy of the sensors in comparison to the co-oximeter samples measured over the COHb range of 0-15% with 95 – 100% SaO2. Accuracy data was calculated using the root-mean-squared (Arms value) for all subjects, per ISO 80601-2-61, Medical Electrical Equipment- Particular requirements for basic safety and essential performance of pulse oximeter equipment.

MetHb Accuracy Testing

MetHb accuracy testing was conducted at an independent research laboratory on healthy, male and female, non-smoking, light to dark-skinned subjects that were 18 years of age and older.

The measured methemoglobin value (%MetHb) of the sensors was compared to simultaneous arterial blood samples as assessed by co-oximetry. The accuracy of the sensors in comparison to the co-oximeter samples measured over the MetHb range of 0 – 15% with 95 – 100% SaO2.

Accuracy data was calculated using the root-mean-squared (Arms value) for all subjects, per ISO 80601-2-61, Medical Electrical Equipment- Particular requirements for basic safety and essential performance of pulse oximeter equipment.

SpO2 Accuracy Testing

During no-motion conditions at an independent research laboratory, SpO2 accuracy testing was conducted during induced hypoxia studies on healthy, male and female, non-smoking, light- to dark-skinned subjects that were 18 years of age and older. The measured arterial hemoglobin saturation value (SpO2) of the sensors was compared to arterial hemoglobin oxygen (SaO2) value, determined from blood samples witha laboratory co-oximeter. The accuracy of the sensors in comparison tothe 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, Medical Electrical Equipment— Particular requirements for basic safety and essential performance of pulse oximeter equipment.

SpO2 Accuracy Testing in Presence of COHb and MetHb

During no-motion conditions at an independent research laboratory, SpO2 accuracy testing in the presence of COHb and MetHb was conducted during induced hypoxia studies on healthy, male and female, non-smoking, light- to dark-skinned subjects that were 18 years of age and older.

The measured arterial hemoglobin saturation value (SpO2) of the sensors was compared to arterial hemoglobin oxygen (SaO2) value, determined from blood samples with a laboratory co-oximeter.

The accuracy of the sensors in comparison to the co-oximeter samples measured over the SpO2 range of 80 – 100%, range 0 – 15% COHb and SpO2 range of 80 – 100%, range 0 – 15% MetHb.

Accuracy data was calculated using the root-mean-squared (Arms value) for all subjects, per ISO 80601-2-61, Medical Electrical Equipment— Particular requirements for basic safety and essential performance of pulse oximeter equipment.

Testing conclusion: the proposed Model X-100C CO-Met Oximetry System meets all acceptance criteria. Based on test results, analysis and comparison to the legally marketed predicates, the Model X-100C CO- Met Oximetry System performance is substantially equivalent to the predicate device for its intended use.

Summary of Substantial Equivalence:

The Model X-100C CO-Met Oximetry System has the following similarities to the predicate devices:

- Similar indications for use
- Similar intended use environments
- Similar patient population
- Same primary mode of operation
- Perform equivalently to the same specifications

Conclusion:

No new questions of safety and effectiveness were raised. Based on the results of clinical, environmental, safety, performance and usability testing, and risk management assessment, Nonin Medical has determined that the proposed Model X-100C CO-Met Oximetry System is substantially equivalent to the predicate Masimo Radical 7 CO-Oximetry System for its intended use.