June 29, 2020

Nonin Medical, Inc.
Brent Geiger
Vice President Quality, Regulatory,Clinical Affairs
13700 1st Avenue North
Plymouth, Minnesota 55441

Re: K192900
Trade/Device Name: Nonin Medical CO-Pilot Model H500 Multi-Sensing Oximetry System
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA, MUD
Dated: May 21, 2020
Received: May 26, 2020

Dear Brent Geiger:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Todd Courtney
Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192900

Device Name
Nonin Medical CO-Pilot™ Model H500 Multi-Sensing Oximetry System

Indications for Use *(Describe)*
The Nonin Medical CO-Pilot™ Model H500 Multi-Sensing Oximetry System is intended for noninvasive measuring of functional oxygen saturation of arterial hemoglobin (%SpO2), pulse rate, carboxyhemoglobin saturation (%COHb), methemoglobin saturation (%MetHb), and cerebral or somatic hemoglobin oxygen saturation (%rSO2). 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.

• For %SpO2 and pulse rate, the H500 System is intended for spot-checking and/or measuring during clinician assessment of adult, pediatric, infant, and neonate patients who are well or poorly perfused, during both motion and non-motion conditions in professional healthcare facilities, mobile, and EMS settings.

• For %rSO2, the H500 System is intended for spot-checking and/or measuring during clinician assessment of adult, pediatric, infant, and neonate patients in professional healthcare facilities, mobile, and EMS settings.

• For %COHb and %MetHb, the H500 System is intended for spot-checking, multiple spot-checks to observe change, and/or measuring during clinician assessment of adult and pediatric patients in professional healthcare facilities, mobile, and EMS settings.

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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K192900 510(k) Summary – H500 Multi-Sensing Oximetry System

Submitter:	Nonin Medical, Inc. 13700 1st Ave. North Plymouth, MN 55441-5443
Phone:	763 553 9968
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Contact Person:	Brent Geiger, MS, RAC Vice President Quality, Regulatory and Clinical Affairs

Date Prepared:	January 31st, 2020
Trade Names:	CO-Pilot™ Model H500 Multi-Sensing Oximetry System
Common Name:	Oximeter
Classification Name:	Oximeter
Regulation Number:	Class II, 21 CFR 870.2700 (Oximeter)
Product Code, Panel:	DQA, Anesthesiology MUD, Cardiovascular

Predicate Devices

Primary Predicate Device - Nonin's SenSmart X-100 Universal Oximetry System (refer to clearance K132402) is the primary predicate and is a modular system that is indicated for use in simultaneously measuring, displaying, monitoring, and recording up to six (6) channels of functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate or cerebral or somatic hemoglobin oxygen saturation (%rSO2) of blood underneath the sensor. Patient populations include adult, pediatric, infant, and neonate through the use of SenSmart compatible sensors. The SenSmart system is intended for use in hospitals, long-term care, medical facilities, sleep laboratories and subacute environments. The X-100 SenSmart system may be used for spot-checking and continuous monitoring with patient alarms. The SenSmart pulse oximetry (%SpO2) functionality is suitable for use in both motion and non-motion conditions, including patients who are well or poorly perfused.

Reference Predicate Devices - Nonin's X-100C/Multi-Sensing Oximetry Systems (refer to clearances K160231 and K172625) are additional reference predicate devices for this submission and are indicated for noninvasive spot-checking and/or continuous monitoring of carboxyhemoglobin (%COHb), methemoglobin (%MetHb), functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate of adult and pediatric patients. The systems are indicated for use by trained personnel in clinical and non-clinical settings, including Emergency Medical Service (EMS), hospitals, medical facilities, mobile environments, and home healthcare environments.

Indications for Use

The Nonin Medical CO-Pilot™ Model H500 Multi-Sensing Oximetry System is intended for noninvasive measuring of functional oxygen saturation of arterial hemoglobin (%SpO2), pulse rate, carboxyhemoglobin saturation (%COHb), methemoglobin saturation (%MetHb), and cerebral or somatic hemoglobin oxygen saturation (%rSO2). 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.

- For %SpO2 and pulse rate, the H500 System is intended for spot-checking and/or measuring during clinician assessment of adult, pediatric, infant, and neonate patients who are well or poorly perfused, during both motion and non-motion conditions in professional healthcare facilities, mobile, and EMS settings.
- For %rSO2, the H500 System is intended for spot-checking and/or measuring during clinician assessment of adult, pediatric, infant, and neonate patients in professional healthcare facilities, mobile, and EMS settings.

- For %COHb and %MetHb, the H500 System is intended for spot-checking, multiple spot-checks to observe change, and/or measuring during clinician assessment of adult and pediatric patients in professional healthcare facilities, mobile, and EMS settings.

Device Description

The Nonin Medical CO-Pilot™ Model H500 Multi-Sensing Oximetry System is a small handheld wireless device intended to measure functional oxygen saturation of arterial hemoglobin (%SpO2), pulse rate, carboxyhemoglobin saturation (%COHb), methemoglobin saturation (%MetHb), and cerebral or somatic hemoglobin oxygen saturation (%rSO2) of adult, pediatric and neonate patients. It is intended for professional use only, in healthcare facilities, mobile and EMS environments. The system is not provided sterile and is not a reprocessed single-use device. The H500 System consists of three components which are the display, the signal processor and associated sensors. It is intended to be used with specific parts, accessories and compatible sensors which are outlined in **Table 1** below.

Parts and Accessories	**Compatible Sensors**		
• H500-PS – Power Supply, 25W and cable • D-HH – H500 System Display • SP-BLE – Signal Processor for use with the H500 System • X-100SL – Signal Processor Sensor Lock, 2-pack • H500CC – Carrying case • INT-100 Intermediate Cable for use with 8204CA only. • INT-200 Intermediate Cable for use with SpO2-only sensors	**Sensor Model**	**510(k)**	**Description**
	8100A Series	K160865	Reusable, Finger Clip Pulse Oximeter Sensor 8100AA: Measures SpO2 and pulse rate of adult and pediatric patients (> 30 kg /66 lb) who are well or poorly perfused, during both motion and non-motion conditions. 8100AP: Measures SpO2 and pulse rate of pediatric patients (8 – 60 kg / 18 – 132 lb) who are well or poorly perfused, during both motion and non-motion conditions
	8100S Series	K132402	Reusable, Soft Pulse Oximeter Sensor 8100SL: Measures SpO2 and pulse rate of adult and pediatric patients who are well or poorly perfused, during both motion and non-motion conditions, with digit height (thickness) of 12.5 – 25.5 mm (0.5 – 1.0 in.). 8100SM: Measures SpO2 and pulse rate of adult and pediatric patients who are well or poorly perfused, during both motion and non-motion conditions, with digit height (thickness) of 10 – 19 mm (0.4 – 0.75 in.). 8100SS: Measures SpO2 and pulse rate of adult and pediatric patients who are well or poorly perfused, during both motion and non-motion conditions, with digit height (thickness) of 7.5 – 12.5 mm (0.3 – 0.5 in.).
	6100C Series	K160865	Single-Patient Use, Disposable Pulse Oximeter Sensors 6100CA: Measures SpO2 and pulse rate of adult patients (> 30 kg / 66 lb) who are well or poorly perfused, during both motion and non-motion conditions. 6100CP: Measures SpO2 and pulse rate of pediatric patients (> 10 kg / 22 lb) who are well

			or poorly perfused, during both motion and non-motion conditions. 6100CI: Measures SpO2 and pulse rate of infant patients (> 2 kg / 4 lb) who are well or poorly perfused, during both motion and non-motion conditions. 6100CN: Measures SpO2 and pulse rate of neonate patients (< 2 kg / 4 lb) and adult patients (> 30 kg / 66 lb) who are well or poorly perfused, during both motion and non-motion conditions.
	8100Q2	K160865	Reusable Ear Clip Pulse Oximeter Sensor Measures SpO2 and pulse rate of adult and pediatric patients (>40 kg / 88 lb) who are well or poorly perfused, during non-motion conditions.
	8004CA	K132402	Single-Patient Use, Non-Sterile, Disposable Regional Oximetry Sensor Measures rSO2 of adult and pediatric patients weighing ≥ 88 pounds (40 kilograms).
	8004CB	K132402	Single-Patient Use, Non-Sterile, Disposable Regional Oximetry Sensor Measures rSO2 of neonate, infant, and pediatric patients weighing ≤ 88 pounds (40 kilograms).
	8004CB-NA	K132402	Non-Adhesive, Single-Patient Use, Non-Sterile, Disposable Regional Oximetry Sensor Measures rSO2 of neonate, infant, and pediatric patients weighing ≤ 88 pounds (40 kilograms).
	8204CA	K151305	Single-Patient Use, Non-Sterile, Disposable Regional Oximetry Sensor Measures rSO2 of adult and pediatric patients weighing ≥ 88 pounds (40 kilograms).
	8330AA	K172625	Multi-Sensing Reusable Finger Clip Sensor Measures SpO2, COHb, MetHb and pulse rate of adult and pediatric patients (> 66 lbs/30 kg).

Table 1: H500 Parts, Accessories and Compatible Sensors

The H500 system is compatible and intended to be used only with Nonin-branded oximeter sensors. Such sensors are manufactured to meet the accuracy specifications for Nonin oximeters and using other manufacturers' sensors can result in improper oximeter performance. Sensor application sites are as specified in the respective instructions for use.

The main function of the H500 System software is to acquire signal data for oximetry measurements and translate that data into pulse rate, %SpO2, %COHb, %MetHb, and/or %rSO2 data for the display device. The H500 system utilizes software separated into three distinct modules: display software, signal processor software and Bluetooth Low-Energy (BLE) radio software. The software modules control and monitor interdependent system operations, generate errors, monitor and report on patient measurements, and provide the operator with a user interface. The software communicates oximetry data using the standard wireless BLE technology and determines when to turn the device on and off based on the user input to the display device. The H500 is not an alarm system and is not intended to be used for monitoring with patient alarms. Required software documentation deliverables and applicable software

testing have been completed in accordance with FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

System Performance Testing
The H500 Multi-Sensing Oximetry System and its associated sensors are supported by 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 H500 system. A summary of such testing is as follows:

Wireless Coexistence Testing
Wireless Coexistence testing has been conducted following the ANSI C63.27:2017 procedure for co-channel and adjacent channel interference including overstress per Annex F.6. The Tier 1 (most rigorous) band-specific guidance per Annex A, Sub-clause A.2.2 for Bluetooth Low Energy was also followed.

Functional and 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.

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	Pass

Table 2 – Summary of Functional and Safety Testing

Clinical Accuracy Testing
COHb
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
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
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 with a laboratory CO-oximeter. The accuracy of the sensors 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, Medical Electrical Equipment—Particular requirements for basic safety and essential performance of pulse oximeter equipment.

SpO2 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.

rSO2
rSO2 accuracy testing using 8004CA/8204CA sensors was conducted during induced hypoxia studies on healthy, non-smoking, light- to dark-skinned subjects that were 18 years of age and older. The measured regional hemoglobin saturation value (rSO2) of the sensors was compared to arterial/venous hemoglobin oxygen (SavO2) value, determined from venous and arterial blood samples. The model used for blood in the brain was 70% venous and 30% arterial, which is applicable under normocapnic conditions. 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 rSO2 range of 45 – 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.

rSO2 accuracy testing using 8004CB/8004CB-NA sensors was conducted in cardiac catheterization laboratories on sick, male and female, pediatric patients ranging in age from 4 days to 10 years with light- to dark-skin. The measured regional hemoglobin saturation value (rSO2) of the sensors is compared to arterial/venous hemoglobin oxygen (SavO2) value, determined from venous and arterial blood samples. The model used for blood in the brain was 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 rSO2 range of 45 – 95%. 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 subject H500 Multi-Sensing Oximetry System meets all testing acceptance criteria. Based on test results, analysis and comparison to the legally marketed predicates, the H500 Multi-Sensing Oximetry System performance is substantially equivalent to the predicate devices for its intended use.

Summary of Substantial Equivalence
The subject and predicate devices are all designed, developed and manufactured by Nonin Medical, Inc. All share the same intended use in that they are intended to be used to noninvasively measure physiological parameters including %SpO2, pulse rate, %COHb, %MetHb, and %rSO2 and similar indications for use including use environment and intended patient populations. The systems all share the same measurement technology, principles of operation, safety specifications, sensor application sites, critical sensor optics technology and level of ingress protection. There are no changes in the optics performance specifications, optics spacing, optics wavelengths, and signal processing algorithms between the subject and predicates. The systems all use the same compatible sensor accessories and share the same specified environmental use conditions. The accuracy specifications are the same among the subject and predicates for their respective parameters. The subject H500 system uses the same SenSmart oximetry signal processing as the X-100 and X-100C systems. As such, there is no accuracy difference between the predicate devices and the CO-Pilot H500 systems. The subject and predicate devices primarily differ in that the H500 System is small, handheld and wireless while the predicate systems are larger, wired and tabletop designs. Please refer to **Table 3** for predicate device comparison table.

Table 3: Predicate Device Comparison Table

Important Parameters	Subject Device CO-Pilot™ Model H500 Multi-Sensing Oximetry System	Primary Predicate Device X-100 System (K132402)	Reference Predicate Devices X-100C/Multi-Sensing Oximetry System (K160231 and K172625)
Intended Use	**Same** All systems are intended to be used to noninvasively measure physiological parameters including functional oxygen saturation of arterial hemoglobin (%SpO2), pulse rate, carboxyhemoglobin saturation (%COHb), methemoglobin saturation (%MetHb), and cerebral or somatic hemoglobin oxygen saturation (%rSO2)		
Product Code	DQA/MUD	DQA/MUD	DQA
FDA Regulation	**Same** 870.2700		

Indications for Use	The Nonin Medical CO-Pilot™ Model H500 Multi-Sensing Oximetry System is intended for noninvasive measuring of functional oxygen saturation of arterial hemoglobin (%SpO2), pulse rate, carboxyhemoglobin saturation (%COHb), methemoglobin saturation (%MetHb), and cerebral or somatic hemoglobin oxygen saturation (%rSO2). 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. • For %SpO2 and pulse rate, the H500 System is intended for spot-checking and/or measuring during clinician assessment of adult, pediatric, infant, and neonate patients who are well or poorly perfused, during both motion and non-motion conditions in professional healthcare facilities, mobile, and EMS settings. • For %rSO2, the H500 System is intended for spot-checking and/or measuring during clinician assessment of adult, pediatric, infant, and neonate patients in professional healthcare facilities, mobile, and EMS settings. • For %COHb and %MetHb, the H500 System is intended for spot-checking, multiple spot-checks to observe change, and/or measuring during clinician assessment of adult and pediatric patients in professional healthcare facilities, mobile, and EMS settings.	The X-100 system is a modular system and is indicated for use in simultaneously measuring, displaying, monitoring, and recording up to six (6) channels of functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate or cerebral or somatic hemoglobin oxygen saturation (%rSO2) of blood underneath the sensor. Patient populations include adult, pediatric, infant, and neonate through the use of SenSmart compatible sensors. The SenSmart system is intended for use in hospitals, long-term care, medical facilities, sleep laboratories, sub-acute environments, and Emergency Medical Services (EMS), including patient transport. The X-100 SenSmart system may be used for spot-checking and continuous monitoring with patient alarms. The SenSmart pulse oxlmetry (SpO2) functionality Is suitable for use In both motion and non-motion conditions, Including patients who are well or poorly perfused.	The X-100C/Multi-Sensing 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/8330AA sensor. The measurements may be multiple spot-checks to observe change and/or continuous monitoring. The systems are 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.
Use Environment	Professional healthcare facilities, mobile, and EMS settings	Hospitals, long-term care, medical facilities, sleep laboratories, sub-acute environments, and EMS settings	Hospitals, medical facilities, mobile environments and EMS settings
Compatible Sensor Accessories	**Same** Compatible and intended to be used only with Nonin-branded oximeter sensors. Such sensors are manufactured to meet the accuracy specifications for Nonin oximeters and using other manufacturers' sensors can result in improper oximeter performance.		
Compatible Sensor Application Sites	**Same** As specified in the respective sensor instructions for use		
Handheld or Tabletop?	Handheld	Tabletop	Tabletop
Wireless?	Yes	No	No
Includes Patient Alarms?	No	Yes	Yes
Principles of Operation	**Same** Non-invasive oximetry using light-based measurement sharing the same measurement technology including optics specifications and signal processing algorithms.		

Range of SpO2	**Same** 0-100%		
Range of Pulse Rate (beats per minute)	18-321 bpm	18-300 bpm	18-321 bpm
Range of rSO2	0-100%	0-100%	N/A
Range of COHb	0-99%	N/A	0-99%
Range of MetHb	0-99.9%	N/A	0-99.9%
Safety Specifications	**Same** IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, ISO 80601-2-61		
Specified Environmental Use Conditions	**Same** All systems share the same specified operating temperature (5-40°C), storage/transport temperature and humidity (-30 to 70°C, up to 93%), operating humidity (15-93%) and operating altitude (0-4000m)		
Enclosure Degree of Ingress Protection	**Same** IP33		
Provided Sterile?	**Same** No		

Conclusion

The subject and predicate devices have the same intended use, fundamental technology, and performance and share similar indications for use, including use environment and intended patient populations. They differ in size, handheld vs tabletop portability and patient alarms however such differences do not raise additional questions of safety and effectiveness. In conclusion, the subject and predicate devices are similar in all critical parameters that are essential for effectively measuring functional %SpO2, pulse rate, %COHb, %MetHb, and %rSO2 and any differences in technological or design characteristics do not raise different questions of safety and effectiveness and thus the devices are substantially equivalent.