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

August 5, 2016

Nonin Medical, Inc.
Ms. Nancy DeAngelo
Senior Regulatory Affairs Specialist
13700 1st Ave. North
Plymouth, Minnesota 55441

Re: K160865
Trade/Device Name: Model 6100C Series Single-Patient Use, Disposable Pulse Oximeter Sensors (6100C Series: 6100CA, 6100CP, 6100CI, 6100CN)
Model 6101C Series Single-Patient Use, Disposable Pulse Oximeter Sensors (6101C Series: 6101CA, 6101CP, 6101CI, 6101CN)
Model 6102C Series Single-Patient Use, Disposable Pulse Oximeter Sensors (6102C Series: 6102CA, 6102CP, 6102CI, 6102CN)
Model 8100AA/8100AP Reusable, Finger Clip Pulse Oximeter Sensor
Model 8101AA/8101AP Reusable, Finger Clip Pulse Oximeter Sensor
Model 8102AA/8102AP Reusable, Finger Clip Pulse Oximeter Sensor
Model 8100Q2 Reusable, Ear Clip Pulse Oximeter Sensor
Model 8101Q2 Reusable, Ear Clip Pulse Oximeter Sensor
Model 8102Q2 Reusable, Ear Clip Pulse Oximeter Sensor
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA, DPZ
Dated: July 5, 2016
Received: July 6, 2016

Dear Ms. DeAngelo:

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 yours,

Tina Kiang -S

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160865

Device Name
Model 6100C Series Single-Patient Use, Disposable Pulse Oximeter Sensors (6100C Series: 6100CA, 6100CP, 6100CI, 6100CN)
Model 6101C Series Single-Patient Use, Disposable Pulse Oximeter Sensors (6101C Series: 6101CA, 6101CP, 6101CI, 6101CN)

Indications for Use *(Describe)*

Model 6100C Series Single-Patient Use, Disposable Pulse Oximeter Sensors
Nonin's Model 6100C Series single-patient use, disposable pulse oximeter sensors are indicated for non-invasive spot-checking and/or continuous monitoring of patients (6100CA: adults > 30 kg / 66 lb; 6100CP: pediatrics > 10 kg / 22 lb.; 6100CI: infants > 2 kg / 4 lb; and 6100CN: neonates < 2 kg / 4 lb and adults > 30 kg / 66 lb), who are well or poorly perfused, during both motion and non-motion conditions.
It is intended for use hospitals, medical facilities, Emergency Medical Service (EMS) environments, home healthcare environments, and mobile environments.

Model 6101C Series Single-Patient Use, Disposable Pulse Oximeter Sensors
Nonin's Model 6101C Series single-patient use, disposable pulse oximeter sensors are indicated for non-invasive spot-checking and/or continuous monitoring of patients (6101CA: adults > 30 kg / 66 lb; 6101CP: pediatrics > 10 kg / 22 lb.; 6101CI: infants > 2 kg / 4 lb; and 6101CN: neonates < 2 kg / 4 lb and adults > 30 kg / 66 lb), who are well or poorly perfused, during both motion and non-motion conditions.
It is intended for use hospitals, medical facilities, Emergency Medical Service (EMS) environments, home healthcare environments, and mobile environments.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K160865

Device Name
Model 6102C Series Single-Patient Use, Disposable Pulse Oximeter Sensors (6102C Series: 6102CA, 6102CP, 6102CI, 6102CN)
Model 8100AA/8100AP Reusable, Finger Clip Pulse Oximeter Sensor

Indications for Use *(Describe)*

Model 6102C Series Single-Patient Use, Disposable Pulse Oximeter Sensors

Nonin's Model 6102C Series single-patient use, disposable pulse oximeter sensors are indicated for non-invasive spot-checking and/or continuous monitoring of patients (6102CA: adults > 30 kg / 66 lb; 6102CP: pediatrics > 10 kg / 22 lb.; 6102CI: infants > 2 kg / 4 lb; and 6102CN: neonates < 2 kg / 4 lb and adults > 30 kg / 66 lb), who are well or poorly perfused, during both motion and non-motion conditions.

It is intended for use hospitals, medical facilities, Emergency Medical Service (EMS) environments, home healthcare environments, and mobile environments.

Model 8100AA/8100AP Reusable, Finger Clip Pulse Oximeter Sensor

The Model 8100AA reusable, finger clip sensor is intended for non-invasive spot-checking and/or continuous monitoring of adult and pediatric patients (> 30 kg / 66 lb) who are well or poorly perfused, during both motion and non-motion conditions.

The Model 8100AP reusable, finger clip sensor is intended for non-invasive spot-checking and/or continuous monitoring of pediatric patients (8 – 60 kg / 18 – 132 lb) who are well or poorly perfused, during both motion and non-motion conditions.

It is intended for use in hospitals, medical facilities, Emergency Medical Service (EMS) environments, home healthcare environments, and mobile environments.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K160865

Device Name
Model 8101AA/8101AP Reusable, Finger Clip Pulse Oximeter Sensor
Model 8102AA/8102AP Reusable, Finger Clip Pulse Oximeter Sensor

Indications for Use *(Describe)*

Model 8101AA/8101AP Reusable, Finger Clip Pulse Oximeter Sensor

The Model 8101AA reusable, finger clip sensor is intended for non-invasive spot-checking and/or continuous monitoring of adult and pediatric patients (> 30 kg / 66 lb) who are well or poorly perfused, during both motion and non-motion conditions.

The Model 8101AP reusable, finger clip sensor is intended for non-invasive spot-checking and/or continuous monitoring of pediatric patients (8 – 60 kg / 18 – 132 lb) who are well or poorly perfused, during both motion and non-motion conditions.

It is intended for use in hospitals, medical facilities, Emergency Medical Service (EMS) environments, home healthcare environments, and mobile environments.

Model 8102AA/8102AP Reusable, Finger Clip Pulse Oximeter Sensor

The Model 8102AA reusable, finger clip sensor is intended for non-invasive spot-checking and/or continuous monitoring of adult and pediatric patients (> 30 kg / 66 lb) who are well or poorly perfused, during both motion and non-motion conditions.

The Model 8102AP reusable, finger clip sensor is intended for non-invasive spot-checking and/or continuous monitoring of pediatric patients (8 – 60 kg / 18 – 132 lb) who are well or poorly perfused, during both motion and non-motion conditions.

It is intended for use in hospitals, medical facilities, Emergency Medical Service (EMS) environments, home healthcare environments, and mobile environments.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K160865

Device Name
Model 8100Q2 Reusable, Ear Clip Pulse Oximeter Sensor
Model 8101Q2 Reusable, Ear Clip Pulse Oximeter Sensor
Model 8102Q2 Reusable, Ear Clip Pulse Oximeter Sensor

Indications for Use *(Describe)*

Model 8100Q2 Reusable, Ear Clip Pulse Oximeter Sensor
The Model 8100Q2 reusable, ear clip sensor is indicated for non-invasive, spot-checking and/or continuous monitoring of adult and pediatric patients (> 40 kg / 88 lb) who are well or poorly perfused, during non-motion conditions. It is intended for use in hospitals, medical facilities, Emergency Medical Service (EMS) environments, home healthcare environments, and mobile environments.
The recommended application site is the earlobe.

Model 8101Q2 Reusable, Ear Clip Pulse Oximeter Sensor
The Model 8101Q2 reusable, ear clip sensor is indicated for non-invasive, spot-checking and/or continuous monitoring of adult and pediatric patients (> 40 kg / 88 lb) who are well or poorly perfused, during non-motion conditions. It is intended for use in hospitals, medical facilities, Emergency Medical Service (EMS) environments, home healthcare environments, and mobile environments.
The recommended application site is the earlobe.

Model 8102Q2 Reusable, Ear Clip Pulse Oximeter Sensor
The Model 8102Q2 reusable, ear clip sensor is indicated for non-invasive, spot-checking and/or continuous monitoring of adult and pediatric patients (> 40 kg / 88 lb) who are well or poorly perfused, during non-motion conditions. It is intended for use in hospitals, medical facilities, Emergency Medical Service (EMS) environments, home healthcare environments, and mobile environments.
The recommended application site is the earlobe.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

“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: Nancy DeAngelo
Senior Regulatory Affairs Specialist

Date Prepared: March 24, 2016

Trade Names: Model 6100C Series Single-Patient Use, Disposable Pulse Oximeter Sensors (6100C Series: 6100CA, 6100CP, 6100CI, 6100CN)
Model 6101C Series Single-Patient Use, Disposable Pulse Oximeter Sensors (6101C Series: 6101CA, 6101CP, 6101CI, 6101CN)
Model 6102C Series Single-Patient Use, Disposable Pulse Oximeter Sensors (6102C Series: 6102CA, 6102CP, 6102CI, 6102CN)
Model 8100AA/8100AP Reusable, Finger Clip Pulse Oximeter Sensor
Model 8101AA/8101AP Reusable, Finger Clip Pulse Oximeter Sensor
Model 8102AA/8102AP Reusable, Finger Clip Pulse Oximeter Sensor
Model 8100Q2 Reusable, Ear Clip Pulse Oximeter Sensor
Model 8101Q2 Reusable, Ear Clip Pulse Oximeter Sensor
Model 8102Q2 Reusable, Ear Clip Pulse Oximeter Sensor

Common Name: Pulse oximeter sensor

Classification Name: Oximeter

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

Product Code, Panel: DQA, Anesthesiology
DPZ, Anesthesiology

Predicate Device(s): The Nonin Model 6100C Series (Models 6100CA, 6100CP, 6100CI, 6100CN,), Model 6101C Series (Models 6101CA, 6101CP, 6101CI, 6101CN), Model 6102C Series (Models 6102CA, 6102CP, 6102CI, 6102CN), Model 8100AA/8100AP,

Model 8101AA/8101AP, Model 8102AA/8102AP, Model 8100Q2, Model 8101Q2 and 8102Q2 Pulse Oximeter Sensors are predicated on Nonin's disposable cloth SpO_2 Model 6000CX Series sensors (Models 6000CA, 6000CP, 6000CI and 6000CN), Nonin Model 8100S(X) Series Soft Pulse Oximetry Sensors (Models 8100SS, 8100SM and 8100SL) and Nonin Model 8000Q2 Ear Clip Sensor cleared under K09853 (June 4, 2010), K132402 (February 21, 2014) and K080255 (May 23, 2008), respectively. The proposed and predicate sensors utilize Nonin's PureLight® technology.

Device Description:

The Model 6100C Series, Model 6101C Series and Model 6102C Series Pulse Oximeter Sensors are single-patient use, non-sterile disposable pulse sensors intended for use with the Nonin Medical Model X-100 SenSmart Universal Oximetry System (Model X-100). The Model 8100AA/8100AP, Model 8101AA/8101AP, Model 8102AA/8102AP, Model 8100Q2, Model 8101Q2 and Model 8102Q2 Pulse Oximeter Sensors are reusable, non-sterile pulse sensors intended for use with the Nonin Medical Model X-100 SenSmart Universal Oximetry System (Model X-100).

Intended Use:

Model 6100C Series Single-Patient Use, Disposable Pulse Oximeter Sensors

Nonin's Model 6100C Series single-patient use, disposable pulse oximeter sensors are indicated for non-invasive spot-checking and/or continuous monitoring of patients (6100CA: adults > 30 kg / 66 lb; 6100CP: pediatrics > 10 kg / 22 lb.; 6100CI: infants > 2 kg / 4 lb; and 6100CN: neonates < 2 kg / 4 lb and adults > 30 kg / 66 lb), who are well or poorly perfused, during both motion and non-motion conditions.

It is intended for use hospitals, medical facilities, Emergency Medical Service (EMS) environments, home healthcare environments, and mobile environments.

Model 6101C Series Single-Patient Use, Disposable Pulse Oximeter Sensors

Nonin's Model 6101C Series single-patient use, disposable pulse oximeter sensors are indicated for non-invasive spot-checking and/or continuous monitoring of patients (6101CA: adults > 30 kg / 66 lb; 6101CP: pediatrics > 10 kg / 22 lb.; 6101CI: infants > 2 kg / 4 lb; and 6101CN: neonates < 2 kg / 4 lb and adults > 30 kg / 66 lb), who are well or poorly perfused, during both motion and non-motion conditions.

It is intended for use hospitals, medical facilities, Emergency Medical Service (EMS) environments, home healthcare environments, and mobile environments.

Model 6102C Series Single-Patient Use, Disposable Pulse Oximeter Sensors

Nonin's Model 6102C Series single-patient use, disposable pulse oximeter sensors are indicated for non-invasive spot-checking and/or continuous monitoring of patients (6102CA: adults > 30 kg / 66 lb; 6102CP: pediatrics > 10 kg / 22 lb.; 6102CI: infants > 2 kg / 4 lb; and 6102CN: neonates < 2 kg / 4 lb and adults > 30 kg / 66 lb), who are well or poorly perfused, during both motion and non-motion conditions.

It is intended for use hospitals, medical facilities, Emergency Medical Service (EMS) environments, home healthcare environments, and mobile environments.

Model 8100AA/8100AP Reusable, Finger Clip Pulse Oximeter Sensor

The Model 8100AA reusable, finger clip sensor is intended for non-invasive spot-checking and/or continuous monitoring of adult and pediatric patients (> 30 kg / 66 lb) who are well or poorly perfused, during both motion and non-motion conditions.

The Model 8100AP reusable, finger clip sensor is intended for non-invasive spot-checking and/or continuous monitoring of pediatric patients (8 – 60 kg / 18 – 132 lb) who are well or poorly perfused, during both motion and non-motion conditions.

It is intended for use in hospitals, medical facilities, Emergency Medical Service (EMS) environments, home healthcare environments, and mobile environments.

Model 8101AA/8101AP Reusable, Finger Clip Pulse Oximeter Sensor

The Model 8101AA reusable, finger clip sensor is intended for non-invasive spot-checking and/or continuous monitoring of adult and pediatric patients (> 30 kg / 66 lb) who are well or poorly perfused, during both motion and non-motion conditions.

The Model 8101AP reusable, finger clip sensor is intended for non-invasive spot-checking and/or continuous monitoring of pediatric patients (8 – 60 kg / 18 – 132 lb) who are well or poorly perfused, during both motion and non-motion conditions.

It is intended for use in hospitals, medical facilities, Emergency Medical Service (EMS) environments, home healthcare environments, and mobile environments.

Model 8102AA/8102AP Reusable, Finger Clip Pulse Oximeter Sensor

The Model 8102AA reusable, finger clip sensor is intended for non-invasive spot-checking and/or continuous monitoring of adult and pediatric patients (> 30 kg / 66 lb) who are well or poorly perfused, during both motion and non-motion conditions.

The Model 8102AP reusable, finger clip sensor is intended for non-invasive spot-checking and/or continuous monitoring of pediatric patients (8 – 60 kg / 18 – 132 lb) who are well or poorly perfused, during both motion and non-motion conditions.

It is intended for use in hospitals, medical facilities, Emergency Medical Service (EMS) environments, home healthcare environments, and mobile environments.

Model 8100Q2 Reusable, Ear Clip Pulse Oximeter Sensor
The Model 8100Q2 reusable, ear clip sensor is indicated for non-invasive, spot-checking and/or continuous monitoring of adult and pediatric patients (> 40 kg / 88 lb) who are well or poorly perfused, during non-motion conditions. It is intended for use in hospitals, medical facilities, Emergency Medical Service (EMS) environments, home healthcare environments, and mobile environments.

The recommended application site is the earlobe.

Model 8101Q2 Reusable, Ear Clip Pulse Oximeter Sensor

The Model 8101Q2 reusable, ear clip sensor is indicated for non-invasive, spot-checking and/or continuous monitoring of adult and pediatric patients (> 40 kg / 88 lb) who are well or poorly perfused, during non-motion conditions. It is intended for use in hospitals, medical facilities, Emergency Medical Service (EMS) environments, home healthcare environments, and mobile environments.

The recommended application site is the earlobe.

Model 8102Q2 Reusable, Ear Clip Pulse Oximeter Sensor

The Model 8102Q2 reusable, ear clip sensor is indicated for non-invasive, spot-checking and/or continuous monitoring of adult and pediatric patients (> 40 kg / 88 lb) who are well or poorly perfused, during non-motion conditions. It is intended for use in hospitals, medical facilities, Emergency Medical Service (EMS) environments, home healthcare environments, and mobile environments.

The recommended application site is the earlobe.

Testing:

The Nonin Model 6100C Series, Model 6101C Series, Model 6102C Series, Model 8100AA/8100AP, Model 8101AA/8101AP, Model 8102AA/8102AP, Model 8100Q2, Model 8101Q2 and Model 8102Q2 Series sensors are supported by electrical 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 Nonin's Medical Model X-100 SenSmart Universal Oximetry System.

Functional and Safety Testing:

The results of the testing demonstrate equivalency with the predicate devices and compliance to recognized standards. **Table 1** summarizes test results for the proposed devices, which met the relevant requirements of the applicable recognized standards.

Table 1

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	Pass
Biocompatibility	ISO 10993-1 ISO 10993-5 ISO 10993-10	Pass

Note: The results reflected in the table above are representative for all sensors covered within this submission.

Clinical Testing: SpO_2 Accuracy testing

Models 6100CA, 6101CA, 6102CA, 6100CP, 6101CP, 6102CP, 6100CI, 6101CI and 6102CI

SpO2 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 oxygen saturation value (SpO2) 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 was measured over the SaO2 range of 70-100% in motion and non-motion. Accuracy data was calculated using the root-mean-squared (A_{RMS} value) for all subjects.

Models 6100CN, 6101CN and 6102CN
SpO2 accuracy testing was conducted at a Children's Hospital on male and female, light to dark-skinned subjects up to 30 days of age. The measured oxygen saturation value (SpO2) 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 was measured over the SaO2 range of 70-100% in non-motion. Accuracy data was calculated using the root-mean-squared (A_{RMS} value) for all subjects.

Models 8100AA, 8101AA, 8102AA, 8100AP, 8101AP and 8102AP
SpO2 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 oxygen saturation value (SpO2) 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 was measured over the SaO2 range of 70-100% in motion and non-motion. Accuracy data was calculated using the root-mean-squared (A_{RMS} value) for all subjects.

Models 8100Q2, 8101Q2 and 8102Q2
SpO2 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 oxygen saturation value (SpO2) 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 was measured over the SaO2 range of 70-100% in non-motion. Accuracy data was calculated using the root-mean-squared (A_{RMS} value) for all subjects.

Testing conclusion: the proposed Model 6100C Series, Model 6101C Series, Model 6102C Series, Model 8100AA/8100AP, Model 8101AA/8101AP, Model 8102AA/8102AP, Model 8100Q2, Model 8101Q2 and Model 8102Q2 Series sensors meet all acceptance criteria. Based on test results and comparison to the legally marketed predicates, the Model the proposed sensors perform equivalently to the predicate sensors for their intended use.

Summary of Substantial Equivalence:

The Model 6100C Series, Model 6101C Series, Model 6102C Series, Model 8100AA/8100AP, Model 8101AA/8101AP, Model 8102AA/8102AP, Model 8100Q2, Model 8101Q2 and Model 8102Q2 sensors have the following similarities to their respective predicate devices:

- Identical indications for use

- Identical intended use environments
- Identical patient population
- Same primary mode of operation
- Identical critical sensor optics technology (PureLight® Technology)
- Perform equivalently to the same specifications
- Similar construction and materials

The following lists the differences and the rationale for those differences between the proposed sensors and their respective predicate devices:

- Model 6100C Series, Model 6101C Series and Model 6102C Series
  - Contraindications – the contraindication regarding the use of device in MR environment was deemed more appropriate as a warning and the contraindication regarding defibrillation proof is no longer applicable due to verification testing according to IEC 60601-1:2005 when used with the X-100 System.
  - SpO_2 Motion Accuracy – internal and clinical testing was performed to verify the addition of accuracy claims in accordance with ISO 80601-2-61:2011.
  - Pulse Rate Accuracy (Motion and Non-motion) – internal and clinical testing was performed to verify the change in motion claims and the addition of non-motion claims in accordance with ISO 80601-2-61:2011.
  - New connector type – the X-100 System, along with the cleared SpO_2 and rSO_2 sensors for the system, utilize a Hirose connector with a Smart chip for authentication of the sensor to the system.
- Model 8100AA/8100AP, Model 8101AA/8101AP, and Model 8102AA/8102AP
  - Contraindications – the contraindication regarding the use of device in MR environment was deemed more appropriate as a warning.
  - Sensor Optic Housing Materials – the direct patient contacting materials used on the proposed sensors are the same as other cleared Nonin oximetry devices.
- Model 8100Q2, Model 8101Q2 and Model 8102Q2
  - Contraindications – the contraindication regarding the use of device in MR environment was deemed more appropriate as a warning and the contraindication regarding defibrillation proof is no longer applicable due to verification testing according to IEC 60601-1:2005 when used with the X-100 System.
  - SpO_2 and Pulse Rate Low Perfusion – internal and clinical testing was performed to verify the addition of these claims in accordance with ISO 80601-2-61:2011.
  - New connector type – the X-100 System, along with the cleared SpO_2 and rSO_2 sensors for the system, utilize a Hirose connector with a Smart chip for authentication of the sensor to the system.

Conclusion:

No new questions of safety and effectiveness were raised. Based on the results of the above referenced testing, the same critical optics technology, and risk management assessment, Nonin Medical has determined that the proposed Model 6100C Series Pulse Oximeter Sensors, Model 6101C Series Pulse Oximeter Sensors, Model 6102C Series Pulse Oximeter Sensors, Model 8100AA/8100AP Pulse Oximeter Sensors, Model 8101AA/8101AP Pulse Oximeter Sensors, Model 8102AA/8102AP Pulse Oximeter Sensors, the Model 8100Q2 Pulse Oximeter Sensor, the Model 8101Q2 Pulse Oximeter Sensor and the Model 8102Q2 Pulse Oximeter Sensor are substantially equivalent to the predicate Nonin Model 6000CX Series Pulse Oximeter Sensors (Models 6000CA, 6000CP, 6000CI, and 6000CN); Model 8100S(X) Series Soft Pulse Oximetry Sensors (Models 8100SS, 8100SM and 8100SL), and the Model 8000Q2 Ear Clip Sensor.