November 17, 2017

Masimo Corporation
Marguerite Thomlinson
Senior Director, Regulatory Affairs
52 Discovery
Irvine, California 92618

Re: K171121
Trade/Device Name: Masimo Root Monitoring System and Accessories
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, CBR, DXN, DQA, FLL, BZQ, CCK, CBS, NHQ, CBQ, NHO, NHP, CCL, DPZ, GXY, GWQ, OLT, OLW, OMC, ORT, CAT
Dated: October 18, 2017
Received: October 18, 2017

Dear Marguerite Thomlinson:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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)*
K171121

Device Name

Masimo Root Monitoring System and Accessories

Indications for Use *(Describe)*

The Masimo Root Monitoring System and Accessories are indicated for use by healthcare professionals for the monitoring of multiple physiological parameters in healthcare environments. The Root Monitoring System, when used with the optional ISA module, is not intended to be used in road ambulances.[1]

The Masimo Root Monitoring System and Accessories can communicate with network systems for supplemental remote viewing and alarming (e.g., at a central station).

The optional Masimo Radical-7 Pulse CO-Oximeter and Accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RRa). The Masimo 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 Radical-7 Pulse CO-Oximeter and accessories are indicated to provide the continuous non-invasive monitoring data obtained from the Masimo Radical-7 Pulse CO-Oximeter and accessories of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate to multi-parameter devices for the display of those devices.

The optional Masimo Radius-7 Wearable Pulse CO-Oximeter and Accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RRa). The Masimo Radius-7 Wearable Pulse CO-Oximeter and accessories are indicated for use with adult and pediatric patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals and hospital-type facilities.

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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Indications for Use
Masimo Root Monitoring System (continued from page 1)

The optional ISA product family consists of three types of sidestream gas analyzers (ISA CO2, ISA AX+ and ISA OR+) and accessories including Nomoline, intended to be connected to other medical backboard devices for monitoring of breath rate and the following breathing gases:

ISA CO2: CO_2

ISA AX+: CO_2, N_2O, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane

ISA OR+: CO_2, O_2, N_2O, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane

ISA CO2, ISA AX+ and ISA OR+ are intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care. The intended environment is the operating suite, intensive care unit and patient room. ISA CO2 is also intended to be used in road ambulances. The intended patient population is adult, pediatric, infant and neonatal patients.

The optional SEDLine Sedation Monitor is indicated for use in the operating room (OR), intensive care unit (ICU), and clinical research laboratory. It is intended to monitor the state of the brain by real-time data acquisition and processing of EEG signals. The system includes the Patient State Index (PSI), a proprietary computed EEG variable that is related to the effect of anesthetic agents.

The optional temperature module is indicated to measure temperature (oral, adult axillary, pediatric axillary, and rectal) of adult and pediatric patients. The device is intended to be used by clinicians and medically qualified personnel. It is available for sale only upon the order of a physician or licensed health care provider.

The optional non-invasive blood pressure (NIBP) module is indicated for the noninvasive measurement of arterial blood pressure in healthcare environments. The NIBP module is designed to measure blood pressure for patient population described in the following table:

Patient Population	Approximate Age Range
Newborn (neonate)	Birth to 1 month of age
Infant	1 month to 2 years of age
Child	2 to 12 years of age
Adolescent	12-21 years of age
Adult	21 years of age and older

[1] The Root Monitoring System, when used with the optional ISA module, is not intended to be used in road ambulances. The optional ISA module can be used in road ambulances with other monitoring systems in accordance with the intended environment of use for those systems.

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Section 5. 510(k) Summary

Submitter and Address of Manufacturing Facility:	Masimo Corporation 52 Discovery Irvine, CA 92618 Phone: (949) 297-7683
Date:	November 17, 2017
Official Correspondent	Marguerite Thomlinson Senior Director, Regulatory Affairs Masimo Corporation Phone: (949) 297-7683 Mthomlinson@Masimo.com
Trade Name:	Masimo Root Monitoring System and Accessories
Common Name:	Patient Monitor
Primary Classification Regulation/ Product Code:	21 CFR 878.2300, Class II/MWI
Secondary Product Code(s):	BZQ, CAT, CBQ, CBR, CBS, CCK, CCL, DPZ, DQA, DXN, FLL, GWQ, GXY, NHO, NHP, NHQ, OLT, OLW, OMC, ORT
Establishment Registration Number:	2031172
Reason for Premarket Notification:	Device modification and new indications for use
Predicate Device:	Primary predicate: K151644, Masimo Root Vital Signs Monitoring System Reference predicate: K103604, PhaseIn AB, ISA CO2, ISA AX+, ISA OR+ K980327, Oridion Microstream Filterline ICU
Performance Standards	No performance standards for the above device have been promulgated pursuant to Section 514.

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Section 5. 510(k) Summary

Device Description

The Masimo Root Monitoring System and Accessories (Root) is a multifunctional device that monitors vital signs for neonatal to adult patients. Parameters monitored by Root are from cleared measurement modules and their corresponding accessories, consisting of:

- Masimo Radical-7 and Radius-7 Pulse CO-Oximeter measurement modules and accessories (i.e. RD SET disposable sensors, RD Rainbow sensors, RAS-45 or RRa sensors) with technologies for the monitoring of non-invasive functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and respiratory rate (RRa);
- Masimo Sweden ISA-Infrared Sidestream Gas Analyzer measurement modules (ISA) and accessories (Nomoline product family) with technologies for breathing gases and respiratory rate monitoring, including inspired/expired gases during anesthesia, recovery and respiratory care;
- Masimo Sedline Sedation Monitor measurement module and accessories (i.e. RD Sedline EEG sensor) with technologies for state of the brain by real-time data acquisition and processing of EEG signals and Patient State Index (PSI) which is an EEG variable that is related to the effect of anesthetic agents;
- Temperature measurement module and accessories (i.e. temperature probe) with technologies for oral/axillary body temperature measurements; and
- Non-invasive blood pressure measurement module and accessories (i.e. reuse and disposable pressure cuffs) with technologies for systolic, diastolic and mean arterial pressure (MAP) measurements.

Root is intended to be used as a user interface to facilitate access control and monitoring device functions. Root displays patient monitoring information from the connected modules. Visual alarms are shown on the Root display and audible alarms are generated through the Root internal speaker. The user accesses the wired or wirelessly connected modules' monitoring functions, using the Root display. When the module is disconnected from Root, the monitoring information from the module is no longer displayed on Root. Data from connected modules, including patient monitoring data, can be communicated to network systems such as the Patient SafetyNet (K071047) and hospital EMR. Root also functions as a pass-through means for communicating information between connected devices and network systems.

The Root under K151644 consists of various measurement modules, including the ISA product family (ISA) and corresponding accessories, Nomoline product family (Nomoline).

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The predicate, Nomoline with the integrated Nomo Section HH, can be used in both high humidity (HH) and low (LH) environments. It is intended for single-patient use and intended to be used with third-party or generic patient interfaces (i.e. nasal cannulas, T-adapter). In addition, the predicate, Nomoline, can be used on an infant/neonate patient if it is used with a generic airway adapter (T-adapter) with less than 0.7 ml of dead space.

The Nomoline Product Family (Nomoline) in this submission includes single use configurations and resposable configurations, (combination of single use sampling line and reuse Nomo Section). The subject device is intended to be used on adult, pediatric, infant and neonatal patients. Same as the predicate, Nomoline, the new Nomoline models are intended to be used with gas analyzers such as ISA, for the measurement of respiratory rate and/or respiratory and anesthetic gases.

Configurations for Nomoline include the following main components:

- sampling line,
- patient interface or airway adapter for connection to patient interface,
- Nomo Section

The patient interface, which directly or indirectly contacts the patient, is attached to one end of the sampling line and the Nomo section is attached to the opposite end of the sampling line. The end with the Nomo section includes a compatible mating connector for connection to a capnography monitoring system such as the ISA gas measurement instrument.

The sampling line in this submission has the same medical grade tubing material, same nominal tubing length, same inner diameter dimension and same standard luer connection as the sampling line for the predicate, Nomoline (K103604).

The subject device, Nomoline, includes configurations with patient interfaces that can either indirectly or directly contact the patient. For all configurations, the patient interface is integral with the sampling line and it is intended for single use.

> *Airway Adapter Set (Connection to Breathing Circuit for Intubated Patient)* – The airway adapter set consists of a T-adapter, which integrates with one end of the sampling line. The airway adapter set does not have direct contact with the patient because the T-adapter allows a connection with the breathing circuit tubing on an intubated patient. The other end of the sampling line attaches to the Nomo section.
>
> Airway adapter sets are available in two sizes. One size with a dead space of < 6 ml in the T-adapter is intended for use with adult/pediatric patients. The other size with

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a dead space of < 0.5 ml in the T-adapter is intended for use with infant/neonatal patients.

Patient Interface - Nasal Cannula – Configurations of the patient interface that directly contact the patient include the nasal cannula (standard), nasal/oral cannula and nasal cannula with single prong. The patient interface is positioned directly on the patient and it is not intended to be detachable from the sampling line. The nasal cannulas are available for use on adult, pediatric and infant patients.

The Nomo section wicks moisture from the sampling line and protects the connected monitoring instrument such as ISA from the ingress of moisture. The end of the Nomo section includes a mating connector for the connection to a compatible gas monitoring instrument such as ISA. The shape of the mating connector for the Nomo section can differ, depending on the different manufacturers of gas monitoring instrument. Validation shall be conducted to ensure compatibility of the connection between the subject device and the different manufacturers' monitors.

Disposable Nomo Section LH – The Nomo Section, LH is intended for use in low moisture conditions, such as applications with low humidity within the sampling line. The collected moisture is then absorbed or stored in a plastic filter cap feature. Since the Nomo Section LH cannot store large amount of moisture, it is intended for a short duration of use.

Disposable Nomo Section HH – The Nomo Section HH is intended for use in high moisture conditions, such as applications with high humidity within the sampling line. The moisture is then removed by evaporating it into the surrounding air, by the hydrophilic, thermoplastic elastomer material filter cap feature. Since the Nomo Section HH collects and removes moisture through evaporation, it is intended for a longer duration of use.

Resposable Nomo Section HH – The reuse component Nomo Section HH is the HH Multi-Patient Use Adapter that is detachable from the sampling line. The Adapter includes a luer for connection with a sampling line. After use is complete, the Adapter is detached from the sampling line and is cleaned in accordance to the directions for use. After cleaning, the Adapter can be reused with a new sampling line. The HH Multi-Patient Use Adapter can be used in applications with high humidity and low humidity.

The Nomoline Product Family is available in many different configurations established by combining different types of sampling lines (i.e. varying lengths, with oxygen delivery line), patient interfaces (i.e. nasal cannula, oral/nasal cannula) and Nomo sections (HH or LH

Section 5. 510(k) Summary

versions). The configurations for the Nomoline family are sorted into three main groups based on the Nomo section and type of use.

Group 1: Configurations in this group are intended for single use. The group consists of configurations with integrated components which include the Nomo Section LH component, sampling line component and patient interface component.

Group 2: Configurations in this group are intended for single use. The group consists of configurations with integrated components which include the Nomo Section HH component, sampling line component and patient interface component.

Group 3: Configurations in this group include both single use and resposable products. The group includes the Nomoline HH Multi-Patient Use Adapter which is detachable from the integrated sampling line and patient interface. The HH Multi-Patient Use Adapter is intended to be reuse and the integrated sampling line and patient interface is intended to be single use.

See the table below for Root with ISA and Nomoline specifications

Table 11.9.1, General Specifications	
Feature	**Specifications**
Root	
Display	Color LCD touchscreen
Measurement modules	Radical-7; Radius-7; ISA; Sedline; temperature; NIBP
Visual/audible alarm	IEC-60601-1-8 compliant
Storage/recording	Trend/data storage
Power	AC power 100-240 volt, 47-63 Hz; Rechargeable battery
Interface	Wired/wireless; MOC-9; Iris; Nurse call; USB; SD card; temperature probe port; NIBP port
Network connectivity	Ethernet; Wi-Fi, 802.11 a/b/g; Bluetooth 2.0
Dimensions/ Weight	11 x 10.5 x 5.5 inch (27.9 x 26.7 x 14 cm)/ 3.37 kg
Operating temperature/ Storage temperature/ Humidity	50 to 104°F (10 to 40°C)/ -4 to 122°F (-20 to 50°C)/ 15 to 95% non-condensing humidity
Electrical safety/ EMC	IEC-60601 compliant
Mode of operation	Continuous
ISA	
Patient population	Adult, pediatric, infant and neonate patients
Sampling flow rate	50 ± 10 ml/min
Respiration rate	0 to 150 ± 10 breaths/min
Rise time	CO2 ≤ 250 ms; N2O ≤ 350 ms; O2 ≤ 450 ms; HAL, ISO, ENF, SEV, DES ≤ 350 ms
Accuracy (for dry single gases at 22 ± 5 °C and 1013 ± 40 hPa)	• CO2: 0-15 vol%; ccuracy: ±0.2 vol% + 2 % of reading • O2: 0-100 vol %; Accuracy: ±1 vol% + 2 % of reading • N2O: 0-100 vol%; Accuracy: ±(2 vol% + 2 % of reading) • HAL/ISO/ENF: 0-8 vol%; Accuracy: ±0.15 vol% + 5 % of reading • SEV: 0-10 vol%; Accuracy: ±0.15 vol% + 5 % of reading • DES: 0-22 vol%; Accuracy: ±0.15 vol% + 5 % of reading

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Table 11.9.1, General Specifications	
Feature	**Specifications**
Agent identification threshold	0.15 vol%
Mixture agent threshold for secondary agent	0.2 vol% + 10% of total agent concentration
Interface	MOC-9 or RS-232
Dimensions/ Weight (with module and cable)	ISA CO2/AX+: 1.3 x 3.1 x 1.9 inch (33 x 78 x 49 mm)/ 130 g ISA OR+: 1.9 x 3.5 x 3.9 inch (49 x 90 x 100 mm)/ 420 g
Operating temperature/ Storage temperature/	• ISA CO2: 32 to 122°F (0 to 50°C)/ -40 to 158°F (-40 to 70°C) • ISA AX+/OR+: 41 to 122°F (5 to 50°C)/ -40 to 158°F (-40 to 70°C)
Operating humidity/ Storage humidity	< 4 kPa H2O, 95% at 30°C, non-condensing/ 5 to 100% RH at 40°C, condensing
Nomoline	
Patient population	Adult, pediatric, infant and neonate patients
Type of use	Resposable (single-use sampling line component connected with reuse Multi-Use Adapter HH component)
	Single-use (sampling line integrated with Nomo Section LH/Nomo Section HH component)
Adapter dead-space	Adult/Pediatric: ≤ 6 ml; Infant ≤ 0.7 ml
Sampling line, length	2m or 3m, nominal
Sampling line, ID	1.0 mm, nominal
Sampling line, material	Soft co-extruded PE/PVC
Patient interface (cannula), material	Soft PVC
Patient interface (airway adapter), material	Hard plastic; methyl methacrylate-acrylonitrite-butadiene-styrene (MABS)
O2 delivery line, material	PVC tubing
Biocompatibility	Patient contacting materials: ISO 10993-1 compliant
Sterility	Supplied non-sterile
Storage temperature; humidity	-40 to +70 ^{0}C; 5 to 100 % RH (condensing) / 100 % RH at 40 ^{0}C

Intended Use

The Masimo Root Monitoring System and Accessories (Root) are indicated for use by healthcare professionals for the monitoring of multiple physiological parameters in healthcare environments.

Root also serves as a convenient alternative user interface to integrate modules to provide health care professionals the ability to access, control and monitor measurement technologies (within the respective modules) that have been previously cleared by the FDA. Root does not affect the intended use for the cleared measurement technologies with which it is intended to function. Additionally, Root is intended to communicate with network systems.

Indications for Use (IFU)

The IFU statement is as follows:

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The Masimo Root Monitoring System and Accessories are indicated for use by healthcare professionals for the monitoring of multiple physiological parameters in healthcare environments. The Root Monitoring System, when used with the optional ISA module, is not intended to be used in road ambulances.[1]

The Masimo Root Monitoring System and Accessories can communicate with network systems for supplemental remote viewing and alarming (e.g., at a central station).

The optional Masimo Radical-7 Pulse CO-Oximeter and Accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RRa). The Masimo 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 Radical-7 Pulse CO-Oximeter and accessories are indicated to provide the continuous non-invasive monitoring data obtained from the Masimo Radical-7 Pulse CO-Oximeter and accessories of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate to multi-parameter devices for the display of those devices.

The optional Masimo Radius-7 Wearable Pulse CO-Oximeter and Accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RRa). The Masimo Radius-7 Wearable Pulse CO-Oximeter and accessories are indicated for use with adult and pediatric patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals and hospital-type facilities.

The optional ISA product family consists of three types of sidestream gas analyzers (ISA CO2, ISA AX+ and ISA OR+) and accessories including Nomoline, intended to be connected to other medical backboard devices for monitoring of breath rate and the following breathing gases:

ISA CO2: CO_2

ISA AX+: CO_2, N_2O, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane

ISA OR+: CO_2, O_2, N_2O, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane

ISA CO2, ISA AX+ and ISA OR+ are intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care. The intended environment is the operating suite, intensive care unit and patient room. ISA CO2 is also intended to be used in road ambulances. The intended patient population is adult, pediatric, infant, and neonatal patients.

[1] The Root Monitoring System, when used with the optional ISA module, is not intended to be used in road ambulances. The optional ISA module can be used in road ambulances with other monitoring systems in accordance with the intended environment of use for those systems.

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The optional SEDLine Sedation Monitor is indicated for use in the operating room (OR), intensive care unit (ICU), and clinical research laboratory. It is intended to monitor the state of the brain by real-time data acquisition and processing of EEG signals. The system includes the Patient State Index (PSI), a proprietary computed EEG variable that is related to the effect of anesthetic agents.

The optional temperature module is indicated to measure temperature (oral, adult axillary, pediatric axillary, and rectal) of adult and pediatric patients. The device is intended to be used by clinicians and medically qualified personnel. It is available for sale only upon the order of a physician or licensed health care provider.

The optional non-invasive blood pressure (NIBP) module is indicated for the noninvasive measurement of arterial blood pressure in healthcare environments. The NIBP module is designed to measure blood pressure for patient population described in the following table:

Patient Population	Approximate Age Range
Newborn (neonate)	Birth to 1 month of age
Infant	1 month to 2 years of age
Child	2 to 12 years of age
Adolescent	12-21 years of age
Adult	21 years of age and older

Technological Characteristics

Principle of Operation

The principle of operation for Root is as follows:

Root functions as a user interface that allows access, control and monitoring from the connected modules (external and internal).

Data from connected modules, including patient monitoring data, can be communicated to network systems. Root also functions as a pass-through means for communicating information between connected devices and network systems.

The principle of operation for ISA and Nomoline is as follows:

The principle of the ISA's gas measurement technology per K151644 (originally cleared in K103604) is based on the absorption of different gases at different wavelengths, using infrared spectrometry.

The subject device, Nomoline, is a conduit for the transport of respiratory gas from the patient to a gas analyzer such as ISA, with an optional oxygen (O2) delivery line. The principle of water/moisture collection from the sampling line is based on the

Section 5. 510(k) Summary

wicking concept. Nomoline can absorb low amount of moisture and store the moisture in its filter cap component. Additionally, Nomoline HH products can remove the collected water/moisture through the principle of evaporating the moisture into the surrounding air. This principle is based on using a hydrophilic, thermoplastic, elastomer material for its high moisture absorption rate and high water permeability.

Mechanism of Action for Achieving the Intended Effect

The mechanism of action for achieving the intended effect for the subject device, Root with ISA and Nomoline, is as follows:

The system begins functioning when the power is turned on for Root.

Root communicates with connected modules and displays the modules' patient monitoring information on the Root display. The healthcare provider controls the functions of each module using the Root touchscreen display. Visual alarms are shown on the Root display and audible alarms are generated through the Root internal speaker.

By connecting external modules or devices to Root, data can be communicated between Root and network systems via wired or wireless connection. Information from network systems can be shown on the Root display for viewing and notification purposes.

For the use with ISA and Nomoline, the Nomoline end with the Nomo section is connected to the gas measurement instrument such as ISA. The other end of Nomoline, the end with the sampling line with integrated patient interface, is connected to the patient breathing circuit or directly to the patient. If the Nomoline model includes the oxygen delivery line, then that line is connected to an oxygen source. Use begins when Nomoline is connected and the gas analyzer is turned on. Once use is completed, disconnect Nomoline from the patient breathing circuit or the patient and turn power off on the system.

Summary of Technological Characteristics of Subject Device Compared to Predicate

Similarities and Differences between Subject Device and Primary Predicate, Masimo Monitoring System (Root) with ISA and Nomoline per K151644

Section 5. 510(k) Summary

The subject device, Root with ISA and Nomoline, and the primary predicate device, Root with ISA and Nomoline (K151644), have the following key similarities:

- Both devices are intended for patient monitoring of multiple physiological parameters, including respiratory gases measurements;
- Both devices have the same principle of operation, same mechanism for achieving the intended effect and same performance specifications;
- Both devices are intended to be used on the same patient population of adult, pediatric and infant patients;
- Both devices, specifically Nomoline, include the technology for moisture/water collection using the wicking concept and moisture/water removal using hydrophilic material; and
- Both devices are supplied non-sterile.

The subject device, Root with ISA and Nomoline, and the primary predicate device, Root with ISA and Nomoline (K151644), have the following key differences:

- The subject device includes the neonatal patient population in the indications for use for ISA and Nomoline; whereas neonatal patient population is not included in the predicate device; and
- The subject device includes additional Nomoline models that were not available with the predicate device;

Similarities and Differences between Subject Device, Root with ISA and Nomoline, and Reference Predicate, ISA – Infrared Sidestream Gas Analyzer (ISA and Nomoline) per K103604

The subject device, Root with ISA and Nomoline, and the reference predicate device, ISA and Nomoline (K103604), have the following key similarities:

- Both devices are intended to be used for respiratory gas measurements;
- Both devices have the same principle of operation, same mechanism for achieving the intended effect and same performance specifications for respiratory gas measurements;
- Both devices are intended to be used on the same patient population of adult, pediatric and infant patients;
- Both devices, specifically Nomoline, include the technology for moisture/water collection using the wicking concept and moisture/water removal using hydrophilic material; and
- Both devices are supplied non-sterile.

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The subject device, Root with ISA and Nomoline, and the reference predicate device, ISA and Nomoline (K103604), have the following key differences:

- The subject device includes the neonatal patient population in the indications for use for ISA and Nomoline; whereas neonatal patient population is not included in the predicate device; and
- The subject device includes additional Nomoline models that were not available with the predicate device;

Similarities and Differences between Subject Device, Nomoline, and Reference Predicate, Microstream Filterline ICU ISA (Microstream) per K980327

The subject device, Nomoline, and the reference predicate device, Microstream (K980327), have the following key similarities:

- Both devices are intended to be used as accessories for respiratory gas measurements;
- Both devices have the same principle of operation, same mechanism for achieving the intended effect;
- Both devices are intended to be used on the same patient population of adult, pediatric, infant and neonate patients;
- Both devices are supplied non-sterile.

The subject device, Nomoline, and the reference predicate device, Microstream (K980327), have the following key differences:

- The subject device and the predicate have different moisture removal technologies, with the subject device has the Nomo Section, using the wicking concept and models having moisture/water removal using hydrophilic material and the predicate having the nafion material; and
- the subject device consists of more variety of product configurations including airway adapters, cannulas and sampling lines with optional oxygen delivery; whereas, the predicate consists of airway adapters and general sampling lines.

Non-clinical Testing

Root with ISA and Nomoline has been subjected to bench testing. The following non-clinical testing was performed in accordance with Masimo design control requirements and quality system to demonstrate substantial equivalence of the subject device with its predicates:

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- Electrical safety testing per IEC-60601-1
- EMC testing per IEC-60601-1-2
- Respiratory gas monitoring testing per ISO 80601-2-55
- Software verification, including integration testing with host monitors, per FDA Software Guidance
- Mechanical testing (same as K151644) per ISTA-2A and MIL-STD 810E
- Environmental testing per IEC-60601-1
- Particulate matter testing per ISO-18562-2
- Shelf life testing
- Cross-contamination and cleaning testing of reuse components
- Biocompatibility testing per the following standards:

ISO-10993-1	Biological evaluation of medical devices – part 1: Evaluation and testing within a risk management process
ISO-10993-5	Biological evaluation of medical devices – part 5: cytotoxicity
ISO-10993-10	Biological evaluation of medical devices – part 10: Tests for irritation and skin sensitization
ISO-10993-12	Biological evaluation of medical devices – part 12: Sample preparation and reference materials
ISO-10993-17	Biological evaluation of medical devices – part 17: Establishment of allowable limits for leachable substances
ISO-10993-18	Biological evaluation of medical devices – part 18: Chemical characterization of materials

Clinical Testing

Clinical testing was not performed with the subject device, Root with ISA and Nomoline, to support substantial equivalence.

Conclusion

The non-clinical testing provided in this 510(k) submission demonstrates that the subject device, Root with ISA and Nomoline, is substantially equivalent to its predicate.