April 22, 2020

Masimo Corporation
Linus Park
Vice President, Regulatory Affairs
52 Discovery
Irvine, California 92618

Re: K191882
Trade/Device Name: Masimo Centroid System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, BZQ, KMI, CCK, DQA, DPZ, GXY, GWQ, OLT, OLW, OMC, ORT, DXN, FLL
Dated: March 23, 2020
Received: March 25, 2020

Dear Linus Park:

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

Section 4. Indications for Use Statement

Indications for Use

510(k) Number: K191882

Device Name: Masimo Centroid System

Indications for Use:

The Root when used with the Centroid is indicated for the following:

The Masimo Root Monitoring System is 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.

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

The Radical-7 and Accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) of 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.

The Radical-7 and Accessories are indicated for the continuous non-invasive monitoring of carboxyhemoglobin saturation (SpCO) of adult, pediatric, and infant patients during no motion conditions in hospitals and hospital-type facilities. The Masimo Radical-7 and Accessories are not intended to be used as the sole basis for making diagnosis or treatment decisions related to suspected carbon monoxide poisoning; it is intended to be used in conjunction with additional methods of assessing clinical signs and symptoms.

The Radical-7 and Accessories are indicated for the continuous non-invasive monitoring of methemoglobin saturation (SpMet) of adult, pediatric, and neonatal patients during no motion conditions in hospitals and hospital-type facilities.

The Radical-7 and Accessories are indicated for the continuous non-invasive monitoring of total hemoglobin concentration (SpHb) of adult and pediatric patients during no motion conditions in hospitals and hospital-type facilities.

Prescription Use _X_ AND/OR Over The Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 4. Indications for Use Statement

The Radical-7 and Accessories are indicated for the continuous non-invasive monitoring of respiratory rate (RRa) for adult, pediatric, and neonatal patients during no motion conditions in hospitals, hospital-type facilities, home environments, and transport within healthcare facilities.

The Radical-7 and Accessories are indicated for the continuous non-invasive monitoring of Respiratory Rate from photoplethysmogram (RRp) for adult and pediatric patients during no motion conditions in hospitals, hospital-type facilities, home environments, and transport within healthcare facilities.

The Radius-7 Accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) of 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.

The Radius-7 and Accessories are indicated for the continuous non-invasive monitoring of carboxyhemoglobin saturation (SpCO) of adult, pediatric, and infant patients during no motion conditions in hospitals and hospital-type facilities. The Masimo Radius and Accessories are not intended to be used as the sole basis for making diagnosis or treatment decisions related to suspected carbon monoxide poisoning; it is intended to be used in conjunction with additional methods of assessing clinical signs and symptoms.

The Radius-7 and Accessories are indicated for the continuous non-invasive monitoring of methemoglobin saturation (SpMet) of adult, pediatric, and neonatal patients during no motion conditions in hospitals and hospital-type facilities.

The Radius-7 and Accessories are indicated for the continuous non-invasive monitoring of total hemoglobin concentration (SpHb) of adult and pediatric patients during no motion conditions in hospitals and hospital-type facilities.

The Radius-7 and Accessories are indicated for the continuous non-invasive monitoring of respiratory rate (RRa) for adult, pediatric, and neonatal patients during no motion conditions in hospitals, hospital-type facilities, home environments, and transport within healthcare facilities.

The Radius-7 and Accessories are indicated for the continuous non-invasive monitoring of Respiratory Rate from Pleth (RRp) for adult and pediatric patients during no motion conditions in hospitals, hospital-type facilities, home environments, and transport within healthcare facilities.

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

Prescription Use _X_ (Part 21 CFR 801 Subpart D)	AND/OR	Over The Counter Use _____ (Part 21 CFR 801 Subpart D)

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Section 4. Indications for Use Statement

ISA CO2: CO2
ISA AX+: CO2, N2O, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane ISA OR+: CO2, O2, N2O, 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. The intended patient population is adult, pediatric and infant 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

The optional Centroid System is intended for monitoring the orientation and activity of patients. The Centroid System is intended to provide alerts when patient orientation or activity deviates from parameters set by healthcare providers. The Centroid System is indicated for monitoring the orientation and activity of patients including those susceptible to pressure ulcers. The Centroid System is intended for use in hospitals, hospital-type facilities, and healthcare facilities.

The Centroid System is indicated for the following:

The Centroid System is intended for monitoring the orientation and activity of patients. The Centroid System is intended to provide alerts when patient orientation or activity deviates from parameters set by healthcare providers. The Centroid System is indicated for monitoring the orientation and activity of

Prescription Use _X_ AND/OR Over The Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart D)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 4. Indications for Use Statement

patients including those susceptible to pressure ulcers. The Centroid System is intended for use in healthcare environments.

The Centroid System is also indicated for the measurement of respiration rate of adults in healthcare environments.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over The Counter Use _____ (Part 21 CFR 801 Subpart D)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 5. 510(k) Summary

Submitter and Address of Manufacturing Facility:	Masimo Corporation 52 Discovery Irvine, CA 92618 Phone: (949) 297-7000 FAX: (949) 297-7592
Date:	April 17, 2020
Contact:	Linus Park Vice President, Regulatory Masimo Corporation Phone: (949) 297-7337
Trade Name:	Masimo Root Monitoring System with Centroid
Common Name:	Patient Monitor
Classification Regulation/ Product Code:	21 CFR 870.2300, Class II/MWI
Additional Product Codes:	KMI BZQ CCK DQA DPZ GXY GWQ OLT OLW OMC ORT DXN FLL
Establishment Registration Number:	2031172
Reason for Premarket Notification:	Device modification to add new indication for use
Primary Predicate Device:	K171121 – Masimo Root Monitoring System and Accessories
Secondary Predicate Device:	K141877 – Leaf Patient Monitoring System
Reference Predicate:	K173976 – Masimo Acoustic Respiration Sensors K152911 – EarlySense Insight System K190916 – VitalPatch Biosensor
Performance Standards	No performance standards for the above device have been promulgated pursuant to Section 514.

MASIMO CORPORATION
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Section 5. 510(k) Summary

5.1 Device Description

The Masimo Root Monitoring System (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 (SpO2), 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;

- 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; and

- Centroid System for monitoring the orientation and activity of patients and the measurement of respiration rate.

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 Masimo Centroid Sensor is a wearable, battery-operated, single-patient use, adhesive sensor intended for the monitoring of body orientation and activity. The Centroid Sensor wirelessly communicates with a back-end user interface, such as the Root monitor display (K171121) to display and provide alerting capabilities for orientations and activity that fall outside of parameters set by healthcare providers. The Centroid System which includes the sensor and the back-end user interface (e.g. Root) is intended to aid

Section 5. 510(k) Summary

caregivers to identify patients who have fallen or who need to be repositioned according to the institution's guidelines. Centroid is indicated for orientation monitoring of patients including those that may be susceptible to pressure ulcers. The Centroid is also capable of detecting chest movements to provide a respiratory rate (RR). The Centroid is designed for hospitals, hospital-type facilities, and healthcare facilities.

The Centroid Sensor specifications are as follows:

Table 5.1
General Specifications

FEATURE	SPECIFICATION
Monitoring Function	
Time in current position	0 to 65,535 minutes
Patient Incline Angle Range (Head of Bed)	-180º to 180º
Respiration Rate Accuracy (Arms)	3 rpm (respirations per minute), 8 to 35 rpm
Interface	
Wireless	Bluetooth LE
Power	
Battery type	Lithium, 3V
Battery life	96 hours
Storage Life	2 years
Mechanical	
Enclosure Material	Plastic, Cycoloy
Dimensions/Weight	12.7 cm x 12.7 cm x 1.27 cm (5" x 5" x 0.5")
Weight	30 g (0.07 lbs.)
Environmental	
Operating Temperature	10°C to 40°C (50°F to 104°F)
Storage Temperature	-20°C to 50°C (-4°F to 122°F)
Operating/ Storage Humidity	15% to 95%, non-condensing
Operating Atmospheric Pressure	540 mbar to 1,060 mbar (540 hPa to 1060 hPa)
Mode of Operation	
Mode of Operation	Continuous

5.2 Intended Use

The Masimo Root Monitoring System is 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.

MASIMO CORPORATION
52 Discovery
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Section 5. 510(k) Summary

The Centroid System is intended for monitoring the orientation and activity of patients. The Centroid System is intended to provide alerts when patient orientation or activity deviates from parameters set by healthcare providers.

5.3 Indications for Use

The Root when used with the Centroid is indicated for the following:

The Masimo Root Monitoring System is 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.

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

The Radical-7 and Accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) of 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.

The Radical-7 and Accessories are indicated for the continuous non-invasive monitoring of carboxyhemoglobin saturation (SpCO) of adult, pediatric, and infant patients during no motion conditions in hospitals and hospital-type facilities. The Masimo Radical-7 and Accessories are not intended to be used as the sole basis for making diagnosis or treatment decisions related to suspected carbon monoxide poisoning; it is intended to be used in conjunction with additional methods of assessing clinical signs and symptoms.

The Radical-7 and Accessories are indicated for the continuous non-invasive monitoring of methemoglobin saturation (SpMet) of adult, pediatric, and neonatal patients during no motion conditions in hospitals and hospital-type facilities.

The Radical-7 and Accessories are indicated for the continuous non-invasive monitoring of total hemoglobin concentration (SpHb) of adult and pediatric patients during no motion conditions in hospitals and hospital-type facilities.

The Radical-7 and Accessories are indicated for the continuous non-invasive monitoring of respiratory rate (RRa) for adult, pediatric, and neonatal patients during no motion conditions in hospitals, hospital-type facilities, home environments, and transport within healthcare facilities.

The Radical-7 and Accessories are indicated for the continuous non-invasive monitoring of Respiratory Rate from photoplethysmogram (RRp) for adult and pediatric patients during no motion conditions in hospitals, hospital-type facilities, home environments, and transport within healthcare facilities.

MASIMO CORPORATION
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Section 5. 510(k) Summary

The Radius-7 Accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) of 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.

The Radius-7 and Accessories are indicated for the continuous non-invasive monitoring of carboxyhemoglobin saturation (SpCO) of adult, pediatric, and infant patients during no motion conditions in hospitals and hospital-type facilities. The Masimo Radius and Accessories are not intended to be used as the sole basis for making diagnosis or treatment decisions related to suspected carbon monoxide poisoning; it is intended to be used in conjunction with additional methods of assessing clinical signs and symptoms.

The Radius-7 and Accessories are indicated for the continuous non-invasive monitoring of methemoglobin saturation (SpMet) of adult, pediatric, and neonatal patients during no motion conditions in hospitals and hospital-type facilities.

The Radius-7 and Accessories are indicated for the continuous non-invasive monitoring of total hemoglobin concentration (SpHb) of adult and pediatric patients during no motion conditions in hospitals and hospital-type facilities.

The Radius-7 and Accessories are indicated for the continuous non-invasive monitoring of respiratory rate (RRa) for adult, pediatric, and neonatal patients during no motion conditions in hospitals, hospital-type facilities, home environments, and transport within healthcare facilities.

The Radius-7 and Accessories are indicated for the continuous non-invasive monitoring of Respiratory Rate from Pleth (RRp) for adult and pediatric patients during no motion conditions in hospitals, hospital-type facilities, home environments, and transport within healthcare facilities.

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

ISA CO2: CO2
ISA AX+: CO2, N2O, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane ISA OR+: CO2, O2, N2O, 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. The intended patient population is adult, pediatric and infant 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.

Section 5. 510(k) Summary

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

The optional Centroid System is intended for monitoring the orientation and activity of patients. The Centroid System is intended to provide alerts when patient orientation or activity deviates from parameters set by healthcare providers. The Centroid System is indicated for monitoring the orientation and activity of patients including those susceptible to pressure ulcers. The Centroid System is intended for use in hospitals, hospital-type facilities, and healthcare facilities.

The Centroid System is indicated for the following:

The Centroid System is intended for monitoring the orientation and activity of patients. The Centroid System is intended to provide alerts when patient orientation or activity deviates from parameters set by healthcare providers. The Centroid System is indicated for monitoring the orientation and activity of patients including those susceptible to pressure ulcers. The Centroid System is intended for use in healthcare environments.

The Centroid System is also indicated for the measurement of respiration rate of adults in healthcare environments.

5.4 Technological Characteristics

Principle of Operations

There have been no changes to the principles of operation from what was previously cleared (K171121). The Root uses the same principles of operation to support the Centroid display on the Root. Similar to how the other supported modules are displayed on Root, the Centroid is provided with a dedicated display window which encompasses each of the displayed parameters and user interface functions supported by the Centroid. There have been no changes to the system architecture of the Root to accommodate the Centroid.

MASIMO CORPORATION
52 Discovery
Irvine, CA 92618

Section 5. 510(k) Summary

For the Centroid, the Centroid monitors the patient orientation and activity using an integrated accelerometer and gyroscope. The accelerometer and gyroscope in the Centroid Sensor provide information about the movement and position of the body by detecting the relative displacement caused by changes in position and movement. The data collected from the Centroid Sensor is then combined and transferred wirelessly to a back-end user interface, such as the Root (K171121), to provide a display of the orientation and activity. The back-end user interface provides a visual display which aids clinicians in identify patient positions that may be more susceptible to pressure injury based upon time. The accelerometer and gyroscope can also detect chest movement displacements associated with breathing to calculate a patient's respiration rate.

Mechanism of Action for Achieving the Intended Effect

There have been no changes to mechanism of action of the Root monitor from the previous clearance. Similar to how the other modules are supported, the Root will activate the dedicated Centroid window when the communication to Centroid has been established. Upon established connection, the Root will begin to collect and display transmitted data from the Centroid sensor through a Bluetooth connection. When the Centroid system detects and transmits violations of alarm thresholds, the Root will provide visual and audible alarms similar to how each module is supported.

As for the Centroid, the Centroid Sensor is battery powered and wirelessly paired with a back-end monitor, such as the Root. Upon successful pairing, a clinician applies the Centroid Sensor to the patient after peeling off a liner to expose the adhesive backing. Once applied to the patient, the Centroid Sensor will detect displacement data that will be processed and transmitted wirelessly to the paired back-end device, such as the Root. Using the back-end device, the alert thresholds can be established to trigger audible and visual indicators to aid clinicians in position and activity monitoring.

5.5 Summary of Technological Characteristics of Subject Device Compared to Predicate Device

Similarities and Differences between Predicate and Subject Device

The subject device, Root with Centroid, and the predicate device, Root Monitoring System (K171121), have the following key similarities:

- Both devices have the same display and alarm characteristics;
- Both devices have the same user interfaces;
- Both devices provide the capabilities of displaying respiration rate;
- Both devices support the communication to multiple modules; and
- Both devices support wireless technology.

The subject device, Root with Centroid, and the predicate device, Root Monitoring System (K171121), have the following key differences:

- The subject device includes the use of the Centroid that utilizes a gyroscope and accelerometer sensor to provide detection of patient activity, orientation, and respiration rate.

Section 5. 510(k) Summary

The subject device, Root with Centroid, and the secondary predicate device, Leaf Patient Monitoring System (K141877), have the following key similarities:

- Both devices have the ability display and alarm based upon patient orientation;
- Both devices provide a user interface that allows for the ability to assess patient orientation compliance;
- Both devices support wireless technology.

The subject device, Root with Centroid, and the secondary predicate device, Leaf Patient Monitoring System (K141877), have the following key differences:

- The subject device includes the use of the Centroid that utilizes a gyroscope and accelerometer sensor to provide detection of patient activity, orientation, and respiration rate.

The main technological difference from the primary predicate device to the subject device is the inclusion of the Centroid. The Centroid utilizes a sensor to provide monitoring of patient orientation and activity similar to the reference predicate, Leaf Patient Monitoring System (K141877). The Centroid is also able to detect chest displacements to provide a respiration rate. The chest displacements used for the respiration rate are detected through the same sensor that includes an accelerator and gyroscope for monitoring patient orientation and activity. To support the differences do not raise different questions of safety and effectiveness, performance bench and clinical testing was used.

5.6 Performance Data

Bench Testing

To support the patient orientation features of the Centroid, bench testing was conducted to confirm the angular measurement performance of the sensor. Bench testing involved the comparison of the angular performance against a reference protractor. Additionally, Gage R&R testing was conducted to support the repeatability and reproducibility of the measurement system. The bench testing was found to support the performance of the patient orientation features.

To support the respiration rate feature of the Centroid, bench testing was conducted on a breathing simulation mannequin. The testing was conducted while the Centroid sensor was attached to breathing simulation mannequin and the respiration rate was adjusted using a connected ventilator's settings. The performance of the Centroid respiration rate was compared against those of the ventilator settings and supported that the Centroid met its performance specification.

To support the fall detection performance of the Centroid, performance bench testing was conducted using a breathing simulation mannequin that was subject to various different types of simulated fall types resulting 200 fall events. The ability of the Centroid to detect the fall event

Section 5. 510(k) Summary

was assessed. The test result supported the Centroid met its product specification.

Biocompatibility Testing
The Centroid includes patient contacting materials as the sensor is positioned on the patient's chest. The testing performed and submitted supports these patient contacting materials are biocompatible in accordance with the approach described in the ISO 10993-1.

Electromagnetic Compatibility, Electrical Safety, Environmental, Mechanical and Cleaning
To support the Centroid does not raise any new questions of safety and effectiveness, testing was performed and submitted with respect to IEC 60601-1-2 standard for EMC compliance, IEC 60601-1 standard for electrical safety, environmental, and mechanical. As the Centroid sensor is disposable, considerations for cleaning were not applicable.

Software Verification and Validation Testing
Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, dated May 11, 2005. The software for this device was considered as a "moderate" level of concern, because a failure or latent flaw in the software could directly result in minor to moderate injury to the patient. The testing was found to support the substantial equivalence of the subject device.

Wireless and Cybersecurity Testing
As the Centroid Sensor uses wireless communication to a back-end device (e.g., Root), wireless and cybersecurity considerations were made in accordance with FDA *Guidance for Industry and Food and Drug Administration Staff- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices,* dated October 2, 2014 and draft guidance dated October 18, 2018.

In accordance with the FDA draft guidance for Cybersecurity, the Root and Centroid was considered a tier 2 device. To support the subject device does not raise any new questions of safety and effectiveness a risk-based assessment and testing in accordance with referenced FDA guidance documents were conducted. The testing was found to support there are no new questions of safety and effectiveness for that of the subject device.

Human Factors Usability Testing
To support the subject device does not raise any new questions of safety and effectiveness, human factors and usability risk were evaluated and acceptably mitigated in accordance with FDA Guidance, *Applying Human Factors and Usability Engineering to Optimize Medical Device Design,* dated February 3, 2016. The testing was found to support there are no new questions of safety and effectiveness from that of the subject device.

Non-clinical Testing

Non-clinical bench testing was performed on the Centroid. The non-clinical testing was conducted in accordance with Masimo requirements to ensure that the specifications of the subject device were met. The following non-clinical testing was performed:

Section 5. 510(k) Summary

- Performance bench testing against ventilator settings
- Electrical safety testing per IEC 60601-1
- EMC testing per IEC 60601-1-2
- Usability testing per FDA Human Factors and Usability Guidance
- Software verification and validation testing per FDA Software Guidance
- Biocompatibility testing per ISO 10993-1
- Mechanical testing per IEC 60601-1

The testing was found to support there are no new questions of safety and effectiveness from that of the subject device.

Clinical Testing

To support substantial equivalence of the Centroid, three separate clinical studies were conducted. The first study was a non-randomized, single arm clinical study where data was collected from 40 adult, healthy volunteer subjects (age range 18 – 67 years, median 42 years; 22 female, 18 male) to evaluate the clinical performance of Masimo Centroid. The clinical study evaluated the clinical performance for detection of subject's posture, position, and activity. The results of this clinical study supported the Masimo Centroid can reliably detect turns, posture transitions, and fall events with sensitivities of 100%, 96.7%, and 100%, respectively. The study also compared the respiration rate detected from the Centroid against those determined by manually scoring data from a gold reference capnography. The results of the first study supported the substantial equivalence of the subject device.

The second study was conducted on 34 ICU adult, healthy volunteer subjects (age range 23 to 84 years, median 59 years; 18 females and 16 males). As the subjects were ICU patients, many subjects suffered from multiple medical conditions including those that could result in higher respiration rates and shallow breathing. The study compared the respiration rate detected by the Centroid against that provided from a capnography. The second study also supported the substantial equivalence of the subject device.

The third study was conducted on 51 healthy volunteers (age range 18-45 years, median 29 years; 30 males and 21 females) who were requested to conduct a series of different types of falls to detect the fall detection performance of the Centroid. The study collected data from 800 falls and was found to have a 93.9% sensitivity to detection of a fall. The results of the study supported the fall detection feature of the Centroid.

5.7 Conclusion

The non-clinical and clinical data support the subject device is substantially equivalent to the predicate device.