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

February 12, 2016

Masimo Corporation
Ms. Marguerite Thomlinson
Sr. Director, Regulatory Affairs
52 Discovery
Irvine, California 92618

Re: K151644
Trade/Device Name: Masimo Root Vital Signs 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, DXN, DQA, FLL
Dated: January 13, 2016
Received: January 15, 2016

Dear Ms. 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.

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,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4. Indications for Use Statement

Indications for Use

510(k) Number: _____

Device Name: Masimo Root Monitoring System and Accessories

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 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 Oximeter and Accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, and/or respiratory rate (RRa). The Masimo Radius-7 Wearable Pulse Oximeter and accessories are indicated for use with adult, and pediatric

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 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+), 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 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.

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

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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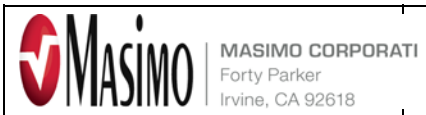
Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 5. 510(k) Summary

	
Submitter and Address of Manufacturing Facility:	Masimo Corporation 40 Parker Irvine, CA 92618 Phone: (949) 297-7683 FAX: (949) 297-7592
Date:	June 17, 2015
Contact:	Marguerite Thomlinson Senior Director, Regulatory Affairs
Trade Name:	Masimo Root Monitoring System and Accessories
Common Name:	Patient Monitor
Classification Regulation/ Product Code:	21 CFR 878.2300, Class II/MWI 21 CFR 862.3220, Class II/JKS 21 CFR 868.1400, Class II/CCK 21 CFR 868.2375, Class II/BZQ 21 CFR 870.2700, Class II/DQA 21 CFR 870.2710, Class II/DPZ 21 CFR 882.1320, Class II/GXY 21 CFR 882.1400, Class II/GWQ 21 CFR 882.1400, Class II/OLT 21 CFR 882.1400, Class II/OLW 21 CFR 882.1400, Class II/OMC 21 CFR 882.1400, Class II/ORT 21 CFR 870.1130, Class II/DXN 21 CFR 880.2910, Class II/FLL
Establishment Registration Number:	2031172
Reason for Premarket Notification:	Device modification and new indications for use
Predicate Devices:	K142394 – Masimo Root Monitoring System K101680 - Welch Allyn Spot Ultra Vital Signs/Welch Allyn Spot Vital Signs LXi K090989 - Zoll R Series with NIBP & EtCO2 Options
Performance Standards	No performance standards for the above device have been promulgated pursuant to Section 514.

Device Description – Disease/Conditions that Device Diagnose, Treat, Prevent, Cure or Mitigate, Including Patient Population

The Root Monitoring System (Root) is a multifunctional device that monitors vital signs of patients from neonates to adults. Parameters monitored by Root include non-invasive functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), respiratory rate (RRa), inspired/expired gases during anesthesia, recovery and respiratory care, state of the brain by real-time data acquisition and processing of EEG signals, temperature, non-invasive blood pressure (NIBP) and Patient State Index (PSI) which is an EEG variable that is related to the effect of anesthetic agents.

Explanation of Why Differences in Indication Statement Are Not Critical to Intended Use, and Why Difference Do Not Affect Safety and Effectiveness of Device When Used as Labeled

Root is intended to be used with the previously FDA cleared measurement technologies for the modules of:

- External Masimo Radical-7 Pulse CO-Oximeter (Radical-7 module), with cleared technologies of SpO2, pulse rate, SpCO, SpMet, SpHb and RRa monitoring per K110028.
- External Masimo Radius-7 Pulse Oximeter (Radius-7 module), with cleared technologies of SpO2, pulse rate and RRa monitoring per K110028.
- External ISA-Infrared Sidestream Gas Analyzer (ISA module), with cleared technologies of breathing gases and respiratory rate monitoring per K103604.
- External Sedline Sedation Monitor with Frontal PSI and SEDTrace EEG Electrode Set (Sedline module), with cleared technologies of EEG and PSI monitoring per K051874.
- Internal temperature module, with cleared temperature measurement technologies (the module was integrated in the Welch Allyn Spot Ultra Vital Signs/Welch Allyn Spot Vital Signs LXi per K101680).
- Internal non-invasive blood pressure (NIBP) module with cleared NIBP measurement technologies (the module was integrated in Zoll R Series per K090989).

Root is also intended to be used as a user interface to facilitate access control and monitoring device functions and to connect system networks such as the Patient SafetyNet (K071047).

Device Description – General Description from Labeling, Including Explanation of How Device Functions, Scientific Concepts that Form Basis For the Device

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 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. Root also functions as a pass-through means for communicating information between connected devices and network systems.

The subject device is the same as the primary predicate (K142394). The main difference is that the subject device has been modified to integrate internal modules for temperature and NIBP measurement technologies.

Device Description – Significant Physical and Performance Characteristics of the Device

The significant physical characteristics for Root include an LCD touchscreen for patient monitoring. The instrument can be powered by AC or by its internal rechargeable battery. The approximate size and weight of the instrument are 11" x 10.5" x 5.5" (27.9 cm x 26.7 cm x 14 cm) and approximately 8 pounds.

The device specifications are shown below for the general functions of the subject device, Root.

FEATURE	**SPECIFICATION**
Display	Color LCD touchscreen
External Module	**Parameter**
Radical-7	Parameters per K110028
Radius-7	Parameters per K110028 for SpO2, pulse rate and RRa
ISA	Parameters per K103604
Sedline	Parameters per K051874
Internal Module	
Temperature	Temperature parameters per K101680
Non-Invasive Blood Pressure (NIBP)	Arterial blood pressure parameters per K090989
General	
Visual/audible alarm	IEC60601-1-8 compliant
Storage/recording	Trend/data storage
Electrical	
AC Power	100-240 volt, 47-63 Hz
Battery	Rechargeable battery
Interface	
Root and Device/Module Connection	Wired/docking interface Wireless interface MOC-9 interface Temperature Probe Port NIBP Port (Nib) Iris interface Nurse call interface USB interface SD card interface
Network Connectivity	Ethernet Wi-Fi, 802.11 a/b/g; Bluetooth 2.0

FEATURE	SPECIFICATION
Mechanical	
Dimensions	11 x 10.5 x 5.5 inch (27.9 x 26.7 x 14 cm)
Weight	3.37 kg
Environmental	
Operating Temperature Storage Temperature Humidity	32 to 122°F (0-50°C) -40 to 158°F (-40 to 70°C), 10-95% non-condensing humidity
Mode of Operation	
Mode of Operation	Continuous

Intended Use

The Masimo Root Monitoring System is 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

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 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 Oximeter and Accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial

hemoglobin (SpO_2), pulse rate, and/or respiratory rate (RRa). The Masimo Radius-7 Wearable Pulse 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+), 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 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

Technological Characteristics

Principle of Operation

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.

Mechanism of Action for Achieving the Intended Effect

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.

Once use is complete, the user then turns the power "off" for Root.

Summary of Technological Characteristics of Subject Device Compared to Predicate Device

Similarities and Differences between the Subject Device, Root and the Primary Predicate Device, Root (K142394)

The subject device and the primary predicate have the following key similarities:

- Both have the same intended use as a patient monitoring device
- Both can function with the same external Radical-7, Radius-7, ISA and/or Sedline modules;
- Both have the same principle of operation and the mechanism of action for achieving the intended effect; and
- Both can communicate with a network system such as the Patient SafetyNet (K071047) through wired or wireless connection.

The subject device and the primary predicate have the following key differences:

- The subject device includes an internal temperature module; whereas the predicate does not; and
- The subject device includes an internal non-invasive blood pressure (NIBP) module; whereas the predicate does not and
- The patient applied parts for the temperature and NIBP modules are connected to the Root; whereas the predicate does not have this feature.

Similarities and Differences between the Subject Device, Root and the Predicate Device, Welch Allyn Spot Ultra Vital Signs/Welch Allyn Spot Vital Signs LXi (K101680)

The subject device and the predicate have the following key similarities:

- Both have the same integrated temperature measurement module;
- Both have the same intended use and similar indications for use (IFU) for the temperature measurement and
- Both include the same temperature probes as accessories.

The subject device and the predicate have the following key differences:

- The subject device and predicate have different IFU for their respective functions except for the IFU for temperature measurement and
- Both have different user interfaces.

Similarities and Differences between the Subject Device, Root and the Predicate Device, Zoll R Series with NIBP & EtCO2 Options (K090989)

The subject device and the predicate have the following key similarities:

- Both have the same integrated NIBP measurement module;
- Both have the same intended use and similar indications for use for the NIBP measurement and
- Both include the same blood pressure cuffs and patient hoses as accessories.

The subject device and the predicate have the following key differences:

- The subject device and predicate have different IFU for their respective functions except for the IFU for NIBP measurement and
- Both have different user interfaces.

Non-clinical Testing

Bench testing was performed on the subject device. 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 to its predicates:

- Alarm testing per IEC60601-1-8
- Usability testing per FDA Human Factors and Usability Draft Guidance
- Software verification per FDA Software Guidance

The results demonstrate that all requirements and performance specifications were satisfied, and that the subject device is substantially equivalent to the predicate.

Clinical Testing

Not applicable. Clinical performance testing was not performed with the subject device, Root, to support substantial equivalence.

Conclusion

It is concluded that the subject device, Masimo Root Monitoring System, is substantially equivalent to its predicates with respect to safety and effectiveness, based on the nonclinical tests discussed above.