



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

June 21, 2016

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

Re: K153225

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, GXY, GWQ, OLT, OLW, OMC, ORT, BZQ, DQA, DPZ, CCK, JKS  
Dated: May 18, 2016  
Received: May 19, 2016

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.

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,

*Tejashri Purohit-Sheth, M.D.*

**Tejashri Purohit-Sheth, M.D.**  
Clinical Deputy Director  
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.  
Director  
Division of Anesthesiology,  
General Hospital, Respiratory,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K153225

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 Masimo Root Monitoring System and Accessories can transmit data 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<sub>2</sub>), 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<sub>2</sub>) 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 (SpO<sub>2</sub>), 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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(K153225, continued from page 1)

### **Indications for Use**

The optional ISA product family consists of three types of sidestream gas analyzers (ISA CO<sub>2</sub>, 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 CO<sub>2</sub>: CO<sub>2</sub>

ISA AX+: CO<sub>2</sub>, N<sub>2</sub>O, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane

ISA OR+: CO<sub>2</sub>, O<sub>2</sub>, N<sub>2</sub>O, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane

ISA CO<sub>2</sub>, 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 CO<sub>2</sub> 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.



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## Section 5. 510(k) Summary

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|--|--|
| Submitter and Address of Manufacturing Facility: | Masimo Corporation<br>52 Discovery<br>Irvine, CA 92618<br>Phone: (949) 297-7683<br>FAX: (949) 297-7592   |
| Date:  | June 20, 2016  |
| Contact:   | Marguerite Thomlinson<br>Senior Director, Regulatory Affairs   |
| Trade Name:                                      | Masimo Root Monitoring System and Accessories  |
| Common Name:                                     | Patient Monitor  |
| Regulation Number/ Name/ Product Class           | 21 CFR 878.2300, Class II/MWI<br>21 CFR 862.3220, Class II/JKS<br>21 CFR 868.1400, Class II/CCK<br>21 CFR 868.2375, Class II/BZQ<br>21 CFR 870.2700, Class II/DQA<br>21 CFR 870.2710, Class II/DPZ<br>21 CFR 882.1320, Class II/GXY<br>21 CFR 882.1400, Class II/GWQ<br>21 CFR 882.1400, Class II/OLT<br>21 CFR 882.1400, Class II/OLW<br>21 CFR 882.1400, Class II/OMC<br>21 CFR 882.1400, Class II/ORT |
| Establishment Registration Number:               | 2031172  |
| Reason for Premarket Notification:               | Device modification and new indications for use  |
| Predicate Devices:                               | K142394 – Masimo Root Monitoring System and Accessories  |
| Performance Standards                            | No performance standards for the above device have been promulgated pursuant to Section 514.   |

### Device Description

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<sub>2</sub>), pulse rate, carboxyhemoglobin



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## Section 5. 510(k) Summary

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, and Patient State Index (PSI) which is an EEG variable that is related to the effect of anesthetic agents.

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

- Masimo Radical-7 Pulse CO-Oximeter (Radical-7 module), with cleared technologies of SpO<sub>2</sub>, pulse rate, SpCO, SpMet, SpHb and RRa monitoring per K110028.
- Masimo Radius-7 Pulse Oximeter (Radius-7 module), with cleared technologies of SpO<sub>2</sub>, pulse rate, SpCO, SpMet, SpHb and RRa monitoring per K110028.
- ISA-Infrared Sidestream Gas Analyzer (ISA module), with cleared technologies of breathing gases and respiratory rate monitoring per K103604.
- Sedline Sedation Monitor with Frontal PSI and SEDTrace EEG Electrode Set (Sedline module), with cleared technologies of EEG and PSI monitoring per K051874.

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

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. 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 predicate device, Masimo Root Monitoring System (Root) was cleared in K142394, is the same as the subject device, Masimo Root Monitoring System (Root). Both the predicate and subject devices include the option to connect the Masimo Radius-7 Pulse Oximeter (Radius-7) module. The main difference is that the Radius-7 in the subject device now provides the same measurement functionality as the Radical-7 module.



## Section 5. 510(k) Summary

### 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  |
| <b>Connected Module</b>           | <b>Parameter</b>   |
| Radical-7                         | Parameters per K110028   |
| Radius-7                          |  |
| ISA Module                        | Parameters per K103604   |
| Sedline Module                    | Parameters per K051874   |
| <b>General</b>                    |  |
| Visual/audible alarm              | IEC60601-1-8 compliant   |
| Storage/recording                 | Trend/data storage   |
| <b>Electrical</b>                 |  |
| AC Power                          | 100-240 volt, 47-63 Hz   |
| Battery                           | Rechargeable battery   |
| <b>Interface</b>                  |  |
| Root and Device/Module Connection | Wired/docking interface<br>Wireless interface<br>MOC-9 interface<br>Iris interface<br>Nurse call interface<br>USB interface<br>SD card interface |
| Network Connectivity              | Ethernet<br>Wi-Fi, 802.11 a/b/g; Bluetooth 2.0   |
| <b>Mechanical</b>                 |  |
| Dimensions                        | 11 x 10.5 x 5.5 inch (27.9 x 26.7 x 14 cm)   |
| Weight                            | Approximately 8 lbs (3.63 kg)  |
| <b>Environmental</b>              |  |
| Operating Temperature             | 32 to 122°F (0-50°C)   |
| Storage Temperature               | -40 to 158°F (-40 to 70°C),  |
| Humidity                          | 10-95% non-condensing humidity   |
| <b>Mode of Operation</b>          |  |
| Mode of Operation                 | Continuous   |

### Intended Use

Root serves as a convenient alternative user interface to integrate modules to provide health care professionals the ability to access, control and monitor measurement technologies



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## **Section 5. 510(k) Summary**

(within the respective modules) that have been previously cleared by the FDA. Root does not affect the intended use, or alter the indications for 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 and Accessories are indicated for use by healthcare professionals for the monitoring of multiple physiological parameters in healthcare environments.

The Masimo Root Monitoring System and Accessories can transmit data 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<sub>2</sub>), 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<sub>2</sub>) and pulse rate to multi-parameter devices for the display of those devices.

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ISA OR+: CO<sub>2</sub>, O<sub>2</sub>, N<sub>2</sub>O, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane  
ISA CO<sub>2</sub>, 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 CO<sub>2</sub> 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.

### **Technological Characteristics**

#### *Principle of Operation*

Root functions as an alternative user interface that allows access, control and monitoring from the connected modules.

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*

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 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.



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## **Section 5. 510(k) Summary**

### **Summary of Technological Characteristics of Subject Device Compared to Predicate Device**

#### *Similarities and Differences between Predicate Device, Root (K142394) and Subject Device, Root*

The predicate, Masimo Root Monitoring System (Root), per K142394, included the key components of the Root monitor with the Radical-7 module, Radius-7 module, ISA module and Sedline module. The subject device, Masimo Root Monitoring System and Accessories (Root), is the same as the predicate with modifications to the Radius-7 module.

In the predicate, the Radius-7 module provided SpO<sub>2</sub>, pulse rate, RRA measurements, which are a sub-set of the measurements included in the Radical-7 module. In this submission, the Radius-7 module provides all measurements in the Radical-7 module which includes SpO<sub>2</sub>, pulse rate, SpCO, SpMet, SpHb and RRA measurements.

### **Summary of Non-Clinical Performance Testing**

The Root Monitoring System and the modified Radius-7 Module have been thoroughly tested through verification and validation, including software validation. Verification of compliance with applicable voluntary standards has also been made to support the use of the device in its intended environment.

- Risk Analysis
- Testing on unit level (module and or component verification)
- Integration testing (system verification)
- Performance testing (verification)

The Root Monitoring System and the modified Radius-7 Module were designed and tested for compliance to the following standards and guidance:

- Electrical safety testing per IEC60601-1
- EMC testing per IEC-60601-1-2
- Alarm testing per IEC-60601-1-8
- Biocompatibility testing per ISO-10993
- Usability testing per FDA Human Factors and Usability Draft Guidance
- Wireless testing per FDA Wireless Guidance
- Software verification per FDA Software Guidance



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## **Section 5. 510(k) Summary**

- Mechanical and environmental testing per Mil-Std-810

### **Clinical Testing**

No clinical testing was done.

### **Substantial Equivalent Conclusion**

The results of the testing demonstrate that all requirements and performance specifications were satisfied, and that the subject device is substantially equivalent to the predicate device. Thus, it is concluded that the subject device, Masimo Root Monitoring System and Accessories, are substantially equivalent to the predicate based on the non-clinical tests discussed above.