May 29, 2025

Masimo Corporation
Jazmin Laidet
Regulatory Affairs Specialist III
52 Discovery
Irvine, California 92618

Re: K250757
Trade/Device Name: Radius VSM and Accessories
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector And Alarm (Including ST-Segment Measurement And Alarm)
Regulatory Class: Class II
Product Code: MHX, BZQ, DQA, DPS, DPZ, DRT, DSJ, DXN, FLL, KMI, DSI, DQK, DXQ
Dated: March 12, 2025
Received: March 12, 2025

Dear Jazmin Laidet:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Stephen C. Browning -S

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K25O757

Please provide the device trade name(s).

Radius VSM and Accessories

Please provide your Indications for Use below.

Radius VSM:
The Radius VSM and accessories are intended to be used as both a wearable multi-parameter patient monitor and an accessory to a multi-parameter patient monitor that is intended for multi-parameter physiological patient monitoring in hospital and healthcare facilities.

The Radius VSM and accessories are indicated for the monitoring of hemodynamic (including ECG, arrhythmia detection, non-invasive blood pressure, SpO2, Pulse Rate, PVi, heart rate, and temperature), and respiratory (e.g., impedance, acoustic, and pleth-based respiration rate) physiological parameters along with the orientation and activity of adults.

The Radius VSM and accessories are indicated for the non-invasive continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and Pulse Rate (PR) of well or poorly perfused adults during both no motion and motion conditions.

The Radius VSM and accessories are indicated for continuous monitoring of skin temperature of adults.

The Radius VSM and accessories are indicated for monitoring of the orientation and activity of patients including those susceptible to pressure ulcers.

The Radius VSM and accessories are indicated for the continuous non-invasive monitoring of PVi as a measure of relative variability of the photoplethysmograph (pleth) of adults during no motion conditions. PVi may be used as a noninvasive dynamic indicator of fluid responsiveness in select populations of mechanically ventilated adult patients. Accuracy of PVi in predicting fluid responsiveness is variable and influenced by numerous patient, procedure and device related factors. PVi measures the variation in the plethysmography amplitude but does not provide measurements of stroke volume or cardiac output. Fluid management decisions should be based on a complete assessment of the patient's condition and should not be based solely on PVi.

Devices with Masimo technology are only indicated for use with Masimo accessories.

Radius VSM Accessories:
Radius VSM ECG Electrodes are disposable, single-patient use ECG electrodes intended to acquire ECG signals from the surface of the body. They are indicated for use on adults for up to 3 days of skin surface contact.

Radius VSM Blood Pressure Cuffs are accessories intended to be used with a noninvasive blood pressure measurement system to measure blood pressure. They are indicated for use on adults during no motion conditions.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

MASIMO CORPORATION
52 Discovery
Irvine, CA 92618

510(k) Summary
K250757

Submitter and Address of Manufacturing Facility:	Masimo Corporation 52 Discovery Irvine, CA 92618 Phone: (949) 297-7000	
Date:	May 20, 2025	
Contact:	Jazmin Laidet Regulatory Affairs Specialist III Masimo Corporation Phone: (949) 577-2849	
Trade Name:	Radius VSM and Accessories	
Common Name:	Patient Monitor (with Arrhythmia Detection)	
Classification Regulation/ Product Code/ Panel:	21 CFR 870.1025 / MHX / Cardiovascular	
Regulatory Class:	Class II	
Additional Product Code:	21 CFR 868.2375/BZQ 21 CFR 870.2700/DQA 21 CFR 870.2340/DPS 21 CFR 870.2710/DPZ 21 CFR 870.2300/DRT 21 CFR 870.1100/DSJ 21 CFR 870.1130/DXN 21 CFR 880.2910/FLL 21 CFR 880.2400/KMI 21 CFR 870.1025/DSI 21 CFR 870.1425/DQK 21 CFR 870.1120/DXQ	
Establishment Registration Number:	3011353843	
Reason for Premarket Notification:	Addition of Mean Arterial Pressure (MAP) feature	
Primary Predicate:	K223489	Radius VSM and Accessories
Reference Device:	K171801	IntelliVue Multi-Measurement Module X3

1. Device Description

The Radius VSM and accessories are an FDA cleared (K223498), wearable, battery-operated, multi-modular patient monitoring platform that allows for the ability to scale and tailor the use of different monitoring technologies based upon the hospital and clinician's assessment of what technologies are appropriate.

MASIMO CORPORATION
52 Discovery
Irvine, CA 92618

510(k) Summary
K250757

As part of this submission, a MAP feature is being added to the Radius VSM. The feature is a software feature that uses the previously cleared systolic and diastolic measurement capabilities to automate the calculation of MAP using the following formula:

$$MAP = 1/3* Systolic + 2/3*Diastolic$$

The MAP is calculated by the Radius VSM NIBP Module and displayed on the Radius VSM Wearable Monitor. There were no other features added as part of this submission.

There were no changes made to the Radius VSM Wearable Monitor specifications from the previous clearance under K223498. The specifications for the Radius VSM Wearable Module are provided in Table 1-1 below:

Table 1-1: Radius VSM Wearable Monitor Specifications

Feature	**Specifications**
Display	
Display Type	Touchscreen
Alarms	
Type of Alarms	Visual/Audible Alarms
Technological Characteristics	
Measured Parameters	SpO2, PR, RRp, RRa
Calculated or Derived Parameters	PVi, Pi
Performance Specifications	
SpO2, No Motion	70-100%, 1.5% Arms, Adults
SpO2, Motion	70-100%, 1.5% Arms, Adults
SpO2, Low perfusion	70-100%, 2% Arms, Adults
PR, No Motion	25-240 bpm, 3 bpm, Adults
PR, Motion	25-240 bpm, 5 bpm, Adults
PR, Low Perfusion	25-240 bpm, 5 bpm, Adults
RRp, No Motion	4-70, 3 rpm Arms, 1 rpm mean error, Adults
RRa	4-70 rpm, 1 rpm Arms, Adults
Interfaces	
Physical	Modules, Charging Adapter
Wireless	Bluetooth LE, Wi-Fi
Electrical	
Internally Powered	Rechargeable, Lithium Ion Battery
Mechanical Specifications	
Dimensions	10.9 cm x 5.8 cm x 2.1 cm (4.28” x 2.28” x 0.83”)
Weight	122 g (0.27 lbs.)
Ingress Protection	IPX4
Environmental Specifications	
Operating Temperature	0°C to 40°C (32°F to 104°F)

510(k) Summary
K250757

Table 1-1: Radius VSM Wearable Monitor Specifications	
Feature	**Specifications**
Storage Temperature	-20°C to 60°C (-4°F to 140°F)
Operating/Storage/ Transport Humidity	10% to 95%, non-condensing
Operating Atmospheric Pressure	540 mbar to 1060 mbar
Classification per IEC 60601-1	
Electrical Safety	IEC 60601-1
EMC	IEC 60601-1-2
Electrical Isolation Type	Class II (Internally Powered)
Applied Part Type	BF Applied Part
Ingress Protection	IP22
Mode of Operation	Continuous

There were no changes made to the Radius VSM ECG Module specifications from the previous clearance under K223498. The specifications for the Radius VSM ECG Module are provided in Table 1-2 below:

Table 1-2: Radius VSM ECG Module Specifications	
Feature	**Specifications**
Technical Characteristics	
Measured Parameters	ECG waveform, HR, RRe, Temperature, Time in Position, Patient Incline Angle
Calculated or Derived Parameters	Arrhythmia Detection, Fall Detection
Performance Specifications	
ECG, Monitoring Bandwidth	0.67 Hz to 40 Hz
ECG, Diagnostic Bandwidth	0.05 Hz to 150 Hz
HR (15bpm to 300 bpm)	1% or ± 2 bpm (whichever is greater)
RRe (4-120 rpm)	≤1 rpm mean error
Patient Incline Angle (-180° to 180°C)	±1°
Laboratory Accuracy (77°F to 109.4°F (25°C to 43°C))	± 0.3°C (±.54°F)
Lethal Arrhythmias Detected	Asystole, Ventricular Fibrillation/Ventricular Tachycardia, Ventricular Tachycardia (greater than 30s)
Non-Lethal Arrhythmias Detected	Atrial Fibrillation greater than 30 seconds, Ventricular Tachycardia (less than 30s)
Interface	
Physical	Module connector
Electrical	
DC Powered	Radius VSM Module
Mechanical	
Dimensions	4.7 cm x 4.06 cm (1.85” x 1.60”)
Weight	20 g (0.04 lbs.)
Ingress Protection	IPX4

510(k) Summary
K250757

Environmental	
Operating Temperature	0°C to 40°C (32°F to 104°F)
Storage/Transport Temperature	-20°C to 60°C (-4°F to 140°F)
Operating/Storage/Transport Humidity	10% to 95%, non-condensing
Operating Atmospheric Pressure	540 mbar to 1060 mbar (540 hPa to 1060 hPa)

Apart from the added MAP feature, there were no changes made to the specifications from the previous clearance under K223498. The specifications for the Radius VSM NIBP Module are provided in Table 1-3 below.

Table 1-3: Radius VSM NIBP Module Specifications	
Feature	**Specifications**
Technical Characteristics	
Measured Parameters	Systolic, Diastolic, Pulse Rate
Calculated or Derived Parameters	Mean Arterial Pressure (MAP)
Performance Specifications	
Pressure Transducer (Between 0 mmHg and 300 mmHg)	±3 mmHg
Blood Pressure	Meets ISO 81060-2 (Mean difference of ≤5 mmHg with a standard deviation of ≤8 mmHg)
Interface	
Physical	Module connector
Electrical	
DC Powered	Radius VSM Module
Mechanical	
Dimensions	9.3 cm x 5.5 cm x 2.9 cm (3.66” x 2.17” x 0.86”)
Weight	111 g (0.24 lbs.)
Ingress Protection	IPX2
Environmental	
Operating Temperature	0°C to 40°C (32°F to 104°F)
Storage/Transport Temperature	-20°C to 60°C (-4°F to 140°F)
Operating/Storage/Transport Humidity	10% to 95%, non-condensing
Operating Atmospheric Pressure	540 mbar to 1060 mbar (540 hPa to 1060 hPa)

2. Intended Use/ Indications for Use

There are no changes to the intended use for the subject device, Radius VSM, from the previous clearance under K223498. The intended use statement is provided below for ease of reference:

Radius VSM:

The Radius VSM and accessories are intended to be used as both a wearable multi-parameter patient monitor and an accessory to a multi-parameter patient monitor that is intended for multi-parameter physiological patient monitoring in hospital and healthcare facilities.

510(k) Summary
K250757

The Radius VSM and accessories are indicated for the monitoring of hemodynamic (including ECG, arrhythmia detection, non-invasive blood pressure, SpO2, Pulse Rate, PVi, heart rate, and temperature), and respiratory (e.g., impedance, acoustic, and pleth-based respiration rate) physiological parameters along with the orientation and activity of adults.

The Radius VSM and accessories are indicated for the non-invasive continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and Pulse Rate (PR) of well or poorly perfused adults during both no motion and motion conditions.

The Radius VSM and accessories are indicated for continuous monitoring of skin temperature of adults. The Radius VSM and accessories are indicated for monitoring of the orientation and activity of patients including those susceptible to pressure ulcers.

The Radius VSM and accessories are indicated for the continuous non-invasive monitoring of PVi as a measure of relative variability of the photoplethysmograph (pleth) of adults during no motion conditions. PVi may be used as a noninvasive dynamic indicator of fluid responsiveness in select populations of mechanically ventilated adult patients. Accuracy of PVi in predicting fluid responsiveness is variable and influenced by numerous patient, procedure and device related factors. PVi measures the variation in the plethysmography amplitude but does not provide measurements of stroke volume or cardiac output. Fluid management decisions should be based on a complete assessment of the patient's condition and should not be based solely on PVi.

Devices with Masimo technology are only indicated for use with Masimo accessories.

Radius VSM Accessories:

Radius VSM ECG Electrodes are disposable, single-patient use ECG electrodes intended to acquire ECG signals from the surface of the body. They are indicated for use on adults for up to 3 days of skin surface contact.

Radius VSM Blood Pressure Cuffs are accessories intended to be used with a noninvasive blood pressure measurement system to measure blood pressure. They are indicated for use on adults during no motion conditions.

3. Technological Characteristics

Principle of Operation

As part of this submission, Masimo is requesting the addition of a mean arterial pressure (MAP) calculation feature. The MAP feature relies on the calculation of the mean arterial pressure using the established weighted average of the systolic and diastolic blood pressure values. The Radius VSM automates the calculation to output an MAP value.

Mechanism of Action for Achieving the Intended Effect

510(k) Summary
K250757

There were no changes to the mechanism of action of the Radius VSM and Accessories in the addition of the MAP feature from the previous clearance under K223498.

The MAP value from the Radius VSM is provided along with the previously cleared systolic and diastolic values without any additional user actions. To obtain the MAP value and the other NIBP parameter data, the Radius VSM NIBP module is attached to the Radius VSM NIBP cuff which is applied to the patient. The Radius VSM NIBP module determines the Systolic Pressure, Diastolic Pressure, Pulse Rate, and MAP values that are communicated to the Radius VSM Wearable Monitor for display and wireless communication.

4. Discussion of Similarities and Differences Between Primary Predicate and Subject Device

Similarities and Differences between Primary Predicate and Subject Device

The subject device, Radius VSM and Accessories, and the predicate device, Radius VSM and Accessories (K223498) have the following key similarities:

- Both devices have the same intended use.
- Both devices have the same principle of operation and mechanism of action.
- Both devices are indicated for the same patient population.

The subject device, Radius VSM and Accessories, and the predicate device, Radius VSM and Accessories (K223498), have the following key difference:

- The subject device includes the Mean Arterial Pressure (MAP) feature.

The purpose of this submission is the addition of a Mean Arterial Pressure (MAP) feature to the predicate device, Radius VSM (K223498). The subject and the predicate device have the same intended use. To support the addition of MAP feature does not raise different questions of safety and effectiveness, clinical testing is provided to support its performance. The testing supports the substantial equivalence of the subject device.

Refer to Table 4-1 below for the detailed comparison between the subject and predicate devices.

MASIMO CORPORATION
52 Discovery
Irvine, CA 92618

510(k) Summary
K250757

Table 4-1 Comparison between Subject and Predicate Devices			
Feature	**Subject Predicate**	**Predicate Device**	**Comparison to Predicate**
	Radius VSM	**Radius VSM (K223498)**	
Intended Use	The Radius VSM and accessories are intended to be used as both a wearable multi-parameter patient monitor and an accessory to a multi-parameter patient monitor that is intended for multi-parameter physiological patient monitoring in hospital and healthcare facilities.	The Radius VSM and accessories are intended to be used as both a wearable multi-parameter patient monitor and an accessory to a multi-parameter patient monitor that is intended for multi-parameter physiological patient monitoring in hospital and healthcare facilities.	Same.
Indications for Use	The Radius VSM and accessories are indicated for the monitoring of hemodynamic (including ECG, arrhythmia detection, non-invasive blood pressure, SpO2, Pulse Rate, PVi, heart rate, and temperature), and respiratory (e.g., impedance, acoustic, and pleth-based respiration rate) physiological parameters along with the orientation and activity of adults. The Radius VSM and accessories are indicated for the non-invasive continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and Pulse Rate (PR) of well or poorly perfused adults during both no motion and motion conditions. The Radius VSM and accessories are indicated for continuous monitoring of skin temperature of adults. The Radius VSM and accessories are indicated for monitoring of the orientation and activity of patients including those susceptible to pressure ulcers. The Radius VSM and accessories are indicated for the continuous non-invasive monitoring of PVi as a measure of relative variability of the photoplethysmograph (pleth) of adults during no motion conditions. PVi may be used as a noninvasive dynamic indicator of fluid responsiveness in select populations of mechanically ventilated adult patients. Accuracy of PVi in predicting fluid responsiveness is variable and influenced by numerous patient, procedure and device related factors. PVi measures the variation in the plethysmography amplitude but does not provide measurements of stroke volume or cardiac output. Fluid management decisions should be based on a complete assessment of the patient's condition and should not be based solely on PVi.	The Radius VSM and accessories are indicated for the monitoring of hemodynamic (including ECG, arrhythmia detection, non-invasive blood pressure, SpO2, Pulse Rate, PVi, heart rate, and temperature), and respiratory (e.g., impedance, acoustic, and pleth-based respiration rate) physiological parameters along with the orientation and activity of adults. The Radius VSM and accessories are indicated for the non-invasive continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and Pulse Rate (PR) of well or poorly perfused adults during both no motion and motion conditions. The Radius VSM and accessories are indicated for continuous monitoring of skin temperature of adults. The Radius VSM and accessories are indicated for monitoring of the orientation and activity of patients including those susceptible to pressure ulcers. The Radius VSM and accessories are indicated for the continuous non-invasive monitoring of PVi as a measure of relative variability of the photoplethysmograph (pleth) of adults during no motion conditions. PVi may be used as a noninvasive dynamic indicator of fluid responsiveness in select populations of mechanically ventilated adult patients. Accuracy of PVi in predicting fluid responsiveness is variable and influenced by numerous patient, procedure and device related factors. PVi measures the variation in the plethysmography amplitude but does not provide measurements of stroke volume or cardiac output. Fluid management decisions should be based on a complete assessment of the patient's condition and should not be based solely on PVi.	Same.

MASIMO CORPORATION
52 Discovery
Irvine, CA 92618

510(k) Summary
K250757

Table 4-1 Comparison between Subject and Predicate Devices			
Feature	**Subject Predicate** **Radius VSM**	**Predicate Device** **Radius VSM (K223498)**	**Comparison to Predicate**
	Devices with Masimo technology are only indicated for use with Masimo accessories. Radius VSM ECG Electrodes are disposable, single-patient ECG electrodes intended to acquire ECG signals from the surface of the body. They are indicated for use on adults for up to 3 days of skin surface contact. Radius VSM Blood Pressure Cuffs are accessories intended to be use with a noninvasive blood pressure measurement system to measure blood pressure. They are indicated for use on adults during no motion conditions.	Devices with Masimo technology are only indicated for use with Masimo accessories. Radius VSM ECG Electrodes are disposable, single-patient ECG electrodes intended to acquire ECG signals from the surface of the body. They are indicated for use on adults for up to 3 days of skin surface contact. Radius VSM Blood Pressure Cuffs are accessories intended to be use with a noninvasive blood pressure measurement system to measure blood pressure. They are indicated for use on adults during no motion conditions.	
Primary Classification Regulation/ Product Code	21 CFR 870.1025/ MHX	21 CFR 870.1025/ MHX	Same.
Additional Classification Regulation/ Product Code(s)	21 CFR 868.2375/ BZQ 21 CFR 870.2700/ DQA 21 CFR 870.2340/ DPS 21 CFR 870.2710/ DPZ 21 CFR 870.2300/ DRT 21 CFR 870.1100/ DSJ 21 CFR 870.1130/ DXN 21 CFR 880.2910/ FLL 21 CFR 870.1025/ DSI 21 CFR 870.1425/ DQK 21 CFR 880.2400/ KMI 21 CFR 870.1120/ DXQ	21 CFR 868.2375/ BZQ 21 CFR 870.2700/ DQA 21 CFR 870.2340/ DPS 21 CFR 870.2710/ DPZ 21 CFR 870.2300/ DRT 21 CFR 870.1100/ DSJ 21 CFR 870.1130/ DXN 21 CFR 880.2910/ FLL 21 CFR 870.1025/ DSI 21 CFR 870.1425/ DQK 21 CFR 880.2400/ KMI 21 CFR 870.1120/ DXQ	Same.
Pulse Oximetry Monitored Parameters/ Features	SpO2, PR, PVi, RRp	SpO2, PR, PVi, RRp	Same.
ECG Monitored Parameters/ Features	ECG waveform, Heart Rate, Impedance Respiration Rate, Arrhythmia Detection.	ECG waveform, Heart Rate, Impedance Respiration Rate, Arrhythmia Detection.	Same.

MASIMO CORPORATION
52 Discovery
Irvine, CA 92618

510(k) Summary
K250757

Table 4-1 Comparison between Subject and Predicate Devices			
Feature	**Subject Predicate** **Radius VSM**	**Predicate Device** **Radius VSM (K223498)**	**Comparison to Predicate**
NiBP Monitored Parameters/ Features	Systolic Pressure, Diastolic Pressure and Pulse Rate, Mean Arterial Pressure (MAP)	Systolic Pressure, Diastolic Pressure and Pulse Rate	Different. The subject device supports a Mean Arterial Pressure (MAP) feature. Clinical performance validation is provided to support the feature does not raise different questions of safety and effectiveness.
Thermometer Monitored Parameters/ Features	Temperature	Temperature	Same.
Acoustic Respiration Rate Monitored Parameters/ Features	RRa	RRa	Same.
Position/Orientation Monitored Parameters/ Features	Time in Position, Patient Incline Angle	Time in Position, Patient Incline Angle	Same.
Aggregate Respiration Rate	Yes	Yes	Same.
Indicated population	Adult	Adult	Same.
Type of display	LCD, Touchscreen	LCD, Touchscreen	Same.
Battery			
Internal Power	Rechargeable, Lithium ion	Rechargeable, Lithium ion	Same.
Alarms			
Notifications	Audible and visual	Audible and visual	Same.
Physical Characteristics			
Dimensions	10.9 cm x 5.8 cm x 2.1 cm	10.9 cm x 5.8 cm x 2.1 cm	Same.
Weight	0.27 lbs	0.27 lbs	Same.
Performance Specifications			
SpO2, No Motion Accuracy	1.5% Arms, 70-100%	1.5% Arms, 70-100%	Same.
SpO2, Motion Accuracy	1.5% Arms, 70-100%	1.5% Arms, 70-100%	Same.
SpO2, Low perfusion	2% Arms, 70-100%	2% Arms, 70-100%	Same.
PR, No motion	3 bpm, 25-240 bpm	3 bpm, 25-240 bpm	Same.
PR, Motion	5 bpm, 25-240 bpm	5 bpm, 25-240 bpm	Same.

MASIMO CORPORATION
52 Discovery
Irvine, CA 92618

510(k) Summary
K250757

Table 4-1 Comparison between Subject and Predicate Devices			
Feature	**Subject Predicate**	**Predicate Device**	**Comparison to Predicate**
	Radius VSM	**Radius VSM (K223498)**	
PR, Low Perfusion	5 bpm, 25-240 bpm	5 bpm, 25-240 bpm	Same.
RRa	1 rpm Arms, 4-70 rpm	1 rpm Arms, 4-70 rpm	Same.
RRp, No Motion	3 rpm Arms, 1 mean error, 4-70 rpm	3 rpm Arms, 1 mean error, 4-70 rpm	Same.
Heart Rate	≤1% or ≤2 bpm (whichever is greater)	≤1% or ≤2 bpm (whichever is greater)	Same.
Impedance Respiration Rate	≤1 rpm Arms, 4-120 rpm	≤1 rpm Arms, 4-120 rpm	Same.
Pressure Transducer (Between 0 mmHg and 300 mmHg)	±3 mmHg	±3 mmHg	Same.
NIBP Performance Standards	ANSI/AAMI SP10 and ISO 81060-2	ANSI/AAMI SP10 and ISO 81060-2	Same.
Temperature	±0.3°C,77°F to 109.4°F (25°C to 43°C)	±0.3°C,77°F to 109.4°F (25°C to 43°C)	Same.
Patient Incline Angle	-180° to 180°	-180° to 180°	Same.
Environmental Specifications			
Operating conditions			
Temperature	0º C to 40 º C	0º C to 40 º C	Same.
Humidity	10% to 95%, non-condensing	10% to 95%, non-condensing	Same.
Storage conditions			
Temperature	-20°C to 60°C	-20°C to 60°C	Same.
Humidity	10% to 95%, non-condensing	10% to 95%, non-condensing	Same.
ECG General			
Lead Configurations Supported	3	3	Same.
Pacemaker Pulse Rejection Capability	± 2 mV to ± 700 mV	± 2 mV to ± 700 mV	Same.
ECG Monitoring Bandwidth	0.67 Hz to 40 Hz	0.67 Hz to 40 Hz	Same.
ECG Diagnostic Bandwidth	0.05 Hz to 150 Hz	0.05 Hz to 150 Hz	Same.
Supported Arrhythmia Classifications	lethal and non-arrhythmia	lethal and non-arrhythmia	Same.

MASIMO CORPORATION
52 Discovery
Irvine, CA 92618

510(k) Summary
K250757

Table 4-1 Comparison between Subject and Predicate Devices			
Feature	**Subject Predicate** **Radius VSM**	**Predicate Device** **Radius VSM (K223498)**	**Comparison to Predicate**
Thermometer Validation Method	ISO 80601-2-56	ISO 80601-2-56	Same.
Thermometer Application Site(s)	Chest	Chest	Same.
Temperature Measurement Mode	Continuous	Continuous	Same.
NIBP Measurement Method	Oscillometric	Oscillometric	Same.
Sensor Technology	3-axis accelerometer 3-axis gyroscope	3-axis accelerometer 3-axis gyroscope	Same.
Mode of Operation per IEC 60601-1			
Mode of Operation	Continuous	Continuous	Same.

510(k) Summary
K250757

5. Performance Data

As part of this submission, clinical and non-clinical testing was included to support the addition of the Mean Arterial Pressure (MAP) Feature.

Performance Bench Testing

Bench testing was conducted to support the performance of the Mean Arterial Pressure (MAP) using a simulator.

Biocompatibility Testing

As there were no changes made to the patient contacting materials of the subject device from the previous clearance under K223498, no new biocompatibility testing was included in this submission.

Electromagnetic Compatibility, Electrical Safety, Environmental, Mechanical and Cleaning

As there were no hardware changes made to the subject device from the previous clearance under K223498, no new electrical safety, environmental, mechanical, and cleaning testing was included as part of this submission.

Software Verification and Validation Testing

Software verification and validation testing were conducted and provided as part of this submission as recommended by the FDA Guidance, *"Content of Premarket Submissions for Software Device Software Functions"*, June 2023 to support the software change to add the Mean Arterial Pressure (MAP) feature.

Wireless Testing

As there were no changes to the wireless capabilities from the previous clearance under K223498, no new wireless testing was included as part of this submission.

Cybersecurity Testing

As there were no changes made to the subject device that would affect its cybersecurity from the previous clearance under K223498, no new cybersecurity testing was included as part of this submission.

Human Factors and Usability Testing

Previous human factors testing of the predicate device were found to support the acceptable human factors and usability risk of the subject device.

Clinical Testing

Clinical study data was included as part of this submission to support the addition of the calculation of the mean arterial pressure (MAP) feature by Radius VSM. The clinical study used invasively measured MAP

values from a 510(k) cleared reference device (K171801) as a comparator in accordance with the FDA recognized standard ISO 81060-2.

The results of the testing supported the clinical performance of the MAP in accordance with ISO 81060-2.

6. Conclusion

The data provided as part of this submission was found to support the substantial equivalent of the subject device.