June 1, 2023

Masimo Corporation
Kertana Shankar
Regulatory Affairs Specialist III
52 Discovery
Irvine, California 92618

Re: K223498
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: April 28, 2023
Received: May 1, 2023

Dear Kertana Shankar:

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,

Aneesh S. Deoras -S

for

Jennifer Shih Kozen
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

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223498

Device Name
Radius VSM and Accessories

Indications for Use *(Describe)*
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 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.

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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MASIMO CORPORATION
52 Discovery
Irvine, CA 92618

510(k) Summary
K223498

Submitter and Address of Manufacturing Facility:	Masimo Corporation 52 Discovery Irvine, CA 92618 Phone: (949) 297-7000
Date:	June 1, 2023
Contact:	Kertana Shankar Senior Regulatory Affairs Specialist Masimo Corporation Phone: (949) 297-7260
Trade Name:	Radius VSM and Accessories
Common Name:	Patient Monitor (with Arrhythmia Detection)
Classification Regulation/ Product Code:	21 CFR 870.2300, Class II/ MHX
Additional Classification Regulation/ Product Codes:	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:	New Device
Primary Predicate:	K200494 – CARESCAPE ONE
Secondary Predicate:	K193242 – Masimo Radius-7 Pulse CO-Oximeter and Accessories
Tertiary Predicate:	K191882 – Masimo Centroid
Performance Standards	There are no performance standards pursuant to Section 514 of the Food, Drug and Cosmetic Act for the above device.

MASIMO CORPORATION
52 Discovery
Irvine, CA 92618

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1.0 Device Description

The Radius VSM and Accessories is a wearable, multi-modular patient monitoring platform that allows for the ability to scale and tailor the use of monitoring technologies based upon the hospital's and clinician's assessment of what technologies are appropriate. The purpose of this submission is the premarket notification for the introduction of Masimo Radius VSM and Accessories, including its use with the previously cleared Root (K191882) and Masimo Patient SafetyNet (K071047).

1.1 Supported Features

The subject device, Radius VSM, supports the following monitoring technologies:

1.1.1 Masimo SET Pulse Oximetry Optical Measurement Technology (e.g., SpO2, PR, RRp, PVi)

Radius VSM incorporates the Masimo SET Pulse Oximetry features (e.g., SpO2, PR, RRp, PVi) that are cleared as part of the secondary predicate, Radius-7 (K193242). The indications for the Pleth Variability Index (PVi) feature provided with the Masimo SET pulse oximetry technology is the same as it was cleared under K193626.

1.1.2 Masimo rainbow Acoustic Monitoring Technology (RRa)

Radius VSM incorporates Masimo rainbow Acoustic Monitoring technology, which provides the same RRa feature that is cleared as part of the secondary predicate, Radius-7 (K193242).

1.1.3 Electrocardiography Technology (e.g., Arrhythmia Detection, Heart Rate, Respiration Rate)

Radius VSM provides an optional ECG module that can be connected to the Radius VSM Wearable Monitor to allow the monitoring of electrocardiograph (ECG) waveforms, heart rate, respiration rate, and the detection of arrhythmias.

1.1.4 Noninvasive Blood Pressure Monitoring Technology (NiBP)

Radius VSM provides an optional Non-invasive Blood Pressure (NIBP) module that can be connected to the Radius VSM Wearable Monitor allowing the periodic monitoring Systolic and Diastolic blood pressure.

1.1.5 Noninvasive Continuous Temperature Monitoring Technology

Radius VSM provides an optional thermometer feature as part of the Radius VSM ECG Module, which can be connected to Radius VSM Wearable Monitor to allow the continuous monitoring of skin temperature.

1.1.6 Position Monitoring Technology

Radius VSM is provided with position monitoring capabilities as part of the Radius VSM ECG Module,

which provides the ability to continuously monitor a patient's orientation and activity. This position monitoring technology remains the same as the tertiary predicate Centroid cleared under K191882. This feature is intended to help support in the prevention of pressure ulcers and in identifying patient falls.

1.1.7 Aggregate Respiration Rate (RR)

The Radius VSM is provided with the Aggregate Respiration Rate feature that utilizes a proprietary algorithm to simplify the display of multiple respiration rate inputs (i.e., RRe, RRa, RRp) into a single respiration rate. This feature is intended to help minimize confusion related to the display of multiple respiration rates from different monitoring technologies.

1.2 System Components

The Radius VSM and Accessories system comprises of the Radius VSM Wearable Monitor, Radius VSM ECG Module and Electrodes, and the Radius VSM NiBP Module and Cuff.

1.2.1 Radius VSM Wearable Monitor

The Radius VSM Wearable Monitor acquires, displays, and provides the user interface for all the data received from the modular measurement technologies. The Radius VSM Wearable Monitor includes a touch screen display and supports wireless communication of the monitored data to a patient monitor (e.g., Root) or supplemental monitoring system (e.g., Patient SafetyNet). It includes a rechargeable battery that supplies power to the entire system. The Radius VSM Wearable Monitor is secured to the patient arm with a single patient use armband.

1.2.2 Radius VSM ECG Module and Radius VSM ECG Electrodes

The Radius VSM ECG Module is a reusable module that provides the monitoring of electrocardiograph (ECG) waveforms, detection of arrhythmias, heart rate, and respiration rate. The Radius VSM ECG Module connects the Radius VSM Wearable Monitor to the Radius VSM ECG Electrodes, which are disposable sensors applied to the patient's intact skin.

The Radius VSM ECG Module also incorporates the temperature sensor, accelerometer, and gyroscope, which supports temperature measurement and patient orientation/activity monitoring features.

1.2.3 Radius VSM NiBP Module and Radius VSM NiBP Cuff

The Radius VSM NiBP module is a reusable module that provides the noninvasive monitoring of Systolic and Diastolic blood pressure. The Radius VSM NiBP module connects the Radius VSM Wearable

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Monitor to the Radius VSM NiBP cuff, which are disposable and are applied to the patient's intact skin. The NiBP cuffs are available in multiple sizes to fit different arm sizes.

1.3 System Specifications

The specifications for Masimo Radius VSM Wearable Monitor are provided in Table 1.3-1 below:

Table 1.3-1 Radius VSM Wearable Monitor Specifications	
Feature	**Specification**
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	
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	IP24
Environmental	
Operating Temperature	0°C to 40°C (32°F to 104°F)
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

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The specifications for the Radius VSM ECG Module are provided in the Table 1.3-2 below:

Table 1.3-2 Radius VSM ECG Module Specifications	
Features	**Specification**
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)
Interfaces	
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	IP24
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)

The specifications for the Radius VSM NiBP Module are provided in the Table 1.3-3 below:

Table 1.3-3 Radius VSM NiBP Module Specifications	
Noninvasive Blood Pressure (NIBP)	**Specifications**
Technical Characteristics	
Measured Parameters	Systolic, Diastolic, Pulse Rate
Performance Specifications	
Pressure Transducer	±3 mmHg

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Table 1.3-3 Radius VSM NiBP Module Specifications	
Noninvasive Blood Pressure (NIBP)	**Specifications**
(Between 0 mmHg and 300 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	IP22
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)

2.0 Intended Use/ Indications For Use

The following is the proposed intended use/ indications for use for the Radius VSM and Accessories:

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.

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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 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.

3. Technological Characteristics

3.1 Principles of Operation

The Radius VSM and Accessories provide a wearable, multi-modular patient monitoring platform that allows for the ability to scale and tailor the use of monitoring technologies based upon the hospital's and clinician's assessment of what technologies are appropriate. The Radius VSM and Accessories rely on the principles of operation of the modular monitoring technologies to provide the monitoring performance.

The subsections below describe the principles of operation of the modular monitoring technologies that are supported by Radius VSM.

3.1.1 Masimo SET Pulse Oximetry Optical Measurement Technology (e.g., SpO2, PR, PVi, and RRp)

Radius VSM incorporates Masimo SET pulse oximetry, which is cleared as part of the secondary predicate, Radius-7 (K193242). There have been no changes to the principle of operation from the previous clearance.

Masimo SET pulse oximetry technology still relies on the Beer-Lambert law and the following principle of operation:

1. Oxyhemoglobin (oxygenated blood) and deoxyhemoglobin (non-oxygenated blood) differ in their absorption of red and infrared light (spectrophotometry).

2. The amount of arterial blood in tissue changes with your pulse (photoplethysmography). Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as well.

The Pleth Variability Index (PVi) feature provided along with the Masimo SET pulse oximetry technology is the same as it was cleared under K193626. The RRp feature provided along with the Masimo SET pulse oximetry technology is the same it was cleared under K193242.

3.1.2 Acoustic Respiration Rate Technology (RRa)

The Radius VSM incorporates Masimo rainbow Acoustic Monitoring technology, which provides the RRa feature that is cleared as part of the secondary predicate device, Radius-7 (K193242). There have been no changes to the principles of operation from the previous clearance.

3.1.3 Electrocardiography Technology (Arrhythmia Detection, Heart Rate, Respiration Rate)

The optional ECG module that can be connected to the Radius VSM Wearable Monitor, allows for the monitoring of the electrical activity associated with the heart to provide an electrocardiograph (ECG), detection of arrhythmias, heart rate, and respiration rate.

The feature relies on the principle that polarized electrical signals are generated as heart muscles contract to deliver blood through the different parts of the heart and these signals can be detected along the electrical axis at the skin surface. Based upon this principle, the electrical activity can be analyzed to determine normal sinus rhythm or abnormal heart rhythms (Arrhythmias). The Heart Rate feature relies on the same principle to detect the depolarization of the right and left ventricles that make up the heart rate.

The Respiration Rate feature provided by the ECG module relies on the principle that the expansion and contraction of the thoracic cavity as part of respiration cycle can be detected as changes in impedance at the skin surface.

The subject device also includes an “Arrhythmia Relearn” feature, which provides the same function as the “QRS Relearn” feature of the primary predicate device (K200494). Both features allow the system to reset and re-start the detection of Arrhythmias using newly captured ECG data.

3.1.4 Noninvasive Blood Pressure Technology (NiBP)

The optional Non-invasive Blood Pressure (NiBP) module that can be connected to Radius VSM Wearable Monitor allows for the monitoring of systolic and diastolic blood pressure. The blood pressure measurements are based on the oscillometric method, which relies on the principle that the amplitude of the cuff pressure changes can be used to determine arterial blood pressure.

3.1.5 Noninvasive Continuous Thermometer Technology

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The Radius VSM is provided with an optional thermometer feature that is included in the Radius VSM ECG Module. The thermometer is intended to provide the direct temperature measurement of the skin where the Radius VSM ECG Module is applied.

3.1.6 Position Monitoring Technology

The Radius VSM is provided with an optional orientation and activity monitoring technology that is cleared under K191882 as part of the tertiary predicate device, Centroid. There have been no changes to the principles of operation from its clearance. The orientation and activity monitoring still relies on the principle of operation that body rotation and activity can be tracked through an accelerometer and gyroscope by detecting relative displacements caused by changes in body position and movement.

3.2 Mechanism of Action for Achieving the Intended Effect

The subject device, Radius VSM, achieves its intended use through the configuration of the wearable system to add and remove different compatible modular technologies based on the clinician's assessment of what technologies are appropriate.

The Radius VSM Wearable Monitor, like the secondary predicate, (Radius-7, K193242), is the essential part of the wearable system that acquires, displays, and provides the user interface for all the data received from the modular measurement technologies. The Radius VSM Wearable Monitor, which is worn on either arm of the patient, also provides the rechargeable battery that supplies power to the entire wearable system and supports wireless communication of the monitored data to a patient monitor (e.g., Root) or supplemental monitoring system (e.g., Patient SafetyNet). The Radius VSM system is provided with optional Radius VSM ECG and NiBP modules that expand the monitoring capabilities to include ECG, NiBP, temperature, and patient orientation parameters.

To use the ECG features, the Radius VSM ECG module is connected via cable to Radius VSM Wearable Monitor, which establishes power and communication to the Radius VSM ECG module. The Radius VSM ECG Module is in turn connected to disposable ECG electrodes to provide the monitoring of the ECG features. The ECG electrodes are applied to the standard areas on the patient chest to detect the electrical potentials that are processed by the Radius VSM ECG module so that they can be displayed as ECG waveforms on the Radius VSM Wearable Monitor. The ECG data is further processed by the Radius VSM ECG module to determine the heart rate, respiration rate, and any detected arrhythmias, which are also displayed on the Radius VSM Wearable Monitor and optionally transmitted wirelessly to a secondary monitor (e.g., Root) or supplemental monitoring system (e.g., Patient SafetyNet). The Radius VSM ECG module also provides an integrated temperature sensor and accelerator/gyroscope that support the thermometer and orientation/activity features, respectively. The signals gathered from the respective sensors are processed by the Radius VSM ECG module to estimate the skin temperature and track the patient's orientation and activity status. The skin temperature and patient orientation/activity data is then communicated to the Radius VSM Wearable Monitor for display and wireless communication.

To use the NIBP features, the Radius VSM NIBP module is connected via cable to the Radius VSM Wearable Monitor. The Radius VSM NIBP module is in turn connected to the Radius VSM NIBP cuff to allow for the inflation, deflation, and pressure signal detection that is used by the Radius VSM NIBP

module to determine the Systolic, and Diastolic pressure. This data is then communicated to the Radius VSM Wearable Monitor for display and wireless communication to a secondary monitor (e.g., Root) or supplemental monitoring system (e.g., Patient SafetyNet).

4.0 Summary of Technological Characteristics of the subject device compared to the predicate device

Similarities and Differences between Primary Predicate and Subject Device

The subject device, Radius VSM, and the primary predicate device, CARESCAPE ONE (K200494), have the following key similarities:

- Both devices have the same intended use;
- Both devices support multi-parameter physiological monitoring of similar parameters;
- Both devices support the expansion of capabilities through communication to optional measurement modules;
- Both devices include Audible and Visual alarms;
- Both devices provide the ability to be used independently or to be used as accessory to another monitor;
- Both devices include rechargeable batteries.

The subject device, Radius VSM, and the primary predicate device, CARESCAPE ONE (K200494), have the following key differences:

- The subject device is wearable;
- The subject device is only indicated for adult population;
- The subject device provides position and activity monitoring;
- The subject device provides respiration rate monitoring using acoustic signals and the variations in the plethysmograph from an SpO2 sensor;
- The subject device includes the ability to continuously monitor skin temperature;
- The subject device includes a feature to aggregate the display of respiration rate from different technologies;

Between the subject and the primary predicate device, there is no difference in the intended use in the physiological monitoring of patients. However, the subject device also combines features from multiple predicates with the same intended use into a single device. The combination of the features does not change the intended use in physiological monitoring of patients. Additionally, the subject device has similar technological characteristics that do not raise different questions of safety and effectiveness from the predicates.

See Table 4-1 for the comparison between the subject and predicate device.

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Table 4-1 Comparison between Subject and Predicate Devices					
Feature	**Radius VSM, Subject Device**	**GE CARESCAPE ONE, Primary Predicate (K200494)**	**Masimo Radius-7, Secondary Predicate (K193242)**	**Masimo Centroid with Root, Tertiary Predicate (K191882)**	**Comparison to Predicate**
General Information					
Intended Use/ Indications for 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 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 CARESCAPE ONE is both a multi-parameter physiological patient monitor and an accessory to a multi-parameter patient monitor intended for use in multiple areas and intra-hospital transport within a professional healthcare facility. The CARESCAPE ONE is indicated for the monitoring of hemodynamic (including ECG, ST segment, arrhythmia detection, invasive pressure, non-invasive blood pressure, SpO2, pulse rate, and temperature), and respiratory (impedance respiration and CO2 airway gas) physiological parameters. The CARESCAPE ONE can	Masimo Radius-7 Wearable Pulse Oximeter and Accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), 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	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	The subject and primary predicate device have the same intended use; however, the subject device also includes features of the Secondary and Tertiary Predicates. There is a difference in the indications from the primary predicate because the subject device combines the features from a secondary and tertiary predicate that have the same intended use in physiological monitoring patients. The added features do not result in a different intended use for physiological monitoring.

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Table 4-1 Comparison between Subject and Predicate Devices					
Feature	**Radius VSM, Subject Device**	**GE CARESCAPE ONE, Primary Predicate (K200494)**	**Masimo Radius-7, Secondary Predicate (K193242)**	**Masimo Centroid with Root, Tertiary Predicate (K191882)**	**Comparison to Predicate**
	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	be used as a standalone monitor. In this mode of operation, the CARESCAPE ONE provides ECG, ST segment, arrhythmia detection, invasive pressure, non-invasive blood pressure, SpO2, pulse rate, temperature, impedance respiration, and CO2 airway gas parameter acquisition and monitoring. The CARESCAPE ONE can be connected as an accessory to a compatible CARESCAPE monitor. In this mode of operation, the CARESCAPE ONE provides ECG, ST segment, arrhythmia detection, invasive pressure, non-invasive blood pressure, SpO2, pulse rate, temperature, impedance respiration, and CO2 airway gas parameter	hospitals, and hospital-type facilities.	hospitals, hospital-type facilities, and healthcare facilities. The Centroid System is also indicated for the measurement of respiration rate of adults in healthcare environments.	

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Table 4-1 Comparison between Subject and Predicate Devices					
Feature	**Radius VSM, Subject Device**	**GE CARESCAPE ONE, Primary Predicate (K200494)**	**Masimo Radius-7, Secondary Predicate (K193242)**	**Masimo Centroid with Root, Tertiary Predicate (K191882)**	**Comparison to Predicate**
	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.	acquisition. Visual and audible alarms, user controls, and user interface on the CARESCAPE ONE are not active in this mode. The CARESCAPE ONE is indicated for use on adult, pediatric, and neonatal patients and on one patient at a time. The CARESCAPE ONE is indicated for use under the direct supervision of a licensed healthcare practitioner, or by personnel trained in the proper use of the equipment in a professional healthcare facility. Contraindications for using CARESCAPE ONE: The			

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Table 4-1 Comparison between Subject and Predicate Devices					
Feature	**Radius VSM, Subject Device**	**GE CARESCAPE ONE, Primary Predicate (K200494)**	**Masimo Radius-7, Secondary Predicate (K193242)**	**Masimo Centroid with Root, Tertiary Predicate (K191882)**	**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.	CARESCAPE ONE is not intended for use within a controlled MR environment.			
Primary Classification Regulation/ Product Code	21 CFR 870.1025/ MHX	21 CFR 870.1025/ MHX	21 CFR 870.2700/ DQA	21 CFR 870.2300/ MWI	Same as primary predicate. The subject device and primary predicate

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Table 4-1 Comparison between Subject and Predicate Devices					
Feature	**Radius VSM, Subject Device**	**GE CARESCAPE ONE, Primary Predicate (K200494)**	**Masimo Radius-7, Secondary Predicate (K193242)**	**Masimo Centroid with Root, Tertiary Predicate (K191882)**	**Comparison to Predicate**
					classification codes is for a physiological monitor which is inclusive of the combined features of the Primary, Secondary, and Tertiary Predicates.
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 868.1400/ CCK 21 CFR 870.1025/ MLD	21 CFR 868.2375/ BZQ 21 CFR 870.2710/ DPZ 21 CFR 862.3200/ JKS	21 CFR 880.2400/ KMI 21 CFR 868.2375/ BZQ	Similar to primary predicate. The subject device supports similar features as the Primary Predicate and combines the features of the Secondary and Tertiary Predicates. The added features do not result in a different intended use for physiological monitoring.
Monitored Parameters/ Features	Pulse Oximetry: SpO2, PR, PVi, RRp ECG: ECG waveform, Heart Rate, Impedance Respiration Rate, Arrhythmia Detection.	Pulse Oximetry: SpO2, PR, PVi ECG: ECG waveform, Heart Rate, Impedance Respiration	Pulse Oximetry: SpO2, PR, PVi, RRp, SpHb, SpCO, SpMet Acoustic Respiration Rate: RRa	Time in Position, Patient Incline Angle, Respiration Rate	The subject device supports similar parameters as the Primary Predicate, with an addition of position monitoring capability and respiration rate monitoring

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Table 4-1 Comparison between Subject and Predicate Devices					
Feature	**Radius VSM, Subject Device**	**GE CARESCAPE ONE, Primary Predicate (K200494)**	**Masimo Radius-7, Secondary Predicate (K193242)**	**Masimo Centroid with Root, Tertiary Predicate (K191882)**	**Comparison to Predicate**
	NiBP: Systolic Pressure, Diastolic Pressure and Pulse Rate Thermometer: Temperature Acoustic Respiration Rate: RRa Position/Orientation: Time in Position, Patient Incline Angle	Rate, Arrhythmia Detection, ST segment NiBP: Systolic, Diastolic, Mean Arterial Pressure, and Pulse Rate Thermometer: Temperature Blood Pressure: Invasive pressure Capnography: CO2 gas parameter acquisition			through acoustic signals and the plethysmograph (RRa and RRp).
Aggregate Respiration Rate	Yes	No	No	No	Different. The Primary and Secondary Predicates also provide respiration rate monitoring from multiple technologies; however, the subject device introduces a way to simplify the respiration rate display.

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Table 4-1 Comparison between Subject and Predicate Devices					
Feature	**Radius VSM, Subject Device**	**GE CARESCAPE ONE, Primary Predicate (K200494)**	**Masimo Radius-7, Secondary Predicate (K193242)**	**Masimo Centroid with Root, Tertiary Predicate (K191882)**	**Comparison to Predicate**
					Clinical performance validation is provided to support the feature.
Indicated population	Adult	Adult, Pediatric, Neonate	Adult, Pediatric, Neonate	Adult	Subject device is indicated for a subset of populations supported by the Primary Predicate.
Type of display	LCD, Touchscreen	LCD, Touchscreen	LCD, Touchscreen	LCD, Touchscreen (Connected Patient Monitor)	Same as primary predicate.
Battery					
Internal Power	Rechargeable, Lithium ion	Rechargeable, Lithium ion	Rechargeable, Lithium ion	Coin cell	Same as primary predicate.
Alarms					
Notifications	Audible and visual	Audible and Visual	Audible and Visual	Audible and Visual	Same.
Dimensions	10.9 cm x 5.8 cm x 2.1 cm	15.5 cm x 27.0 cm x 6.5 cm	10.9 cm x 5.8 cm x 2.1 cm	12.7 cm x 12.7 cm x 1.3 cm	Different. Subject device is wearable like the Secondary Predicate, while the Primary Predicate is transportable and not wearable.
Weight	0.27 lbs	4 lbs	0.27 lbs	0.07 lbs	Different from the Primary Predicate but the same as the Secondary Predicate.

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Table 4-1 Comparison between Subject and Predicate Devices					
Feature	**Radius VSM, Subject Device**	**GE CARESCAPE ONE, Primary Predicate (K200494)**	**Masimo Radius-7, Secondary Predicate (K193242)**	**Masimo Centroid with Root, Tertiary Predicate (K191882)**	**Comparison to Predicate**
					Subject device is lighter than the Primary Predicate.
SpO2, No Motion Accuracy	1.5% Arms, 70-100%	2% Arms, 70-100%	1.5% Arms, 70-100%	-	Different from the Primary Predicate but the same as the Secondary Predicate.
SpO2, Motion Accuracy	1.5% Arms, 70-100%	3% Arms, 70-100%	1.5% Arms, 70-100%	-	Different from the Primary Predicate but the same as the Secondary Predicate.
SpO2, Low perfusion	2% Arms, 70-100%	2% Arms, 70-100%	2% Arms, 70-100%	-	Same as primary predicate.
PR, No motion	3 bpm, 25-240 bpm	3 bpm, 25-240 bpm	3 bpm, 25-240 bpm	-	Same as primary predicate.
PR, Motion	5 bpm, 25-240 bpm	5 bpm, 25-240 bpm	5 bpm, 25-240 bpm	-	Same as primary predicate.
PR, Low Perfusion	5 bpm, 25-240 bpm	5 bpm, 25-240 bpm	5 bpm, 25-240 bpm	-	Same as primary predicate.
RRa	1 rpm Arms, 4-70 rpm	-	1 rpm Arms, 4-70 rpm	-	Different from the Primary Predicate but the same as the Secondary Predicate.
RRp, No Motion	3 rpm Arms, 1 mean error, 4-70 rpm	-	3 rpm Arms, 1 mean error, 4-70 rpm	-	Different from the Primary Predicate but the same as the Secondary Predicate.
Heart Rate	≤1% or ≤2 bpm (whichever is greater)	±1% or ±1bpm	-	-	Different from the Primary Predicate, but both the Subject and Primary Predicate devices meet the

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Table 4-1 Comparison between Subject and Predicate Devices					
Feature	**Radius VSM, Subject Device**	**GE CARESCAPE ONE, Primary Predicate (K200494)**	**Masimo Radius-7, Secondary Predicate (K193242)**	**Masimo Centroid with Root, Tertiary Predicate (K191882)**	**Comparison to Predicate**
					requirements of IEC 60601-2-27.
Impedance Respiration Rate	≤1 rpm Arms, 4-120 rpm	±1 rpm, 0 to 120 rpm,	-	-	Similar to Primary Predicate.
Pressure Transducer (Between 0 mmHg and 300 mmHg)	3 mmHg	5 mmHg	-	-	Different. Subject device has a tighter pressure transducer specification as compared to the Primary Predicate.
NIBP Systolic and Diastolic Performance	ANSI/AAMI SP10 and ISO 81060-2	ANSI/AAMI SP10 and ISO 81060-2	-	-	Same as Primary Predicate.
Temperature	±0.3°C,77°F to 109.4°F (25°C to 43°C)	±0.3°C (±0.5°F), 77°F to 109.4°F (25°C to 43°C)	-	-	Same as Primary Predicate.
Patient Incline Angle	-180° to 180°	-	-	-180° to 180°	Different from the Primary Predicate but the same as the Tertiary Predicate.
Environmental Specifications					
Operating conditions					
Temperature	0º C to 40 º C	0º C to 35 º C	0º C to 40 º C	10º C to 40º C	Similar to Primary Predicate but the same as the Secondary Predicate.
Humidity	10% to 95%, non-condensing	5% to 95%, non-condensing	10% to 95%, non-condensing	15% to 90%, non-condensing	Similar to Primary Predicate but the same as the

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Table 4-1 Comparison between Subject and Predicate Devices					
Feature	**Radius VSM, Subject Device**	**GE CARESCAPE ONE, Primary Predicate (K200494)**	**Masimo Radius-7, Secondary Predicate (K193242)**	**Masimo Centroid with Root, Tertiary Predicate (K191882)**	**Comparison to Predicate**
					Secondary Predicate.
Storage conditions					
Temperature	-20°C to 60°C	-30°C to 70°C	-20°C to 60°C	-20°C to 50°C	Similar to Primary Predicate and the same as the Secondary Predicate.
Humidity	10% to 95%, non-condensing	5% to 95%, non-condensing	10% to 95%, non-condensing	15% to 95%, non-condensing	Similar to Primary Predicate and the same as the Secondary Predicate.
ECG General					
Lead Configurations Supported	3	3-,5-,6-, and 10	-	-	Similar to Primary Predicate. Subject and Primary Predicate devices both support a 3 lead ECG configuration.
Pacemaker Pulse Rejection Capability	± 2 mV to ± 700 mV	± 2 mV to ± 700 mV	-	-	Same as Primary Predicate.
ECG Monitoring Bandwidth	0.67 Hz to 40 Hz	0.05 to 32 Hz	-	-	Similar to Primary Predicate. Subject device has wider range, but higher low frequency range.
ECG Diagnostic Bandwidth	0.05 Hz to 150 Hz	0.05 Hz to 150 Hz	-	-	Same as Primary Predicate.

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Table 4-1 Comparison between Subject and Predicate Devices					
Feature	**Radius VSM, Subject Device**	**GE CARESCAPE ONE, Primary Predicate (K200494)**	**Masimo Radius-7, Secondary Predicate (K193242)**	**Masimo Centroid with Root, Tertiary Predicate (K191882)**	**Comparison to Predicate**
Supported Arrhythmia Classifications	lethal and non-arrhythmia	lethal and non-arrhythmia	-	-	Similar to Primary Predicate. Subject device supports subset of arrhythmias.
Thermometer Validation Method	ISO 80601-2-56	ISO 80601-2-56	-	-	Same as Primary Predicate.
Thermometer Application Site(s)	Chest	Sublingual, Axial, Rectal	-	-	Different. Subject device is applied to the skin without the need of a probe, unlike the Primary Predicate. Testing is provided to support the application site.
Temperature Measurement Mode	Continuous	Spot-check	-	-	Different. Subject device provides continuous temperature measurements. Testing is provided to support the difference.
Measurement Method	Oscillometric	Oscillometric	-	-	Same as Primary Predicate.
Sensor Technology	3-axis accelerometer 3-axis gyroscope	-	-	3-axis accelerometer 3-axis gyroscope	Same as the Tertiary Predicate. Primary Predicate does not include the feature.

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Table 4-1 Comparison between Subject and Predicate Devices					
Feature	**Radius VSM, Subject Device**	**GE CARESCAPE ONE, Primary Predicate (K200494)**	**Masimo Radius-7, Secondary Predicate (K193242)**	**Masimo Centroid with Root, Tertiary Predicate (K191882)**	**Comparison to Predicate**
Mode of Operation per IEC 60601-1					
Mode of Operation	Continuous	Continuous	Continuous	Continuous	Same.

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5.0 Performance Data

Bench Testing

Performance bench testing for the Radius VSM is included in this submission to support the substantial equivalence of the subject device to the predicate device.

Biocompatibility Testing

The patient contacting materials of the Radius VSM system were tested to be biocompatible in accordance with ISO 10993.

Electromagnetic Compatibility, Electrical Safety, Environmental, Mechanical and Cleaning

Electromagnetic compatibility testing was conducted in accordance with IEC 60601-1-2 and electrical safety in accordance with IEC 60601-1 standard. The environmental, mechanical, cleaning, and chemical resistance testing has also been provided to support the substantial equivalence of the Radius VSM system.

Software Verification and Validation Testing

Masimo has established, implemented, and maintains procedures for software design, development, review, verification, and validation of its products in accordance with FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005).

The software for the subject device, Radius VSM, was considered as a "Major" level of concern, because a failure or latent flaw in the software could directly result in death or serious injury of the patient. The testing was found to support the substantial equivalence of the subject device.

Wireless Testing

Radius VSM uses wireless radio that allows the communication of monitored data to a secondary monitor (e.g., Root) or supplemental monitoring system (e.g., Patient SafetyNet). Wireless testing for the subject device, Radius VSM, was performed in accordance with FDA Guidance[1].

The wireless testing also considered the ability to maintain the minimum Quality of Service (QoS) in the presence of in-band interferes in addition to a risk-based assessment to support the adequacy of the electromagnetic` testing conducted. The testing supports the acceptability of the wireless capabilities of the subject device.

Guidance for Industry and FDA Staff – Radio-Frequency Wireless Technology in Medical Devices, dated August 14, 2013.

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Cybersecurity Testing

Cybersecurity documentation is included in this submission in accordance with the FDA Guidance[2]. The cybersecurity of Radius VSM was implemented using a risk-based approach which included the STRIDE threat model for identifying cybersecurity risks and the implementation of appropriate risk controls. In accordance with the guidance, the cybersecurity for the Radius VSM considered design aspects as well as mitigations to ensure processes were in place to maintain the cybersecurity of the Radius VSM while under Masimo control and to address any post-market security concerns.

Human Factors and Usability Testing

To support the usability of Radius VSM, human factors and usability risks were evaluated and mitigated to acceptable levels in accordance with the FDA Guidance, *Applying Human Factors and Usability Engineering to Medical Devices, February 3, 2016*. The HFE/UE testing included a risk-based approach, which took into account the expected intended clinical use of the Radius VSM and analyzed the tasks to determine those that were user related. The user related tasks were then categorized based upon risk to establish critical user tasks. Knowledge Task Assessment and Simulate Use testing was conducted to assess the completion of the critical user tasks and that the use of the device did not result in any unacceptable human factors and usability risks. The testing was found to support the acceptability of the human factors and usability risks.

Non-clinical Testing

Non-clinical bench testing is included with this submission to support the performance of Radius VSM and to ensure that the specifications of the subject device were met.

The following non-clinical testing was performed:

- 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
- Performance testing per ISO 80601-2-61, IEC 60601-2-27, ISO 80601-2-30, ISO 80601-2-56,

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 IEC 80601-2-49

The following are the list of standards that were used as part of the evaluation:

- ANSI/AAMI EC 12:2000/2015
- ANSI/AAMI EC 57:2012
- IEC 60601-1:2005/2012
- IEC 60601-1-2:2014
- IEC 60601-1-6:2013
- IEC 60601-1-8:2012
- IEC 60601-1-11:2015
- IEC 60601-2-27:2011
- IEC 80601-2-30:2018
- IEC 80601-2-49:2018
- ISO 80601-2-56:2017
- ISO 80601-2-61:2017
- ISO 10993-1:2018
- IEC 62304:2015
- IEC 62366-1:2015

The testing was found to support there the subject device does not raise different questions of safety and effectiveness from that of the predicate devices.

Clinical Testing

To support the clinical performance and substantial equivalence of the subject device, clinical data from five clinical studies have been provided as part of this submission.

One study was conducted to validate the clinical performance of the NiBP feature of Radius VSM in accordance with ISO 81060-2:2018 on 89 subjects. The clinical performance of the NiBP feature was validated through the comparison of the blood pressure outputs obtained from Radius VSM against the reference blood pressure measurements.

The clinical performance analysis for the NiBP feature supported the subject device met the acceptance criteria for mean difference and standard deviation:

Parameter	Value (mmHg)	Acceptance Criteria	Pass/Fail
Mean value of the differences ($\bar{x}_n$)	Systolic: -1.23 Diastolic: -2.67	$\lvert\bar{x}_n\rvert \leq 5$ mmHg	Pass
Standard deviation of differences (s_n),	Systolic: 7.32 Diastolic: 7.13	$s_n \leq 8$mmHg	Pass

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Parameter	Value (mmHg)	Acceptance Criteria	Pass/Fail
Standard deviation of differences per subject (s_m)	Systolic: 6.17 Diastolic: 6.26	Systolic: ≤ 6.82 mmHg Diastolic: ≤ 6.39 mmHg	Pass

The results of the testing were found to meet the acceptance criteria and support clinical performance of Radius VSM in accordance with ISO 81060-2:2018.

A second study was conducted to compare the ECG waveform from the subject device with an FDA cleared ECG monitor and electrodes on 31 subjects. The results of the study supported the equivalence of the subject device and the reference FDA cleared device in the detection of the ECG signals.

A third study was conducted to evaluate the performance of the patient posture, position, and activity feature provided by the Radius VSM on 20 subjects. The testing was conducted to support the correct integration of the algorithm that was previously cleared under K191882.

A fourth study was conducted to validate the performance of the aggregate respiration rate feature provided by the subject device using 48 subjects. The Aggregate Respiration Rate was compared to a reference respiration rate derived from manual annotated capnography data. The testing supported the performance of the Aggregate Respiration Rate.

A fifth study was conducted to evaluate the Aggregate Respiration Rate feature integrated as part of the final finished form of the Radius VSM system on healthy volunteer subjects. The Aggregate Respiration Rate was compared to a reference respiration rate derived from manual annotated capnography data. The testing supported the correct integration of the Aggregate Respiration Rate feature on the Radius VSM.

6.0 Conclusion

The data provided as part of this submission was found to support the Radius VSM and Accessories are substantially equivalent to the predicate devices.