August 11, 2023

GE Medical Systems Information Technologies, Inc.
Joel Kent
Director, Regulatory Affairs Strategy
9900 Innovation Drive
Wauwatosa, Wisconsin 53226

Re: K230626
Trade/Device Name: Portrait™ Central Viewer Application (Portrait CV A01), Portrait ™ Core Services (Portrait CSS01), Portrait™ Clinical Alarming Unit (Portrait CAU01); Portrait™ Mobile Patient Monitor (Portrait HUB01), Portrait™ Sensor Battery (Portrait SBT01), Portrait™ Bedside Charger (Portrait BCH01); Portrait™ Wearable Pulse Oximetry Sensor (Portrait SpO2 P-SA01, Portrait SpO2 P-SP01, Portrait SpO2 P-W01 and Portrait SpO2 P-SE01); Portrait™ SpO2 Attachment Accessory Band (Portrait AAB01), Portrait™ Mobile Patient Monitor Pouch (Portrait MMP01); Portrait™ Wearable Respiration Rate Sensor (Portrait RR P-RR01), Portrait™ RR Electrode Patch (Portrait RRP01)
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, MSX, DRG, BZQ, DQA
Dated: March 6, 2023
Received: March 7, 2023

Dear Joel Kent:

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,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

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

510(k) Number *(if known)*
K230626

Device Name
Portrait Mobile Monitoring Solution

Indications for Use *(Describe)*

Portrait Mobile Monitoring Solution:

The Portrait Mobile Monitoring Solution is intended to acquire, store, calculate, display and export patient monitoring data as well as provide real time alarming for monitoring adult and pediatric patients (3 years of age and older, and weighing more than 10 kg).
Physiological parameters and waveforms supported are:
• Pulse oximetry (SpO2/pulse rate)
• Respiration rate (RR)
Continuous pulse oximetry and respiration rate monitoring may be used for patients at risk of cardiorespiratory and infectious complications.
The Portrait Mobile Monitoring Solution is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.
This device is not an Apnea monitor (i.e., do not rely on the device for detection or alarm for the cessation of breathing).
This device should not be used for life sustaining/supporting purposes.
The Portrait Mobile Monitoring Solution is not intended for use in a controlled Magnetic Resonance (MR) environment.

Portrait Central Viewer Application (Portrait CVA01):

The Portrait Central Viewer Application (Portrait CVA01) provides monitoring station capability running as an application for the Portrait Mobile Monitoring Solution on a PC platform that meets minimum system requirements. It provides the ability to view real-time data for multiple patients and historical data for a single patient including configurable visual and audible alarm notifications.

The Portrait Central Viewer Application is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

Portrait Core Services (Portrait CSS01):

The Portrait Core Services are a set of software services that enable the communication and interaction of the Portrait Monitoring Solution components and will integrate into existing healthcare facility infrastructure and clinical information systems. The Portrait Core Services can transmit patient physiological trends and numerics (IHE PCD DEC) and alarm events (IHE PCD ACM) outbound. The Portrait Core Services can also receive HL7 ADT information to admit patients to the Portrait Monitoring Solution.

Portrait Clinical Alarming Unit (Portrait CAU01):

The Portrait Clinical Alarming Unit (Portrait CAU01) is a required accessory to the Portrait Central Viewer Application that provides audio alarming capability.

The Portrait Clinical Alarming Unit is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

Portrait Mobile Patient Monitor (Portrait HUB01):

The Portrait Mobile Patient Monitor (Portrait HUB01) is intended for use with adult and pediatric patients (3 years of age and older, and weighing more than 10 kg) for continuous monitoring of oxygen saturation (SpO2), pulse rate (PR) and respiration rate (RR) parameters. The Portrait Mobile Patient Monitor enables non-invasive continuous monitoring of patients by acquiring signals from body-worn sensors through a Medical Body Area Network (MBAN) connection as well as displaying trends and events. The device can be configured to provide local audible and visual alarms and can also provide real-time, trend and event data to Portrait Core Services.

The Portrait Mobile Patient Monitor is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

The Portrait Mobile Patient Monitor is not intended for use in a controlled Magnetic Resonance (MR) environment.

Portrait Wearable Pulse Oximetry Sensor P-SA01 (Portrait SpO2 P-SA01):

The Portrait Wearable Pulse Oximetry Sensor (Portrait SpO2 P-SA01) is intended for use with adult and pediatric patients (3 years of age and older, and weighing more than 30 kg) for continuous physiologic monitoring of oxygen saturation (SpO2) and pulse rate (PR) parameters. The Wearable Pulse Oximetry Sensor acquires parameter data from the patient and transmit it to the sensor battery for communication to a host device through the Medical Body Area Network (MBAN) connection.

The Portrait Wearable Pulse Oximetry Sensor is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

The Portrait Wearable Pulse Oximetry Sensor is not intended for use in a controlled Magnetic Resonance (MR) environment.

Portrait Wearable Pulse Oximetry Sensor (Portrait SpO2 P-SP01):

The Portrait Wearable Pulse Oximetry Sensor (Portrait SpO2 P-SP01) is intended for use with pediatric patients (3 years of age and older, and weighing 15 kg to 30 kg) for continuous physiologic monitoring of oxygen saturation (SpO2) and pulse rate (PR) parameters. The Wearable Pulse Oximetry Sensor acquires parameter data from the patient and transmit it to the sensor battery for communication to a host device through the Medical Body Area Network (MBAN) connection.

The Portrait Wearable Pulse Oximetry Sensor is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

The Portrait Wearable Pulse Oximetry Sensor is not intended for use in a controlled Magnetic Resonance (MR) environment.

Portrait Wearable Pulse Oximetry Sensor (Portrait SpO2 P-W01, Portrait SpO2 P-SE01):

The Portrait Wearable Pulse Oximetry Sensor (Portrait SpO2 P-SE01, Portrait SpO2 P-W01) is intended for use with adult and pediatric patients (3 years of age and older, and weighing more than 10 kg) for continuous physiologic monitoring of oxygen saturation (SpO2) and pulse rate (PR) parameters. The Wearable Pulse Oximetry Sensor acquires parameter data from the patient and transmit it to the sensor battery for communication to a host device through the Medical Body Area Network (MBAN) connection.

The Portrait Wearable Pulse Oximetry Sensor is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

The Portrait Wearable Pulse Oximetry Sensor is not intended for use in a controlled Magnetic Resonance (MR) environment.

Portrait SpO2 Attachment Accessory Band (Portrait AAB01):

The Portrait SpO2 Attachment Accessory Band (Portrait AAB01) is intended to provide a means to secure the Portrait Wearable Pulse Oximetry Sensor with Portrait Sensor Battery to the patient's wrist.

The Portrait Attachment Accessory Band is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

Portrait Wearable Respiration Rate Sensor (Portrait RR P-RR01):

The Portrait Wearable Respiration Rate Sensor (Portrait P-RR01) is intended for use with adult and pediatric patients (3 years of age and older, and weighing more than 10 kg) for continuous physiologic monitoring of respiration rate (RR) parameter. The Wearable Respiration Rate Sensor acquires parameter data from the patient and transmits it to the sensor battery for communication to a host device through the Medical Body Area Network (MBAN) connection.

The Portrait Wearable Respiration Rate Sensor is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

The Portrait Wearable Respiration Rate Sensor is not intended for use in a controlled Magnetic Resonance (MR) environment.

Portrait RR Electrode Patch (Portrait RRP01):

The Portrait RR Electrode Patch (Portrait RRP01) is intended for use with adult and pediatric patients (3 years of age and older, and weighing more than 10 kg) for continuous physiologic monitoring of respiration rate (RR) parameter. The electrode patch transfers carrier signals from the wearable respiration rate sensor and transfers impedance and biopotential signals from the patient and transmits them to the wearable respiration rate sensor.

The Portrait RR Electrode Patch is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

The Portrait RR Electrode Patch is not intended for use in a controlled Magnetic Resonance (MR) environment.

Portrait Sensor Battery (Portrait SBT01):

The Portrait Sensor Battery (Portrait SBT01) is intended for use as a power supply for the Portrait wearable sensors and to provide wireless communication to a host device.

The Portrait Sensor Battery is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

The Portrait Sensor Battery is not intended for use in a controlled Magnetic Resonance (MR) environment.

Portrait Bedside Charger (Portrait BCH01):

The Portrait Bedside Charger (Portrait BCH01) is intended for charging the Portrait Sensor Batteries and the Portrait Mobile Patient Monitor (including while the Portrait Mobile Patient Monitor is in use).

The Portrait Bedside Charger is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

The Portrait Bedside Charger is not intended for use in a controlled Magnetic Resonance (MR) environment.

Portrait Mobile Patient Monitor Pouch (Portrait MMP01):

The Portrait Mobile Patient Monitor Pouch (Portrait MMP01) is an optional accessory intended to enable the Mobile Patient Monitor to be carried while the patient is ambulatory.

The Portrait Mobile Patient Monitor pouch is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

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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GE Medical Systems Information
Technologies, Inc.
9900 Innovation Drive
Wauwatosa, WI 53226, USA

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Owner/Contact/Date (807.92(a)(1)):

Date: August 11, 2023

Owner/Submitter: GE Medical Systems Information Technologies, Inc.
9900 Innovation Drive
Wauwatosa, WI 53226, USA

Primary Contact Person: Joel Kent
Director, Regulatory Affairs Strategy
GE HealthCare, Patient Care Solutions
Phone: 617-851-0943
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Secondary Contact Person: William Jung
Regulatory Affairs Director
GE HealthCare, Monitoring Solutions
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Device names (807.92(a)(2)):

Trade Name: Portrait Mobile Monitoring Solution consists of the following:
Portrait™ Central Viewer Application (Portrait CVA01)
Portrait™ Core Services (Portrait CSS01)
Portrait™ Clinical Alarming Unit (Portrait CAU01)
Portrait™ Mobile Patient Monitor (Portrait HUB01)
Portrait™ Sensor Battery (Portrait SBT01)
Portrait™ Bedside Charger (Portrait BCH01)
Portrait™ Wearable Pulse Oximetry Sensor (Portrait SpO2 P-SA01, Portrait SpO2 P-SP01, Portrait SpO2 P-W01 and Portrait SpO2 P-SE01)
Portrait™ SpO2 Attachment Accessory Band (Portrait AAB01)
Portrait™ Mobile Patient Monitor Pouch (Portrait MMP01)
Portrait™ Wearable Respiration Rate Sensor (Portrait RR P-RR01)
Portrait™ RR Electrode Patch (Portrait RRP01)

Common/Usual Name: Multiparameter patient monitor (Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms))

Classification Names: 21 CFR 870.2300 Cardiac monitor (including cardiotachometer and rate alarm
21 CFR 870.2910 Radiofrequency physiological signal transmitter and receiver
21 CFR 868.2375 monitor, breathing frequency
21 CFR 870.2700 oximeter

Product Code: MWI

Subsequent Product Codes: MSX
DRG
BZQ
DQA

Predicate Device(s) (807.92(a)(3)):	The primary predicate for this submission is K171121 Masimo Root Monitoring System Additional reference devices: K180472, Sotera Wireless ViSi Mobile Monitoring System K213234, CARESCAPE ONE

Device Description (807.92(a)(4)):

The Portrait Mobile Monitoring Solution is a new wireless monitoring system for monitoring SpO2, pulse rate and respiration rate of adult and pediatric patients. The system can be used for monitoring adult and pediatric patients (3 years of age and older, and weighing more than 10 kg) within a hospital or healthcare facility. The system acquires, stores, calculates, displays, and exports patient physiological parameter data, alarms, and information. It supports pulse oximetry (SpO2/pulse rate) and respiration rate parameters. Measurement values are displayed as graphic or numeric values, like waveforms and numbers, and when applicable, also as alarm messages. This device is not an Apnea monitor (i.e., do not to rely on the device for detection or alarm for the cessation of breathing). This device should not be used for life sustaining/supporting purposes. Do not attempt to use this device to detect sleep apnea.

The Portrait Mobile Monitoring Solution consists of the following general categories of medical devices:

Central Monitoring Devices:

- Portrait Core Services hosted on the GE HealthCare non-medical device Edison Health Link platform. Portrait Core Services is a set of software services that enable the communication and interaction of the system components and are capable of integrating into existing healthcare facility infrastructure and clinical information systems.

- Portrait Central Viewer Application software hosted on a Windows off-the-shelf computer. Portrait Central Viewer Application provides the ability to view patient real-time and historical data, capable of displaying data from multiple patients.

- Portrait Clinical Alarming Unit provides audible alarms at each Central Viewer.

Mobile Monitoring Devices:

- Portrait Mobile Patient Monitor, a battery-powered, wireless, hand-held patient monitor. The Portrait Mobile Patient Monitor is a completely wireless, hand-held device that is capable of acting as a standalone patient monitor

including alarming, with a 3.7-inch capacitive touchscreen capable of displaying numeric data and waveforms for SpO2, Pulse Rate (PR), and Respiration Rate (RR).

- Portrait Wearable SpO2 sensors for acquiring SpO2 and pulse rate data from a patient wirelessly.

- Portrait Wearable Respiration Rate sensor and Portrait RR electrode patch for acquiring impedance respiration data from a patient wirelessly.

- Portrait Sensor battery used for powering the wearable sensors and provide wireless communication to the Portrait Mobile Patient Monitor.

- Portrait Bedside Charger for charging the Portrait Sensor Batteries and Portrait Mobile Patient Monitor (including when the Portrait Mobile Patient Monitor is in clinical use).

- Portrait SpO2 Attachment accessory band which provides means to secure the SpO2 sensors to the patient's wrist.

- Portrait Mobile Patient Monitor Pouch, which allows the Portrait Mobile Patient Monitor to be carried while the patient is ambulatory.

Intended Use: (807.92(a)(5)):

The Intended Use of the Portrait™ Mobile Monitoring Solution as a vital sign monitor is identical to the predicate primary predicate K171121 Masimo Root Monitoring System.

The indications for use are described separately for each of the individual subsystems/components of the Portrait Mobile Monitoring Solution and for the system as a whole. Indications for Use are described below:

Portrait™ Mobile Monitoring Solution
The Portrait Mobile Monitoring Solution is intended to acquire, store, calculate, display and export patient monitoring data as well as provide real time alarming for monitoring adult and pediatric patients (3 years of age and older, and weighing more than 10 kg).

Physiological parameters and waveforms supported are:
- Pulse oximetry (SpO2/pulse rate)
- Respiration rate (RR)

Continuous pulse oximetry and respiration rate monitoring may be used for patients at risk of cardiorespiratory and infectious

complications.

The Portrait Mobile Monitoring Solution is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

This device is not an Apnea monitor (i.e., do not rely on the device for detection or alarm for the cessation of breathing). This device should not be used for life sustaining/supporting purposes.

The Portrait Mobile Monitoring Solution is not intended for use in a controlled Magnetic Resonance (MR) environment.

Portrait™ Central Viewer Application (Portrait CVA01)
The Portrait Central Viewer Application (Portrait CVA01) provides monitoring station capability running as an application for the Portrait Mobile Monitoring Solution on a PC platform that meets minimum system requirements. It provides the ability to view real-time data for multiple patients and historical data for a single patient including configurable visual and audible alarm notifications.

The Portrait Central Viewer Application is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

Portrait™ Core Services (Portrait CSS01)
The Portrait Core Services (Portrait CSS01) are a set of software services that enable the communication and interaction of the Portrait Mobile Monitoring Solution components and will integrate into existing healthcare facility infrastructure and clinical information systems. The Portrait Core Services can transmit patient physiological trends and numerics (IHE PCD DEC) and alarm events (IHE PCD ACM) outbound. The Portrait Core Services can also receive HL7 ADT information to admit patients to the Portrait Mobile Monitoring Solution.

Portrait™ Clinical Alarming Unit (Portrait CAU01)
The Portrait Clinical Alarming Unit (Portrait CAU01) is a required accessory to the Portrait Central Viewer Application that provides audio alarming capability.

The Portrait Clinical Alarming Unit is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

Portrait™ Mobile Patient Monitor (Portrait HUB01)
The Portrait Mobile Patient Monitor (Portrait HUB01) is intended for use with adult and pediatric patients (3 years of age and older, and weighing more than 10 kg) for continuous monitoring of oxygen saturation (SpO2), pulse rate (PR) and respiration rate (RR) parameters. The Portrait Mobile Patient Monitor enables non-invasive continuous monitoring of patients by acquiring signals from Portrait wearable sensors through a Medical Body Area Network (MBAN) connection as well as displaying trends and events. The Portrait Mobile Patient Monitor can be configured to provide local audible and visual alarms and can also provide real-time, trend and event data to Portrait Core Services.

The Portrait Mobile Patient Monitor is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

The Portrait Mobile Patient Monitor is not intended for use in a controlled Magnetic Resonance (MR) environment.

Portrait™ Wearable Pulse Oximetry Sensor (Portrait SpO2 P-SA01)
The Portrait Wearable Pulse Oximetry Sensor (Portrait SpO2 P-SA01) is intended for use with adult and pediatric patients (3 years of age and older, and weighing more than 30 kg) for continuous physiologic monitoring of oxygen saturation (SpO2) and pulse rate (PR) parameters. The Portrait Wearable Pulse Oximetry Sensor acquires parameter data from the patient and transmits it to the Portrait Sensor Battery for communication to a host device through the Medical Body Area Network (MBAN) connection.

The Portrait Wearable Pulse Oximetry Sensor is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

The Portrait Wearable Pulse Oximetry Sensor is not intended for use in a controlled Magnetic Resonance (MR) environment.

Portrait™ Wearable Pulse Oximetry Sensor (Portrait SpO2 P-SP01)
The Portrait Wearable Pulse Oximetry Sensor (Portrait SpO2 P-SP01) is intended for use with pediatric patients (3 years of age and older, and weighing 15 kg to 30 kg) for continuous physiologic monitoring of oxygen saturation (SpO2) and pulse rate (PR) parameters. The Portrait Wearable Pulse Oximetry

Sensor acquires parameter data from the patient and transmits it to the Portrait Sensor Battery for communication to a host device through the Medical Body Area Network (MBAN) connection.

The Portrait Wearable Pulse Oximetry Sensor is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

The Portrait Wearable Pulse Oximetry Sensor is not intended for use in a controlled Magnetic Resonance (MR) environment.

Portrait™ Wearable Pulse Oximetry Sensor (Portrait SpO2 P-W01, Portrait SpO2 P-SE01)

The Portrait Wearable Pulse Oximetry Sensor (Portrait SpO2 P-SE01, Portrait SpO2 P-W01) is intended for use with adult and pediatric patients (3 years of age and older, and weighing more than 10 kg) for continuous physiologic monitoring of oxygen saturation (SpO2) and pulse rate (PR) parameters. The Portrait Wearable Pulse Oximetry Sensor acquires parameter data from the patient and transmits it to the Portrait Sensor Battery for communication to a host device through the Medical Body Area Network (MBAN) connection.

The Portrait Wearable Pulse Oximetry Sensor is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

The Portrait Wearable Pulse Oximetry Sensor is not intended for use in a controlled Magnetic Resonance (MR) environment.

Portrait™ SpO2 Attachment Accessory Band (Portrait AAB01)

The Portrait SpO2 Attachment Accessory Band (Portrait AAB01) is intended to provide a means to secure the Portrait Wearable Pulse Oximetry Sensor with Portrait Sensor Battery to the patient's wrist.

The Portrait SpO2 Attachment Accessory Band is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

Portrait™ Wearable Respiration Rate Sensor (Portrait RR P-RR01)

The Portrait Wearable Respiration Rate Sensor (Portrait P-RR01) is intended for use with adult and pediatric patients (3 years of age and older, and weighing more than 10 kg) for continuous physiologic monitoring of the respiration rate (RR)

parameter. The Portrait Wearable Respiration Rate Sensor acquires parameter data from the patient and transmits it to the Portrait Sensor Battery for communication to a host device through the Medical Body Area Network (MBAN) connection.

The Portrait Wearable Respiration rate Sensor is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

The Portrait Wearable Respiration Rate Sensor is not intended for use in a controlled Magnetic Resonance (MR) environment.

Portrait™ RR Electrode Patch (Portrait RRP01)
The Portrait RR Electrode Patch (Portrait RRP01) is intended for use with adult and pediatric patients (3 years of age and older, and weighing more than 10 kg) for continuous physiologic monitoring of the respiration rate (RR) parameter. The Portrait Electrode Patch transfers carrier signals from the Portrait Wearable Respiration Rate Sensor and transfers impedance and biopotential signals from the patient and transmits them to the Portrait Wearable Respiration Rate Sensor.

The Portrait RR Electrode Patch is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

The Portrait RR Electrode Patch is not intended for use in a controlled Magnetic Resonance (MR) environment.

Portrait™ Sensor Battery (Portrait SBT01)
The Portrait Sensor Battery (Portrait SBT01) is intended for use as a power supply for the Portrait Wearable Sensors and to provide wireless communication to a host device.

The Portrait Sensor Battery is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

The Portrait Sensor Battery is not intended for use in a controlled Magnetic Resonance (MR) environment.

Portrait™ Bedside Charger (Portrait BCH01)
The Portrait Bedside Charger (Portrait BCH01) is intended for charging the Portrait Sensor Batteries and the Portrait Mobile Patient Monitor (including while the Portrait Mobile Patient Monitor is in use).

The Portrait Bedside Charger is intended for use under the direct

supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

The Portrait Bedside Charger is not intended for use in a controlled Magnetic Resonance (MR) environment.

Portrait™ Mobile Patient Monitor Pouch (Portrait MMP01)
The Portrait Mobile Patient Monitor Pouch (Portrait MMP01) is an optional accessory intended to enable the Portrait Mobile Patient Monitor to be carried while the patient is ambulatory.

The Portrait Mobile Patient Monitor pouch is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

Technology (807.92(a)(6)): The Portrait Mobile Monitoring Solution uses the same fundamental technology and functionality as the primary predicate primary predicate K171121 Masimo Root Monitoring System.

Both the Portrait Mobile Monitoring Solution and the primary predicate K171121 Masimo Root Monitoring System are lightweight, portable, wireless monitoring systems for monitoring of patient physiological parameters in a professional healthcare environment. Both have similar system topologies, which include sensors that attach to the patient, small portable patient monitors that can be worn or carried by the patient, a set of centralized services installed on a server which is connected to the healthcare facility's enterprise network, and remote viewers with alarming capability that can monitor multiple patients simultaneously.

The main difference between the Portrait Mobile Monitoring Solution and the predicate is that the Portrait Mobile Monitoring Solution only supports SpO2, Pulse Rate, and Respiration Rate while the predicate also supports additional optional parameters The Portrait Mobile Monitoring Solution is substantially equivalent to the predicate.

A summary of the main changes compared to the predicate are listed below in the comparison table.

Product Comparison versus Predicate Main features chart follows below.

Specification	Primary Predicate Masimo Root Monitoring System and Accessories (K171121)	Reference Predicate Device ViSi Mobile Monitoring System – Predicate (K180472)	Proposed device Portrait Mobile Monitoring Solution –	Discussion of differences between Portrait Mobile Monitoring Solution and Predicates
Intended Use	Vital Sign Monitor	Vital Sign Monitor	Vital Sign Monitor	Identical
FDA Primary Product Code	MWI	MHX	MWI	Identical to primary predicate
FDA Classification Regulation	21 CFR 2300	21 CFR 1025	21 CFR 2300	Identical to primary predicate
Indications for Use (entire system)	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 Root Monitoring System, when used with the optional ISA module, is not intended to be used in road ambulances.[1] The Masimo Root Monitoring System and Accessories can communicate with network systems for supplemental remote viewing and alarming (e.g., at a central station). The optional Masimo Radical-7 Pulse CO-Oximeter and Accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (Rra). The Masimo Radical-7 Pulse CO-Oximeter and accessories are indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments. In addition, the Masimo Radical-7 Pulse CO-Oximeter and accessories are indicated to provide the continuous non-invasive monitoring data obtained from the Masimo Radical-7 Pulse CO-Oximeter and accessories of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate to multi- parameter devices for the display of those devices. The optional Masimo Radius-7 Wearable Pulse CO-Oximeter and Accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (Rra). The	The ViSi Mobile Monitoring System is intended for use by clinicians and medically qualified personnel for single or multi-parameter vital signs monitoring of adult patients (18 years or older). It is indicated for ECG (3 or 5 lead-wire), respiration rate (RESP), heart rate (HR), non-invasive blood pressure (NIBP), continuous non-invasive blood pressure (cNIBP), non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), and skin temperature (TEMP), posture tracking and alarms, skin temperature (TEMP) and basic arrhythmia (Ventricular Tachycardia, Ventricular Fibrillation, Asystole, Atrial Fibrillation) analysis/alarm in hospital-based facilities; including, general medical- surgical floors, intermediate care floors, and	The Portrait Mobile Monitoring Solution is intended to acquire, store, calculate, display and export patient monitoring data as well as provide real time alarming for monitoring adult and pediatric patients (3 years of age and older, and weighing more than 10 kg). Physiological parameters and waveforms supported are: • Pulse oximetry (SpO2/pulse rate) •Respiration rate (RR) Continuous pulse oximetry and respiration rate monitoring may be used for patients at risk of cardiorespiratory and infectious complications. The Portrait Mobile Monitoring Solution is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility. This device is not an Apnea monitor (i.e., do not rely on the device for detection or alarm for the cessation of breathing). This device should not be used for life sustaining/supporting purposes. The PORTRAIT Mobile Monitoring Solution is not intended for use in a controlled Magnetic Resonance (MR) environment.	Equivalent The Portrait Mobile Monitoring Solution provides substantially equivalent vital sign monitoring parameters including SpO2, Pulse Rate (PR), and Respiration Rate (RR) in adults and pediatrics patients as indicated in the primary predicate device. While the primary predicate device provides optional additional parameters not available in the subject device and allows neonatal monitoring for some parameters, the monitoring parameters needed are based on the individual monitoring needs as determined by a clinician. Neither the subject device nor the primary predicate device monitors ECG or arrhythmia. The Portrait Mobile Monitoring Solution provides substantially equivalent vital sign monitoring parameters including SpO2, Pulse Rate (PR), and Respiration Rate (RR) compared to the secondary predicate as well. The secondary predicate only measures in adult patients and can monitor ECG and other vital signs in addition to those monitored by the subject device. The subject device and predicate devices have similar system topologies, which include sensors that attach to the patient, small portable patient monitors that can be worn or carried

Specification	Primary Predicate Masimo Root Monitoring System and Accessories (K171121)	Reference Predicate Device ViSi Mobile Monitoring System – Predicate (K180472)	Proposed device Portrait Mobile Monitoring Solution –	Discussion of differences between Portrait Mobile Monitoring Solution and Predicates
	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. The optional ISA product family consists of three types of sidestream gas analyzers (ISA CO2, ISA AX+ and ISA OR+) and accessories including Nomoline, intended to be connected to other medical backboard devices for monitoring of breath rate and the following breathing gases: ISA CO2: CO_2 ISA AX+: CO_2, N_2O, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane ISA OR+: CO_2, O_2, N_2O, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane ISA CO2, ISA AX+ and ISA OR+ are intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care. The intended environment is the operating suite, intensive care unit and patient room. ISA CO2 is also intended to be used in road ambulances. The intended patient population is adult, pediatric, infant, and neonatal patients. [1] The Root Monitoring System, when used with the optional ISA module, is not intended to be used in road ambulances. The optional ISA module can be used in road ambulances with other monitoring systems in accordance with the intended environment of use for those systems. The optional SEDLine Sedation Monitor is indicated for use in the operating room (OR), intensive care unit (ICU), and clinical research laboratory. It is intended to monitor the state of the brain by real-time data acquisition and processing of EEG signals. The system includes the Patient State Index (PSI), a proprietary computed EEG variable that is related to the effect of anesthetic agents. The optional temperature module is indicated to measure temperature (oral, adult axillary, pediatric axillary, and	emergency departments. Continuous non-invasive blood pressure (cNIBP) measurements have not been evaluated on patients during ambulation. The arrhythmia analysis feature is intended for use by healthcare professionals trained in the identification and treatment of arrhythmia events. Automated arrhythmia analysis is an adjunct to clinical assessment; clinician review of the analysis should precede any therapeutic intervention.		by the patient, a set of centralized services installed on a server which is connected to the healthcare facility's enterprise network, and remote viewers with alarming capability that can monitor multiple patients simultaneously. This difference does not significantly affect safety and/or effectiveness.

<table>
<tr><th>Specification</th><th>Primary Predicate
Masimo Root Monitoring System and Accessories (K171121)</th><th>Reference Predicate Device
ViSi Mobile Monitoring System – Predicate (K180472)</th><th>Proposed device
Portrait Mobile Monitoring Solution –</th><th>Discussion of differences between Portrait Mobile Monitoring Solution and Predicates</th></tr>
<tr><td></td><td>rectal) of adult and pediatric patients. The device is intended to be used by clinicians and medically qualified personnel. It is available for sale only upon the order of a physician or licensed health care provider.

The optional non-invasive blood pressure (NIBP) module is indicated for the noninvasive measurement of arterial blood pressure in healthcare environments. The NIBP module is designed to measure blood pressure for patient population described in the following table:
<table><tr><th>Patient Population</th><th>Approximate Age Range</th></tr><tr><td>Newborn (neonate)</td><td>Birth to 1 month of age</td></tr><tr><td>Infant</td><td>1 month to 2 years of age</td></tr><tr><td>Child</td><td>2 to 12 years of age</td></tr><tr><td>Adolescent</td><td>12-21 years of age</td></tr><tr><td>Adult</td><td>21 years of age and older</td></tr></table></td><td></td><td></td><td></td></tr>
<tr><td>Patient Population</td><td>adult, pediatric, and neonatal patients</td><td>Adult patients (18 years or older)</td><td>Adult and pediatric patients (3 years of age and older, and weighing more than 10 kg).</td><td>Equivalent

The specified patient population for the proposed device is a subset of the patient population of the primary predicate.

While the primary predicate device allows neonatal monitoring for some parameters, the monitoring parameters needed are based on the individual monitoring needs as determined by a clinician.

This difference does not significantly affect safety and/or effectiveness.</td></tr>
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Specification	Primary Predicate Masimo Root Monitoring System and Accessories (K171121)	Reference Predicate Device ViSi Mobile Monitoring System – Predicate (K180472)	Proposed device Portrait Mobile Monitoring Solution –	Discussion of differences between Portrait Mobile Monitoring Solution and Predicates
Environments of Use	Hospitals, Hospital-type facilities, mobile, and home environments	Hospital-based facilities; including general medical-surgical floors, intermediate care floors, and emergency departments	A professional healthcare facility	Equivalent The Environment of Use for the Portrait Mobile Monitoring Solution is a subset of the Environment of Use for the primary predicate. This difference does not significantly affect safety and/or effectiveness.
Location of devices in the patient vicinity	In the Masimo Root Monitoring System and Accessories, the sensor must be located on the patient. The Masimo Root is connected wirelessly to the sensor, and as such, must only be located in the vicinity of the patient. The Battery Module connected to the sensor also has a small display for viewing clinical data and user interaction, including alarming capability and connection to Patient SafetyNet in case connectivity to the Masimo Root is lost.	In the ViSi Mobile Monitoring System, the Monitor and Sensors are located on the patient. The monitor is wired to the sensors, and as such, must be worn on the patent's wrist.	In the Portrait Mobile Monitoring Solution, only the sensors must be located on the patient. The monitor is connected wirelessly to the sensors, and as such, must only be located in the vicinity of the patient. However, the monitor may be worn by the patient using Portrait Mobile Patient Monitor Pouch. The monitor is also capable of being carried in one hand.	Equivalent As in the primary predicate the Portrait Mobile Patient Monitor component of the Portrait Mobile Monitoring Solution wirelessly aggregates data from patient worn sensors and therefore does not need to be located on the patient. If the patient moves out of range of the Portrait Mobile Patient Monitor, an alarm will sound warning the clinician and patient that the patient has moved out of range. Data from the sensors will not be collected or displayed until the patient returns within range of the Mobile Patient Monitor. The Portrait Mobile Patient Monitor is capable of being worn or carried by the patient. In this configuration, patient monitoring continues as long as the patient stays within the range of the wireless network, exactly as with the primary predicate device. This difference does not significantly affect safety and/or effectiveness.

Specification	Primary Predicate Masimo Root Monitoring System and Accessories (K171121)	Reference Predicate Device ViSi Mobile Monitoring System – Predicate (K180472)	Proposed device Portrait Mobile Monitoring Solution –	Discussion of differences between Portrait Mobile Monitoring Solution and Predicates
Remote Viewing and Monitoring Modes	The Masimo Root Monitoring System and Accessories can communicate with network systems for supplemental remote viewing and alarming (e.g., at a central station)	The ViSi Mobile Monitoring System may be used as standalone devices or networked to ViSi Mobile Remote Viewers through wireless 802.11 communication.	Once a patient is admitted, the Portrait Mobile Patient Monitor component of the Portrait Mobile Monitoring Solution can be used standalone (viewing of data and alarm annunciation) if properly configured or if it becomes disconnected from the rest of the system. In addition, patient data and alarms are always remotely displayed on the Portrait Central Viewer unless there is a system or network failure.	Equivalent Both the Portrait Mobile Patient Monitor and the predicate allow for local and remote (i.e., networked) monitoring, even though the system topology is different. This difference does not significantly affect safety and/or effectiveness.
	STANDARDS COMPLIANCE			
Medical Standards	IEC 60601-1 IEC 60601-1-2 ISO 80601-2-55 ISTA 2A, MIL-STD 810E ISO-18562-2 ISO-10993-1 ISO-10993-5 ISO-10993-10 ISO-10993-12 ISO-10993-17 ISO-10993-18 IEC 60601-1-8	IEC 60601-1 3rd Edition IEC 60601-1-2 IEC 60601-1-8 IEC 60601-2-27 (ECG) IEC 60601-2-49 IEC 80601-1-30 (NIBP) IEC 60601-1-6 IEC 62471 ANSI/AAMI EC13 ANSI/AAMI EC53 ISO 80601-2-61 ISO 81060-1	IEC 60601-1:2005 + A1:2012 IEC 60601-1-2:2014 IEC 60601-1-8:2012 / EN 60601-1-8:2007/A1:2013 IEC 80601-2-49:2018 ISO 80601-2-61:2017/EN ISO 80601-2-61:2017 IEC 60601-1-6:2013/EN 60601-1-6:2010/A1:2015 IEC 62366-1:2015 / EN 62366-1:2015 ISO 10993-1:2018 IEC 62304:2015 / EN 62304:2006 / A1:2016 Labeling ISO 20417:2021 ISO 15223-1:2021 ISO 17664:2017 ISO 17664-2:2021 Battery: UL 2054:2004 IEC 62133-2:2017 UL 1642:2012 RFID: AIM 7351731:2017 Wireless Coexistence: ANSI IEEE C63.27:2017	Equivalent The Portrait Mobile Monitoring Solution complies with the FDA recognized standards applicable to the product and supported parameters. This difference does not significantly affect safety and/or effectiveness.
	System Components			
Patient Device	Masimo Radius-7 Wearable Pulse CO-Oximeter	ViSi Mobile Monitor	PORTRAIT Mobile Patient Monitor	Equivalent Both devices are battery powered handheld monitors displaying numerics and waveforms. The predicate has a larger monitoring unit at bedside for numerics, waveforms and alarms. This difference does not significantly affect safety and/or effectiveness.

Specification	Primary Predicate Masimo Root Monitoring System and Accessories (K171121)	Reference Predicate Device ViSi Mobile Monitoring System – Predicate (K180472)	Proposed device Portrait Mobile Monitoring Solution –	Discussion of differences between Portrait Mobile Monitoring Solution and Predicates
Sensors	Masimo SpO2 Sensors Masimo Acoustic Respiration Rate (RRa) RAS-125c Sensor - Cloth	Visi Mobile Thumb Sensor (SpO2) Visi Mobile Chest Sensor (RR) (wired to the Mobile Monitor)	PORTRAIT SpO2 Wearable Pulse Oximetry Sensors PORTRAIT Wearable Respiration Rate Sensor (wireless to the Mobile Patient Monitor)	Equivalent Parameters supported on the Portrait Mobile Monitoring Solution are also available on the predicate. This difference does not significantly affect safety and/or effectiveness.
Sensor Battery	Masimo Radius-7 Battery Module, detachable, interchangeable.	RR and SpO2 Sensors powered by Mobile Patient Monitor	Detachable sensor battery. Interchangeable. May be used with any sensor.	Equivalent The primary predicate Battery Module has a small display. This difference does not significantly affect safety and/or effectiveness.
SpO2 Probes	Multiple alternatives, probe is connected to Instrument Module.	Integrated in sensors	Integrated in sensors	Equivalent The Portrait Mobile Monitoring Solution has the SpO2 probe integrated to the SpO2 sensor while the predicate has interchangeable probes connected to the SpO2 sensor (Instrument Module). This difference does not significantly affect safety and/or effectiveness.
Respiration Electrode Patches	Masimo Acoustic Respiration Rate (RRa) RAS-125c Sensor - Cloth	Integrated with Chest Sensor	Portrait RR Electrode Patch	Equivalent The operating principle of the primary predicate sensor differs from the operating principle of the Portrait Mobile Monitoring Solution (acoustic vs. impedance), but the measured parameter is the same (Respiration Rate). The subject device uses impedance based respiration measurement technology, same as the secondary predicate Visi Mobile Monitoring system. This difference does not significantly affect safety and/or effectiveness.

Specification	Primary Predicate Masimo Root Monitoring System and Accessories (K171121)	Reference Predicate Device ViSi Mobile Monitoring System – Predicate (K180472)	Proposed device Portrait Mobile Monitoring Solution –	Discussion of differences between Portrait Mobile Monitoring Solution and Predicates
Battery Charger	Masimo Root	Visi Mobile Charger	Portrait Bedside Charger	Equivalent The Portrait Bedside Charger can charge the Portrait Mobile Patient Monitor while in use and can also charge the detachable sensor batteries. The Masimo Root acts as both a charger for the Battery Module and as a bedside patient monitor. This difference does not significantly affect safety and/or effectiveness.
Central Viewing	Masimo Patient SafetyNet	Visi Mobile Remote Viewer	Portrait Central Viewer Software Application with Portrait Clinical Alarming Unit	Equivalent Portrait Central Viewer software on an off-the-shelf PC, along with the Portrait Clinical Alarming Unit, provide for central viewing/monitoring and standards compliant alarms. Portrait Central Viewer software can only be installed on hardware that meets minimum specifications which are checked during the installation process. The PC on which the Portrait Central Viewer is installed is customer supplied, while the viewer PC for the predicate is always supplied by the manufacturer of the Masimo Patient SafetyNet System. This difference does not significantly affect safety and/or effectiveness.
Storage and Centralized Services	Masimo Patient SafetyNet	ViSi Mobile Appliance	Portrait Core Services	Equivalent Both the Portrait Core Services within the Portrait Mobile Monitoring System and the Masimo Patient SafetyNet in the predicate distribute data between the bedside devices and other devices such as a central monitoring unit or EMR system. This difference does not significantly affect safety and/or effectiveness.

Specification	Primary Predicate Masimo Root Monitoring System and Accessories (K171121)	Reference Predicate Device ViSi Mobile Monitoring System – Predicate (K180472)	Proposed device Portrait Mobile Monitoring Solution –	Discussion of differences between Portrait Mobile Monitoring Solution and Predicates
Accessories for SpO2 and Resp	Masimo Radius-7 Armband	Visi Mobile Wrist Cradle Visi Mobile Thumb Wrap Visi Mobile Chest Sensor Securements	Portrait Mobile Patient Monitor Pouch Portrait SpO2 Attachment Accessory Band	Equivalent Both the Portrait Mobile Monitoring Solution and the predicate have accessories allowing the sensors to be attached to or carried by the patient. This difference does not significantly affect safety and/or effectiveness.
	Patient Device – General Hardware Specifications			
Device Name		**Visi Mobile Monitor**	**Portrait Mobile Patient Monitor**	
Size (H x W x D)	119.5 mm x 63.2 mm x 27.2 mm	9.4 cm x 4.9 cm x 2.6 cm	14.1 cm x 6.3 cm x 2.1 cm	Equivalent Both the Portrait Mobile Patient Monitor and the predicate device are small enough to be held in one hand and are capable of being worn by the patient. This difference does not significantly affect safety and/or effectiveness.
Weight	Battery Module 93 g Instrument Module 67g Total 160 g	110 g	223 g	Equivalent Both the Portrait Mobile Patient Monitor and the primary predicate device are small enough to be held in one hand and are capable of being worn by the patient. During normal use, the Portrait Mobile Patient Monitor does not need to be held or worn by the patient because the device is completely wireless. This difference does not significantly affect safety and/or effectiveness.
Power source	Battery (integrated into device)	Battery (integrated into device)	Battery (integrated into device)	Identical
Battery Type	Lithium-ion	Lithium-ion	Lithium-ion	Identical
	Patient Device – User Interface			
Device Name		**Visi Mobile Monitor**	**Portrait Mobile Patient Monitor**	
Touch display interface	Yes (Touchpad for Battery Module and Touch Screen for Root)	Yes	Yes	Identical
Visual and Audible Alarm capability	Available	Available	Available	Identical
	Patient Device – Display Specifications			

Specification	Primary Predicate Masimo Root Monitoring System and Accessories (K171121)	Reference Predicate Device ViSi Mobile Monitoring System – Predicate (K180472)	Proposed device Portrait Mobile Monitoring Solution –	Discussion of differences between Portrait Mobile Monitoring Solution and Predicates
Device Name		**Visi Mobile Monitor**	**Portrait Mobile Patient Monitor**	
Display type	OLED	OLED	SFT LCD (Super Fine TFT)	Equivalent Both the Portrait Mobile Patient Monitor and the predicates utilize proven display technologies that are widely used across a variety of industries. This difference does not significantly affect safety and/or effectiveness.
Display Size and resolution	160 X 128 (Dot pitch 0.073 (W) mm X 0.219 (H) mm)	160 x 128 pixels (size unspecified)	480 x 800 pixels, 3.7 inches in 16:9 format	Equivalent Greater resolution on Portrait Mobile Patient Monitor display allows for more information to be displayed than the predicate devices. This difference does not significantly affect safety and/or effectiveness.
Number of traces (waveforms)	One waveform	One waveform, user selectable	One waveform per page in detailed parameter view	Identical
Trends	Trends available on the Masimo Root. No trends on the Battery Module.	Not available for comparison / Not specified	Displays graphical trend of connected parameters for the last 4 hours. Movable cursor displays details for the given point in time.	Equivalent The Portrait Mobile Patient Monitor is capable of displaying the last 4 hours of trend data directly on the monitor. Trends are available on the Masimo Root, but not on the Battery Module. This difference does not significantly affect safety and/or effectiveness.
	Patient Device – Connectivity			

Specification	Primary Predicate Masimo Root Monitoring System and Accessories (K171121)	Reference Predicate Device ViSi Mobile Monitoring System – Predicate (K180472)	Proposed device Portrait Mobile Monitoring Solution –	Discussion of differences between Portrait Mobile Monitoring Solution and Predicates
Device Name		**Visi Mobile Monitor**	**Portrait Mobile Patient Monitor**	
Wireless connection to network	May be networked to Masimo Patient SafetyNet through wireless IEEE 802.11 a/b/g communication.	May be networked to ViSi Mobile Remote Viewers through wireless 802.11 communication. (802.11a/b/g/n – Dual band)	Requires a wireless network connection to begin monitoring. IEEE 802.11 a/b/g/n supported (dual band). After patient admission, the Portrait Mobile Patient Monitor will continue to monitor locally in the event of a network failure.	Equivalent Both the Portrait Mobile Patient Monitor and the predicate support a dual band 802.11 a/b/g connection to the Wi-Fi network of the responsible organization (i.e., hospital wireless network). The Portrait Mobile Patient Monitor requires a network connection for admitting the patient and beginning monitoring but can monitor locally after admission in the event of a network failure. The predicate Masimo Radius-7 does not require a network connection to begin monitoring. This difference does not significantly affect safety and/or effectiveness.
Connection to Sensors	The Masimo Instrument Module and Battery Module communicates with the sensors via a wired interface and with the Masimo Root over a Bluetooth interface.	The Visi Mobile Monitor communicates with the sensors via a wired interface.	The Portrait Mobile Patient Monitor communicates with the sensors over a wireless Medical Body Area Network (MBAN) using a proprietary protocol. The MBAN connection to the sensors includes a GE-proprietary protocol and a low-power radio interface that can operate on both the unlicensed 2.4 GHz ISM band and certain other protected frequency bands where MBAN traffic is allowed. In the USA, the MBAN communication occurs in the 2390-2400 MHz band, which has been reserved by the FCC for use by Medical Body Area Networks.	Equivalent The Portrait Mobile Patient Monitor communicates to the sensors over a wireless Medical Body Area Network (MBAN), a feature that is not supported by the predicate. MBAN communication includes multiple retries spread over time and frequency to ensure reliable transmission of data. Loss of MBAN communication (e.g., moving out of range) results in a technical alarm informing the caregiver of the communication loss. This difference does not significantly affect safety and/or effectiveness. See GE's response to the FDA Guidance document "Radio Frequency Wireless Technology in Medical Devices; Guidance for Industry and Food and Drug Administration Staff, Document issued on: August 14, 2013", referenced in section 9 of

Specification	Primary Predicate Masimo Root Monitoring System and Accessories (K171121)	Reference Predicate Device ViSi Mobile Monitoring System – Predicate (K180472)	Proposed device Portrait Mobile Monitoring Solution –	Discussion of differences between Portrait Mobile Monitoring Solution and Predicates
				this 510(k) submission, for detailed information about the wireless interfaces in the Portrait Mobile Monitoring Solution.
	Respiration Sensors – Hardware			
Device Name		**ViSi Mobile Chest Sensor**	**Portrait Wearable Respiration Rate Sensor**	
Dimensions	119.5 mm x 63.2 mm x 27.2 mm	152.4 cm L	6.9 x 5.3 x 1.9 cm	Equivalent Both the Portrait Wearable Respiration Rate Sensor and the sensor in the predicate device (i.e., the Masimo Radius-7) are small, lightweight sensors that attach to the patient for measuring respiration rate, although they differ somewhat in weight and geometry. This difference does not significantly affect safety and/or effectiveness.
Weight	67 g	62 g (3-Lead wire)	34 g	Equivalent Both the Portrait Wearable Respiration Rate Sensor and the predicate sensor (Masimo Radius-7) are small, lightweight sensors that attach to the patient, although they differ somewhat in weight and geometry. This difference does not significantly affect safety and/or effectiveness.
	Pulse Oximetry Sensor – Hardware			

Specification	Primary Predicate Masimo Root Monitoring System and Accessories (K171121)	Reference Predicate Device ViSi Mobile Monitoring System – Predicate (K180472)	Proposed device Portrait Mobile Monitoring Solution –	Discussion of differences between Portrait Mobile Monitoring Solution and Predicates
Device Name		**ViSi Mobile Thumb Sensor**	**Portrait Wearable Pulse Oximetry Sensor**	
Sensor Application Site	Finger	Thumb	Finger	Identical
Dimensions	119.5 mm x 63.2 mm x 27.2 mm	22.5 cm L	SpO2 P-SA01: 27.2 x 5.3 x 1.9 cm – or - SpO2 P-SP01: 23.6 x 5.3 x 1.9 cm – or - SpO2 P-W01: 26.2 x 5.3 x 1.9 cm – or - SpO2 P-SE01: 27.1 x 5.3 x 1.9 cm	Equivalent Both the Portrait Wearable Pulse Oximetry Sensor and the Masimo Radius-7 in the predicate device are small, lightweight SpO2 sensors that attach to the patient for measuring SpO2 and pulse rate. The Portrait Wearable Pulse Oximetry Sensor also contains the electronics and software for calculating SpO2 and pulse rate. This difference does not significantly affect safety and/or effectiveness.
Weight	67 g	8 g	SpO2 P-SA01: 52 g – or - SpO2 P-SP01: 43 g - or - SpO2 P-W01: 38 g - or - SpO2 P-SE01: 38 g	Equivalent Both the Portrait Wearable Pulse Oximetry Sensor and the Masimo Radius-7 in the predicate device are small, lightweight SpO2 sensors that attach to the patient for measuring SpO2 and pulse rate. The Portrait Wearable Pulse Oximetry Sensor also contains the electronics and software for calculating SpO2 and pulse rate. This difference does not significantly affect safety and/or effectiveness.
	Sensor Batteries - Hardware			
		N/A	**Portrait Sensor Battery**	
Battery Type	Lithium-ion	N/A - ViSi Mobile Chest Sensor (Respiration Rate) and ViSi Mobile Thumb Sensor (SpO2) are powered by Visi Mobile Monitor. See comparison of Portrait Mobile Patient Monitor vs. ViSi Mobile Monitor (above)	Lithium-ion	Identical
Dimensions	119.5 mm x 63.2 mm x 27.2 mm	N/A - ViSi Mobile Chest Sensor (Respiration Rate) and ViSi Mobile	3.6 x 5.3 x 1.7 cm	Equivalent Portrait Sensor batteries are small and lightweight and so

Specification	Primary Predicate Masimo Root Monitoring System and Accessories (K171121)	Reference Predicate Device ViSi Mobile Monitoring System – Predicate (K180472)	Proposed device Portrait Mobile Monitoring Solution –	Discussion of differences between Portrait Mobile Monitoring Solution and Predicates
		Thumb Sensor (SpO2) are powered by Visi Mobile Monitor. See comparison of Portrait Mobile Patient Monitor vs. ViSi Mobile Monitor (above)		not significantly increase the size or weight of the components attached to or carried by the patient. This difference does not significantly affect safety and/or effectiveness.
Weight	93 g	N/A - ViSi Mobile Chest Sensor (Respiration Rate) and ViSi Mobile Thumb Sensor (SpO2) are powered by Visi Mobile Monitor. See comparison of Portrait Mobile Patient Monitor vs. ViSi Mobile Monitor (above)	31 g	Equivalent Portrait Sensor batteries are small and lightweight and so not significantly increase the size or weight of the components attached to or carried by the patient. This difference does not significantly affect safety and/or effectiveness.
	Charger - Hardware			
		VISI MOBILE BATTERY CHARGER	**Portrait Bedside Charger**	
Input voltage and frequency	Masimo Root 100-240 VAC~, 47-63 Hz	100-240 V, 50-60 Hz (using external power supply)	100-240 V, 50-60 Hz (using external power supply)	Equivalent. The slight difference in AC frequency range does not significantly affect safety and/or effectiveness.
Power	65 VA	2 Position: 30 W (all bays charging) 8 Position: 75 W (all bays charging)	36 W (Output power - 3.0 A at 12 Vdc)	Equivalent. Both the Portrait Bedside charger and the chargers for the predicate have sufficient output power to charge the devices specified in their use. The Portrait Bedside Charger is capable of charging the Portrait Mobile Patient Monitor while it is in use. This difference does not significantly affect safety and/or effectiveness.
Dimensions (exclusive of power supply and cable)	Masimo Root 27.94 cm x 26.67 cm x 13.97 cm	2 Position: 7.6 cm H x 6.0 cm W x 12.7 cm L 8 Position: 7.6 cm H x 6.0 cm W x 47 cm L	11.5 x 23.8 x 4.3 cm	Equivalent. The Portrait Bedside Charger is intended to be installed in the patient room and can charge the Portrait Mobile Patient Monitor

Specification	Primary Predicate Masimo Root Monitoring System and Accessories (K171121)	Reference Predicate Device ViSi Mobile Monitoring System – Predicate (K180472)	Proposed device Portrait Mobile Monitoring Solution –	Discussion of differences between Portrait Mobile Monitoring Solution and Predicates
				while use in addition to 4 Portrait Sensor Batteries. The Masimo Root in the predicate charges one Battery Unit. Both the Portrait Bedside charger and the predicate are small and easily transportable. This difference does not significantly affect safety and/or effectiveness.
Weight (exclusive of power supply and cable)	Masimo Root 3.63 kg	2 Position: 240 g 8 Position: 670 g	412 g Wall mount: 603 g Table mount: 908 g	Equivalent. Both the Portrait Bedside charger and the predicate charger are lightweight and easily transportable. This difference does not significantly affect safety and/or effectiveness.
	Central/Remote Viewer			
		ViSi Remote Viewer	**Portrait Central Viewer Application with Portrait Clinical Alarming Unit**	
Display	23”	23 in display / 1920 x 1080 resolution (screen is touch sensitive to issue commands alternative to mouse/keyboard)	Required Specification for customer supplied display: 20 in (minimum), 1920 x 1080 resolution (minimum)	Equivalent The display for the Portrait Central Viewer Application is customer supplied and needs to meet certain minimum requirements which are checked by the installer at the time of install. The display for the remote viewer of the predicate is supplied by the manufacturer. This difference does not significantly affect safety and/or effectiveness.
Operating System	Windows 7 Professional Edition	Microsoft® Windows® 7 Professional (version 6.1) x64 Bit SP1	Required Specification for customer supplied PC: Windows 10, build 10.0.17763 (minimum)	Equivalent The PC on which the Portrait Central Viewer Application is installed is customer supplied and needs to meet certain minimum requirements

Specification	Primary Predicate Masimo Root Monitoring System and Accessories (K171121)	Reference Predicate Device ViSi Mobile Monitoring System – Predicate (K180472)	Proposed device Portrait Mobile Monitoring Solution –	Discussion of differences between Portrait Mobile Monitoring Solution and Predicates
				which are checked by the installer at the time of install. The PC for the remote viewer of the predicate is supplied by the manufacturer. This difference does not significantly affect safety and/or effectiveness.
Number of patients per viewer	Maximum 40	Maximum 32	Maximum 24	Equivalent Each Portrait Central Viewer Application with Portrait Clinical Alarming Unit supports up to 24 patients, vs. 40 for the predicate. Multiple instances of the Portrait Central Viewer Application with Portrait Clinical Alarming Unit (one per PC) can be used in order to view all patients being monitored by the Portrait Mobile Monitoring Solution (up to maximum system capacity). This difference does not significantly affect safety and/or effectiveness.
Simultaneous view of numerics for all patients on viewer	Supported for all measured parameters	Supported for all measured parameters	Supported on for all measured parameters on Multiple Patient View – SpO2%, Pulse Rate, Respiration Rate	Equivalent Both the Portrait Central Viewer Application and the predicate are capable of simultaneously displaying numerics of monitored parameters for all patients monitored for that viewer. This difference does not significantly affect safety and/or effectiveness.
Viewing of patient waveforms	One patient at a time	One patient at a time	One patient at time – Supported on single patient view	Equivalent Both the Portrait Central Viewer Application and the Predicate are capable of viewing waveforms for all parameters in scope of their intended use. Waveforms

Specification	Primary Predicate Masimo Root Monitoring System and Accessories (K171121)	Reference Predicate Device ViSi Mobile Monitoring System – Predicate (K180472)	Proposed device Portrait Mobile Monitoring Solution –	Discussion of differences between Portrait Mobile Monitoring Solution and Predicates
				are only viewable for one patient at a time. For the Portrait Central Viewer Application, waveforms are viewable by selecting an individual patient, which brings up the single patient view. The single patient view obscures numerics for other patients will that window is opened. However, the highest priority, most recent active alarms for all patients viewed by that instance of the Portrait Central Viewer Application are always visible in a protected area on the top of the screen. Numeric values for all monitored patients are visible while viewing waveforms for a single patient on the predicate. This difference does not significantly affect safety and/or effectiveness.
Viewing of patient trends	Graphical trend view supported for one patient at time	One patient at a time. Tabular or graphic trends	Graphical trend view supported for one patient at time – single patient view	Equivalent Both the Portrait Central Viewer Application and the Predicate are capable of viewing trends for all parameters in scope of their intended use. Trends are

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				only viewable for one patient at a time. For the Portrait Central Viewer Application, graphical trends are viewable by selecting an individual patient, which brings up the single patient view. The single patient view obscures numerics for other patients will that window is opened. However, the highest priority, most recent active alarms for all patients viewed by that instance of the Portrait Central Viewer Application are always visible in a protected area on the top of the screen. These differences do not significantly affect safety and/or effectiveness.
Visual/Audible alarms supported	Supported	Supported	Supported	Identical
	Storage and Centralized Services – General			
		ViSi Mobile Appliance	**Portrait Core Services**	
Description	Patient SafetyNet™ is a supplemental remote monitoring and clinician notification system. It provides a secondary display of Masimo SET® pulse oximetry, rainbow® SET pulse CO-Oximetry and acoustic respiration rate monitors. Patient SafetyNet enables clinicians to view and monitor patient physiological conditions when used in hospitals or hospital-type environments.	In the ViSi Mobile Monitoring System, data is captured in the ViSi Mobile Appliance, which acts as an enterprise hub. The Appliance is dedicated hardware installed in the IT datacenter for secure network connectivity and emergency power backup.	The Portrait Core Services are a set of software services that enable the communication and interaction of the Portrait Monitoring Solution components and will integrate into existing healthcare facility infrastructure and clinical information systems. The Portrait Core Services provide system configuration, administration, data storage, and transmission of patient physiological trends and events. The Portrait Core Services are installed on the Portrait non-medical device EHL (Edison Health Link) Server.	Equivalent The Portrait Core Services and the Masimo Patient SafetyNet system provide for centralized services and data storage. This difference does not significantly affect safety and/or effectiveness.
HL7 outbound support	Supported	Supported – Vital signs.	Supported - The Portrait Core Services can transmit patient physiological trends and numerics (IHE PCD DEC) and alarm events (IHE PCD ACM) outbound.	Equivalent The Portrait Core Services and the Masimo Patient SafetyNet support outbound HL7 for patient vital signs. The Portrait Core Services additionally supports patient

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				physiological trends and alarm events. This difference does not significantly affect safety and/or effectiveness.
HL7 Inbound support	Supported	Supported - The inbound ADT data is utilized by the Sotera application to provide patient identity information for display on the ViSi Mobile Monitors.	Supported - The Portrait Core Services can also receive HL7 ADT information to admit patients to the Portrait Monitoring Solution.	Equivalent The Portrait Core Services and the Masimo Patient SafetyNetsupport inbound ADT data. The inbound ADT data can be used to admit patients to the Portrait Mobile Monitoring Solution. This difference does not significantly affect safety and/or effectiveness.
	Storage and Centralized Services – Hardware			
		ViSi Mobile Appliance (when using Sotera supplied hardware)	**Portrait Core Services**	
Server Model	minimum Quad-Core Intel Xeon 2.0 GHz minimum 4 GB RAM minimum 1 TB RAID 1 storage array	Not available for comparison / Not specified	HP ProLiant DL360 Gen10	Equivalent Portrait Core Services use a HP ProLiant server which is widely used in multiple industries. This difference does not significantly affect safety and/or effectiveness.
	Monitored Parameters			
Monitored Parameters	Arterial oxygen saturation (SpO2) Pulse rate (PR) Perfusion index (Pi) Pleth Variability Index (PVi) Hemoglobin (SpHb) Carboxyhemoglobin (SpCO) Total oxygen content (SpOC) Methemoglobin (SpMet) Acoustic Respiration Rate (RRa).	Oxygen saturation (SpO2) Pulse Rate (PR) Respiration Rate (RR) Heart Rate (HR) Non-Invasive Blood Pressure (NIBP) Continuous NIBP (cNIBP) Skin Temperature	Oxygen saturation (SpO2) Pulse rate (PR) Respiration Rate (RR)	Equivalent. The parameters monitored by the proposed device are also monitored by the predicate. This difference does not significantly affect safety and/or effectiveness.
Parameters Acquisition Method	The Masimo Radius-7 acquires parameters from a wireless Instrument module to which an SpO2 probe and an acoustic respiration rate sensor are connected.	The Sotera Visi Mobile Monitor acquires parameter data from wired sensors. The available wired sensors include: ViSi Mobile Chest Sensor (Respiration, Heart Rate, Skin Temperature) ViSi Mobile Thumb Sensor	The Portrait Mobile Monitor acquires parameter data from wireless patient sensors over the MBAN wireless link. The parameter electronics are encapsulated into the respective wireless sensors. The sensors include: Portrait SpO2 P-SA01, SpO2 Wearable Pulse Oximetry Sensor (SpO2, Pulse Rate) Portrait SpO2 P-SP01, SpO2 Wearable Pulse Oximetry Sensor (SpO2, Pulse Rate)	Equivalent Both the Portrait Mobile Monitoring Solution and the predicate include sensors for collecting of physiological data from all monitored parameters included in their intended use. The sensors for the Portrait Mobile Monitoring Solution communicate to the Portrait Mobile Patient Monitor via a wireless MBAN connection, while

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		(SpO2, Pulse Rate) Visi Mobile Cuff Module (NIBP)	Portrait SpO2 P-W01, SpO2 Wearable Pulse Oximetry Sensor (SpO2, Pulse Rate) Portrait SpO2 P-SE01, SpO2 Wearable Pulse Oximetry Sensor (SpO2, Pulse Rate) Portrait RR P-RR01, Wearable Respiration Rate Sensor (Respiration Rate)	the sensors for the predicate communicate over a wired connection to the Instrument Module and Battery Module which communicate wirelessly with the Masimo Root over Bluetooth. This difference does not significantly affect safety and/or effectiveness.
	Alarms			
Classification / Alarm Levels	Two levels – High (flashing red) and Medium (flashing yellow)	Four levels – Life Threatening (white/red), High (red), Equipment High (cyan). Equipment Low (cyan)	Three levels - High (red), Medium (yellow), Low (cyan) in compliance with IEC 60601-1-8 Informational messages (gray) also included	Equivalent Both the Portrait Mobile Monitoring Solution and the predicate contain multiple alarm levels to distinguish between alarms based on criticality (i.e., the level of hazard to the patient). The alarm system for the Patient Mobile Monitoring Solution is compliant to IEC 60601-1-8:2012. This difference does not significantly affect safety and/or effectiveness.
Notification	Audible and visual	Audible and visual	Audible and visual	Identical
List of Physiological Alarms supported (for parameters included in the proposed device)	PR High PR Low SpO2 High SpO2 Low Rapid Desat RR High RR Low Respiratory Pause	HIGH PULSE RATE LOW PULSE RATE HIGH RESP LOW RESP LOW SpO2 THUMB NO PULSE	PR High PR Low RR High RR Low SpO2 High SpO2 Low SpO2 Critically low Apnea (This device is not an apnea monitor (i.e., do not to rely on the device for detection or alarm for the cessation of breathing). This device should not be used for life sustaining/supporting purposes) .	Equivalent Both the Portrait Mobile Monitoring Solution and the predicate contain a list of physiological alarms consistent with the parameters monitored as part of their intended use. This difference does not significantly affect safety and/or effectiveness. All physiological alarms supported in the Portrait Mobile Monitoring Solution

Specification	Primary Predicate Masimo Root Monitoring System and Accessories (K171121)	Reference Predicate Device ViSi Mobile Monitoring System – Predicate (K180472)	Proposed device Portrait Mobile Monitoring Solution –	Discussion of differences between Portrait Mobile Monitoring Solution and Predicates
				are also supported in the CARESCAPE ONE reference device (K213234).
Technical / Equipment Alarms	Supported	Supported	Supported	Equivalent Both the Portrait Mobile Monitoring Solution and the predicate device contain alarms to indicate equipment failure, low battery, loss of wireless connection, etc. The list of alarms is different between the two devices due to the differences in the design of the equipment. This difference does not significantly affect safety and/or effectiveness.
	Trending			
Trend Visualization	Graphical Trends	Graphical Trends and List (tabular) Trends	Graphical Trends only. Individual values for each trended value are visible at the position of the cursor.	Identical
Trend Visualization Duration	Up to 96 hours	Not available for comparison / Not specified	Up to 4 Hours on the Portrait Mobile Patient Monitor Up to 24 Hours on the Portrait Central Viewer Application	Equivalent The Portrait Mobile Monitoring Solution supports viewing of up to the last 4 Hours of trend data on the Portrait Mobile Patient Monitor and up to the last 24 Hours on the Portrait Central Viewer Application. The duration of trend data viewable on the predicate is 96 hours. The Portrait Mobile Patient Monitoring Solution also supports transmission of trend data to an EMR system over an HL7 interface, to allow for a complete record of patient trends to be accessed. This difference does not significantly affect safety and/or effectiveness.
Trend Smoothing	Not specified	Not specified	On the Portrait Central Viewer Application, the trend data undergoes an additional smoothing process. The purpose of this smoothing is to remove brief changes and normal variations in the physiological trend data acquired by the Portrait Mobile Patient Monitor.	Equivalent The trended data that is displayed on the Portrait Central Viewing Application undergoes an additional smoothing process to remove brief variations (i.e., discontinuities) in the raw trend data to make visualization of trends over

Specification	Primary Predicate Masimo Root Monitoring System and Accessories (K171121)	Reference Predicate Device ViSi Mobile Monitoring System – Predicate (K180472)	Proposed device Portrait Mobile Monitoring Solution –	Discussion of differences between Portrait Mobile Monitoring Solution and Predicates
				a period of time easier. This feature is not available when viewing trend data at the source (i.e., the Portrait Mobile Patient Monitor) or the predicate. This difference does not significantly affect safety and/or effectiveness.
Event management	Clinical and Technical events are stored and can be exported as Event Reports	Not available for comparison / Not specified	Physiological Events (i.e., alarms) of medium or high priority are stored in the Portrait Mobile Monitoring Solution and are viewable in the Trend display on the Portrait Central Viewer Application.	Equivalent The Portrait Mobile Monitoring Solution supports viewing of historical events (i.e., alarms) in the Trend display. The predicate provides event storage and viewing through even reports. This difference does not significantly affect safety and/or effectiveness.
	RESPIRATION			
Measurement Method	Acoustic Respiration Measurement	Impedance Pneumography (i.e., Impedance Respiration)	Impedance Respiration (i.e., Impedance Pneumography)	Equivalent Although the measurement method is different, both methods measure the same parameter, i.e., respiration rate. The subject devices uses the same impedance respiration technology as the secondary predicate Visi Mobile Monitoring system. This difference does not significantly affect safety and/or effectiveness.
Display Range	0 bpm to 70 bpm	0 to 50 breaths/min	0 to 99 breaths/min	Equivalent Respiration display range on the Portrait Mobile Monitoring Solution is slightly wider than on predicate. This difference does not significantly affect safety and/or effectiveness.
Units	Respiration Rate (RR) in breaths/min	Respiration Rate (RR) in breaths/min	Respiration Rate (RR) in breaths/min	Identical
Resolution	1 breath/min	1 breath/min	1 breath/min	Identical

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Accuracy Range	4 to 70 bpm	3 to 50 breaths/min	4 to 60 breaths/min	Equivalent Both the Portrait Mobile Monitoring Solution and the predicate specify accuracy over a wide range of respiration rate values. These ranges encompass the range of respiration rate values expected from patient populations included in the intended use of the product. This difference does not significantly affect safety and/or effectiveness.
Accuracy	1 bpm	+/- 3 breaths/min or 10% or reading, whichever is greater	+/- 3 breaths/min	Equivalent The primary predicate has somewhat better accuracy. Both the Portrait Mobile Monitoring Solution and the predicate have sufficient accuracy to meet the clinical needs of the intended use environment. The subject devices have the same accuracy as the secondary predicate Visi Mobile Monitoring system. This difference does not significantly affect safety and/or effectiveness.
Waveforms	Acoustic Respiration waveform	Impedance Respiration waveform, 6.25mm/s sweep speed	Impedance Respiration waveform with automatic scaling, 6.25 mm/s sweep speed (Portrait Mobile Patient Monitor), 25 m/s sweep speed (Portrait Central Viewer Application)	Equivalent Both the Portrait Mobile Monitoring Solution and the predicate support impedance respiration waveforms. This difference does not significantly affect safety and/or effectiveness.
	PULSE OXIMETRY – SpO2			
Measurement	Arterial oxygen saturation (SpO2)	Arterial oxygen saturation (SpO2)	Arterial oxygen saturation (SpO2)	Identical

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Units	Percent	Percent	Percent	Identical
Display Range	0% to 100%	49 to 100%	0 to 100%	Identical
Resolution	1%	1%	1%	Identical
Accuracy Range	70 to 100%	70 to 100%	70 to 100%	Identical
Accuracy	No Motion (SpO2 from 60% to 80%), Adults, Pediatrics - 3% No Motion (SpO2 from 70% to 100%), Adults, Pediatrics - 2% Motion (SpO2 from 70% to 100%), Adults, Pediatrics - 3% Low perfusion (SpO2 from 70% to 100%), Adults, Pediatrics - 2%	<= 2% from 70 to 100% (no motion) Unspecified from 49 to 69%	SpO2 (70 to 100%) <= 2% Low perfusion SpO2: <= 3% With motion: <= 3% SpO2 (<70%) - Unspecified	Equivalent Both the Portrait Mobile Monitoring Solution and the predicates have a specified accuracy of 2% from 70 to 100% SpO2 under normal condition. The proposed device has identical accuracy specification compared to the primary predicate under motion conditions. The accuracy specification at low perfusion is slightly better for the primary predicate. This difference does not significantly affect safety and/or effectiveness.
Averaging	2-4, 4-6, 8, 10, 12, 14, or 16 seconds, default 8	12 beat averaging following initialization	Adjustable from 0 to 60 seconds (default 10 seconds)	Equivalent SpO2 averaging in the Portrait Mobile Monitoring Solution from 0 to 60 seconds with a 10 second default. Adjustments are restricted to an authorized user. The SpO2 averaging in the primary predicate is adjustable between 2 and 16 seconds with a default of 8 seconds. This difference does not significantly affect safety and/or effectiveness.
Waveforms	Pleth Waveform	Pleth Waveform, normalized amplitude, 25mm/s sweep speed	Pleth Waveform, Not normalized (Amplitude of the displayed plethysmographic waveform reflects the strength of the arterial blood pulsation at the measurement site.) 25mm/s sweep speed (Portrait Mobile Patient Monitors and Portrait Central Viewer Application)	Equivalent Both the Portrait Mobile Monitoring Solution and the predicates support pleth waveform. The Portrait Mobile Monitoring Solution differs from the secondary predicate in that the waveform is not normalized but instead the waveform amplitude reflects the strength of the arterial blood pulsation at the measurement site. This difference does not significantly affect safety and/or effectiveness.

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	PULSE OXIMETRY – Pulse Rate			
Measurement	Peripheral Pulse rate (PR)	Pulse rate (PR) (From SpO2)	Peripheral Pulse rate (PR)	Identical
Units	Beats per minute (bpm)	Beats per minute (bpm)	Beats per minute (bpm)	Identical
Display Range	0 to 240 bpm	0 to 240 bpm	30 to 300 bpm	Equivalent Both the Portrait Mobile Monitoring Solution and the predicate are capable of displaying a wide range of pulse rate values, although the display range between the two devices is slightly different. Measured values outside the display range will automatically result in a limit alarm violation for both products. This difference does not significantly affect safety and/or effectiveness.
Resolution	1 bpm	1 bpm	1 bpm	Identical
Accuracy Range	25 to 240 bpm	30 to 240 bpm	30 to 250 bpm	Equivalent The Portrait Mobile Monitoring Solution specifies accuracy up to 250 bpm, vs. 240 bpm for the predicate and 30 bpm vs. 25 bpm for the primary predicate. This difference does not significantly affect safety and/or effectiveness.
Accuracy	No motion, Adults, Pediatrics - 3 bpm Motion, Adults, Pediatrics - 5 bpm Low Perfusion, Adults, Pediatrics - 3 bpm	<= 3 bpm (from SpO2)	<= 2 bpm (30 to 250 bpm) Low perfusion: <= 2 bpm (30 to 250 bpm) With motion: <=5 bpm (30 to 250 bpm)	Equivalent The Pulse rate accuracy of the Portrait Mobile Monitoring Solution is <= 2 bpm under all conditions except under motion, which is <= 5 bpm. The pulse rate accuracy for the predicate is specified as <= 3 bpm under all conditions except under motion, which is <= 5 bpm. This difference does not significantly affect safety and/or effectiveness.

Determination of Substantial Equivalence (807.92(b)(1)):

Summary of Non-Clinical Tests:

Bench testing related to software, hardware and performance including applicable consensus standards was conducted on the Portrait Mobile Monitoring Solution, demonstrating the design meets the specifications.

This section addresses the Non-Clinical testing for Portrait Mobile Monitoring Solution relied on for a determination of substantial equivalence to the predicate K171121 Masimo Root Monitoring System.

Per the FDA guidance titled “Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions; Guidance for Industry and Food and Drug Administration Staff, Document issued on December 20, 2019”, the following was verified:

- SpO2 measurement,
- Impedance Respiration
- Testing of Wireless Interfaces (WLAN and MBAN testing)
- Hardware Bench Testing
- Packaging Bench Testing
- Alarms Bench Testing
- Manuals Bench Testing

The Portrait Mobile Monitoring Solution meets the EMC requirements described in IEC 60601-1-2 Edition 4.0 2014-02 "Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests". Compliance according to the “Electromagnetic Compatibility (EMC) of Medical Devices Guidance for Industry and Food and Drug Administration Staff, issued on June 6, 2022” The Portrait Mobile Monitoring Solution has been evaluated for electromagnetic compatibility and potential risks from common emitters in the Portrait Mobile Monitoring Solution environment, such as radio frequency identification readers, by testing per the AIM 7351731 Rev 2.00 "Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers" standard.

The Portrait Mobile Monitoring Solution meets the electrical

safety requirements of IEC 60601-1:2012 "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Edition 3.1".This testing was performed by a recognized independent and Certified Body Testing Laboratory (CBTL) under the IECEE CB Scheme. The Portrait Mobile Monitoring Solution was designed and tested for compliance to the FDA 21 CFR Part 898, § 898.12 (Performance standard for electrode lead wires and cables). The performance standard is fulfilled because of compliance with IEC 60601-1:2012, Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance – Edition 3.1. clause 8.5.2.3 which is equivalent with clause 56.3c in IEC 60601-1:1988.

Additional data is provided for compliance to:

- IEC 60601-1-8 Edition 2.1 2012-11 Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 80601-2-49 Edition 1.0 2018-03 - Medical electrical equipment – Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitors - Edition 1.0
- ISO 80601-2-61 Second edition 2017-12 (Corrected version 2018-02) Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

Environmental testing, based on the Portrait Mobile Monitoring Solution proposed uses and locations, was confirmed to meet the specifications listed in the requirements. Portrait Mobile Monitoring Solution specifications verification evidence is included for the following:

- Operating temperature
- Operating humidity
- Operating pressure
- Storage and transport temperature
- Storage and transport humidity
- Storage and transport pressure
- Fluid ingress

The Portrait Mobile Monitoring Solution follows the FDA Biocompatibility guidance document “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", Guidance for Industry and Food and Drug Administration Staff issued on September 4, 2020” and ISO 10993-1:2018 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process. Testing data for showing biocompatibility of patient contacting devices is provided in the submission.

The Portrait Mobile Monitoring Solution follows the guidance “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, Guidance for Industry and Food and Drug Administration Staff. Document issued on: March 17, 2015” and the following standards:

- ISO 17664 Second edition 2017-10 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices
- 17664-2 First edition 2021-02 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices.

Reprocessing efficacy validation has been conducted in accordance with the documented reprocessing instructions using worst-case devices/components of the Portrait Mobile Monitoring Solution. The reprocessing efficacy validation met the acceptance criteria for the reprocessing efficacy validation tests.

The Portrait Mobile Monitoring Solution follows the Applying Human Factors and Usability Engineering to Medical Devices; Guidance for Industry and Food and Drug Administration Staff, Document issued on: February 3, 2016 and the following standards:

- IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62366-1 Edition 1.0 2015-02 Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]

Summative Usability testing has been concluded with 15 US

Clinical and 15 US Technical users. The usability testing of the Portrait Mobile Monitoring Solution follows the FDA Guidance for Industry and Food and Drug Administration Staff "Applying Human Factors and Usability Engineering to Medical Devices" (Feb 3, 2016).

Batteries performance data is provided related to:

- IEC 62133-2 Edition1.0 2017-02 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems
- UL 2054 2nd Edition Household and Commercial Batteries

Wireless performance data was provided related to:

- Radio Frequency Wireless Technology in Medical Devices; Guidance for Industry and Food and Drug Administration Staff, Document issued on: August 14, 2013
- IEEE ANSI C63.27-2017 American National Standard for Evaluation of Wireless Coexistence

Additional Labeling standards followed:

- ISO 20417:2021 Medical devices — Information to be supplied by the manufacturer
- ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

The Portrait Mobile Monitoring Solution follows the FDA software guidance documents as outlined in this submission.

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, Document issued on May 11, 2005
- General Principles of Software Validation; Final Guidance for Industry and FDA Staff, Document issued on January 11, 2002
- Off-The-Shelf Software Use in Medical Devices; Guidance for Industry and Food and Drug Administration Staff, Document issued on September 27, 2019
- Content of Premarket Submissions for Management of

Cybersecurity in Medical Devices, Draft Guidance for Industry and Food and Drug Administration Staff issued October 18, 2018

- Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices, Document issued on September 6, 2017

Software testing was conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device is considered as a "Major" level of concern. Software standards IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes and risk management standard ISO 14971 Third Edition 2019-12 Medical devices - Application of risk management to medical devices were also applied to the design.

Patient safety, security, and privacy risks have been addressed in the design and development of Portrait Mobile Monitoring Solution including a Security Risk Assessment, Threat model and Penetration testing. This includes system integrity controls, access controls, audit controls, network controls, and remote service controls which address the General Principles and Security Capabilities outlined in the "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Draft Guidance for Industry and Food and Drug Administration Staff issued October 18, 2018".

Clinical (807.92(b)(2)): Summary of Clinical Tests:

The Portrait Mobile Monitoring Solution measures SpO2, Respiration Rate and Pulse Rate. Two clinical studies are presented below in support of substantial equivalence. The first is a standard clinical study to support the new SpO2 algorithm and sensors used and is conducted in accordance with ISO 80601-2-61:2017 Medical electrical equipment — Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment and FDA guidance: Pulse Oximeters -- Premarket Notification Submissions [510(k)s] -Guidance for Industry and Food and Drug Administration Staff Issued March 2013.

	The second study evaluated the performance of the Portrait Mobile Monitoring Solution dual vector impedance-based respiration rate monitoring in general ward patients. The population was representative of the general population anticipated to require Portrait Mobile Monitoring Solution in clinical practice. During the study, patients were able to perform normal activities , for example, eat, talk, sit, walk, and ability to use toilet. Reference method was CO2 monitoring, which is considered a gold standard for RR. In the data analysis, mean absolute difference between Portrait Mobile and CO2 RR was used as the metric to quantify performance of the Portrait Mobile RR measurement.
Conclusion (807.92(b)(3)):	GE HealthCare considers the Portrait Mobile Monitoring Solution to be substantially equivalent to the predicate device.