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

March 20, 2024

Re: K234130

Trade/Device Name: Portrait™ Mobile Monitoring Solution consists of:

- Portrait™ Central Viewer Application (Portrait CVAXB)
- Portrait™ Core Services (Portrait CSSXB)
- Portrait™ Clinical Alarming Unit (Portrait CAU01)
- Portrait™ Mobile Patient Monitor Hardware (Portrait HUBXB)
- Portrait™ Mobile Patient Monitor Software (Portrait HSWXB)
- Portrait™ Wearable Pulse Oximetry Sensor (Portrait SpO2 P-SA01)
- Portrait™ Wearable Pulse Oximetry Sensor (Portrait SpO2 P-SP01)
- Portrait™ Wearable Pulse Oximetry Sensor (Portrait SpO2 P-W01, Portrait SpO2 P-SE01)
- Portrait™ SpO2 Attachment Accessory Band (Portrait AAB01)
- Portrait™ Wearable Respiration Rate Sensor (Portrait RR P-RR01)
- Portrait™ RR Electrode Patch (Portrait RRP01)
- Portrait™ Sensor Battery (Portrait SBT01)
- Portrait™ Bedside Charger (Portrait BCH01)
- Portrait™ Mobile Patient Monitor Pouch (Portrait MMP01)

Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, MSX, DRG, BZQ, DQA
Dated: December 28, 2023
Received: December 28, 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 (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls

provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the

Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K234130

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 healthcare 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 of 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.

The Portrait™ Mobile Monitoring Solution consists of:

Portrait™ Central Viewer Application (Portrait CVAXB):
The Portrait Central Viewer Application (Portrait CVAXB) 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 healthcare practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

Portrait™ Core Services (Portrait CSSXB):
The Portrait Core Services (Portrait CSSXB) 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), waveforms (IHE PCD WCM), 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 healthcare practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

Portrait™ Mobile Patient Monitor Hardware (Portrait HUBXB):
The Portrait Mobile Patient Monitor Hardware (Portrait HUBXB) is intended for use with adult and pediatric patients as a handheld, mobile device which supports running the Portrait Mobile Patient Monitor Software to monitor patients, and to provide audible and visual alarms. The Portrait Mobile Patient Monitor Hardware enables non-invasive continuous vital sign monitoring of patients by acquiring signals wirelessly from Portrait wearable sensors, as well as wireless clinical and service data communication.

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

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

Portrait™ Mobile Patient Monitor Software (Portrait HSWXB):
The Portrait Mobile Patient Monitor Software (Portrait HSWXB) is intended to run on Portrait Mobile Patient Monitor Hardware for the continuous monitoring of oxygen saturation (SpO2), pulse rate (PR) and respiration rate (RR) parameters. Portrait Mobile Patient Monitor Software is intended for use with adult and pediatric patients (3 years of age and older, and weighing more than 10 kg). It enables non-invasive continuous monitoring of patients by acquiring signals from Portrait wearable sensors, as well as displaying trends, events, and a QR code containing patient demographics and parameter data. When installed on the Portrait Mobile Patient Monitor Hardware, the Portrait Mobile Patient Monitor Software provides real-time, trend and event data to Portrait Core Services. The Portrait Mobile Patient Monitor Software, when configured to do so, also enables the Portrait Mobile Patient Monitor Hardware to provide audible and visual alarms locally.

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

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 healthcare 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 healthcare 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 healthcare 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 healthcare 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 healthcare 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 RR Electrode Patch 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 healthcare 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 healthcare 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 healthcare 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 healthcare 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: February 26, 2024

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
E-mail: joel.kent@gehealthcare.com

Secondary Contact Person: William Jung
Regulatory Affairs Director
GE HealthCare, Monitoring Solutions
Phone: 571-396-1558
E-mail: william.jung@gehealthcare.com

Device names (807.92(a)(2)):

Trade Name:	Portrait Mobile Monitoring Solution V1.1 consists of the following: Portrait™ Central Viewer Application (Portrait CVAXB) Portrait™ Core Services (Portrait CSSXB) Portrait™ Clinical Alarming Unit (Portrait CAU01) Portrait™ Mobile Patient Monitor Hardware (Portrait HUBXB) Portrait™ Mobile Patient Monitor Software (Portrait HSWXB) Portrait™ Wearable Pulse Oximetry Sensor (Portrait SpO2 P-SA01) Portrait™ Wearable Pulse Oximetry Sensor (Portrait SpO2 P-SP01) Portrait™ Wearable Pulse Oximetry Sensor (Portrait SpO2 P-W01, Portrait SpO2 P-SE01) Portrait™ SpO2 Attachment Accessory Band (Portrait AAB01) Portrait™ Wearable Respiration Rate Sensor (Portrait RR P-RR01) Portrait™ RR Electrode Patch (Portrait RRP01) Portrait™ Sensor Battery (Portrait SBT01) Portrait™ Bedside Charger (Portrait BCH01) Portrait™ Mobile Patient Monitor Pouch (Portrait MMP01)
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 K230626 Portrait Mobile Monitoring Solution v1.0
Device Description (807.92(a)(4)):	The Portrait Mobile Monitoring Solution V1.1 is a 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.

The Portrait Mobile Monitoring Solution V1.1 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 Hardware, 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 alarms, with a 3.7-inch capacitive touchscreen capable of displaying numeric data and waveforms for SpO2, Pulse Rate (PR), and Respiration Rate (RR). Compared to the predicate (K230626), the Portrait Mobile Patient Monitor has been split into separate hardware and software components for serviceability. The Portrait Mobile Patient Monitor Hardware is shipped with no clinical software installed. The clinical software (i.e., Portrait Mobile Patient Monitor Software) is installed at the customer site before the device is put into use. The Portrait Mobile Patient Monitor Hardware when the Portrait Mobile Patient Monitor Software is installed (prior to patient use) is then what we will refer to as the Portrait Mobile Patient Monitor. Portrait Wearable SpO2 sensors for acquiring SpO2 and pulse rate data from a patient wirelessly.

• Portrait Mobile Patient Monitor Software is the clinical software which gets installed at the customer site on the Portrait Mobile Patient Monitor Hardware. The Portrait Mobile Patient Monitor Software is this submission is equivalent to the software installed on the predicate Portrait Mobile Patient Monitor cleared in K230626 with minor changes as discussed in this

submission.

• 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 v1.1 as a vital sign monitor is identical to the primary predicate K230626 Portrait Mobile Monitoring Solution v1.0.

The indications for use are described separately for each of the individual subsystems/components of the Portrait Mobile Monitoring Solution V1.1 and for the system as a whole.

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 healthcare 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 of 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.

The Portrait Mobile Monitoring Solution consists of:

Portrait™ Central Viewer Application (Portrait CVAXB)

The Portrait Central Viewer Application (Portrait CVAXB) 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 healthcare practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

Portrait™ Core Services (Portrait CSSXB)

The Portrait Core Services (Portrait CSSXB) 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), waveforms (IHE PCD WCM), 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 healthcare practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

Portrait™ Mobile Patient Monitor Hardware (Portrait HUBXB)

The Portrait Mobile Patient Monitor Hardware (Portrait HUBXB) is intended for use with adult and pediatric patients as a handheld, mobile device which supports running the Portrait Mobile Patient Monitor Software to monitor patients, and to provide audible and visual alarms. The Portrait Mobile Patient Monitor Hardware enables non-invasive continuous vital sign monitoring of patients by acquiring signals wirelessly from Portrait wearable sensors, as well as wireless clinical and service data communication.

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

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

Portrait™ Mobile Patient Monitor Software (Portrait HSWXB)

The Portrait Mobile Patient Monitor Software (Portrait HSWXB) is intended to run on Portrait Mobile Patient Monitor Hardware for the continuous monitoring of oxygen saturation (SpO2), pulse rate (PR) and respiration rate (RR) parameters. Portrait Mobile Patient Monitor Software is intended for use with adult and pediatric patients (3 years of age and older, and weighing more than 10 kg). It enables non-invasive continuous monitoring of patients by acquiring signals from Portrait wearable sensors, as well as displaying trends, events, and a QR code containing patient demographics and parameter data. When installed on the Portrait Mobile Patient Monitor Hardware, the Portrait Mobile Patient Monitor Software provides real-time, trend and event data to Portrait Core Services. The Portrait Mobile Patient Monitor Software, when configured to do so, also enables the Portrait Mobile Patient Monitor Hardware to provide audible and visual alarms locally.

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

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 healthcare 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 healthcare 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 healthcare 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 healthcare 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 healthcare 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 RR Electrode Patch 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 healthcare 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 healthcare 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 healthcare 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 healthcare 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 K230626 Portrait Mobile Monitoring Solution v1.0.

The basis for this TRADITIONAL 510(k) submission is that the Portrait Mobile Monitoring Solution with software v1.1 is a revised version of the predicate Portrait™ Mobile Monitoring Solution K230626 with changes as described below.

The Intended Use of the Portrait™ Mobile Monitoring Solution with software v1.1 as a vital sign monitor is identical to the predicate primary predicate Portrait™ Mobile Monitoring Solution K230626 with software version 1.0.

The Portrait Mobile Monitoring Solution with software v1.1 uses the same fundamental technology and functionality as the primary predicate primary predicate Portrait™ Mobile Monitoring Solution K230626.

Changes since the previous submission (K230626)

The main change is a new software version 1.1 replacing software 1.0 and revised labeling. There are no changes to the hardware of the devices that comprise Portrait Mobile Monitoring Solution.

The main differences with respect to the predicate discussed throughout this submission are summarized below:

Service enhancements to support ease of deployment

- Installation enhancements for Portrait Core Services to make for a more streamlined software installation process.
- Ability to do over-the-air updates to sensor software from the Portrait Mobile Patient Monitor and to update

batteries from the Portrait Mobile Patient Monitor when both are docked on the charger
- Service enhancements to allow the ability for a reset of all configured parameters to factory defaults when performing a software update of the Portrait Mobile Patient Monitor.
- Electronic delivery to a field engineer laptop of software for the Portrait Central Viewer and Portrait Mobile Patient Monitor, as well as electronic delivery of software updates for sensors, sensor battery, and charger to a field engineer laptop. This feature eliminates the need to ship physical software kits (i.e., USB sticks) to customer sites.

Cybersecurity improvements

- Updates to off-the-shelf software to address open cybersecurity vulnerabilities and software end-of-life issues.
- Software signing key updates.
- Improvements to device authentication of a Sensor Battery and Sensor (from the Portrait Mobile Patient Monitor).
- Adding support for WPA3 wireless security to the Portrait Mobile Patient Monitor.

Minor Software functional enhancements

- Alarm improvements to support a 2 stage check probe alarm and adding a 60s delay option for Resp High, Resp Low, Pulse Rate High and Pulse Rate Low.
- QR code display in the Portrait Mobile Patient Monitor to allow patient vital signs to be read by an external vital signs monitor.
- Adding IHE WCM outbound feeds (i.e., HL7) for Pleth/Resp waveforms.

Minor Changes to the Indications for Use

We have revised the Indications for Use statement from the predicate for clarity and to reflect the following changes that are new for this submission:

- Separating the Portrait Mobile Patient Monitor hardware and software into 2 separate medical devices with corresponding indication statements (Portrait HUBXB and Portrait HSWXB).
- Updates to device model numbers for the Portrait Central Viewer Application and Portrait Core Services.

- Addition of IHE WCM outbound feeds (i.e., HL7) to the indications for Portrait Core Services (licensed feature).
- Addition of a QR code containing patient demographics and parameter data (used to allow patient vital signs to be read by external vital signs monitor) to the indications for the Portrait Mobile Patient Monitor Software.

The scope of modifications does not affect the patient population or environment of use or parameters monitored compared to the predicate Portrait Mobile Monitoring Solution (K230626).

Miscellaneous updates

- Bluetooth beaconing to enable RTLS (real-time location system) support. Used for device tracking only. This added feature is not used for clinical use.
- Localization support of Portrait Mobile Monitoring Solution user interface and manuals to support new languages required for new target countries.
- Adding a compatibility check to Sensor, Sensor Battery, and Portrait Mobile Patient Monitor Software to ensure that only verified software configurations can be used for patient monitoring.
- Updates to shared communication libraries to support functional enhancements referenced above.
- Separating the Portrait Mobile Patient Monitor hardware and software into 2 separate medical devices, which resulted in changes to device labels.
- Miscellaneous updates to packaging labels including the following:
- Updates to the minimum hardware specifications required for the Portrait Central Viewer Application software (to support expanded functionality in the future).
- Updates to the humidity specifications for the Portrait Mobile Patient Monitor to 10-90% from 5-95%.
- Deliver new IOU and software upgrade parts (i.e., new part numbers for service parts).
- Updates to user and service documentation needed to explain the changes, as well as continuous improvement clarifications

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	Reference Predicate Device Portrait Mobile Monitoring Solution – K230626	Proposed device Portrait Mobile Monitoring Solution –	Discussion of differences between Portrait Mobile Monitoring Solution and Predicate
Intended Use	Vital Sign Monitor	Vital Sign Monitor	Identical
FDA Primary Product Code	MWI	MWI	Identical
FDA Classification Regulation	21 CFR 870.2300	21 CFR 870.2300	Identical
Indications for Use (entire system)	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 of 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.	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 healthcare 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 of 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 A typo was corrected in the indications statement to add the word “healthcare” so that “…licensed professional, …” changes to “…licensed healthcare professional, …” This difference does not significantly affect safety and/or effectiveness.
Patient Population	Adult and pediatric patients (3 years of age and older, and weighing more than 10 kg).	Adult and pediatric patients (3 years of age and older, and weighing more than 10 kg).	Identical
Environments of Use	A professional healthcare facility	A professional healthcare facility	Identical
Location of devices in the patient vicinity	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.	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.	Identical

Specification	Reference Predicate Device Portrait Mobile Monitoring Solution – K230626	Proposed device Portrait Mobile Monitoring Solution –	Discussion of differences between Portrait Mobile Monitoring Solution and Predicate
Remote Viewing and Monitoring Modes	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.	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.	Identical
	STANDARDS COMPLIANCE		
Medical Standards	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 ISO 14971 Third Edition 2019-12 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: ANSI IEEE C63.27:2017	ANSI AAMI ES60601-1:2005/®2012 & A1:2012, C1:2009/®2012 & A2:2010/®2012 (Cons. Text) [Incl. AMD2:2021] 60601-1-2 Edition 4.1 2020-09 IEC 60601-1-8 Edition 2.2 2020-07 IEC 80601-2-49 Edition 1.0 2018-03 ISO 80601-2-61 Second edition 2017-12 IEC 60601-1-6 Edition 3.2 2020-07 IEC 62366-1 Edition 1.1 2020-06 ISO 10993-1 Fifth edition IEC 62304 Edition 1.1 2015-06 ISO 14971 Third Edition 2019-12 Labeling ISO 20417 First edition 2021-04 Corrected version 2021-12 15223-1 Fourth edition 2021-07 17664-2 First edition 2021-02 Battery: UL 2054 2nd Edition IEC 62133-2:2017/AMD1:2021 UL 1642:2012 Wireless: IEEE ANSI C63.27-2021	Equivalent Newer updated versions of standards were used for the following standards: • ANSI AAMI ES60601-1:2005/®2012 & A1:2012, C1:2009/®2012 & A2:2010/®2012 (Cons. Text) [Incl. AMD2:2021] • 60601-1-2 Edition 4.1 2020-09 • 60601-1-8 Edition 2.2 2020-07 • 60601-1-6 Edition 3.2 2020-07 • IEC 62366-1 Edition 1.1 2020-06 • IEEE ANSI C63.27-2021 The AIM 7351731 standard was removed since the new IEC 60601-1-2 Edition 4.1 now takes the same testing into account. Similarly, the ISO 17664:2017 standard was dropped since relevant content for Portrait V1.1 devices are covered by the newer ISO 17664-2: 2021. Updating to newer standard versions does not significantly affect safety and/or effectiveness.
	System Components		
Patient Device	PORTRAIT Mobile Patient Monitor	Portrait HUBXB with software Portrait HSWXB	Equivalent The Portrait Mobile Patient Monitor had been split into separate hardware and software components. The Portrait Mobile Patient Monitor is shipped with no clinical software installed. The clinical software (i.e., Portrait Mobile Patient Monitor Software) is installed at the customer site before the device is put into use. This difference does not significantly affect safety and/or effectiveness.
Sensors	PORTRAIT SpO2 Wearable Pulse Oximetry Sensors PORTRAIT Wearable Respiration Rate Sensor (wireless connection to the Mobile Patient Monitor)	PORTRAIT SpO2 Wearable Pulse Oximetry Sensors PORTRAIT Wearable Respiration Rate Sensor (wireless connection to the Mobile Patient Monitor)	Identical

Specification	Reference Predicate Device Portrait Mobile Monitoring Solution – K230626	Proposed device Portrait Mobile Monitoring Solution –	Discussion of differences between Portrait Mobile Monitoring Solution and Predicate
Sensor Battery	Detachable sensor battery. Interchangeable. May be used with any sensor.	Detachable sensor battery. Interchangeable. May be used with any sensor.	Identical
SpO2 Probes	Integrated in sensors	Integrated in sensors	Identical
Respiration Electrode Patches	Portrait RR Electrode Patch	Portrait RR Electrode Patch	Identical
Battery Charger	Portrait Bedside Charger	Portrait Bedside Charger	Identical
Accessories for Portrait Mobile Patient Monitor	Portrait Mobile Patient Monitor Pouch	Portrait Mobile Patient Monitor Pouch	Identical
Central Viewing	Portrait Central Viewer Software Application with Portrait Clinical Alarming Unit	Portrait Central Viewer Software Application with Portrait Clinical Alarming Unit	Identical
Storage and Centralized Services	Portrait Core Services	Portrait Core Services	Identical
Accessories for SpO2	Portrait SpO2 Attachment Accessory Band	Portrait SpO2 Attachment Accessory Band	Identical
	Patient Device – General Hardware Specifications		
Device Name	**Portrait Mobile Patient Monitor**	**Portrait HUBXB with software Portrait HSWXB**	Equivalent The Portrait Mobile Patient Monitor had been split into separate hardware and software components. The Portrait Mobile Patient Monitor is shipped with no clinical software installed. The clinical software (i.e., Portrait Mobile Patient Monitor Software) is installed at the customer site before the device is put into use. This difference does not significantly affect safety and/or effectiveness.
Size (H x W x D)	14.1 cm x 6.3 cm x 2.1 cm	14.1 cm x 6.3 cm x 2.1 cm	Identical
Weight	223 g	223 g	Identical
Power source	Battery (integrated into device)	Battery (integrated into device)	Identical
Battery Type	Lithium-ion	Lithium-ion	Identical
Run-time on battery	16 Hours with full capacity (display off)	16 Hours with full capacity (display off)	Identical
Charge time	8 Hours from empty to full capacity.	8 Hours from empty to full capacity.	Identical
	Patient Device – User Interface		
Device Name	**Portrait Mobile Patient Monitor**		
Touch display interface	Yes	Yes	Identical
Visual and Audible Alarm capability	Available	Available	Identical
	Patient Device – Display Specifications		
Display type	SFT LCD (Super Fine TFT)	SFT LCD (Super Fine TFT)	Identical
Display Size and resolution	480 x 800 pixels, 3.7 inches in 16:9 format	480 x 800 pixels, 3.7 inches in 16:9 format	Identical
Parameter Blocks Displayed Simultaneously	3 Parameters (all available parameters)	3 Parameters (all available parameters)	Identical
Number of traces (waveforms)	One waveform per page in detailed parameter view	One waveform per page in detailed parameter view	Identical
Trends	Displays graphical trend of connected parameters for the last 4 hours. Movable cursor displays details for the given point in time.	Displays graphical trend of connected parameters for the last 4 hours. Movable cursor displays details for the given point in time.	Identical

Specification	Reference Predicate Device Portrait Mobile Monitoring Solution – K230626	Proposed device Portrait Mobile Monitoring Solution –	Discussion of differences between Portrait Mobile Monitoring Solution and Predicate
	Patient Device – Connectivity		
Wireless connection to network	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.	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.	Identical
Connection to Sensors	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.	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.	Identical
RTLS	None	Portrait HUBXB with software Portrait HSWXB transmits Bluetooth beacons to support RTLS (real time location services).	Equivalent Bluetooth beacons sent in the proposed device are intended for asset tracking only and are not intended for clinical use. This difference does not significantly affect safety and/or effectiveness.
QR Code	None	Portrait HUBXB with software Portrait HSWXB supports QR code for reading of patient demographics and vital signs by external device.	Equivalent In V1.1, Portrait HUBXB with software Portrait HSWXB adds a QR code that can be read by an external device to transfer patient demographics and current vital signs information. This difference does not significantly affect safety and/or effectiveness.
	Accessories for Portrait Mobile Patient Monitor		
Device Name	Portrait Mobile Patient Monitor Pouch		
Single Use / Multiple Use	Single Use	Single Use	Identical
	Respiration Sensors – Hardware		
Device Name	**Portrait Wearable Respiration Rate Sensor**		
Dimensions	6.9 x 5.3 x 1.9 cm	6.9 x 5.3 x 1.9 cm	Identical
Weight	34 g	34 g	Identical
	Accessories for Respiration Rate sensor		
Device Name	**Portrait RR Electrode Patch**		
Operating Temperature	0 to 40 °C	0 to 40 °C	Identical
Single Use / Multiple Use	Single Use	Single Use	Identical
Shelf Life	18 months	18 months	Identical

Specification	Reference Predicate Device Portrait Mobile Monitoring Solution – K230626	Proposed device Portrait Mobile Monitoring Solution –	Discussion of differences between Portrait Mobile Monitoring Solution and Predicate
	Pulse Oximetry Sensor – Hardware		
Device Name	**Portrait Wearable Pulse Oximetry Sensor**		
Sensor Application Site	Finger	Finger	Identical
Dimensions	SpO2 P-SA01: 27.2 x 5.3 x 1.9 cm SpO2 P-SP01: 23.6 x 5.3 x 1.9 cm SpO2 P-W01: 26.2 x 5.3 x 1.9 cm SpO2 P-SE01: 27.1 x 5.3 x 1.9 cm	SpO2 P-SA01: 27.2 x 5.3 x 1.9 cm SpO2 P-SP01: 23.6 x 5.3 x 1.9 cm SpO2 P-W01: 26.2 x 5.3 x 1.9 cm SpO2 P-SE01: 27.1 x 5.3 x 1.9 cm	Identical
Weight	SpO2 P-SA01: 52 g SpO2 P-SP01: 43 g SpO2 P-W01: 38 g SpO2 P-SE01: 38 g	SpO2 P-SA01: 52 g SpO2 P-SP01: 43 g SpO2 P-W01: 38 g SpO2 P-SE01: 38 g	Identical
Fluid Ingress Rating	SpO2 P-SA01, SpO2 P-SP01: IP67 SpO2 P-W01 and SpO2 P-SE01: IP44	SpO2 P-SA01, SpO2 P-SP01: IP67 SpO2 P-W01 and SpO2 P-SE01: IP44	Identical
Operating Temperature	0 to 40 °C	0 to 40 °C	Identical
Non-Operating Temperature	-30 to 70 °C	-30 to 70 °C	Identical
Operating Humidity	5 to 95% non-condensing	5 to 95% non-condensing	Identical
Non-Operating Humidity	5 to 95% non-condensing	5 to 95% non-condensing	Identical
Operating Pressure	620 to 1060 hPa Note: For comparison purposes this is 62 kPa to 106 kPa	620 to 1060 hPa Note: For comparison purposes this is 62 kPa to 106 kPa	Identical
Non-Operating Pressure	500 to 1060 hPa Note: For comparison purposes this is 50 kPa to 106 kPa	500 to 1060 hPa Note: For comparison purposes this is 50 kPa to 106 kPa	Identical
	Accessories for SpO2 sensors		
Device Name	**Portrait SpO2 Attachment Accessory Band**		
Indications for Use	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	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 healthcare practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.	Equivalent A typo was corrected in the indications statement to add the word "healthcare" so that "…licensed professional, …" changes to "…licensed healthcare professional, …". This difference does not significantly affect safety and/or effectiveness.
Operating Temperature	0 to 40 °C	0 to 40 °C	Identical
Non-Operating Temperature	-30 °C to -70 °C	-30 °C to -70 °C	Identical
Non-Operating Humidity	5 to 95% non-condensing	5 to 95% non-condensing	Identical
Non-Operating pressure	500 to 1060 hPa Note: For comparison purposes this is 50 kPa to 106 kPa	500 to 1060 hPa Note: For comparison purposes this is 50 kPa to 106 kPa	Identical
Sterility	The SpO2 Attachment is supplied as non-sterile and is not intended to be sterilized.	The SpO2 Attachment is supplied as non-sterile and is not intended to be sterilized.	Identical
Single Use / Multiple Use	Single Use	Single Use	Identical

Specification	Reference Predicate Device Portrait Mobile Monitoring Solution – K230626	Proposed device Portrait Mobile Monitoring Solution –	Discussion of differences between Portrait Mobile Monitoring Solution and Predicate
	Sensor Batteries - Hardware		
Device Name	**Portrait Sensor Battery**		
Dimensions	3.6 x 5.3 x 1.7 cm	3.6 x 5.3 x 1.7 cm	Identical
Weight	31 g	31 g	Identical
	Charger - Hardware		
Device Name	**Portrait Bedside Charger**		
Input voltage and frequency	100-240 V, 50-60 Hz (using external power supply)	100-240 V, 50-60 Hz (using external power supply)	Identical
Power	36 W (Output power - 3.0 A at 12 Vdc)	36 W (Output power - 3.0 A at 12 Vdc)	Identical
Dimensions (exclusive of power supply and cable)	11.5 x 23.8 x 4.3 cm	11.5 x 23.8 x 4.3 cm	Identical
Weight (exclusive of power supply and cable)	412 g Wall mount: 603 g Table mount: 908 g	412 g Wall mount: 603 g Table mount: 908 g	Identical
	Central/Remote Viewer		
Device Name	**Portrait Central Viewer Application with Portrait Clinical Alarming Unit**		
Display	Required Specification for customer supplied display: 20 in (minimum), 1920 x 1080 resolution (minimum)	Required Specification for customer supplied display: 20 in (minimum), 1920 x 1080 resolution (minimum)	Identical
Operating System	Required Specification for customer supplied PC: Windows 10, build 10.0.17763 (minimum)	Required Specification for customer supplied PC: Windows 10, build 10.0.17763 (minimum)	Identical
Number of patients per viewer	Maximum 24	Maximum 24	Identical
Simultaneous view of numerics for all patients on viewer	Supported on for all measured parameters on Multiple Patient View – SpO2%, Pulse Rate, Respiration Rate	Supported on for all measured parameters on Multiple Patient View – SpO2%, Pulse Rate, Respiration Rate	Identical
Viewing of patient waveforms	One patient at time – Supported on single patient view	One patient at time – Supported on single patient view	Identical
Viewing of patient trends	Graphical trend view supported for one patient at time – single patient view	Graphical trend view supported for one patient at time – single patient view	Identical
Visual/Audible alarms supported	Supported	Supported	Identical
	Storage and Centralized Services – General		
Device Name	**Portrait Core Services**		
Description	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.	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.	Identical
HL7 outbound support	Supported - The Portrait Core Services can transmit patient physiological trends and numerics (IHE PCD DEC) and alarm events (IHE PCD ACM) outbound.	Supported - The Portrait Core Services can transmit patient physiological trends and numerics (IHE PCD DEC) and alarm events (IHE PCD ACM) outbound and waveforms (IHE PCD WCM).	Equivalent The addition of transmitting IHE PCD WCM waveforms in addition to physiological trends and numerics in the predicate does not significantly affect safety and/or effectiveness.

Specification	Reference Predicate Device Portrait Mobile Monitoring Solution – K230626	Proposed device Portrait Mobile Monitoring Solution –	Discussion of differences between Portrait Mobile Monitoring Solution and Predicate
HL7 Inbound support	Supported - The Portrait Core Services can also receive HL7 ADT information to admit patients to the Portrait Monitoring Solution.	Supported - The Portrait Core Services can also receive HL7 ADT information to admit patients to the Portrait Monitoring Solution.	Identical
	Storage and Centralized Services – General		
Server Model	HP ProLiant DL360 Gen10	HP ProLiant DL360 Gen10	Identical
	Monitored Parameters		
Monitored Parameters	Oxygen saturation (SpO2) Pulse rate (PR) Respiration Rate (RR)	Oxygen saturation (SpO2) Pulse rate (PR) Respiration Rate (RR)	Identical
Parameters Acquisition Method	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) 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 Portrait HUBXB with software Portrait HSWXB 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) 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)	Identical (except for name change of the device)
	Alarms		
Classification / Alarm Levels	Three levels - High (red), Medium (yellow), Low (cyan) in compliance with IEC 60601-1-8 Informational messages (gray) also included	Three levels - High (red), Medium (yellow), Low (cyan) in compliance with IEC 60601-1-8 Informational messages (gray) also included	Identical
Notification	Audible and visual	Audible and visual	Identical
List of Physiological Alarms supported (for parameters included in the proposed device)	PR High PR Low RR High RR Low SpO2 High SpO2 Low SpO2 Critically low Apnea	PR High PR Low RR High RR Low SpO2 High SpO2 Low SpO2 Critically low Apnea	Identical
Technical / Equipment Alarms	Supported	Supported The proposed device supports the same Technical/Equipment alarms with a modified SpO2 check probe technical alarm from a single level alarm to a 2-stage (i.e., escalating) alarm.	Equivalent This change allows for the responsible organization flexibility in configuring alarm priority defaults. The configurations options in the predicate device remain available in the proposed device. The proposed device provides the responsible organization to escalate the alarm priority after a configurable delay. The configuration of alarm priorities and time delay are password protected.

Specification	Reference Predicate Device Portrait Mobile Monitoring Solution – K230626	Proposed device Portrait Mobile Monitoring Solution –	Discussion of differences between Portrait Mobile Monitoring Solution and Predicate
			This difference does not significantly affect safety and/or effectiveness.
	Trending		
Trend Visualization	Graphical Trends only. Individual values for each trended value are visible at the position of the cursor.	Graphical Trends only. Individual values for each trended value are visible at the position of the cursor.	Identical
Trend Visualization Duration	Up to 4 Hours on the Portrait Mobile Patient Monitor Up to 24 Hours on the Portrait Central Viewer Application	Up to 4 Hours on the Portrait Mobile Patient Monitor Up to 24 Hours on the Portrait Central Viewer Application	Identical
Trend Smoothing	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.	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.	Identical
Event management	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.	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.	Identical
Trend resolution	1-minute resolution	1-minute resolution	Identical
	RESPIRATION		
Measurement Method	Impedance Respiration (i.e., Impedance Pneumography)	Impedance Respiration (i.e., Impedance Pneumography)	Identical
Display Range	0 to 99 breaths/min	0 to 99 breaths/min	Identical
Units	Respiration Rate (RR) in breaths/min	Respiration Rate (RR) in breaths/min	Identical
Resolution	1 breath/min	1 breath/min	Identical
Accuracy Range	4 to 60 breaths/min	4 to 60 breaths/min	Identical
Accuracy	+/- 3 breaths/min	+/- 3 breaths/min	Identical
Waveforms	Impedance Respiration waveform with automatic scaling, 6.25 mm/s sweep speed (Portrait Mobile Patient Monitor), 25 mm/s sweep speed (Portrait Central Viewer Application)	Impedance Respiration waveform with automatic scaling, 6.25 mm/s sweep speed (Portrait HUBXB with software Portrait HSWXB, 25 mm/s sweep speed (Portrait Central Viewer Application)	Identical (except for name change of the device)
	PULSE OXIMETRY – SpO2		
Measurement	Arterial oxygen saturation (SpO2)	Arterial oxygen saturation (SpO2)	Identical
Units	Percent	Percent	Identical
Display Range	0 to 100%	0 to 100%	Identical
Resolution	1%	1%	Identical
Accuracy Range	70 to 100%	70 to 100%	Identical
Accuracy	SpO2 (70 to 100%) <= 2% Low perfusion SpO2: <= 3% With motion: <= 3% SpO2 (<70%) - Unspecified	SpO2 (70 to 100%) <= 2% Low perfusion SpO2: <= 3% With motion: <= 3% SpO2 (<70%) - Unspecified	Identical
Averaging	Adjustable from 0 to 60 seconds (default 10 seconds)	Adjustable from 0 to 60 seconds (default 10 seconds)	Identical
Optical Wavelengths / power	Pulse oximetry sensor LED peak wavelengths are within 600 to 1000 nm and the maximum optical output power for each LED is less than 15 mW.	Pulse oximetry sensor LED peak wavelengths are within 600 to 1000 nm and the maximum optical output power for each LED is less than 15 mW.	Identical

Specification	Reference Predicate Device Portrait Mobile Monitoring Solution – K230626	Proposed device Portrait Mobile Monitoring Solution –	Discussion of differences between Portrait Mobile Monitoring Solution and Predicate
Waveforms	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)	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)	Identical
	PULSE OXIMETRY – Pulse Rate		
Measurement	Peripheral Pulse rate (PR)	Peripheral Pulse rate (PR)	Identical
Units	Beats per minute (bpm)	Beats per minute (bpm)	Identical
Display Range	30 to 300 bpm	30 to 300 bpm	Identical
Resolution	1 bpm	1 bpm	Identical
Accuracy Range	30 to 250 bpm	30 to 250 bpm	Identical
Accuracy	<= 2 bpm (30 to 250 bpm) Low perfusion: <= 2 bpm (30 to 250 bpm) With motion: <=5 bpm (30 to 250 bpm)	<= 2 bpm (30 to 250 bpm) Low perfusion: <= 2 bpm (30 to 250 bpm) With motion: <=5 bpm (30 to 250 bpm)	Identical

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 v1.1, demonstrating the design meets the specifications.

This section addresses the Non-Clinical testing for Portrait Mobile Monitoring Solution v1.1 relied on for a determination of substantial equivalence to the predicate K230626 Portrait Mobile Monitoring Solution v1.0.

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 (no changes have been made to the SpO2 algorithms since K230626, only regression testing performed)
- low perfusion condition (this testing covers the full accuracy range in challenging low-perfusion conditions using a simulator, proving that there has been no system regression)
- Pulse Rate (PR) measurement, non-motion condition
- Pulse Rate (PR) measurement, motion condition
- Pulse Rate (PR) measurement, low perfusion condition
- Impedance Respiration (no changes have been made to the Respiration Rate algorithms since K230626, only regression testing performed)
- Respiration Rate (RR)
- Apnea
- Alarms Bench Testing
- Manuals Bench Testing
- Compliance to FDA Recognized Standards
- Compliance to FDA Human Factors Guidance
- Compliance to FDA ECG Electrodes Guidance
- Compliance to FDA Pulse Oximeters Guidance

The Portrait Mobile Monitoring Solution v1.1 meets the EMC requirements described in 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests. In addition, Portrait Mobile Monitoring Solution v1.1 shows 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 meets the electrical safety requirements of ANSI AAMI ES60601-1:2005/2012 & A1:2012, C1:2009/2012 & A2:2010/2012 (Cons. Text) [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]".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 60601-1:2005 + A1:2012+A2:2020, Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance – Edition 3.2, clause 8.5.2.3, which is equivalent with clause 56.3c in IEC 60601-1:1988.

Additional data is provided for compliance to:

- 60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION 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

- Guidance for Industry - Pulse Oximeters-Premarket Notification submission 510(k)s: Document issued on March 4, 2013
- Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Electrocardiograph Electrodes, Document issued on: July 21, 2011, NOTE: Included because the Portrait Mobile Monitoring Solution includes electrodes used to measure changes in thoracic impedance in order to measure a patient's respiratory rate.

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- Document issued on: September 8, 2023" 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:

- 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.

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 3.2 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

- IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION Medical devices - Part 1: Application of usability engineering to medical devices

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 62133-2:2017/AMD1:2021 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 C63.27-2021 American National Standard for Evaluation of Wireless Coexistence

Additional Labeling standards followed:

- ISO 20417 First edition 2021-04 Corrected version 2021-12 Medical devices — Information to be supplied by the manufacturer
- 15223-1 Fourth edition 2021-07 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.

- Content of Premarket Submissions for Device Software Functions, Guidance for Industry and Food and Drug Administration Staff Document issued on June 14, 2023
- General Principles of Software Validation; Final

Guidance for Industry and FDA Staff, January 11, 2002

- Off-The-Shelf Software Use in Medical Devices, Guidance for Industry and Food and Drug Administration Staff, August 11, 2023
- Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices, Guidance for Industry and Food and Drug Administration Staff. Document issued on: September 6, 2017

Software testing was conducted, and documentation was provided as recommended by Content of Premarket Submissions for Device Software Functions, Guidance for Industry and Food and Drug Administration Staff: Document issued on June 14, 2023" The software for this device is considered as a "Enhanced" documentation level. Software standards IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes and the 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 v1.1 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 "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions Guidance for Industry and Food and Drug Administration Staff Document issued on September 27, 2023".

In addition, the Portrait Mobile Monitoring Solution v1.1 complies with section 524B "Ensuring Cybersecurity of Medical Devices" of the FD&C Act. The Portrait Mobile Monitoring Solution v1.1 meets the definition of a "cyber device" per Section 524B(c) of the FD&C Act . To meet the requirements under section "3305 of the Consolidated Appropriations Act, 2023, enacted on December 29, 2022, section 524B "Ensuring Cybersecurity of Medical Devices" to the FD&C Act" GE HealthCare has also specifically attached a complete cybersecurity management plan and SBOMs.

Clinical (807.92(b)(2)):	Summary of Clinical Tests: The Portrait Mobile Monitoring Solution v1.1 does not contain clinical testing data.
Conclusion (807.92(b)(3)):	GE HealthCare considers the Portrait Mobile Monitoring Solution v1.1 to be substantially equivalent to the predicate device.