April 25, 2024

GE Medical Systems Information Technologies, Inc.
Jung William
Regulatory Affairs Director
9900 Innovation Drive
Wauwatosa, Wisconsin 53226

Re: K233810
Trade/Device Name: Portrait VSM
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, DXN, DQA, DPZ, FLL, MHX
Dated: November 30, 2023
Received: November 30, 2023

Dear Jung William:

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,

for Robert T. Kazmierski -S

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices

Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233810

Device Name
Portrait VSM

Indications for Use *(Describe)*

The Portrait VSM vital signs monitor is intended to monitor a single patient's vital signs at the site of care or during intra-hospital transport.
The noninvasive oscillometric blood pressure parameter is intended for measurement of systolic, diastolic, and mean arterial blood pressure, as well as pulse rate, for adult, pediatric and neonatal patients.
The optional GE TruSignal pulse oximetry and accessories are indicated for the continuous noninvasive monitoring of functional Oxygen Saturation (SpO2) and pulse rate, including monitoring during conditions of clinical patient motion or low perfusion, with adult, pediatric and neonatal patients.
The optional Masimo SET® pulse oximetry and accessories are indicated for the continuous noninvasive monitoring of functional Oxygen Saturation (SpO2) and pulse rate, during both no motion and motion conditions, and for patients who are well or poorly perfused (low perfusion) for adult, pediatric and neonatal patients.
The optional Nellcor™ pulse oximetry and accessories are indicated for the continuous noninvasive monitoring of functional Oxygen Saturation (SpO2) and pulse rate of adult, pediatric, and neonatal patients during both motion and non-motion conditions, and for patients who are well or poorly perfused.
The optional Welch Allyn® SureTemp® Plus electronic thermometer is intended to measure one of oral, axillary, and rectal temperature of adult and pediatric patients.
The optional Exergen TemporalScanner thermometer is intended for the intermittent measurement of human body temperature of patients of all ages.
The optional HeTaiDa electronic infrared non-touch thermometer is intended for the intermittent measurement of human body temperature of patients of all ages.
A wireless network connection is provided to transmit clinical data into various hospital information systems. An optional remote alarm cable connection is intended to complement visual and audible alarms and not replace the need for the presence of a caregiver.
The portable device is designed for use in hospitals and hospital-type facilities. The Portrait VSM vital signs monitor can also be used in satellite areas or alternate care settings.

The Portrait VSM vital signs monitor is intended for use under the direct supervision of a licensed health care practitioner.
The Portrait VSM vital signs monitor is not intended for use during MRI.

"Portable" refers to the ability of the Portrait VSM vital signs monitor to be easily moved by the caregiver, such as on a roll stand.

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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9900 Innovation Drive
Wauwatosa, WI 53226, USA

510(k) Summary for K233810

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

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

Date: November 30th, 2023

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

Primary Contact Person: William Jung
Regulatory Affairs Director
GE HealthCare
Phone: 571-396-1558
E-mail: William.Jung@gehealthcare.com

Secondary Contact Person:
Joel Kent
Director, Regulatory Affairs Strategy
GE HealthCare
Phone: 617-851-0943
E-mail: joel.kent@gehealthcare.com

Sun Yanli
Regulatory Affairs Manager
GE HealthCare
Phone: +86-18051597363
E-mail: yanli.sun@gehealthcare.com

Device names (807.92(a)(2):

Trade Name: Portrait™ VSM

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

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Classification Names:	21 C.F.R. §870.2300 Cardiac monitor (including cardiotachometer and rate alarm). 21 C.F.R. §870.1130 Noninvasive blood pressure measurement system. 21 C.F.R. §870.2700 Oximeter 21 C.F.R. §870.2710 Ear oximeter. 21 C.F.R. §880.2910 Clinical electronic thermometer. 21 C.F.R. §870.1100 alarm, blood-pressure
Product Code:	MWI
Subsequent Product Code:	DXN, DQA, DPZ, FLL
Predicate Device(s) (807.92(a)(3)):	Primary Predicate: K133810 Vital Signs Monitor VC150 Additional Predicate Devices: K213490 B105M Patient Monitor K171888 Non-contact infrared body thermometer
Device Description (807.92(a)(4)):	The proposed Portrait™ VSM is a vital signs monitor which is developed based on primary predicate vital signs monitor VC150(K133810) with integrated NIBP and SpO2 design from a secondary predicate monitor B105M (K213490) and provided additional non-contact infrared body temperature measurement option by supporting OEM thermometer (K171888) previously cleared by FDA. In addition to the added non-contact infrared body thermometer, the proposed monitor Portrait™ VSM also offer several enhancements: • New hardware platform • Adopted equivalent NIBP design from B105M(K213490) • Adopted equivalent SpO2 design from B105M(K213490) • Compatible with Recorder B1X5-REC • Support Round Advisor in spot check mode • Support automatically screens brightness adjustment. • Improved Early Warning Score • Addtional alarm management enhancement. • Additional cybersecurity enhancement

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The proposed monitor Portrait™ VSM adopts larger 10-inch LCD touch screen with improved Industrial Design (ID) to be more portable and more compact for clinicians than the primary predicate monitor VC150 (K133810) while maintaining the same primary function and operation.

As with the predicate Monitor VC150 (K133810), the proposed Portrait™ VSM is Vital Signs Monitor, utilizing an LCD display and can measure the most commonly used vital signs of patient: Non-invasive Blood Pressure (NIBP), Pulse Rate (PR), Temperature (Temp), and Pulse Oxygen Saturation (SpO2).

Same as the predicate monitor VC150 (K133810), the proposed monitor Portrait™ VSM also has three choices for SpO2 include GE TruSignal™; Nellcor™ or Masimo SET® and temperature measurement from Exergen® TemporalScanner™, and Welch Allyn® SureTemp®.

Both the predicate monitor VC150 (K133810) and the proposed monitor Portrait™ VSM can be configured to be used for Spot-checking or for continuous morning, the device can send measured patients' data to EMR (Electronic Medical Record) system by interfacing to Hospital Information Systems (HIS) over a wired or wireless network.

Moreover, same as the predicate monitor VC150 (K133810), the proposed monitor Portrait™ VSM can be powered by battery or AC, has a carrying handle and can be placed on a shelf or table or mounted in a variety of ways using a mounting plate located on the bottom of the monitor.

Indications for Use (807.92(a)(5)):

The Portrait™ VSM vital signs monitor is intended to monitor a single patient’s vital signs at the site of care or during intra-hospital transport.

The noninvasive oscillometric blood pressure parameter is intended for measurement of systolic, diastolic, and mean arterial

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blood pressure, as well as pulse rate, for adult, pediatric and neonatal patients.

The optional GE TruSignal pulse oximetry and accessories are indicated for the continuous noninvasive monitoring of functional Oxygen Saturation (SpO2) and pulse rate, including monitoring during conditions of clinical patient motion or low perfusion, with adult, pediatric and neonatal patients.

The optional Masimo SET® pulse oximetry and accessories are indicated for the continuous noninvasive monitoring of functional Oxygen Saturation (SpO2) and pulse rate, during both no motion and motion conditions, and for patients who are well or poorly perfused (low perfusion) for adult, pediatric and neonatal patients.

The optional Nellcor™ pulse oximetry and accessories are indicated for the continuous noninvasive monitoring of functional Oxygen Saturation (SpO2) and pulse rate of adult, pediatric, and neonatal patients during both motion and non-motion conditions, and for patients who are well or poorly perfused.

The optional Welch Allyn SureTemp Plus electronic thermometer is intended to measure one of oral, axillary, and rectal temperature of adult and pediatric patients.

The optional Exergen TemporalScanner thermometer is intended for the intermittent measurement of human body temperature of patients of all ages.

The optional HeTaiDa electronic infrared non-touch thermometer is intended for the intermittent measurement of human body temperature of patients of all ages.

A wireless network connection is provided to transmit clinical data into various hospital information systems. An optional remote alarm cable connection is intended to complement visual and audible alarms and not replace the need for the presence of a caregiver.

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The portable device is designed for use in hospitals and hospital-type facilities. The Portrait™ VSM vital signs monitor can also be used in satellite areas or alternate care settings.

The Portrait™ VSM vital signs monitor is intended for use under the direct supervision of a licensed health care practitioner.
The Portrait™ VSM vital signs monitor is not intended for use during MRI.

"Portable" refers to the ability of the Portrait™ VSM vital signs monitor to be easily moved by the caregiver, such as on a roll stand.

Contraindications for using the monitor

The Portrait™ VSM vital signs monitor is not intended for use during MRI.

Technology (807.92(a)(6)):

The proposed monitor Portrait™ VSM is a vital signs monitor where features and parameters are essentially same as in predicate monitor VC150 (K133810). This 510 (k) introduces non-contact infrared body thermometer by supporting additional optional OEM module (K171888) previously cleared by FDA and enhancements of several features.

The fundamental technology of the proposed monitor Portrait™ VSM is same as the predicate device.

The proposed monitor Portrait™ VSM are substantially equivalent to the predicate devices.

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

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Product Comparison versus Predicate Main Features:

The proposed monitor Portrait™ VSM shares equivalent indications for use, intended use patient populations, and functional features as the predicate devices. The proposed monitor Portrait™ VSM consists of improvements and optional features outlined below that are substantially equivalent to the predicate device.

Specification	Primary Predicate Vital Sings Monitor VC150(K133810)	Proposed Portrait™ VSM Vital Signs Monitor	Differences
• Indications for Use	The VC150 is intended to monitor a single patient's vital signs at the site of care or during intra-hospital transport.	The Portrait™ VSM is intended to monitor a single patient's vital signs at the site of care or during intra-hospital transport.	**Equivalent.**
	The noninvasive oscillometric blood pressure parameter is intended for measurement of systolic, diastolic, and mean arterial blood pressure, as well as pulse rate, for adult, pediatric and neonatal patients.	The noninvasive oscillometric blood pressure parameter is intended for measurement of systolic, diastolic, and mean arterial blood pressure, as well as pulse rate, for adult, pediatric and neonatal patients.	Same features found in the predicate Monitor VC150 are retained, with the addition of infrared non-touch intermittent temperature measurement.
	The optional GE TruSignal pulse oximetry and accessories are indicated for continuous noninvasive monitoring of functional oxygen saturation (SpO2) and pulse rate, including monitoring during conditions of clinical patient motion or low perfusion, with adult, pediatric and neonatal patients.	The optional GE TruSignal pulse oximetry and accessories are indicated for the continuous noninvasive monitoring of functional Oxygen Saturation (SpO2) and pulse rate, including monitoring during conditions of clinical patient motion or low perfusion, with adult, pediatric and neonatal patients.	The addition of the infrared non-touch intermittent temperature measurement is supported through previously cleared HeTaida thermometer (K203332)
	The optional Masimo SET® pulse CO-oximetry and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate, during both no motion and motion conditions, and for patients who are well or poorly perfused (low perfusion) for adult, pediatric and neonatal patients.	The optional Masimo SET® pulse CO-oximetry and accessories are indicated for the continuous noninvasive monitoring of functional Oxygen Saturation (SpO2) and pulse rate, during both no motion and motion conditions, and for patients who are well or poorly perfused (low perfusion) for adult, pediatric and neonatal patients.	The proposed device only displays the measurement result from The HeTaida thermometer.
	The optional Nellcor™ oximetry and accessories are indicated for the continuous, noninvasive monitoring of arterial oxygen saturation (SpO2) and pulse rate of adult, pediatric, and neonatal patients during both motion and non-motion conditions, and for patients who are well or poorly perfused.	The optional Nellcor™ pulse oximetry and accessories are indicated for the continuous noninvasive monitoring of functional Oxygen Saturation (SpO2) and pulse rate of adult, pediatric, and neonatal patients during both motion and non-motion conditions, and for patients who are well or poorly perfused.	
	The optional Welch Allyn SureTemp Plus electronic thermometer is intended to measure oral, axillary, and rectal temperature of adult and pediatric patients.	The optional Welch Allyn SureTemp Plus electronic thermometer is intended to measure one of oral, axillary, and rectal temperature of adult and pediatric patients.	
	The optional Exergen TemporalScanner thermometer is intended for the intermittent measurement of human body temperature of patients of all ages.	The optional Exergen TemporalScanner thermometer is intended for the intermittent measurement of human body temperature of patients of all ages.	
		The optional HeTaiDa electronic infrared non-touch thermometer is intended for the intermittent measurement of human body temperature of patients of all ages.	

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	A wireless network connection is provided to transmit clinical data into various hospital information systems. An optional remote alarm cable connection is intended to complement visual and audible alarms and not replace the need for the presence of a caregiver. The portable device is designed for use in hospitals and hospital-type facilities. The VC150 can also be used in satellite areas or alternate care settings. "Portable" refers to the ability of the VC150 to be easily moved by the caregiver, such as on a roll stand. The VC150 is not intended to be used for continuous monitoring during patient transport.	A wireless network connection is provided to transmit clinical data into various hospital information systems. An optional remote alarm cable connection is intended to complement visual and audible alarms and not replace the need for the presence of a caregiver. The portable device is designed for use in hospitals and hospital-type facilities. The Portrait™ VSM can also be used in satellite areas or alternate care settings. **The Portrait™ VSM is intended for use under the direct supervision of a licensed health care practitioner.** "Portable" refers to the ability of the Portrait™ VSM to be easily moved by the caregiver, such as on a roll stand. **The Portrait™ VSM is not intended for use during MRI.**	Add few clarification to clarify the device need be used under the direct supervision of a licensed health care practitioner and can't be used during the MRI and removed one sentence regarding continuous monitoring to keep consistent with GE other monitors. Nothing change for the device itself. Both the predicate and the proposed device can use in the same condition, the modification of the description in indication for use is only to keep consistent description with GE other family products. Therefore, the changes do not significantly affect safety and/or effectiveness.
• Patient Population	Adult, pediatric and neonate	Adult, pediatric and neonate	**Identical**
• Use Environment	The Patient Monitor is intended for use in multiple areas within a professional healthcare facility	The Patient Monitor is intended for use in multiple areas within a professional healthcare facility	**Identical**
• Intrahospital transport within a professional healthcare facility	Yes	Yes	**Identical**
• Intended application site	NIBP- limb SpO2- finger, toe, ear Temperature- Oral/Rectal/Axillary/Forehead	NIBP- limb SpO2- finger, toe, ear Temperature- Oral/Rectal/Axillary/Forehead	**Identical**

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• Available Parameters	Pulse rate Non-invasive blood pressure (NIBP) Oxygen saturation (SpO2) Temperature Respiration rate (only available with Masimo technology)	Pulse rate Non-invasive blood pressure (NIBP) Oxygen saturation (SpO2) Temperature Respiration rate **(only support manually entered values of Respiration Rate)**	**Equivalent** The predicate monitor could support measure respiration rate by choose Masimo technology. The proposed monitor doesn't provide the respiration rate measurement due to employ different Masimo technology. respiration rate measurement is not provided in Masimo board MS-2011SB (K053269). However, the proposed monitor supports care giver to enter the respiration rate value manually for patient. The change does not affect safety or effectiveness.
• Peripheral Interfaces	Network interface Mains input Nurse call Connector 3 USB Connector SpO2 connector NIBP hose connection	Network interface Mains input Nurse call Connector 3 USB Connector SpO2 connector NIBP hose connection **HDMI Connector** **Recorder Connector**	**Equivalent** The proposed device adds HDMI (High-Definition Multimedia Interface) as connector to provide a slave video interface for a secondary display. The proposed device also supports connect to thermal recorder B1X5-REC(K213490) for printing through recorder connector. The recorder B1x5-REC(K213490) is identical and cleared in the predicate monitor B105M (K213490). The function was verified on the proposed device, and it demonstrated has equivalence to the predicate device. The change does not affect safety or effectiveness.
Display size	8.4-inch LCD display	**10.1-inch** LCD display	**Equivalent** The proposed device supports larger LCD display with better user experience. The change does not affect safety or effectiveness.

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Display type	Resistive touch screen	**Capacitive touch screen**	**Equivalent** The proposed device uses the capacitive touch screen due to technology improvement as capacitive touch screen has low power, long service life and stable operation compare with resistive touch screen. The change does not affect safety or effectiveness.
Operating System	Linux	Linux	**Identical**
Networking Interface	WLAN	WLAN **LAN**	**Equivalent** The proposed device additional support wired network connectivity. The proposed device adopts equivalent LAN design as B105M (K213490) The change does not affect safety or effectiveness.
Networking Protocol	HL7 Cerner-iBus LDAP NTP	HL7 Cerner-iBus LDAP NTP	**Identical**
Networks Supported Devices	CARESCAPE Gateway	**EMR Gateway Pro V2**	**Equivalent** The proposed device supports EMR Gateway Pro V2 which has better cost/product ratio. Both CARESCAPE Gateway and EMR Gateway Pro V2 acts as a communication conduit between the EMR system and the monitor and use the same HL7 interface engine. The change does not affect safety or effectiveness.
Audible Indicators	High, Medium, and Low alarm have audible tones that differentiate them from each other.	High, Medium, and Low alarm have audible tones that differentiate them from each other.	**Identical**
Visual Indicators	Alarm light. Highly visible Red/Yellow/Cyan light LCD Display: Red/Yellow/Cyan alarm notification	Alarm light. Highly visible Red/Yellow/Cyan light LCD Display: Red/Yellow/Cyan alarm notification.	**Identical**

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Alarm Volume	Adjustable. - Minimum level >= 40dBA, - Maximum level<= 90dBA	Adjustable. - Minimum level >= 45dBA, - Maximum level<= 85dBA	**Equivalent** Slight difference for range due to different hardware. Both ranges meet the requirements of IEC60601-1-8 standard. The change does not affect safety or effectiveness.
Alarm Volume adjustment	High/medium/low three priorities share same alarm volume setting.	**Provide two options:** Option 1: High/Medium/Low three priorities share same alarm volume setting. **Option 2: Separate alarm volume setting for Low priority alarms**	**Equivalent** The proposed device provided the additional option for Separate alarm volume setting for low priority alarms. Separate alarm volume setting for low priority alarms already implemented in the predicate monitor B105M (K213490) in the identical way. The change does not affect safety or effectiveness.
Allowed Minimum Alarm Volume Adjustment Range	The allowed minimum volume adjustment range is 50%-100% Adjustment the minimum volume is password protected	The allowed minimum volume adjustment range is **1-10 (equivale to 10% -100%)** Adjustment the minimum volume is password protected	**Equivalent** The proposed device changed the minimum volume level range to 10% to 100% to align with GE other monitors. Minimum volume adjustment range to 10% to 100% has been implemented in the predicate monitor B105M (K213490) with the identical way. The change does not affect safety or effectiveness.
Work mode	Spot check mode Monitoring mode	Spot check mode Monitoring mode	**Identical**

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NIBP measurement	Support	Support	**Equivalent** The proposed device incorporated the NIBP design from the predicate monitor B105M (213490). It adopts identical NIBP algorithm SuperSTAT (K022834), identical hardware design with the predicate Monitor B105M (K213490) except the NIBP circuit board has been re-arranged to adjust the layout of the same hardware to fit new industry design size. The change does not affect safety or effectiveness.
Masimo SpO2 measurement	Masimo SpO2	Masimo **MS-2011SB (K053269)**	**Equivalent** Same as primary predicate VC150 (K133810), the proposed device also supports Masimo SpO2 but adopts different Masimo OEM board MS-2011SB (K053269) which has been implemented in the predicate monitor B105M (K213490) in equivalent way. The change does not affect safety or effectiveness.
Nellcor SpO2 measurement	Nellcor SpO2	**Nellcor NELL1-SR OxiMax OEM(K060576)**	**Equivalent** Same as primary predicate VC150(K133810), the proposed device also supports Nellcor SpO2 but adopts different Nellcor OEM board NELL1-SR (K060576) which has been implemented in the predicate monitor B105M (K213490) in equivalent way. The change does not affect safety or effectiveness.
GE SpO2 measurement	GE TruSginal SpO2	GE TruSginal SpO2	**Equivalent** The proposed device adopts identical GE TruSginal SpO2 design as the predicate monitor B105M (K213490) try to share the most elctric boards design amog the GE monitors. The change does not affect safety or effectiveness.

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Temperature Measurement	Welch Allyn SureTemp Exergen Temporal Scanner Thermometer	Welch Allyn SureTemp Exergen Temporal Scanner Thermometer **HeTaiDa Non-Contact Infrared Body Thermometer**	**Equivalent** The proposed device additional support HeTaiDa Non-Contact Infrared Body Thermometer (K203332) which has been 510(k) cleared. The change does not affect safety or effectiveness.
Printers Supported	Integrated Thermal Recorder	B1X5-REC thermal recorder	**Equivalent** The B1X5-REC recorder provides the user the same thermal recording functions as the thermal recorders that were used in the predicate VC150 Vital Signs Monitor (K133810). The B1X5-REC (K213490) already cleared in K201941 and used in the predicate Monitor B105M (K213490). The change does not affect safety and effectiveness.
Host Operating temperature	5° to 40°C (41° to 104°F)	5° to 40°C (41° to 104°F)	**Identical**
Operating humidity range	5 to 95% non-condensing	15 to 90% non-condensing	**Equivalent** Slightly different in Operating humidity range due to hardware difference. The change does not affect safety and effectiveness.
Operating atmospheric pressure	700 to 1060 hPa (525 to 795 mmHg)	700 to 1060 hPa (525 to 795 mmHg)	**Identical**
Storage temperature	-20 to 50 °C (-4 to 122 °F) (Host)	-20 to 60 °C (-4 to 140 °F) (Host)	**Equivalent** Slightly different in Storage environment range due to hardware difference. The change does not affect safety and effectiveness.
Storage humidity	5 to 95% non-condensing (Host)	10 to 90% non-condensing (Host)	
Storage atmospheric pressure	500 to 1060 hPa (525 to 795 mmHg)	700 to 1060 hPa (525 to 795 mmHg)	
Power supply	From AC mains power adapte, internal battery	From AC, internal battery	**Identical**
Power Requirements	100 - 240 V ±10%, 50 /60 Hz	100 - 240 V ±10%, 50 /60 Hz	**Identical**
Power Consumption	<=48 VA	<=150 VA	**Identical**
Protection	Class I	Class I	**Identical**

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Battery	Lithium Ion	Lithium Ion	**Equivalent** The proposed monitor used a different battery compared with predicate monitor VC150. However, the battery used by proposed monitor is identical with predicate device B105M (K213490) The change does not affect safety and effectiveness.
Height	247±5mm	275±5mm	**Equivalent** Physical specifications are different due to different industry design. The change does not affect safety and effectiveness.
Width	242±5mm (Without Welch Allyn temperature option)	265±5mm (Without Welch Allyn temperature option)	
Depth	136±5mm	175±5mm	
Weight	2.8 kg (6.2 lb)	3.8 kg (8.4 lb)	

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™ VSM Vital Signs Monitor to demonstrate that the design meets the specifications.

This section addresses the non-clinical testing for Portrait™ VSM Vital Signs Monitor relied on for a determination of substantial equivalence to the primary predicate monitor K133810 VC150 and the secondary predicate monitor K213490 B105M.

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:

- Hardware Bench Testing
- Alarms Bench Testing
- IEC 80601-2-30: 2018
- ISO 80601-2-56: 2017+AMD1:2018
- ISO 80601-2-61: 2017+ C1:2018

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The Portrait™ VSM Vital Signs Monitor meets the EMC requirements described in IEC 60601-1-2:2014+A1:2020 "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™ VSM Vital Signs Monitor also passed the testing for IEC TR 60601-4-2:2016 "Medical electrical equipment -Part 4-2: Guidance and interpretation -Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems. The Portrait™ VSM Vital Signs Monitor has been evaluated for electromagnetic compatibility and potential risks from common emitters in the Portrait™ VSM Vital Signs Monitor environment.

The Portrait™ VSM Vital Signs Monitor meet the electrical safety requirements of IEC 60601-1:2005+A1:2012+A2:2020 " Medical electrical equipment – Part 1: General requirements for basic safety and essential performance". This testing was performed by a recognized independent and Certified Body Testing Laboratory (CBTL) under the IECEE CB Scheme.

Additional data is provided for compliance to:

- IEC 60601-1-8:2006+A1:2012+A2:2020: 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 80601-2-30:2018: Medical electrical equipment Part 2-30: Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
- IEC 80601-2-49:2018: Medical electrical equipment Part 2-49: Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
- ISO 80601-2-56:2017+A1:2018: Medical electrical equipment - Part 2-56: Particular requirements for basic

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safety and essential performance of clinical thermometers for body temperature measurement
- ISO 80601-2-61:2017+C1:2018: Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
- ASTM E1112-00 (2018) Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature

Environmental (Mechanical, and Thermal Safety) testing, based on the Portrait™ VSM Vital Signs Monitor proposed uses and locations, was confirmed to meet the specifications listed in the requirements. The Portrait™ VSM Vital Signs Monitor 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
- Mechanical stress
- Fluid ingress
- Packaging Bench Testing

The Portrait™ VSM Vital Signs Monitor follow the guidance "Reprocessing Medical Devices in Health Care Settings Validation Methods and Labeling, Document issued on March 17, 2015". Reprocessing efficacy validation has been conducted in accordance with the documented reprocessing instructions using worst-case devices/components of the Portrait™ VSM Vital Signs Monitor. The reprocessing efficacy validation met the acceptance criteria for the reprocessing efficacy validation tests.

The Portrait™ VSM Vital Signs Monitor 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:

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- IEC 60601-1-6:2010+A1:2013+A2:2020: Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62366-1:2015+A1:2020: Medical devices - Part 1: Application of usability engineering to medical devices

Summative Usability testing has been concluded with 15 US Clinical, 15 US Technical users. The usability testing of the Portrait™ VSM Vital Signs Monitor follows the FDA Guidance for Industry and Food and Drug Administration Staff "Applying Human Factors and Usability Engineering to Medical Devices, Document issued on: February 3, 2016".

Wireless performance data was provided related to:

- EMC testing per IEC 60601-1-2:2020, including electromagnetic immunity in the exclusion band and proximity fields from RF wireless communication.
- FDA Guidance-Radio Frequency Wireless Technology in Medical Devices, Document issued on: August 14, 2013
- IEEE ANSI C63.27-2021 American National Standard for Evaluation of Wireless Coexistence.

The Portrait™ VSM Vital Signs Monitor follow 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, Guidance for Industry and FDA Staff, January 11, 2002
- Off-The-Shelf Software Use in Medical Devices, Document issued on August 11, 2023
- Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software, Document issued on January 14, 2005
- 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

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- Design Considerations and Pre-market 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, "Content of Premarket Submissions for Device Software Functions." Bases on the risk level of the Portrait™ VSM Vital Signs Monitor, the document level for this submission is considered as "Enhanced" documentation level. Software standards IEC 62304:2006+A1:2015 Medical device software - Software life cycle processes and risk management standard ISO 14971:2019 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™ VSM Vital Signs Monitor including a Security Risk Assessment, Threat model and Penetration testing. This includes system integrity controls, access controls, audit controls, network controls which address the General Principles and Security Capabilities outlined in the "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions. Draft Guidance for Industry and Food and Drug Administration Staff. Document issued on April 8, 2022."

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

The subject of this premarket submission, the proposed monitor Portrait™ VSM did not require clinical studies to support substantial equivalence.

Conclusion (807.92(b)(3)): GE HealthCare considers the proposed monitor Portrait™ VSM to be substantially equivalent to the predicate devices.