April 1, 2022

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

Re: K213490
Trade/Device Name: Monitor B105M, Monitor B125M, Monitor B155M, Monitor B105P, Monitor B125P
Regulation Number: 21 CFR 870.1025
Regulation Name: Monitor, Physiological, Patient(With Arrhythmia Detection Or Alarms) Regulatory
Class: Class II
Product Code: MHX, BZQ, CBR, CBS, CBQ, CCK, CCL, DXN, DQA, DRT, DSJ, DSK, GWQ, FLL, NHO, NHP, NHQ, DPZ, DQK, DSI, KRB, MLD, OLT, OLW, OMC, ORT, KOI
Dated: February 28, 2022
Received: March 2, 2022

Dear Joel Kent:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

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

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Jennifer Shih Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K213490

Device Name
Monitor B105M, Monitor B125M, Monitor B155M,Monitor B105P, Monitor B125P

Indications for Use *(Describe)*
The monitor B105M, B125M,B155M, B105P and B125P are portable multi-parameter patient monitors intended to be used for monitoring, recording, and to generate alarms for multiple physiological parameters of adult, pediatric, and neonatal patients in a hospital environment and during intra-hospital transport.

The monitor B105M, B125M, B155M, B105P and B125P are intended for use under the direct supervision of a licensed health care practitioner.

The monitor B105M, B125M, B155M, B105P and B125P are not intended for use during MRI.

The monitor B105M, B125M, B155M, B105P and B125P can be stand-alone monitors or interfaced to other devices via network.

The monitor B105M, B125M, B155M, B105P and B125P monitor and display: ECG (including ST segment, arrhythmia detection, ECG diagnostic analysis and measurement), invasive blood pressure, heart/pulse rate, oscillometric non-invasive blood pressure (systolic, diastolic and mean arterial pressure), functional oxygen saturation (SpO2) and pulse rate via continuous monitoring(including monitoring during conditions of clinical patient motion or low perfusion), temperature with a reusable or disposable electronic thermometer for continual monitoring Esophageal/Nasopharyngeal/ Tympanic/Rectal/Bladder/Axillary/Skin/Airway/Room/Myocardial/Core/Surface temperature, impedance respiration, respiration rate, airway gases (CO2, O2, N2O, anesthetic agents, anesthetic agent identification and respiratory rate), Cardiac Output (C.O.), Entropy and neuromuscular transmission (NMT).

The monitor B105M, B125M, B155M, B105P and B125P are able to detect and generate alarms for ECG arrhythmias: Asystole, Ventricular tachycardia, VT>2, Ventricular Bradycardia, Accelerated Ventricular Rhythm, Ventricular Couplet, Bigeminy, Trigeminy, “R on T”, Tachycardia, Bradycardia, Pause, Atrial Fibrillation, Irregular, Multifocal PVCs, Missing Beat, SV Tachy, Premature Ventricular Contraction (PVC), Supra Ventricular Contraction (SVC) and Ventricular fibrillation.

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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510(k) Summary

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

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

Date: February 28, 2022

Submitter: GE Medical Systems *Information Technologies,* Inc.
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Device names (807.92(a)(2):

Trade Name: Monitor B105M, Monitor B125M, Monitor B155M, Monitor B105P, Monitor B125P

Common/Usual Name: Multiparameter patient monitor (monitor, physiological, patient (with arrhythmia detection or alarms)

Classification Names:	21 C.F.R. §868.1400 Carbon dioxide gas analyzer. 21 C.F.R. §868.1500 Enflurane gas analyzer. 21 C.F.R. §868.1620 Halothane gas analyzer. 21 C.F.R. §868.1700 Nitrous oxide gas analyzer. 21 C.F.R. §868.1720 Oxygen gas analyzer. 21 C.F.R. §868.2375 Breathing frequency monitor. 21 C.F.R. §870.1025 Arrhythmia detector and alarm (including ST-segment measurement and alarm). 21 C.F.R. §870.1110 Blood pressure computer. 21 C.F.R. §870.1130 Noninvasive blood pressure measurement system. 21 C.F.R. §870.1425 Programmable diagnostic computer. 21 C.F.R. §870.1915 Thermodilution probe. 21 C.F.R. §870.2300 Cardiac monitor (including cardiotachometer and rate alarm). 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. §882.1400 Electroencephalograph 21 C.F.R. §870.1100 alarm, blood-pressure 21 C.F.R. §868.2775 Electrical peripheral nerve stimulator
Product Code:	MHX
Subsequent Product Code:	BZQ, CBR, CBS, CBQ, CCK, CCL, DXN, DQA, DRT, DSJ, DSK, GWQ, FLL, NHO, NHP, NHQ, DPZ, DQK, DSI, DSJ, KRB, MLD, OLT, OLW, OMC, ORT, KOI
Predicate Device(s) (807.92(a)(3)):	Primary Predicate: K201941 Monitor B125/B105 Additional Predicate Devices: K191249 CARESCAPE B450 K133810 CARESCAPE VC150 K200494 CARESCAPE ONE
Device Description (807.92(a)(4)):	The proposed monitors B105M, B125M, B155M, B105P and B125P are multi-parameter patient monitors that were developed based on predicate Monitor B125/B105(K201941) to provide additional monitored parameter: neuromuscular transmission (NMT), by supporting additional optional modules previously cleared by FDA: E-NMT module (K051635) with existing interface rack and/or second frame (B1X5-F2).

In addition to the added parameter, the proposed monitors B105M, B125M, B155M, B105P and B125P offer several software enhancements:

- Support 12-lead ECG measurement mode;
- Additional SPV (Systolic Pressure Variation) and PPV (Pulse Pressure Variation) values calculation;
- Enabled the Impedance Respiration measurement from lead RL-LL;
- Display Pulse Rate (PR) from NIBP when performing NIBP determination;
- Display real-time GE SpO2 Perfusion Index (PI) value;
- Adoption of TruSignal V3 SpO2 algorithm;
- Additional optimizing IBP waveform scale function;
- Additional connectivity capabilities within GE CARESCAPE network (K032582) including Bed-to-Bed View and Automatic View on Alarm (AVOA);
- Additional remote service function;
- Additional cybersecurity enhancements.

The proposed monitors B105M, B125M, B155M, B105P and B125P include improved Industrial Design (ID) to be more portable and more compact for clinicians than the primary predicate Monitor B125/B105(K201941) while maintaining the same primary function and operation.

The five models (B105M, B125M, B155M, B105P and B125P) share the same hardware platform and software platform to support the data acquisition and algorithm modules. The differences between them are the LCD screen size and configuration options.

As with the predicate Monitor B125/B105 (K201941), the proposed monitors B105M, B125M, B155M, B105P and B125P are multi-parameter patient monitors, utilizing an LCD display and pre-configuration basic parameters: ECG, RESP, NIBP, IBP, TEMP, SpO2, and optional parameters whic include CO2 and Gases parameters provided by the E-MiniC module (K052582), CARESCAPE Respiratory modules E-sCO and E-sCAiO (K171028), Airway Gas Option module N-CAiO (K151063), Entropy parameter provided by the E-Entropy module (K150298), Cardic Output parameter provided by the E-COP module (K052976), and thermal recorder B1X5-REC.

	In addition, the predicate Monitor B125/B105 (K201941) and the proposed monitors B105M, B125M, B155M, B105P and B125P consists of the same interface to a variety of existing central station systems via a cabled or wireless network interface which implemented with identical integrated WIFI module. (WIFI feature is disabled in B125P/B105P) Moreover, both the predicate Monitor B125/B105(K201941) and the proposed monitors B105M, B125M, B155M, B105P and B125P can be mounted in a variety of ways (e.g. shelf, countertop, table, wall, pole, or head/foot board) using existing mounting accessories.
Indications for Use (807.92(a)(5)):	The monitor B105M, B125M, B155M, B105P and B125P are portable multi-parameter patient monitors intended to be used for monitoring, recording, and to generate alarms for multiple physiological parameters of adult, pediatric, and neonatal patients in a hospital environment and during intra-hospital transport. The monitor B105M, B125M, B155M, B105P and B125P are intended for use under the direct supervision of a licensed health care practitioner. The monitor B105M, B125M, B155M, B105P and B125P are not intended for use during MRI. The monitor B105M, B125M, B155M, B105P and B125P can be stand-alone monitors or interfaced to other devices via network. The monitor B105M, B125M, B155M, B105P and B125P monitors and displays: ECG (including ST segment, arrhythmia detection, ECG Diagnostic Analysis and Measurement), invasive blood pressure, heart/pulse rate, oscillometric non-invasive blood pressure (systolic, diastolic and mean arterial pressure), functional oxygen saturation (SpO2) and pulse rate via continuous monitoring(including monitoring during conditions of clinical patient motion or low perfusion), temperature with a reusable or disposable electronic thermometer for continual monitoring Esophageal/Nasopharyngeal/Tympanic/Rectal/Bladder/Axillary/Skin/Airway/Room/Myocardial/ Core/Surface temperature, impedance respiration, respiration rate, airway Gases (CO2, O2, N2O, anesthetic agents, anesthetic agent identification and

respiratory rate), Cardiac output (C.O.) and Entropy and neuromuscular transmission (NMT).

The monitors B105M, B125M, B155M, B105P and B125P are able to detect and generate alarms for ECG arrhythmias: Asystole, Ventricular tachycardia, VT>2, Ventricular Bradycardia, Accelerated Ventricular Rhythm, Ventricular Couplet, Bigeminy, Trigeminy, "R on T", Tachycardia, Bradycardia, Pause, Atrial Fibrillation, Irregular, Multifocal PVCs, Missing Beat, SV Tachy, Premature Ventricular Contraction (PVC), Supra Ventricular Contraction (SVC) and Ventricular fibrillation.

Contraindications for using the monitor
The monitors B105M, B125M, B155M, B105P and B125P are not intended for use during MRI.

Technology (807.92(a)(6)): The monitors B105M, B125M, B155M, B105P and B125P are multi-parameter patient monitors. The hardware functionality is unchanged compared to the predicate Monitor B125/B105(K201941), however this 510(k) introduces monitoring of additional (previously cleared) parameter through an existing cleared and marketed measurement module, enhancements of several software features and additional cybersecurity enhancements.

The fundamental technology of the proposed monitors B105M, B125M, B155M, B105P and B125P are the same as the predicate devices.

The proposed monitors B105M, B125M, B155M, B105P and B125P are substantially equivalent to the predicate devices.

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

Product Comparison versus Predicate Main Features:

The proposed monitors B105M, B125M, B155M, B105P and B125P share identical indications for use, intended use patient populations, and functional features as the predicate devices. The monitors B105M, B125M, B155M, B105P and B125P consist of improvements and optional features outlined below that are substantially equivalent to the primary predicate device B125/B105 (K201941).

Specification	Predicate monitors B125/B105 (K201941)	Proposed monitors B105M/B125M/B155M/B105P	Differences
Size (H x W x D)	Physical size without extension rack and modules: B105: 270 mm x 290 mm x 150 mm B125: 280 mm x 317 mm x 150 mm	Physical size without extension rack and modules: **B105P/B105M: 275 mm x 265 mm x 175 mm** **B125P/B125M: 280 mm x 312 mm x 175 mm** **B155M: 305 mm x 405 mm x 175 mm**	Equivalent to predicate. Slight change in physical size for 10 inch and 12-inch devices as the proposed device improved Industrial Design for more portable and compact design than the predicate devices. The proposed device also introduced a 15-inch screen version to meet customer requests. Regardless of the display size, all monitors have the same functionality and options. The change doesn't impact the safety or effectiveness.
Weight	Weight with battery, without extension rack and modules: B105: ≤ 3.9 kg B125: ≤ 4.3 kg	Weight with battery, without extension rack and modules: **B105P/B105M: ≤ 3.8 kg** **B125P/B125M: ≤ 4.2 kg** **B155M: ≤ 5.2 kg**	Equivalent to predicate. Decrease in display size for B105 and B125 have resulted in decreased weight. B155M is a larger monitor with higher weight. B155M has the same functionality and options as B125M and B105M except different display size. The change doesn't impact the safety or effectiveness.
Hard keys	three functional hard keys on front panel: Alarm Audio Pause, Take Snapshot and Manual NIBP	**No functional hard keys on front panel**	Equivalent to predicate The proposed device removed the three functional hard keys for better cleaning. Instead, the proposed device provides three soft keys with same functionality. The change doesn't impact the safety or effectiveness.
Battery Type	Rechargeable Lithium-Ion battery	**Rechargeable Lithium-Ion battery**	Equivalent to predicate The predicate monitor supports one standard Lithium-Ion battery. The proposed device provides two different capacity Lithium-Ion battery options to meet different customer needs, however only one battery can be selected/installed in each device. The change doesn't impact the safety or effectiveness.

Waveforms and parameter windows	Up to 6 waveforms Up to 10 parameter windows	**Up to 12 waveforms** Up to 10 parameter windows	Equivalent to predicate The proposed device can display more waveforms on the screen simultaneously to let the clinician to view more information on one screen. The change doesn't impact the safety or effectiveness.
E-Modules	E-MiniC E-sCO E-sCAiO N-CAiO E-ENTROPY E-COP	E-MiniC E-sCO E-sCAiO N-CAiO E-ENTROPY E-COP **E-NMT**	Equivalent to predicate. Support added for additional parameter measurement module E-NMT (K051635). The E-NMT module is cleared and available on the market. This change solely adds the capability to display these additional parameters on the proposed device's display, similar to the other displayed parameters. The change doesn't impact the safety or effectiveness.
Maximum E-Modules Support	Maximum three E-Modules can be supported at the same time: One through module rack, two through external Second Frame B1X5-F2.	B1x5M: Maximum three E-Modules can be supported at the same time: One through module rack, two through external Second Frame B1X5-F2. **B1x5P:** **Maximum one E-Module can be support through the module rack.**	Equivalent to predicate Identical for the proposed monitors B1x5M. The Second Frame B1X5-F2 is not available for the proposed monitors B1x5P per different customer needs so only one E-module may be connected for those devices. The change doesn't impact the safety or effectiveness.
Available parameters	ECG, ST segment, arrhythmia detection, ECG diagnostic analysis and measurement, invasive pressure, heart/pulse rate, non-invasive blood pressure, pulse oximetry, temperature, impedance respiration, airway gases (CO2, O2, N2O, and anesthetic agents), Entropy, cardiac output.	ECG, ST segment, arrhythmia detection, ECG diagnostic analysis and measurement, invasive pressure, heart/pulse rate, non-invasive blood pressure, pulse oximetry, temperature, impedance respiration, airway gases (CO2, O2, N2O, and anesthetic agents), Entropy, cardiac output, **neuromuscular transmission (NMT)**.	Equivalent to predicate. The NMT parameter has been added and can be displayed on the screen through the compatibility/support for the E-NMT module (K051635). This change solely adds the capability to display these additional parameters on the proposed device's display, similar to the other displayed parameters. The change doesn't impact the safety or effectiveness.
ECG Measurement Mode	3-lead and 5-lead	3-lead, 5-lead and **12-lead**	Equivalent to predicate. The proposed monitor adds the additional option for a 12-lead ECG mode measurement and display. This is equivalent to the 12-lead ECG measurement and display already implemented in the predicate device B450 V3 (K191249).

			The change doesn't impact the safety or effectiveness.
SPV and PPV values calculation	Not supported	**Support SPV (Systolic Pressure Variation) and PPV (Pulse Pressure Variation) values calculation from arterial Invasive Blood Pressure (IBP) monitoring**	Equivalent to predicate. SPV (Systolic Pressure Variation) and PPV (Pulse Pressure Variation) values are calculated based on existing arterial Invasive Blood Pressure (IBP) monitoring already in the predicate. SPV and PPV values can support an assessment of the patient's arterial pressure variation and reflect patient's respiratory changes in arterial pressure during positive pressure ventilation. This feature is already implemented in the equivalent way in the predicate monitor CARESCAPE Monitor B450 V3 (K191249). The change doesn't impact the safety or effectiveness.
Impedance respiration source lead	I, II and III	I, II and **RL-LL**	Equivalent to predicate. The proposed device no longer provides Impedance respiration measurement from ECG lead III, but provide additional Impedance respiration source from ECG lead RL-LL. The Impedance respiration from ECG lead RL-LL is equivalent to ECG lead I and II. Impedance respiration measurement from lead RL-LL is already implemented in the equivalent way in the predicate device CARESCAPE Monitor B450 V3 (K191249). The change doesn't impact the safety or effectiveness.
NIBP measurement	Systolic pressure, Diastolic pressure and Mean pressure	Systolic pressure, Diastolic pressure, Mean pressure and **Pulse Rate**	Equivalent to predicate. The proposed device uses the identical NIBP design as the predicate monitor B125/B105 (K201941). The only difference is the predicate Monitor B125/B105 (K201941) does not offer Pulse Rate (PR) display on the screen, although PR is already calculated by the algorithm when performing NIBP measurement. The proposed device now displays the PR value on screen. There is no change to the NIBP measurement algorithm or calculations. The PR monitoring from NIBP measurement has been implemented in an equivalent way in the CARESCAPE VC150 (K133810). The change doesn't impact the safety or effectiveness.

Perfusion Index (PI) for GE TruSignal SpO2	Monitors PI and saves PI in trend as "Pleth"	Monitors PI and saves PI in trend as "PI" and **displays real-time PI value in digit field**.	Equivalent to predicate. The predicate Monitor B125/B105 (K201941) monitors PI and saves PI in the trend as "Pleth" but does not display the real-time PI value in the digit field in the user interface. The proposed device provides the real-time PI value display in digit field in addition to saving in the trend. The change doesn't impact the safety or effectiveness.
TruSignal SpO2 algorithm	TruSignal V2	TruSignal **V3**	Equivalent to predicate. The TruSignal V3 algorithm was cleared with CARESCAPE ONE in K200494. This cleared algorithm provides equivalent functionality. The change doesn't impact the safety or effectiveness.
IBP waveform scale adjustment	Manual adjustment	Manual adjustment and **automatic optimizing scale.**	Equivalent to predicate. The proposed device provides an automatic optimizing scale feature. Optimizing IBP waveform scale is the function of adjusting the "Scale" menu selection automatically to let the current IBP waveform fully utilize the IBP waveform area, to avoid waveform too small or too large. It is an option the user can select and is not required. It does not change the data displayed, only the scaling and use of the space on the screen. This is a workflow enhancement. Optimizing IBP waveform scale has been implemented in an equivalent way in the predicate device CARESCAPE Monitor B450 V3 (K191249).
Bed-to-Bed View and Automatic View on Alarm (AVOA)	Not supported	**Bed-to-Bed View and AVOA is supported**	Bed-to-Bed View and AVOA share a feature to allow the monitor to display a view of another patient monitor (for another bed) that is on the same GE CARESCAPE network. The AVOA allows configurable prioritization of displaying highest to lowest risk alarms. Bed-to-Bed view and AVOA functionality has been implemented in an equivalent way in the predicate device CARESCAPE Monitor B450 V3 (K191249). The change doesn't impact the safety or effectiveness.

Remote Service	Not supported	**Remote Service is supported**	With this feature, when the proposed device is connected to network, authorized service personnel can transfer the service log from the proposed device to GE Healthcare server via HTTPS for remote trouble shooting and support. The service log does not include patient information and the log files are encrypted before transmitting. The remote service feature is password protected and for service-use only. The service log does not include any patient information and the log files are encrypted before transmitting. This remote service functionality has been implemented in an equivalent way in the predicate device CARESCAPE Monitor B450 V3 (K191249). The change doesn't impact the safety or effectiveness.
Operating System	Linux (Rev 4.4)	Linux **(Rev 4.19)**	Equivalent to predicate. The two versions of the Operation System use the same technology. Since the 4.4 version Linux is going end of life, the updated version of Linux allows better technical support and cybersecurity while maintaining the same functionality, operation and performance. The change doesn't impact the safety or effectiveness.

The proposed monitors B105M, B125M, B155M, B105P and B125P consist of improvements and optional features outlined below that are substantially equivalent to the additional predicate device CARESCAPE B450(K191249).

Specification	**Predicate monitor CARESCAPE B450 (K191249)**	**Proposed monitors B105M/B125M/B155M/B105P**	**Differences**
NMT measurement module	E-NMT module (K051635)	E-NMT module (K051635)	Identical
ECG Measurement Mode	3-lead, 5-lead, 12-lead, **6-lead and 12RL**	3-lead, 5-lead and 12-lead	Equivalent to predicate. Although the proposed device only supports 3-lead, 5-lead and 12-lead ECG mode those modes are identical to those used in CARESCAPE **B450 (K191249).** The change has been verified and validated and does not affect safety or effectiveness.

SPV and PPV values calculation	Support SPV (Systolic Pressure Variation) and PPV (Pulse Pressure Variation) values calculation from arterial Invasive Blood Pressure (IBP) monitoring	Support SPV (Systolic Pressure Variation) and PPV (Pulse Pressure Variation) values calculation from arterial Invasive Blood Pressure (IBP) monitoring	Identical
Impedance respiration source lead	I, II and RL-LL	I, II and RL-LL	Identical
IBP waveform scale adjustment	Manual adjustment and automatic optimizing scale.	Manual adjustment and automatic optimizing scale.	Identical
Bed-to-Bed View and Automatic View on Alarm (AVOA)	Bed-to-Bed View and AVOA are supported	Bed-to-Bed View and AVOA are supported	Identical
Remote Service functionalities	Transfer service log **Configure the device** **Update device software**	Transfer service log	Equivalent to predicate. The proposed device limits the supported remote service functionality to transferring the service log only. That functionality is equivalent to the predicate and has been implemented with the equivalent security controls and verification, including encryption. The change doesn't impact the safety or effectiveness.

The proposed monitors B105M, B125M, B155M, B105P and B125P consist of improvements and optional features outlined below that are substantially equivalent to the additional predicate device CARESCAPE VC150 (K133810).

Specification	**Predicate monitor CARESCAPE VC150 (K133810)**	**Proposed monitors B105M/B125M/B155M/B105P**	**Differences**
NIBP measurement	Systolic pressure, Diastolic pressure, Mean pressure and Pulse Rate	Systolic pressure, Diastolic pressure, Mean pressure and Pulse Rate	Identical

The proposed monitors B105M, B125M, B155M, B105P and B125P consist of improvements and optional features outlined below that are substantially equivalent to the additional predicate device CARESCAPE ONE (K200494).

Specification	Predicate monitor CARESCAPE ONE (K200494)	Proposed monitors B105M/B125M/B155M/B105P	Differences
TruSignal SpO2 algorithm	TruSignal V3	TruSignal V3	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 proposed monitors B105M, B125M, B155M, B105P and B125P, demonstrating the design meets the specifications.

The hardware bench testing included electromagnetic compatibility, electrical safety, environmental, WLAN, and usability.

The proposed monitors B105M, B125M, B155M, B105P and B125P have been found to be equivalent to the predicate devices for the intended users, functionality, and use environments. Usability evaluation has been completed for the proposed monitor and the predicate devices including critical task identification through use-based hazard analysis, multiple rounds of formative usability testing and summative testing, among other activities.

Software testing included software design, development, verification, validation and traceability. Documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device is considered "Major" level of concern, the same as the predicate.

The proposed monitors B105M, B125M, B155M, B105P and B125P have introduced and verified one additional battery optional. The battery is equivalent to the predicate and tested to comply with UL 2054 2nd Edition, UL1642 5th Edition and IEC 62133-2:2017 standards. Integration of the battery management has been successfully verified the functionality of proposed monitors can respond to certain battery and power management conditions as specified And also tested as part of system EMC testing.

Patient safety, security, and privacy risks have been addressed in the design and development of the proposed B1x5M/B1x5P including a Security Risk Assessment and Threat model. This includes system integrity controls, access, controls audit controls and network controls which map to the General Principles and Security Capabilities outlined in the FDA Guidance for Content of Premarket Submissions for Management of Cybersecurity in Medical Devices issued on October 18, 2018. The proposed monitors B1x5M/B1x5P have been subjected to rigorous testing for cybersecurity vulnerability including penetration testing via an independent firm has been completed with acceptable conclusion, security controls verification testing including network port scan, vulnerability scan and virus scan were conducted, the results demonstrated that the potential cybersecurity risks are appropriately mitigated in the proposed devices and the cybersecurity protections are at least substantially equivalent to the predicate.

Testing was completed to show the device can withstand network storm, i.e. continue to monitor patients without rebooting when connected by wire to GE Unity networks which suffer broadcast storm traffic.

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

The subject of this premarket submission, the proposed monitors B105M, B125M, B155M, B105P and B125P did not require clinical studies to support substantial equivalence.

Conclusion (807.92(b)(3)): GE Healthcare considers the proposed monitors B105M/B125M/B155M/B105P/B125P to be substantially equivalent to the predicate devices.