November 04, 2020

GE Medical Systems Information Technologies, Inc.
Joel Kent
Senior Regulatory Affairs Manager
8200 West Tower Avenue
Milwaukee, Wisconsin 53223

Re: K201941
Trade/Device Name: Monitor B125/B105
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector And Alarm (Including ST-Segment Measurement And Alarm)
Regulatory Class: Class II
Product Code: MHX
Dated: October 2, 2020
Received: October 5, 2020

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)*
K201941

Device Name
Monitor B125/B105

Indications for Use *(Describe)*
The monitor B125/B105 is a portable multi-parameter unit 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 B125/B105 is intended for use under the direct supervision of a licensed health care practitioner.

The monitor B125/B105 is not intended for use during MRI.

The monitor B125/B105 can be a stand-alone monitor or interfaced to other devices via network.

The monitor B125/B105 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.

The monitor B125/B105 is 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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Section 5: 510(k) Summary

Monitor B125/B105

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: July 10th, 2020
Submitter: GE Medical Systems *Information Technologies*, Inc.
8200 West Tower Avenue
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USA

Primary Contact Person: Joel Kent
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Device names (807.92(a)(2):

Trade Name: Monitor B125/B105
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
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.
Predicate Device(s) (807.92(a)(3)):	Primary Predicate: K171580 Monitor B125/B105 Additional Predicate Devices: K151063 Monitor B40 K191323 CARESCAPE B850 K143676 B40i Patient Monitor K162012 CARESCAPE Central Station V2 K122223 IntelliVue MP5SC with IntelliVue Guardian Software
Device Description (807.92(a)(4)):	The proposed Monitor B125/B105 is a multi-parameter patient monitor that was developed based on predicate Monitor B125/B105 (K171580) to provide additional monitored parameters: Airway gases, Entropy and Cardiac output, by supporting additional optional modules previously cleared by FDA: CARESCAPE Respiratory module (K171028), Airway Gas Option N-CAiO(K151063), E-Entropy Module (K150298) (E-ENTROPY-01) and E-COP module (K052976) with extension interface rack and/or second frame(B1X5-F2). In addition to the added parameters, the proposed Monitor

B125/B105 offers several enhanced software features:

- Enabled the Impedance Respiration measurement for Neonates (in addition to Ped/Adult);
- Option called “Full Disclosure” to allow the display of parameter waveforms for up to 36 hours;
- National Early Warning Score (NEWS) calculation provided ;
- Additional printing capabilities to a remote recorder/Laser printer connected to a central station;
- Adoption of EK-Pro V14 ECG algorithm (previously cleared K191323) to support enhanced arrhythmia detection performance;
- Added Irregular, SV Tachy and Supra Ventricular Contraction (SVC), three more arrhythmia alarms;
- Enhanced parameter alarm priority adjustment/ configuration options,
- Cybersecurity enhancements.

The proposed monitor B125 and B105 is based on the previous design, and therefore shares a common software and hardware platform with its primary predicate, the Monitor B125/B105 (K171580). The primary function and operation of the monitors remain unchanged from the predicate. The difference between the two models (B125 and B105) is the LCD screen size. B125 has a 12-inch display; B105 has a 10-inch display. There is no change from the predicate in the display size.

As with the predicate Monitor B125/B105 (K171580), the proposed Monitor B125/B105 is a multi-parameter patient monitor, utilizing an LCD display with an integrated keypad and an identical pre-configuration patient parameter measurement module (Hemo module) which provides basic parameters: ECG, RESP, NIBP, IBP, TEMP, SpO2. The proposed Monitor B125/B105 uses the identical E-MiniC module (K052582) and equivalent optional thermal recorder module as the predicate B125/B105 (K171580).

As with the predicate Monitor B125/B105 (K171580), the proposed Monitor B125/B105 interfaces to a variety of existing central station systems via a cabled or wireless network interface. The wireless interface is implemented with the identical integrated WIFI module (WLAN module type: B1x5-01, FCC ID: OU5B1X501) as used in the predicate Monitor B125/B105 (K171580).

As with the predicate Monitor B125/B105 (K171580), proposed Monitor B105/B125 includes features and subsystems that are optional or configurable. It 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 B125/B105 is a portable multi-parameter unit 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 B125/B105 is intended for use under the direct supervision of a licensed health care practitioner.

The monitor B125/B105 is not intended for use during MRI.

The monitor B125/B105 can be a stand-alone monitor or interfaced to other devices via network.

The monitor B125/B105 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.

The monitor B125/B105 is 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 monitor B125/B105 is not intended for use during MRI

Technology (807.92(a)(6)):

The Monitor B125/B105 is a multi-parameter patient monitor. The hardware functionality is unchanged compared to the predicate Monitor B125/B105 (K171580), however this 510(k) introduces monitoring of additional (previously cleared) parameters through existing cleared and marketed measurement modules, enhancements of several software features and additional cybersecurity enhancements.

The fundamental technology of the proposed Monitor B125/B105 is the same as the predicate devices.

The proposed Monitors B125/B105 is 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:

Specification	Predicate monitor B125/B105 (K171580)	Proposed monitor B125/B105	Differences
Patient type	Adult, pediatric & neonatal	Adult, pediatric & neonatal	Identical
Use environments	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
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 Horizontal space projection size without extension rack and modules: B105: 265 mm x 290 mm x 165 mm B125: 280 mm x 320 mm x 165 mm	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 Horizontal space projection size without extension rack and modules: B105: 265 mm x 290 mm x 165 mm B125: 280 mm x 320 mm x 165 mm	Identical

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: B105: ≤ 3.9 kg B125: ≤ 4.3 kg	Identical
Module Housing	Optional rack which provides one slot for E-Modules	Optional rack which provides one slot for E-Modules. **Optional Second Frame B1x5-F2 which provides two slots for E-Modules.**	Equivalent to predicate. The Proposed monitor supports the optional Second Frame to provide more slots for E-Modules to improve parameter acquisition capability. One monitor can connect to one rack and one Second Frame at a time.
Display/screen	TFT LCD with Touch screen B105: 10.1-inch B125: 12.1-inch	TFT LCD with Touch screen B105: 10.1-inch B125: 12.1-inch	Equivalent to predicate 12.1inch LCD qualified a new supplier. The display from new supplier meets the same specifications and functionality.
Battery Type	Rechargeable Lithium-Ion batteries	Rechargeable Lithium-Ion batteries	Identical
Waveforms and parameter windows	Up to 6 waveforms Up to 10 parameter windows	Up to 6 waveforms Up to 10 parameter windows	Identical
Operating System	Linux (Rev 3.18)	Linux (Rev 4.4)	Equivalent to predicate. The two versions of the Operation System use the same fundamental technology. The newer version of Linux includes equivalent clinical user functionality with improved operating system security.
Modules	E-MiniC	E-MiniC **E-sCO, E-sCAiO** **N-CAiO** **E-ENTROPY-01** **E-COP**	Equivalent to predicate. Support added for additional parameter measurement modules including: CARESCAPE Respiration Module (K123195) (E-sCO, E-sCAiO) Airway Gas Module N-CAiO (Cleared with B40(K151063)) E-Entropy Module E-ENTROPY-01(K150298) And COP module (K052976). The measurement modules are cleared and available on the market. This change solely adds the capability to display these additional parameters on

			the B105/B125 display, similar to the other displayed parameters.
Available parameters	ECG, ST segment, arrhythmia detection, ECG diagnostic analysis and measurement, invasive pressure, non-invasive blood pressure, pulse oximetry, temperature, impedance respiration, airway gases (CO2)	ECG, ST segment, arrhythmia detection, ECG diagnostic analysis and measurement, invasive pressure, non-invasive blood pressure, pulse oximetry, temperature, impedance respiration, airway gases (CO2, **O2, N2O, and anesthetic agents), Entropy, cardiac output.**	Equivalent to predicate. Additional airway gases parameters (O2, N2O, Anesthetic Agents) are added and can be displayed on the screen, through the compatibility/support for CARESCAPE Respiration module (K123195) and Airway Gas Module N-CAiO (cleared with B40(K151063)) Additional Entropy monitoring capability is added through the compatibility/support for additional supporting for E-Entropy Module E-ENTROPY-01(K150298) Additional Cardiac Output monitoring is added through the compatibility/support for additional supporting for E-COP module (K052976) This change solely adds the capability to display these additional parameters on the B105/B125 display, similar to the other displayed parameters.
EK-Pro arrhythmia detection algorithm	EK-Pro V12	EK-Pro V14	Equivalent to predicate. The Ek-Pro V14 algorithm was cleared with CARESCAPE B850 in K191323. This cleared algorithm provides equivalent functionality and was updated to further enhance the analysis.
Printing	Local thermal recorder for printings waveforms, alarms waveforms, numeric trends	Local thermal recorder for printing waveforms, alarms waveforms, numeric trends Remote printer via central station for printing waveforms, alarms waveforms, numeric trends	Equivalent to predicate. Equivalent functionality with an additional supported printer option. Proposed device supports additional remote printing via central station to address customer requests.

Thermal Recorder Module	B1X5-REC thermal recorder module with "off the shelf" printer core XE-50	B1X5-REC thermal recorder module with "off the shelf" printer core GPR212-M0	Equivalent to predicate. Both XE-50 and GPR212-M0 are Industry's standard 50mm thermal printer. XE-50 and GPR212-M0 have the same specifications except GPR212-M0 (APS) has lower power consumption.
Alarm Classification (IEC)	Four levels — High, Medium, Low and Informational	Four levels — High, Medium, Low and Informational	Identical
Alarm Notification	Audible and visual	Audible and visual	Identical
Alarm Priority adjustment	Support to adjust ECG (only Arrhythmia) alarm priority	Support to adjust **ECG, IBP, SpO2, NIBP, Respiration, CO2, Gas and Temperature technical alarm and physiological alarms priority**	Equivalent to predicate. The predicate already included the option to adjust and configure some alarm settings and priorities. In the proposed monitor, more flexibility was added for the user to adjust alarm priorities for additional parameter alarms to meet the user requirements of different hospitals and departments within each hospital. This alarm priority configuration option and mechanism has already been implemented in the identical way in the predicate CARESCAPE B850 (K191323). The default settings are according to IEC 60601-1-8
Full Disclosure	Not supported	**Acquires ECG and mixed parameters waveforms data from monitor and displays for review and storage for up to 36 hours.**	Equivalent to predicate. Full disclosure is an optional license-based feature to display parameter waveforms up to 36 hours. It provides the clinician the flexibility to view historical waveforms on bedside monitors, rather than solely relying on an additional central station. It is equivalent to the full disclosure functionality within the predicate CARESCAPE Central Station V2 (K162012).

Early Warning Score	Not supported	**NEWS (National Early Warning Score)** **NEWS is an optional license-based feature which allows the display of the NEWS Early Warning Score on the monitor. The monitor calculates the score based on the measured parameters following the exact formula for NEWS published from the Royal College of Physicians (a published/well-established clinical score).**	Equivalent to Predicate. The proposed Monitor B125/B105 V1.5 supports display/calculation of the National Early Warning Score (NEWS). NEWS is an optional license-based feature which allows for the display of a calculated/ well-established "Early Warning Score" that clinicians often use as one part of patient assessments/ clinical decision support looking for early signs of deterioration. The Early Warning Score concept is used in many monitors and even EMRs to provide standardized calculations. This is equivalent to the early warning score implemented in the legally marketed predicate Monitor IntelliVue MP5SC with IntelliVue Guardian Software (K122223).
ECG Alarms	ECG arrhythmias alarms: Asystole, Ventricular tachycardia, VT>2, Ventricular Bradycardia, Accelerated Ventricular Rhythm, Ventricular Couplet, Bigeminy, Trigeminy, "R on T", Tachycardia, Bradycardia, Pause, Atrial Fibrillation, Multifocal PVCs, Missing Beat, Premature Ventricular Contraction (PVC), and Ventricular fibrillation.	Three additional alarm types added (highlighted in **bold**). ECG arrhythmias alarms: 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.	Equivalent to predicate. Added additional ECG arrhythmia alarms types based on the implemented algorithm. The additions are: Irregular, SV Tachy and Supra Ventricular Contraction (SVC). Provides additional options within the same monitored parameter as the predicate.
Neonatal respiration	Adult, Pediatric	Adult, Pediatric, **Neonatal**	Equivalent to predicate The proposed device uses the identical Impedance Respiration design and algorithm as both the predicate Monitor B125/B105 V1(K171580) and B40i (K143676). It is now being implemented for neonates in the equivalent way to the Monitor B40i (K143676).
Networking Interface	LAN WLAN (Optional)	LAN WLAN (Optional)	Identical
Networking Protocol	CARESCAPE Network HL7	CARESCAPE Network HL7	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 Monitor B125/B105, demonstrating the design meets the specifications.

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

The proposed Monitor B125/B105 has been found to be equivalent to the predicate device(s) for the intended users, uses 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.

Patient safety, security, and privacy risks have been addressed in the design and development of the proposed B125/B105 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 Guidance for Industry and Food and Drug Administration Staff Document issued on October 2, 2014.

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 Monitor B125/B105 did not require clinical studies to support substantial equivalence.
Conclusion (807.92(b)(3)):	GE Healthcare considers the proposed Monitor B125/B105 to be substantially equivalent to the predicate device(s).