November 1, 2017

GE Medical Systems (China) Co., Ltd.
% Mr. Robert Casarsa
Regulatory Affairs Leader
GE Medical Systems Information Technologies, Inc.
8200 West Tower Avenue
Milwaukee, Wisconsin 53223

Re: K171580
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, BZQ, CBR, CBS, CBQ, CCK, CCL, DXN, DQA, DRT, DSB, DSK, GWQ, FLL, NHO, NHP, NHQ
Dated: May 30, 2017
Received: May 31, 2017

Dear Mr. Robert Casarsa:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171580

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, CO2.

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, Multifocal PVCs, Missing Beat, Premature Ventricular Contraction (PVC) 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

510k Summary

K171580

I. SUBMITTER

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II. DEVICE

Name of Device: Monitor B125/B105
Common or Usual Name: Multi-parameter Patient Monitor
Classification Name:
21 CFR 870.1025 monitor, physiological, patient (with arrhythmia detection or alarms)
21 CFR 868.2375 monitor, breathing frequency
21 CFR 868.1700 analyzers, gas, nitrous-oxide, gaseous phase (anesthetic conc.)
21 CFR 868.1620 analyzers, gas, halothane, gaseous-phase (anesthetic conc.)
21 CFR 868.1500 analyzers, gas, enflurane, gaseous-phase (anesthetic concentration)
21 CFR 868.1400 analyzers, gas, carbon-dioxide, gaseous-phase
21 CFR 868.1720 analyzers, gas, oxygen, gaseous-phase
21 CFR 870.1130 system, measurement, blood-pressure, non-invasive
21 CFR 870.2700 oximeters
21 CFR 870.2300 monitor, cardiac (incl. cardiotachometer & rate alarm)

21 CFR 870.2770 plethysmographs, impedance
21 CFR 870.1110 computers, blood-pressure
21 CFR 882.1400 full-montage standard electroencephalograph
21 CFR 880.2910 thermometers, electronic, clinical
21 CFR 868.1500 analyzers, gas, desflurane, gaseous-phase (anesthetic concentration)
21 CFR 868.1500 analyzer, gas, sevoflurane, gaseous-phase (anesthetic concentration)
21 CFR 868.1500 analyzer, gas, isoflurane, gaseous-phase (anesthetic concentration)

Regulatory Class: II
Product Code:
MHX, BZQ, CBR, CBS, CBQ, CCK, CCL, DXN, DQA, DRT, DSB, DSK, GWQ, FLL, NHO, NHP, NHQ

III. PREDICATE DEVICE

K151063 Monitor B40 and K102239 CARESCAPE Monitor B650
These predicates have not been subject to a design-related recall.
No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Monitor B125/B105 is a multi-parameter patient monitor that is developed based on the predicate Monitor B40 (K151063) platform. The Monitor B125/B105 provides additional support for ECG full arrhythmia (has been claimed in CARESCAPE Monitor B650(K102239)), WLAN (FCC ID: OU5B1X501) and touch screen.

As with the predicate Monitor B40(K151063), the proposed Monitor B125/B105 is a multi-parameter patient monitor, utilizes 12inches /10inches LCD display with an integrated keypad and a pre-configuration (hemodynamic module (Hemo module) which provide basic parameters: ECG, RESP, NIBP, IBP, TEMP, SPO2.

As with the predicate Monitor B40(K151063), the proposed Monitor B125/B105 has optional CO2 parameter provided by the identical E-MiniC module (K052582).

As with the predicate Monitor B40(K151063), the proposed Monitor B125/B105 has a mounting plate on the bottom of the monitor. The monitor can be mounted in a variety of ways (e.g. shelf, countertop, table, wall, pole, or head/foot board) using existing mounting accessories.

V. INDICATONS FOR USE

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, CO2.

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, Multifocal PVCs, Missing Beat, Premature Ventricular Contraction (PVC) and Ventricular fibrillation.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed Monitor B125/B105 is a multi-parameter patient monitor that is developed based on the predicate Monitor B40 (K151063) platform. The proposed Monitor B125/B105 provides additional support for ECG full arrhythmia (has been claimed in CARESCAPE Monitor B650 (K102239)), WLAN (FCC ID: OU5B1X501) and touch screen

The proposed Monitor B125/B105 uses the identical hemodynamic module (Hemo module) as the predicate Monitor B40 (K151063) in the monitoring of ECG, Resp, NIBP, IBP, SpO2 and Temp parameters data.

The proposed Monitor B125/B105 uses identical E-MiniC module (K052582) as the predicate Monitor B40 (K151063).

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

The proposed Monitors B125/B105 is as safe and effective as the predicate devices.

The following table includes comparisons of the main features of the device, and includes the features that are different from the predicate.

WLAN	Support wireless communication. WLAN module is FCC qualified, FCC ID: OU5B1X501)
Touch screen	Support touch screen per customer needs
ECG arrhythmia analysis	Enabled ECG full arrhythmia analysis The proposed device uses the same ECG algorithm (EK-Pro V12) as predicate device B40 (K151063) The proposed device enabled full arrhythmia analysis which disabled in the predicate device B40 (K151063). Full arrhythmia analyses implemented with EK -ProV12 ECG algorithm was cleared in B650 (K102239)
CARESCAPE Central Station V2 (K162012) compatibility	Added the compatibility with CARESCAPE Central Station V2 (K162012) CARESCAPE Central Station V2 (K162012) has the same communication protocol as CARESCAPE central station V1 (K133882) which has been cleared in predicate device B40 (K151063)
Improved operating workflow	• Add standby and night mode • Up to 168 hours trending storage and 200 snapshot checks • Add event view software feature to combine alarm history and snapshot
Peripheral I/O interface	• Add DVI-D connector to support slave display. • Add USB connector to support USB disk for service purpose
Masimo SpO2 accessories change	Add Masimo RD sensors and related cables, the sensors are compatible with MS-2011SB board (K053269) Two reusable sensors (K051212) MASIMO-RD-4050 MASIMO-RD-4051

	Four adhesive sensors (K042346): MASIMO-RD-4000 MASIMO-RD-4001 MASIMO-RD-4003 MASIMO-RD-4004 Two RD cables (K042536) MASIMO-RD-4085 MASIMO-RD-4084

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

No biocompatibility testing was performed as the Monitor B125/B105 is not in contact with the patient**.** All supplies and accessories for use with the proposed Monitor B125/B105 that contact the patient have been previously cleared by FDA.

Electrical safety and electromagnetic compatibility (EMC)

The Monitor B125/B105 is designed and tested for compliance with the following performance standards:

- IEC 60601-1:2005 + A1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC60601-1-2: 2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-1-8:2006 + A1:2012 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 60601-2-27: 2011 + C1:2012 Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
- IEC 80601-2-30:2009 + A1:2013 Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
- IEC 60601-2-34:2011 Medical electrical equipment - Part 2-34: Particular requirements for the basic safety, including essential performance, of invasive blood pressure monitoring equipment
- IEC 60601-2-49:2011 Medical electrical equipment – Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment

- ISO 80601-2-55:2011 Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
- ISO 80601-2-56:2009 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
- ISO 80601-2-61:2011 Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
- IEC 62366-1:2015 Medical devices—Part 1: Application of usability engineering to medical devices
- IEC 60601-1-6:2010+A1:2013 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability

Software Verification and Validation Testing
Software verification and validation testing was conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Major" level of concern, where a failure could result in death or serious injury, either to a patient or to a user of the device.
The following bench tests were performed:

Software Verification include below Testing:

- Unit Testing: Code reviews and/or static code analysis are the methods are adopted for the software unit verification to ensure the unit acceptance criteria, as defined in the SDLC procedure, are met.
- Software Integration Test: Performed to confirm that integrated (changed) SW units conform to the architecture and requirements, and other portions of the system have not been adversely affected.
- Software Regression Test: The purpose of this test is to verify the side effect of code changes. Software leader and engineering team shall review the side effect of all SPRs and it shall be mentioned in the SPR test description or individual test procedure.
- System Testing: Performance testing included the system level testing and subsystem level testing. System level procedures were executed to confirmed that all product system requirements specified in the product specifications were met. Design Specifications specify design requirements for each subsystem of Patient Monitor B125/B105. Each Design Specification has one or more corresponding Verification Procedures that were used to verify that the design requirements have been met.

Software Validation is integrated with System Validation: System Validation will confirm that the product fulfills the user needs and intended uses under actual or simulated use conditions.

Environmental Testing:
Perform Rapid Change of Temperature, Change of Temperature, Dry heat for non-heat-dissipating specimen with gradual change of temperature, Damp heat, Cold for non-heat dissipating specimen with gradual change of temperature, Cold for heat-dissipating specimen with gradual change of temperature and steady state testing to ensure the unit preference meet the environmental requirements.
Mechanical stress Testing:
Perform sinusoidal vibration, shock, free fall, altitude test and broadband random vibration testing to ensure the unit meet the Mechanical stress requirements.
Package Testing
Perform package transport testing to ensure the packaged product withstand the distribution environment and to show the serviceability of the transport packages.
Animal Study
No animal studies have been performed on the Monitor B125/B105.
Clinical Studies
No clinical studies have been performed on the Monitor B125/B105.

VIII. CONCLUSIONS

GE Healthcare considers the proposed Monitor B125/B105 to be as safe, as effective, and performance is substantially equivalent to the predicate devices.
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