



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 15, 2015

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

Re: K151063

Trade/Device Name: Monitor B40

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, OLW, OMC, ORT

Dated: November 17, 2015

Received: November 19, 2015

Dear 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 at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

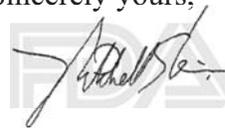
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go 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 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 yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a faint, large watermark of the FDA logo.

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K151063

Page 1 of 1

Device Name
Monitor B40

Indications for Use (Describe)

The Monitor B40 is a portable multi-parameter unit to be used for monitoring and recording of, 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 B40 is intended for use under the direct supervision of a licensed health care practitioner. The Monitor B40 is not intended for use during MRI.

The Monitor B40 can be a stand-alone monitor or interfaced to other devices via a network.

The Monitor B40 monitors and displays: ECG (including ST segment, arrhythmia detection), 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) and Entropy.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."



GE Medical Systems
Information Technologies

gemedicalsystems.com

8200 West Tower Avenue
Milwaukee, Wisconsin, 53223

510(k) Summary

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

Date: November 30, 2015

Submitter: Sun YanLi
Regulatory Affairs Manager
GE MEDICAL SYSTEMS CHINA CO., LTD.
No. 19 Changjiang road National Hi-Tech Dev. Zone
Wuxi, Jiangsu, China 214028

Primary Contact Person: Robert Casarsa
Regulatory Affairs Leader
GE Medical Systems *Information Technologies*, Inc.
Telephone: 414-362-3063
Fax at 414-362-2585
E-mail: Robert.casarsa@ge.com

Secondary Contact Person: Douglas Kentz
Regulatory Affairs Director
GE Medical Systems *Information Technologies*, Inc.
8200 West Tower Avenue
Milwaukee, Wisconsin 53223
Phone: 414 362-2038
Fax: 414-262-2585
E-mail: Douglas.kentz@ge.com

Device: Trade Name: Monitor B40
Common/Usual Name: Multi-parameter patient monitor

Classification Names: 21 CFR 870.1025 monitor, physiological, patient(with arrhythmia detection or alarms)
 21 CFR 868.2375 monitor, breathing frequency
 21 CFR 868.1700 analyzer, gas, nitrous-oxide, gaseous phase (anesthetic conc.)
 21 CFR 868.1620 analyzer, gas, halothane, gaseous-phase (anesthetic conc.)
 21 CFR 868.1500 analyzer, gas, enflurane, gaseous-phase (anesthetic concentration)
 21 CFR 868.1400 analyzer, gas, carbon-dioxide, gaseous-phase
 21 CFR 868.1720 analyzer, gas, oxygen, gaseous-phase
 21 CFR 870.1130 system, measurement, blood-pressure, non-invasive
 21 CFR 870.2700 oximeter
 21 CFR 870.2300 monitor, cardiac (incl. cardiometer & rate alarm)
 21 CFR 870.2770 plethysmograph, impedance
 21 CFR 870.1110 computer, blood-pressure
 21 CFR 882.1400 full-montage standard electroencephalograph
 21 CFR 880.2910 thermometer, electronic, clinical
 21 CFR 868.1500 analyzer, 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)

Product Code:

MHX, BZQ, CBR, CBS, CBQ, CCK, CCL, DXN
 DQA, DRT, DSB, DSK, GWQ, FLL, NHO, NHP, NHQ, OLW, OMC, ORT

Predicate Device(s): K133576 Monitor B40

Device Description: The proposed Monitor B40V3 is still a multi-parameter patient monitor. It retains the features of the predicate Monitor B40V2.1 (K133576) and now complies with IEC60601-1 3rd edition and RoHS (Restriction of Hazardous Substances) requirements, enabled time synchronization in HL7(Health Level 7) network environment, verified compatibility with CARESCAPE Central Station (K133882) and supported OAC (Optional Activation Codes) tool used in manufacturing and service for product license control.

As with the predicate Monitor B40V2.1 (K133576), the proposed Monitor B40V3 continues to interface with following optional extension modules: E-MiniC module (K052582), Airway Gas

Option Module (N-CAiO) (K133576), CARESCAPE Respiratory modules (E-sCO and E-sCAiO) (K123195) and Entropy module. Comparing with E-Entropy module version (E-ENTROPY-00) (K061907) supported in predicate device, the proposed Monitor B40V3 supports improved E-Entropy module version (E-ENTROPY-01) (K150298).

As with the predicate Monitor B40V2.1 (K133576), the proposed Monitor B40V3 continues to be compatible with CARESCAPE Respiratory modules (E-sCOV and E-sCAiOV) (K123195) with spirometry function disabled.

As with the predicate Monitor B40V2.1 (K133576), the proposed Monitor B40V3 still includes features and subsystems that are optional or configurable. The proposed Monitor B40V3 will continue interfacing to a variety of existing central station systems via a cabled network interface.

As with the predicate Monitor B40V2.1 (K133576), the proposed Monitor B40V3 keeps 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.

Intended Use: The Monitor B40 is a portable multi-parameter unit to be used for monitoring and recording of, 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 B40 is intended for use under the direct supervision of a licensed health care practitioner.

The Monitor B40 is not intended for use during MRI.

The Monitor B40 can be a stand-alone monitor or interfaced to other devices via a network.

The Monitor B40 monitors and displays: ECG (including ST segment, arrhythmia detection), 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) and Entropy.

Technology: The proposed Monitor B40V3 is a system design based on predicate monitor B40V2.1 (K133576). It retains the nearly identical design of the predicate Monitor B40V2.1 (K133576).

The proposed Monitor B40V3 uses the same NIBP and GE SpO₂ design, identical ECG EKPRO V12 algorithm (K102239) and identical E-MiniC module (K052582), Airway Gas Option Module (N-CAiO) (K133576), CARESCAPE Respiratory modules (E-sCO and E-sCAiO) (K123195).

The proposed Monitor B40V3 uses updated E-Entropy module (K150298), OEM Masimo SpO₂ board MS-2011SB (K053269) and OEM Nellcor SpO₂ board NELL1-SR (K060576). However, E-Entropy module and OEM Masimo/Nellcor board modification major focus on RoHS compliance doesn't impact the module or boards' hardware, software and mechanical interface with host monitor and does not result in the design change for host monitor.

The proposed Monitor B40V3 employs the same functional scientific technology as the predicate Monitor B40V2.1 (K133576).

The proposed Monitor B40V3 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. Additional comparison information can be found in Comparison Matrix in Section 12.1.

IEC60601-1 3 rd Edition Compliance	<p>Made design changes to comply with IEC60601-1 3rd edition:</p> <ul style="list-style-type: none"> • Added alarm reset feature to meet alarm requirement. • Updated mechanical parts to meet fire protection requirement. • Upgraded existing optional E-entropy
-----------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

	Module from E-ENTROPY-00(K061907) to E-ENTROPY-01(K150298).
Enable Time Synchronization in HL7 (Health Level 7) Network Environment	<ul style="list-style-type: none"> • Enabled time Synchronization between proposed monitor B40V3 and NTP (Network Time Protocol) server when connecting with HL7 network. • Supported daylight saving time (DST) on the proposed Monitor B40V3.
CARESCAPE Central Station (K133882) Compatibility	<p>Added the compatibility with CARESCAPE Central Station (K133882) in proposed Monitor B40V3.</p> <p>The compatibility with CARESCAPE Central Station (K133882)previous version Clinical Information Center (K032582) has been cleared in predicated monitor B40V2.1 (K 133576)</p>
Product License Control Support	Supported Optional Activation Codes (OAC) tool for product license control which is used in manufacturing and service to manage product configuration.
Boards upgrade due to technology and Cost Efficient Improvement	<ul style="list-style-type: none"> • TP (Temperature, Invasive Blood Pressure)and ECG three parameter boards updated: Replaced the general purpose electric components (CPU and AD converter) with modernized version in TP and ECG boards as well as simplifying the overall board design by removing unused circuits. • Component update in Power Board Existing component t- Smart Battery Charger (MAX1535CETJ+T) on Power board was end of life. Replace it with compatible charger (LTC1759CG#PBF)
RoHS Restriction of the use of certain Hazardous Substances (RoHS)	<ul style="list-style-type: none"> • Upgraded Masimo OEM SpO2 Board from MS-2011 (K053269) to MS-2011SB (K053269) for RoHS compliance. • Upgraded Nellcor OxiMax OEM SpO2 Board from NELL1-S (K060576) to NELL1-SR (K060576) for RoHS compliance.

Compliance)	<ul style="list-style-type: none"> • Changed Thermal Recorder Module from XE-50 to XE-50B for RoHS compliance • Changed MCU and related peripheral circuit in recorder conversion board for RoHS compliance
Accessory Removal	<ul style="list-style-type: none"> • Removed eight non-RoHS SpO2 accessories. • Removed two non-RoHS ECG NEO accessories. • Removed eleven thigh NIBP accessories per business needs.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The proposed Monitor B40V3 and its applications comply with voluntary standards as detailed in this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final acceptance testing (Validation)
- Performance testing (Verification)
- Safety testing (Verification)

The proposed Monitor B40V3 has been thoroughly tested through verification of specifications and validation, including software validation. Verification of compliance with applicable voluntary standards has also been made to support safe use of the device in its intended environment.

The proposed Monitor B40V3 and its applications were designed and tested for compliance to the following standards:

1. IEC 60601-1:2005 + A1:2012 Medical Electrical Equipment, part 1: General Requirements for Basic Safety and Essential Performance
2. IEC60601-1-2: 2007 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
3. IEC60601-2-27: 2011+ C1: 2012 Medical electrical equipment – Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment.

4. IEC60601-1-8: 2006 +A1:2012 Medical electrical equipment - Part 1-8: General requirements for safety - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
5. IEC 62304:2006, Medical devices - Medical device software – Software life cycle processes
6. IEC 60601-2-34: 2011 Medical electrical equipment – Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment.
7. IEC60601-2-49: 2011 Medical electrical equipment – Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment.
8. 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.
9. ISO 80601-2-61: 2011 Medical electrical equipment — Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.
10. IEC 60601-2-26:2012 Medical electrical equipment – Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs.
11. IEC 62366:2014 Medical devices - Application of usability engineering to medical devices
12. IEC 60601-1-6: 2010 General Requirements for Safety and essential performance Collateral Standard – Usability

Summary of Clinical Tests:

The subject of this premarket submission, The proposed Monitor B40V3 did not require clinical studies to support substantial equivalence.

Conclusion: The design changes made to the proposed Monitor B40V3 have no effect on the device's ability to obtain patient measurements as there are no changes to the parameter measuring principle. To assess if the changes had any significant impact to the device, all related risks were re-evaluated and found to be unchanged. GE Healthcare considers the proposed Monitor B40V3 to be as safe, as effective, and performance is substantially equivalent to the predicate device.