K133576

FEB 2 1 2014

GE Medical Systems
Information Technologies

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510(k) Summary

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

Date: Nov. 20, 2013

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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. cardiotachometer & 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
Predicate Device(s):	K130584 Monitor B40
Device Description:	The proposed Monitor B40V2.1 still is a multi-parameter patient monitor. It retains the features of the predicate Monitor B40V2 (K130584) and now includes supporting for an additional optional extension module Airway Gas Option (N-CAiO), and few software improvements by adding alarm breakthrough, extending the upper limit of ECG PVC (Premature Ventricular Contraction) alarm and providing four waveform scale options for Masimo SpO2 and Nellcor SpO2. Same as the predicate Monitor B40V2 (K130584), the proposed Monitor B40V2.1 continues interfacing with following optional extension modules: E-MiniC module (K052582), CARESCAPE Respiratory modules (E-sCO and E-sCAiO) (K123195) and E-Entropy module (K061907). The compatibility with

CARESCAPE Respiratory modules (E-sCOV and E-sCAiOV) (K123195) is also provided but with spirometry function disabled.

The proposed Monitor B40V2.1 still has a 12.1 inch LCD display but is from different LCD manufacturer and LCD backlight is changed from CCFL to LED due to RoHS compliance.

As with the predicate Patient Monitor B40V2 (K130584), the proposed Patient Monitor B40V2.1 still includes features and subsystems that are optional or configurable. The proposed Patient Monitor B40V2.1 will continue interfacing to a variety of existing central station systems via a cabled network interface.

As with the predicate Patient Monitor B40V2 (K130584), the proposed Patient Monitor B40V2.1 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 B40V2.1 employs the same functional scientific technology as the predicate Monitor B40V2 (K120598).

Determination of Substantial Equivalence:

Changes from the predicate Monitor B40V2(K130584)

- Supporting Optional Extension Module: Airway Gas Option (N-CAiO)

  The Airway Gas Option (N-CAiO) is identical to CARESCAPE Respiration module (E-sCAiO) (K123195) except different color and base material of the front bezel. There are three functions from the N-CAiO module that are not supported by the B40V2.1. The B40V2.1 disables the N-CAiO's Secondary Anesthetic Agent, MACage and Balance Gas parameters.

- Alarm breakthrough
  Provided new Alarm Breakthrough feature that allows the proposed Monitor B40V2.1 to give alarm sound for certain predefined alarm conditions even if alarm sounds are turned off in the monitor.

- ECG PVC Alarm Upper Limit Change
  Extended ECG Premature Ventricular Contraction the upper limit adjustable range from 30/min to 100/min to provide more flexibility for user to set alarm limit: "1-100/ min" from lower to upper limits.

- SpO2 Waveform Scale Change for Masimo and Nellcor SpO2
  Changed the SpO2 waveform scale for Masimo SpO2 and Nellcor SpO2 from fixed 2X to four options (1X, 2X, 4X and 8X).

- LCD Display Change
  Replaced the existing 12 inch Sharp LCD display with 12 inch TianMa LCD display that uses the LED instead of CCFL backlight for RoHS compliance purpose.

- Instruction Manual Change
  Added instruction for extension Module Airway Gas Option (N-CAiO).
  Added instruction for alarm breakthrough.
  Modified instruction for ECG PVC alarm limits, SpO2 waveform scale and new LCD display.

Summary of Non-Clinical Tests:

The proposed Monitor B40V2.1 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)

Summary of Clinical Tests:

The subject of this premarket submission, The proposed Monitor B40V2.1 did not require clinical studies to support substantial equivalence.

Conclusion: The design changes made to the proposed Monitor B40V2.1 have no effect on the device's ability to obtain patient measurements as there are no changes to the parameter measuring hardware. 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 B40V2.1 to be as safe, as effective, and performance is substantially equivalent to the predicate device.

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

February 21, 2014

GE Medical Systems China Co., Ltd.
Robert Casarsa
8200 West Tower Ave
Milwaukee, WI 53223 US

Re: K133576
Trade/Device Name: Monitor b40
Regulation Number: 21 CFR 870.1025
Regulation Name: Multiparameter Patient Monitor
Regulatory Class: Class II
Product Code: MHX, BZQ, CBR, CBS, CBQ, CCK, CCL, DXN
DQA, DRT, DSB, DSK, GWQ, FLL, NHO, NHP, NHQ
Dated: January 24, 2014
Received: January 21, 2014

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Owen P. Faris -S

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): K133576

Device Name: **Monitor B40**

Indications for use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen P. Faris -S
Date: 2014.02.21 10:47:24 -05'00'