K120598
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JUL 19 2012

GE Medical Systems
Information Technologies

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: February 27, 2012

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Device: Trade Name: PROCARE™ Monitor B40
Common/Usual Name: Multi-parameter patient monitor
Classification Names: 21 CFR 870.1025 Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Product Code: MHX

Predicate Device(s): K043276 Datex-Ohmeda S/5™ FM Monitor
K062576 Datex-Ohmeda S/5 E-PSM Module
K073203 CARESCAPE V100 Vital Signs Monitor
K102239 CARESCAPE Monitor B650

Device Description: The PROCARE Monitor B40 is a multi-parameter patient monitor including both new and existing subsystems. The PROCARE Monitor B40 has a12 inch display with integrated keypad and a fixed pre-configuration patient parameter measurement module (Hemo module). The PROCARE Monitor B40 also supports a thermal recorder and Airway gas module (E-MiniC, K052582) with an extension rack.

The PROCARE Monitor B40 includes features and subsystems that are optional or configurable. The PROCARE Monitor B40 interfaces to a variety of existing central station systems via a cabled network interface.

Intended Use: The PROCARE Monitor B40 is a portable multiparameter 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 PROCARE Monitor B40 is intended for use under the direct supervision of a licensed health care practitioner.

The PROCARE Monitor B40 is not intended for use during MRI.

The PROCARE Monitor B40 monitors and displays oscillometric non-invasive blood pressure (systolic, diastolic and mean arterial pressure), invasive blood pressure, end-tidal carbon dioxide, heart/pulse rate, respiration rate, ECG (including arrhythmia and ST segment analysis), temperature with a reusable or disposable electronic thermometer for continual monitoring

Esophageal/Nasopharyngeal/Tympanic/Rectal/Bladder/Axillary/Skin/Airway/Room/Myocardial/Core/Surface temperature, and functional oxygen saturation (SpO2) and pulse rate via continuous monitoring, including monitoring during conditions of clinical patient motion or low perfusion.

Technology: The PROCARE Monitor B40 is a new monitor that essentially is a combination of the features and parameters of three existing predicate monitor platforms. The predicate devices are the S/5™ FM Monitor (K043276) with E-PSM (K062576), the

CARESCAPE V100 Vital Signs Monitor (K073203) and CARESCAPE Monitor B650 (K102239).

The PROCARE Monitor B40 has the identical arrhythmia algorithm, EK-Pro V12, as the CARESCAPE Monitor B650 (K102239).

The PROCARE Monitor B40 has identical NIBP hardware and SuperStat algorithm with CARESCAPE V100 Vital Signs Monitor (K073203) with only one exception being an equivalent processor.

Refer to the Comparison Matrix in Section 12.1 for additional information

The fundamental technology of the PROCARE Monitor B40 is the same as the predicate devices.

The PROCARE Monitor B40 is as safe and effective as the predicate devices.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The PROCARE Monitor B40 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 PROCARE Monitor B40 did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the PROCARE Monitor B40 to be as safe, as effective, and performance is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

JUL 19 2012

GE Medical Systems Information Technologies, Inc.
c/o Mr. Robert Casarsa
Regulatory Affairs Leader
8200 West Tower Avenue
Milwaukee, WI 53223

Re: K120598
Trade/Device Name: PROCARE™ Monitor B40
Regulatory Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor (with arrhythmia detection or alarms)
Regulatory Class: II (two)
Product Code: MHX
Dated: July 10, 2012
Received: July 13, 2012

Dear Mr. 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,

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

Enclosure

K120598

Indications for Use

510(k) Number (if known): _____

Device Name: **PROCARE™ Monitor B40**

Indications for use:

The PROCARE Monitor B40 is a portable multiparameter 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.

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Esophageal/Nasopharyngeal/Tympanic/Rectal/Bladder/Axillary/Skin/Airway/Room/Myocardial/Core/Surface temperature, and functional oxygen saturation (SpO2) and pulse rate via continuous monitoring, including monitoring during conditions of clinical patient motion or low perfusion.

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)

(Division Sign-Off)
Division of Cardiovascular Devices

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