MAR 2 2 2013

GE Medical Systems
Information Technologies
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8200 West Tower Avenue
Milwaukee, Wisconsin, 53223

510(k) Summary (revised Aug 29, 2012)

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

Date: July 27, 2012

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Device: Trade Name: PROCARE™ Monitor B20
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): K120598 PROCARE Monitor B40
Device Description: The PROCARE Monitor B20 is a multi-parameter patient monitor. The PROCARE Monitor B20 has a10.4 inch LCD display with integrated keypad and a pre-configuration patient parameter measurement module (Hemo module), the PROCARE Monitor B20 also supports a thermal recorder and Airway gas

module (E-MiniC, K052582) with an extension rack.

The PROCARE Monitor B20 includes features and subsystems that are optional or configurable. The PROCARE Monitor B20 interfaces to a variety of existing central station systems via a cabled network interface.

Intended Use: The PROCARE Monitor B20 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 B20 is intended for use under the direct supervision of a licensed health care practitioner.

The PROCARE Monitor B20 is not intended for use during MRI.

The PROCARE Monitor B20 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 B20 employs the same functional scientific technology as the predicate device the PROCARE Monitor B40 (K120598).

Determination of Substantial Equivalence: Changes from the predicate PROCARE Monitor B40:

- Product name - New Model name is PROCARE Monitor B20
- Display - LCD display size was changed from 12 inch to 10.4 inch to meet customer needs.
  - LCD backlight was changed from CCFL to LED for ROHS compliance.
- Accessories - Expanded the Spo2 Sensors in accessories list, the additional SpO2 sensors are equivalent to the existing SpO2 sensors used with the predicate B40 and

have been 510(k) cleared under separate submissions. These added accessories are also applicable to the predicate PROCARE B40 Monitor

Summary of Non-Clinical Tests:

The PROCARE Monitor B20 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 B20 did not require clinical studies to support substantial equivalence.

Conclusion: The design changes made to create the new model 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.

With the exception of the screen size, all technical specification remains the same.

GE Healthcare considers the PROCARE Monitor B20 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 20993-002

March 22, 2013

GE Healthcare
c/o Mr. Robert L. Casarsa
Regulatory Affairs Leader
GE Healthcare
8200 West Tower Avenue
Milwaukee, WI 53223

Re: K122253
Trade/Device Names: PROCARE™ Monitor B20
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (including ST-Segment Measurement and Alarm)
Regulatory Class: Class II (two)
Product Code: MHX
Dated: February 12, 2013
Received: February 20, 2013

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,

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): _____

Device Name: **PROCARE™ Monitor B20**

Indications for use:

The PROCARE Monitor B20 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/Myo cardial/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)

Owen P. Faris -S
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