K022834

GE Medical Systems
Information Technologies

General Electric Company
4502 Woodland Corporate Blvd., Tampa, FL 33614
813 887-2000

MAY 13 2003

April 7, 2003

SUMMARY OF SAFETY AND EFFECTIVENESS

DINAMAP® Pro 1000 Monitor with SuperStat

A. Submitter

GE Medical Systems Information Technologies.
4502 Woodland Corporate Boulevard
Tampa, FL 33614

B. Company Contact

Primary:
Melissa Robinson, Regulatory Affairs Specialist
Secondary:
Thomas English, Global QA/RA

C. Device Name

Trade Name: Pro 1000 Monitor with SuperStat
Common Name: Physiological Monitor, Patient Monitor
Classification/Device Product Code:
System, Measurement, Blood Pressure, Noninvasive-870.1130-DXN
Computer, Blood Pressure-870.1110-DSK
Alarm, Blood Pressure-870.1100-DSJ
Oximeter-870.2700-DQA
Oximeter, Ear-870.2710-DPZ
Thermometer, Clinical Electronic-880.2910-FLL
Monitor, Cardiac (including cardiotachometer & rate alarm)-870.2300-DRT
Electrocardiograph-870.2340-DPS
Adapter, Lead Switching, Electrocardiograph-870.2350-DRW
Arrhythmia Detection and Alarm-870.1025-DSI
Monitor, Breathing Frequency-868.2375-BZQ
Recorder, Paper Chart-870.2810-DSF

D. Predicate/Legally Marketed Devices

DINAMAP® Pro 1000 V2 Monitor, K012915
GE Medical Systems Information Technologies

E. Device Description

The DINAMAP® Pro 1000 Monitor w/ SuperStat is intended to monitor a single patient's vital signs in the hospital, outpatient surgery and healthcare practitioner facilities. The patient populations include adult, pediatric, and neonatal. The device's networking capabilities include connection to a central station via VHF, 900 MHz or hardwire communication; host communications for use with other devices. In addition, the DINAMAP Pro 1000 Monitor may be operated from internal batteries making the device portable and suitable for intra-hospital transport.

F. Intended Use

The DINAMAP® Pro 1000 with SuperStat Monitor is intended to monitor the following adult, pediatric and neonate patient vital signs:

Non-Invasive Blood Pressure:

- Able to measure oscillometric non-invasive blood pressure (systolic, diastolic and mean arterial pressure)
- Will optimize performance in the presence of artifact due to vibration and patient motion.
- Non-invasive blood pressure determinations acquired concurrently with the ECG parameter will report a determination in the presence of an irregular heart rhythm in the adult/pediatric mode.

Heart/pulse rate, respiration rate, ECG

Oxygen saturation (SpO_2) by noninvasive pulse oximetry and

Predictive temperature by resistive thermometry.

The Pro 1000 with SuperStat Monitor also detects alarm limit conditions and is capable of recording up to two waveforms. Using the monitor a clinician can view, record and recall clinical data derived from each parameter.

G. Technological Characteristics

The DINAMAP® Pro 1000 Monitor with SuperStat has the same technological characteristics as the predicate device, the DINAMAP® Pro 1000 V2 Monitor. There are no new technological characteristics. The Pro 1000 Monitor with SuperStat and the Pro 1000 V2 Monitor are both software-driven electronic devices that include the same monitoring parameters.

H. Parameter Technology

The DINAMAP PRO 1000 Monitor with SuperStat has the following parameter technologies:

- SuperStat NIBP algorithm tested according to the ANSI/AAMI SP10 standard.
- Temperature-Same as the PRO 1000 V2 Monitor
- SpO2-Same as the PRO 1000 V2 Monitor
- ECG-Same as the PRO 1000 V2 Monitor

•Respiration-Same as the PRO 1000 V2 Monitor

I. Testing

Clinical studies were conducted to demonstrate performance (safety and effectiveness) of the DINAMAP PRO 1000 with SuperStat Monitor to the ANSI/AAMI SP10 Standard: American National Standard for Electronic or Automated Sphygmomanometers.

J. Conclusion

The DINAMAP® Pro 1000 with SuperStat Monitor is substantially equivalent to the currently marketed DINAMAP® Pro 1000 V2 Monitor, K012915 cleared 3/21/02.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 13 2003

GE Medical Systems Information Technologies
c/o Ms. Melissa Robinson
Regulatory Affairs Specialist
4502 Woodland Corporate Blvd.
Tampa, FL 33614

Re: K022834
Trade Name: DINAMAP® Pro 1000 Monitor with SuperStat
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm
Regulatory Class: Class III (three)
Product Code: MHX
Dated: March 17, 2003
Received: March 19, 2003

Dear Ms. Robinson:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

April 7, 2003

510(K) Number (if known): K022834

Device Name: DINAMAP® Pro 1000 Monitor with SuperStat

Indications for Use:

The DINAMAP® Pro 1000 with SuperStat Monitor is intended to monitor the following adult, pediatric and neonate patient vital signs:

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(Please Do Not Write Below This Line-Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-The Counter Use ____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K022834