K012915

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GE Medical Systems
Information Technologies

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

MAR 21 2002

SUMMARY OF SAFETY AND EFFECTIVENESS

DINAMAP® Pro 1000 V2 Monitor **August 28, 2001**

A. Submitter

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

B. Company Contact

Thomas J English, Director, Regulatory and Quality Affairs
Phone: 813-887-2107 Fax: 813-887-2413

C. Device Name

Trade Name: Pro 1000 V2 Monitor
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 Monitor, K002248
Critikon Company LLC

E. Device Description

The DINAMAP® Pro 1000 V2 Monitor 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 V2 Monitor may be operated from internal batteries making the device portable and suitable for intra-hospital transport.

F. Intended Use

The DINAMAP® Pro 1000 V2 Monitor is intended to monitor oscillometric non-invasive blood pressure (systolic, diastolic and mean arterial pressure), heart/pulse rate, respiration rate, ECG, oxygen saturation (SpO_2) by non-invasive pulse oximetry, and predictive temperature with an electronic thermometer in the adult, pediatric and neonate populations. An additional feature is the detection of three lethal arrhythmias- asystole, ventricular tachycardia (v-tach), and ventricular fibrillation (v-fib). The Pro 1000 V2 Monitor also detects alarm limit conditions and is capable of recording up to two waveforms. Using this monitor a clinician can view, record and recall clinical data derived from each parameter.

G. Technological Characteristics

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

H. Testing

The Pro 1000 V2 Monitor complies with the same regulatory standards as the Pro 1000 predicate device. A software validation was performed to demonstrate the implementation of the arrhythmia detection feature.

I. Conclusion

The DINAMAP® Pro 1000 V2 Monitor is substantially equivalent to the currently marketed DINAMAP® Pro 1000 Monitor, K002248 cleared on 9/21/00 and the EkPro ECG algorithm in the DASH 3000/4000 Patient Monitor, K001359 cleared on 7/18/00.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 21 2002

Mr. Thomas J. English
Director, Regulatory and Quality Affairs
GE Medical Systems Information Technologies
4502 Woodland Corporate Blvd.
Tampa, FL 33614

Re: K012915
Trade Name: DINAMAP® Pro 1000 V2 Monitor
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm
Regulatory Class: Class III (three)
Product Code: MHX
Dated: December 18, 2001
Received: December 21, 2001

Dear Mr. English:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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.
Acting Director
Division of Cardiovascular
And Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

August 24, 2001

510(K) Number (if known): K012915

Device Name: DINAMAP® Pro 1000 V2 Monitor

Indications for Use:

The DINAMAP® Pro 1000 V2 Monitor is intended to monitor oscillometric non-invasive blood pressure (systolic, diastolic and mean arterial pressure), heart/pulse rate, respiration rate, ECG, oxygen saturation (SpO_2) by non-invasive pulse oximetry, and predictive temperature with an electronic thermometer in the adult, pediatric and neonate populations. An additional feature is the detection of three lethal arrhythmias- asystole, ventricular tachycardia (v-tach), and ventricular fibrillation (v-fib). The Pro 1000 Monitor also detects alarm limit conditions and is capable of recording up to two waveforms. Using this monitor a clinician can view, record and recall clinical data derived from each parameter.

(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 of Cardiovascular & Respiratory Devices
510(k) Number K012915

(Optional Format 1-2-96)