K014255

JUL - 2 2002

GE Medical Systems
Information Technologies

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

SUMMARY OF SAFETY AND EFFECTIVENESS

Dec 21, 2001

DINAMAP® ProCare Series Monitor

A. Submitter

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

B. Company Contact

Thomas J English
Director, Regulatory Affairs
Phone: 813-887-2170
Fax: 813-887-2413

C. Common Name

Physiological or Vital Signs Monitor, Patient Monitor

Classification Name	Product Code	21 CFR
System, Measurement, Blood Pressure, Noninvasive	DXN	870.1130
Computer, Blood Pressure	DSK	870.1110
Alarm, Blood Pressure	DSJ	870.1100
Oximeter	DQA	870.2700
Oximeter, Ear	DPZ	870.2710
Thermometer, Clinical Electronic	FLL	880.2910
Recorder, Paper Chart	DSF	870.2810

D. Predicate/Legally Marketed Devices

DINAMAP® Pro Series Monitor 100-400-K992638
Critikon Company, LLC

Welch Allyn Vital Signs Monitor-K951193
Welch Allyn Protocol/Tycos Industries Inc.

E. Device Description

The DINAMAP ProCare Series Monitor is a prescription device intended for use only by health care professionals. Four configurations of the monitor-all with integrated printer-will offer the following vital signs parameters:

- DPC XXX: Non-Invasive Blood Pressure and Pulse Rate
- DPC XXX: Non-Invasive Blood Pressure and Pulse Rate, Pulse Oximetry
- DPC XXX: Non-invasive Blood Pressure and Pulse Rate, Temperature
- DPC XXX: Non-Invasive Blood Pressure and Pulse Rate, Pulse Oximetry and Temperature.

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This portable device includes an integrated printer and is capable of operation from an external AC mains power source or an internal lead-acid rechargeable battery.

F. Intended Use

The DINAMAP® ProCare Series Monitor is intended to monitor a single adult, pediatric or neonatal patient's vital signs at the bedside or during intra-hospital transport. Vital signs parameters include non-invasive blood pressure (systolic, diastolic, and mean arterial pressure), pulse rate, and/or oxygen saturation (pulse oximetry) and/or temperature. The portable device is designed for use in numerous clinical settings in various hospital departments such as emergency, radiology, recovery, medical/surgical, labor and delivery, endoscopy, cardiac step-down. It can also be used in satellite areas, physicians' offices, or alternate care settings.

G. Technological Characteristics

The DINAMAP® ProCare Series Monitor has the same technological characteristics as the predicate device, the DINAMAP® Pro Series 100-400 Monitor. There are no new technologies used on the DINAMAP® ProCare Series Monitor.

H. Parameter Technology

The DINAMAP® ProCare Series Monitor has the following parameter technologies:

- NIBP oscillometric algorithm wholly implemented from the DINAMAP Pro Series 100- 400 Monitor **or** an NIBP ascultatory algorithm tested according to the ANSI/AAMI SP10 standard..
- Wholly implemented Alaris thermometry technology
- Wholly implemented Masimo SpO2 technology

I. Testing

Several bench studies were conducted which demonstrate safety and effectiveness of the DINAMAP® ProCare Series Monitor:

- AAMI/ANSI SP10
- Mechanical and Environmental
- Electromagnetic Compatibility
- Battery Power
- Electrical Safety

K. Substantial Equivalence

ProCare Series	Predicate Device & Model	**510(k) Numbers**
Monitor	DINAMAP Pro Series 100-400	K992638
SpO2	•Masimo SET Pulse Oximeter	K992238
Temperature	Alaris Medical System	K955846
NIBP	•DINAMAP Pro Series 100-400 •Welch Allyn Vital Signs Monitor	K992638 K951193

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 2 2002

GE Medical Systems Information Technologies
c/o Mr. Thomas English
Director, Regulatory Affairs
4502 Woodland Corporate Blvd.
Tampa, FL 33614

Re: K014255
Trade Name: DINAMAP® ProCare Series Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Patient Physiological Monitor (without Arrhythmia Detection)
Regulatory Class: Class II (two)
Product Code: MWI
Dated: April 2, 2002
Received: April 3, 2002

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.

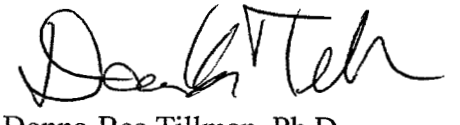
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

December 21, 2001 Page 1 of 1

510(K) Number (if known): K014255

Device Name: DINAMAP® ProCare Series Monitor

Indications for Use:

The DINAMAP® ProCare Series Monitor is intended to monitor a single adult, pediatric or neonatal patient's vital signs at the bedside or during intra-hospital transport. Vital signs parameters include non-invasive blood pressure (systolic, diastolic, and mean arterial pressure), pulse rate, and/or oxygen saturation (pulse oximetry) and/or temperature. The portable device is designed for use in numerous clinical settings in various hospital departments such as emergency, radiology, recovery, medical/ surgical, labor and delivery, endoscopy, cardiac step-down. It can also be used in satellite areas, physicians' offices, or alternate care settings.

(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)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular
and Respiratory Devices
510(k) Number K014255