FEB 24 2000

CRITIKON VITAL ANSWERS™

K992638

# 510(k) Summary

August 3, 1999

**Device Identification**
Dinamap® Pro Monitor, Series 100, 200, 300, 400

**Submitted by**
Critikon Company, L.L.C., 4110 George Road, Tampa, Florida 33634

**Contact Person**
Tom English, Director, Regulatory Affairs and Clinical Services, Critikon Company LLC, Tampa, FL

**Common Name**
Physiological or Vital Signs Monitor, Patient Monitor includes:

- Non-Invasive Blood Pressure and Pulse Rate
- Pulse Oximetry and Pulse Rate
- Temperature, Predictive and Monitor Mode

| 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 |

**Indications for use**
The DINAMAP® Pro Series 100, 200, 300, 400 Monitor is intended to monitor a single adult, pediatric or neonatal patient's vital signs at the bedside or during intra-hospital or ground transport. Vital signs parameters include non-invasive blood pressure (systolic, diastolic, and mean arterial pressure), pulse rate and/or temperature and/or oxygen saturation (pulse oximetry). 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.

**Device Description**
The DINAMAP Pro Monitor, Series 100, 200, 300, 400 is a prescription device intended for use only by health care professionals. Four configurations of the monitor – all with an integrated printer – will offer the following vital signs parameters:

- DINAMAP Pro Series 100: Non-Invasive Blood Pressure and Pulse Rate
- DINAMAP Pro Series 200: Non-Invasive Blood Pressure and Pulse Rate; and Monitor/Predictive Oral/Rectal Temperature
- DINAMAP Pro Series 300: Non-Invasive Blood Pressure and Pulse Rate; and Nellcor® Pulse Oximetry and Pulse Rate
- DINAMAP Pro Series 400: Non-Invasive Blood Pressure and Pulse Rate; Monitor/Predictive Oral/Rectal Temperature; and Nellcor® Oxygen Saturation and Pulse Rate (Pulse Oximetry)

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. The device uses the same technology and materials as the predicate devices, the DINAMAP MPS™ *Select*™ Multiparameter System (K955113 cleared 8/15/96); the DINAMAP MPS™ *Select*™ Portable Monitor (K971569 cleared 9/19/97); and the DINAMAP® *Compact* Monitor (K970182 cleared 8/18/97).

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**Clinical and Bench Testing**

***Non-Invasive Blood Pressure (NIBP)***

For NIBP performance, Critikon used ANSI/AAMI SP10-1992: "Electronic or automated sphygmomanometers" and ANSI/AAMI SP10A-1996: Amendment to ANSI/AAMI SP10-1992: American National Standard for Electronic or Automated Sphygmomanometers.

The following requirements of ANSI/AAMI SP10 and SP10A were met:

- Labeling (4.1)
- Stability (4.2.4, environmental requirements, 4.2.1, 4.2.2, and 4.2.3 were not included)
- Safety (4.3)
- Performance (4.4)

To evaluate environmental performance, Critikon met the requirements contained in the November 1993 Draft Reviewer Guidance for Premarket Notification Submissions of the Anesthesiology and Respiratory Devices Branch of the Division of Cardiovascular, Respiratory, and Neurological Devices.

*Clinical Study for Accuracy - Overall System Efficacy:*
Accuracy of the NIBP algorithm was established in the adult, pediatric, and neonatal populations with the ANSI/AAMI SP10 clinical study for the DINAMAP MPS *Select* NIBP Module used in the DINAMAP MPS *Select* Multiparameter System and the DINAMAP MPS *Select* Portable Monitor (K955113 cleared 8/15/96).

The NIBP parameter of the new monitor has the same NIBP algorithm that calculates blood pressure from measured oscillations as the DINAMAP MPS™ *Select*™ Multiparameter System (K955113 cleared 8/15/96); the DINAMAP MPS™ *Select*™ Portable Monitor (K971569 cleared 9/19/97); and the DINAMAP® *Compact* Monitor (K970182 cleared 8/18/97).

Moreover, the NIBP parameter of the new monitor has the same intended use and labeling claims as the DINAMAP MPS *Select* NIBP Module; the same software runs in the same processor family under the same operating system as the predicate device; and the same accessories – air hoses and blood pressure cuffs.

*Bench Testing, ANSI/AAMI SP10*
With the exception of the environmental performance, the new device was subjected to the remainder of ANSI/AAMI SP10 bench testing requirements, including:

- Stability: 4.2.4.1 Voltage Range; and 4.2.4.2 Life
- Safety Requirements: 4.3.1.1 Maximum Cuff Pressure; 4.3.1.2. Cuff Deflation; 4.3.2 Electrical Safety; and 4.3.3 Conductive Components
- Performance Requirements: 4.4.1 Pressure Indicator Accuracy; and 4.4.3 Battery-Powered Devices.

The new device passed all tests.

***Oxygen Saturation ($SpO_2$)***

Nellcor Puritan Bennett, Inc. (NPB) conducted studies (two clinical and three bench) to demonstrate the accuracy of the pulse oximetry parameter to the new device with Nellcor FE101 hardware, BE3050 software and the Nellcor sensor line.

*Clinical Studies*
Two clinical studies were performed to evaluate the accuracy of the new device's derived oxygen.

- Co-Oximeter Correlation Study – compared oxygen saturation measurements obtained with three new devices with arterial blood oxygen saturation co-oximeter measurements obtained from three healthy subjects. Breathedown progressed in five plateaus from 100% to 70% in increments of approximately 5%. After data collection at the lowest plateau was complete, the subjects were rapidly re-saturated to 100%. Pooled results for all three subjects indicated that the three new devices met sensor specifications.
- Non-Invasive Controlled Hypoxia Study – compared oxygen saturation measurements obtained with three new devices with arterial blood oxygen saturation pulse oximeter measurements obtained from 35 subjects across the full Nellcor sensor line.

The oxygen saturation parameter of the new devices met oxygen saturation accuracy specifications with all Nellcor sensors.

*Bench Testing*
The following three bench tests were performed:

- Saturation Comparison Verification Study
- Low Perfusion/Low Signal Saturation Study
- Pulse Rate Comparison Study

In all cases the new devices met the acceptance criteria

***Temperature***

Temperature tests performed were:

- To establish monitor mode or probe accuracy, liquid-bath testing according to ASTM E 1112 – 86 (Reapproved 1991): Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature was followed.
- To establish predictive mode accuracy; liquid-bath testing was conducted to establish equivalence between the new device and the Alaris Medical Systems IVAC® 2080 Measurement according to a Critikon-developed procedure.
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*Bench Testing*
To determine clinical accuracy, Critikon conducted an in-house study comparing temperatures obtained from 78 subjects using the new device and a mercury-in-glass thermometer. The ability of two new devices to accurately read resistance was confirmed before and after liquid-bath testing. Four probes were then tested with the two new devices over the operational temperature range – both in monitor and predictive modes. Test results demonstrated the ability of the new device to determine monitor mode temperatures relative to a mercury-in-glass thermometer and predictive mode temperatures relative to an IVAC 2080 Measurement System within the maximum error ranges specified in Table 1 of ASTM E 1112 – 86 (Reapproved 1991).

*Clinical Studies*
Temperature data was collected orally from 78 adult and pediatric subjects. A predictive temperature was obtained from the test device and compared to a reference mercury-in-glass thermometer temperature reading collected over a three-minute period. A clinically significant difference was defined as a mean difference > 1.0°F. Data analysis showed a mean difference of 0.13°F, with a S.D. of 0.31 – well within acceptance criteria of 2.0°F.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 24 2000

Mr. Thomas English
Critikon Company, L.L.C.
4502 Woodland Corporate Boulevard
Tampa, FL 33614

Re: K992638
Dinamap® Pro Series Monitor, Models 100, 200, 300, 400 Monitor
Regulatory Class: II (two)
Product Code: MWI
Dated: November 23, 1999
Received: November 26, 1999

Dear Mr. English:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## INDICATIONS FOR USE

510(k) Number (if known): K992638

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K992638

Prescription Use ✓ OR Over-The Counter Use ____
(per 21 CFR 801.109 (Optional Format 1-2-96)