

AUG 14 1998

K982342

510(k) Summary

Date July 1, 1998

Contact Annette M. Hillring
Director, Regulatory Affairs
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Device Name DINAMAP MPS® *Select*® Portable Monitor

Common Names Physiological or Vital Signs Monitor, Patient Monitor
Includes the following monitoring modules:

- Noninvasive Blood Pressure & Heart Rate Monitor
- Invasive Blood Pressure & Heart Rate Monitor
- Endtidal Carbon Dioxide & Respiration Rate Monitor
- Pulse Oximetry & Heart Rate Monitor
- Electrocardiograph (ECG), Respiration Rate, Heart Rate & Temperature Monitor
- Recorder

Classification The classification names, 21 Code of Federal Regulations (CFR) Part and Paragraph numbers, and classification of the modified DINAMAP MPS® *Select*® Portable Monitor and its modules follow. The tier categorization based on the list (January 27, 1994) distributed by the Office of Device Evaluation is also included.

Classification Name	21 CFR § & Class	Tier
Monitor, Cardiac (including cardiometer & rate alarm)	870.2300 II	2
Electrocardiograph	870.2340 II	2

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Classification (continued)

Classification Name	21 CFR § & Class	Tier
Adapter, Lead Switching, Electrocardiograph	870.2350 II	1
Analyzer, Gas, CO2, Gaseous Phase	868.1400 II	2
Monitor, Breathing Frequency	868.2375 II	2
System, Measurement, Blood Pressure, Noninvasive	870.1130 II	2
Computer, Blood Pressure	870.1110 II	2
Alarm, Blood Pressure	870.1100 II	2
Oximeter	870.2700 II	2
Oximeter, Ear	870.2710 II	2
Thermometer, Clinical Electronic	880.2910 II	2
Recorder, Paper Chart	870.2810 II	1

Predicate Device

The modified DINAMAP MPS® *Select*® Portable Monitor is substantially equivalent to the currently-marketed DINAMAP MPS® *Select*® Portable Monitor which received marketing clearance September 19, 1997, via 510(k) K971569.

Device Description

The modified DINAMAP MPS® *Select*® Portable Monitor device description is identical to the currently-marketed device. The difference between the two devices lies only in the electromagnetic compatibility (EMC) emissions classification. The modified Portable Monitor meets CISPR 11 Class A emissions requirements; the original Portable Monitor met CISPR 11 Class B emissions requirements. All other EMC specifications remain unchanged.

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Indications The modified DINAMAP MPS® *Select*® Portable Monitor indications for use remain unchanged from the currently-marketed DINAMAP MPS® *Select*® Portable Monitor:

The DINAMAP MPS® *Select*® Portable 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 Portable Monitor networking capabilities are identical to the predicate device (K955113) and include connection to the OBSERVER® Central Station via VHF, spread spectrum or hardwire communication; host communications for use on the auxiliary serial port or RS-232 serial port; and remote view protocol over Ethernet enabling communication with other devices such as currently-marketed DINAMAP® Monitors, remote display, data collection or hospital information system, or remote alarm. In addition, the Portable Monitor may be operated from internal NiMH batteries making the device portable. This device is intended for use by qualified healthcare personnel trained in its use.

Technological Characteristics The modified DINAMAP MPS® *Select*® Portable Monitor has the same technological characteristics as the predicate device, the currently-marketed DINAMAP MPS® *Select*® Portable Monitor. There are no new technological characteristics.

Testing Testing of a fully configured modified DINAMAP MPS® *Select*® Portable Monitor was performed by an ANSI-certified test facility to demonstrate compliance with CISPR 11 (Group 1, Class A) for both radiated and conducted emissions.

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Conclusions In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Part 807, and based on the information provided in this premarket notification, Johnson & Johnson Medical concludes that the modified device, the DINAMAP MPS® *Select*® Portable Monitor, is safe, effective and substantially equivalent to the predicate device, the currently-marketed DINAMAP MPS® *Select*® Portable Monitor, as described herein.

Other Information Critikon will update and include in this summary any other information deemed reasonably necessary by the FDA.

AUG 14 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Annette M. Hillring
Director, Regulatory Affairs
Critikon, Inc.
4110 George Road
Tampa, FL 33634

Re: K982342
DINAMAP MPS® *Select*® Portable Monitor
Regulatory Class: II (two)
Product Code: MSX
Dated: July 1, 1998
Received: July 6, 1998

Dear Ms. Hillring:

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" (21CFR 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,

A handwritten signature in cursive script that reads "Thomas J. Callahan".

Thomas J. Callahan, Ph.D.
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:

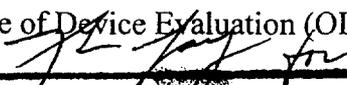
Device Name: DINAMAP MPS® Select® Portable Monitor

Indications for Use:

The DINAMAP MPS® Select® Portable 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 Portable Monitor networking capabilities are identical to the predicate device and include connection to the OBSERVER® Central Station via VHF, spread spectrum or hardwire communication; host communications for use on the auxiliary serial port or RS-232 serial port; and remote view protocol over Ethernet enabling communication with other devices such as currently-marketed DINAMAP® Monitors, remote display, data collection or hospital information system, or remote alarm. In addition, the Portable Monitor may be operated from internal NiMH batteries making the device portable. This device is intended for use by qualified healthcare personnel trained in its use.

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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 K982342

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)