Johnson & Johnson
MEDICAL INC.

K971569

510(k) Summary

SEP 19

Date April 28, 1997

Contact

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Device Name DINAMAP MPS* 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 DINAMAP *Select* MPS 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 cardiotachometer & rate alarm)	870.2300 II	2
Electrocardiograph DPS	870.2340 II	2
Adapter, Lead Switching, Electrocardiograph	870.2350 II	1

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Classification (continued)

Classification Name	21 CFR § & Class	Tier
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
Display, Cathode-Ray Tube, Medical	870.2450 II	1

Predicate Device

The DINAMAP MPS Portable Monitor is substantially equivalent to the currently-marketed DINAMAP MPS *Select* Monitor ("*Select* Monitor") which received marketing clearance August 15, 1996, via 510(k) K955113.

Device Description

The DINAMAP MPS Portable Monitor is a prescription device intended for use only by health care professionals. It can be used in hospital and/or outpatient surgery center settings and functions as a portable and/or transport multiparameter monitoring unit. It is designed for monitoring adult, pediatric and neonatal patients in acute care settings such as critical care, emergency room, radiology, labor and delivery, operating room, and same-day surgery.

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Device Description, continued

Using this monitor, the clinician can view, record and recall clinical data derived from the user-selectable monitoring parameter modules. This clinical data includes heart rate, ECG waveforms, oxygen saturation (SpO2), invasive pressure, noninvasive pressure (systolic, diastolic, mean), endtidal carbon dioxide (CO2), respiration rate and temperature. These are the same modules utilized in the currently-marketed Johnson & Johnson Medical, Inc. (JJMI) DINAMAP MPS* *Select** Monitor which received marketing clearance August 15, 1996, via 510(k) premarket notification K955113:

- ECG (3 lead)/Respiration/Heart Rate/Continuous Temperature
- ECG (6 lead)/Respiration/Heart Rate/Continuous Temperature
- Noninvasive Blood Pressure/Heart Rate
- Invasive Pressure/Heart Rate
- Pulse Oximetry (Oxygen Saturation)/Heart Rate
- Endtidal Carbon Dioxide/Respiration
- Recorder (double wide)

The Portable Monitor accepts modules in any combination and the waveforms and parameter measurements on the screen vary according to the modules that are in the Monitor. The Monitor will detect module type and will disable modules as appropriate (e.g. duplicates) to prevent the system from operating improperly. Modules can be inserted or removed, as necessary, while the Monitor is operating. When a module is inserted, the Monitor automatically detects it. When a module is removed, the patient can continue to be monitored with any of the remaining modules.

The Portable Monitor is self-contained and has a carrying handle. It can be operated from internal battery or AC (via an in-line DC power supply). At the side of the Monitor are six slots for modules. All patient connectors are on the modules. On the front of the Monitor are three indicators that let the user know when the backup battery is being charged or if the Monitor is operating on AC or battery power. The internal battery is capable of powering the Portable Monitor for 60 minutes (± 10 minutes). The two optional user-replaceable batteries are capable of adding 60 minutes each to the operating time.

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Device Description, continued

On the back of the monitor are the on/off button, power supply connection, optional user-replaceable Nickel Metal Hydride (NiMH) batteries, network and device connections, and an optional pullout hanging bracket. On the bottom of the Monitor is the mounting plate. The Portable Monitor provides connections for the currently-marketed JJMI OBSERVER* Central Station (K933404; hardwire, digital spread spectrum or VHF communication); other monitoring devices, such as the currently-marketed JJMI DINAMAP *PLUS* Monitors (K943709 & K912188); a remote monitor (display); a full-page printer; data collection or hospital information system; remote alarm and/or Ethernet network. If the Portable is networked, the user may observe vital signs data from other devices by using the Remote View feature. As with the monitoring parameter modules, communications protocols for the Portable Monitor are the same as the currently-marketed DINAMAP MPS* *Select** Monitor.

Indications

The DINAMAP MPS Portable Monitor is intended to monitor a single patient's vital signs. The patient populations include adult, pediatric and neonatal. Remote monitoring is available if a network of monitors exists.

Technological Characteristics

The DINAMAP MPS Portable Monitor has the same technological characteristics as the predicate device, the DINAMAP MPS *Select* Monitor. There are no new technological characteristics. The Portable and *Select* Monitors are all software-driven electronic devices. The Portable Monitor utilizes the same monitoring parameter modules as the *Select* Monitor.

Testing

Several bench studies were conducted which demonstrate safety and effectiveness of the DINAMAP MPS Portable Monitor:

- Environmental
- Electromagnetic Compatibility
- Battery Life

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510(k) Summary, Continued

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 new device, the DINAMAP MPS Portable Monitor is safe, effective and substantially equivalent to the predicate device, the DINAMAP MPS *Select* Monitor, as described herein.
Other Information	Johnson & Johnson Medical will update and include in this summary any other information deemed reasonably necessary by the FDA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 19 1997

Ms. Annette M. Hillring
Johnson & Johnson Medical Inc.
4110 George Road
Tampa, Florida 33634

Re: K971569
DINAMAP MPS* Select* Portable Monitor
Regulatory Class: II (two)
Product Code: 74 MSX
Dated: August 5, 1997
Received: August 6, 1997

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 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/dsmamain.html".

Sincerely yours,

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: K971569

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 (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.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

Prescription Use ✓
(Per 21 CFR 801.109)

510(k) Number _____ OR ~~Over-The-Counter~~ Use _____

(Optional Format 1-2-96)

*Trademark