

510(k) Summary

AUG 15 1996

Date November 7, 1995

Contact Annette M. Hillring
 Director, Regulatory Affairs
 Johnson & Johnson Medical, Inc.
 4110 George Road
 Tampa, Florida 33634
 Telephone: (813) 887-2256
 Telefax: (813) 887-2263

Device Name DINAMAP* *Select* Multi-Parameter System (MPS)

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 cardiometer & rate alarm)	870.2300 II	2
Electrocardiograph	870.2340 II	2
Adapter, Lead Switching, Electrocardiograph	870.2350 II	1

Continued on next page

510(k) Summary, Continued

Classification (continued)

Classification Name	21 CFR § & Class	Tier
Analyzer, Gas, CO ₂ , 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 Devices

The following table summarizes the predicate devices for the MPS and its monitoring parameters/modules and 510(k) numbers:

Select MPS	Predicate Device & Model	510(k) Number(s)
System	Hewlett Packard Component Monitoring System (CMS) HP M1175A & M1176A	K941811 K922058 K910490 K896030
System	Hewlett Packard Omnicare™ Monitor	Unknown
System	Marquette Medical Tramscope™ System	K900598
ECG	JJMI DINAMAP PLUS Monitor Models 8710/9710 & 8720/9720	K943709 K912188
Respiration	Hewlett Packard HP M1002A ECG/Respiration Module for the Hewlett Packard CMS	K941811
Temperature	JJMI DINAMAP PLUS Monitor Models 8700/9700, 8710/9710 & 8720/9720	K943709 K912188
NIBP	JJMI DINAMAP PLUS Monitor Models 8700/9700, 8710/9710 & 8720/9720	K943709 K912188
IP	JJMI DINAMAP PLUS Monitor Model 8720/9720	K943709 K912188

Continued on next page

510(k) Summary, Continued

Predicate Devices (continued)

Select MPS	Predicate Device & Model	510(k) Number(s)
Oximetry	Nellcor® Model N-180 Pulse Oximeter	K913695
CO2	Novametrix Model 1265 Endtidal CO2 Monitor	K910019
Recorder	JJMI DINAMAP <i>PLUS</i> Monitor Recorder Model 8726	K943709 K912188

Device Description

The DINAMAP *Select* Multi Parameter System (MPS) 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 patient bedside 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, and operating room. Using this monitoring system, the clinician can view, record and recall clinical data derived from the user-selectable modules/monitoring parameters. This clinical data includes heart rate, ECG waveforms, oxygen saturation (SpO₂), invasive pressure, noninvasive pressure (systolic, diastolic, mean), entidal carbon dioxide (CO₂), respiration rate and temperature.

The DINAMAP *Select* MPS functions as a single-patient monitor or as part of an Ethernet network. Patient data may be viewed in graphical or text form and is stored for twenty-four hours. If the MPS is networked, the user may observe vital signs data from other devices by using the Remote View feature. The MPS is modular and monitors multiple parameters simultaneously. When necessary, the user can temporarily suspend all activity of the monitor while in Standby mode. The MPS consists of the mainframe, modules and monitor (display).

Continued on next page

510(k) Summary, Continued

Device Description, continued

The mainframe provides a single rack with nine slots for modules. All patient connectors are on the front of the mainframe. All network and device connectors are on the back. The indicators, on the right side of the mainframe, informs the user when the battery is being charged and when the MPS is operating on AC or battery power. The mainframe provides connection for the currently marketed Johnson & Johnson Medical, Inc. (JJMI, formerly Critikon, Inc.) OBSERVER* Central Station (K933404), other monitoring devices, such as the currently marketed Johnson & Johnson Medical, Inc., DINAMAP PLUS Monitors (K943709 & K912188), a remote monitor, a full-page printer, data collection system, remote alarm and/or host information system.

Modules measure patient vital signs and patient airway gases, and provide thermal paper strip records. The MPS accepts two types of modules: parameter modules and recorder modules. Parameter modules process data from transducers to generate waveforms and numeric data on the display screen. The waveforms and parameter measurements on the screen vary according to the modules inserted into the mainframe. The user can continue to monitor a patient with any of the remaining modules while inserting or removing other modules.

Currently, the *Select* MPS will offer the following modules:

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

Indications

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

Continued on next page

510(k) Summary, Continued

Technological Characteristics

The DINAMAP *Select* MPS and its monitoring modules/parameters have the same technological characteristics as the predicate devices. There are no new technological characteristics. The MPS and the predicate devices are all software-driven electronic devices. The MPS monitoring parameters and predicate devices monitoring parameters utilize the following technologies:

- ECG & Heart Rate: Electrocardiography
 - Respiration: Thoracic impedance (ECG) and spectroscopy (endtidal CO₂)
 - Noninvasive Blood Pressure & Heart Rate: Oscillometry
 - Invasive Pressure & Heart Rate: Direct measurement with strain-gauge pressure transducer
 - Pulse Oximetry & Heart Rate: Nellcor®, Inc., red & infrared spectroscopy
 - Endtidal CO₂: Novamatrix Medical Systems, Inc., infrared spectroscopy
 - Recorder: Thermal
-

Nonclinical Tests

Several bench studies were conducted which demonstrate safety and effectiveness of the MPS and modules/monitoring parameters:

- ECG & Heart Rate
 - Respiration (Impedance)
 - Continuous Temperature
 - Invasive Pressure
 - CO₂ & Respiration
 - Pulse Oximetry
 - Environmental
 - Electromagnetic Compatibility
-

Clinical Tests

Several clinical studies were conducted which demonstrate safety and effectiveness of the MPS and modules/monitoring parameters:

- Noninvasive Blood Pressure in the adult, pediatric and neonatal populations
 - Pulse Oximetry
-

Continued on next page

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 Select Multi-Parameter System and modules, is safe, effective and substantially equivalent to the predicate devices as described herein.

Other Information Johnson & Johnson Medical will update and include in this summary any other information deemed reasonably necessary by the FDA
