

AUG 18 1997

510(k) Summary

Date January 16, 1997

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* Compact Monitor

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

- Noninvasive Blood Pressure & Heart Rate
- Pulse Oximetry & Heart Rate
- Predictive Temperature

An optional recorder is also available.

Classification The classification names, 21 Code of Federal Regulations (CFR) Part and Paragraph numbers, and classification of the DINAMAP Compact Monitor and its monitoring parameters follow. The tier categorization based on the list (January 27, 1994) distributed by the Office of Device Evaluation is also included.

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Classification (continued)

Classification Name	21 CFR § & Class	Tier
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 Compact Monitor and its monitoring parameters and 510(k) numbers:

Compact	Predicate Device & Model	510(k) Number(s)
System	DINAMAP PLUS Monitor Model 9700	K943709 K912188
System	DINAMAP XL Monitor	K942700
Temperature	DINAMAP XL Monitor	K942700
NIBP	DINAMAP PLUS Monitor Model 9700	K943709 K912188
	DINAMAP XL Monitor	K942700
Oximetry	Nellcor® Model N-180 Pulse Oximeter	K913695
	DINAMAP PLUS Monitor Model 9700	K943709 K912188

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**Device
Description**

The DINAMAP Compact Monitor is a prescription device intended for use only by health care professionals. Three configurations of the monitor with the following vital signs parameters will be available:

- Noninvasive Blood Pressure and Heart Rate,
- Noninvasive Blood Pressure and Heart Rate, and Predictive Oral/Rectal Thermometry
- Noninvasive Blood Pressure and Heart Rate, Predictive Thermometry, and Nellcor® Pulse Oximetry and Heart Rate

In addition, the currently-marketed Sherwood Medical Inc. FirstTemp™ Genius™ Infrared Tympanic Thermometry Unit (K920713) may be physically attached to the side of (but not electrically integrated with) the DINAMAP Compact Monitor.

The device is designed for monitoring adult, pediatric and neonatal patients in hospital, outpatient surgery center, physician office and/or alternate healthcare settings. It is portable and capable of operation from an external AC mains power source or an internal lead-acid rechargeable battery. An optional printer is also available.

The Compact Monitor provides connection for the currently marketed Johnson & Johnson Medical, Inc. (JJMI, formerly Critikon, Inc.) OBSERVER* Central Station (K933404), other monitoring devices, a remote display, data collection system, remote alarm and/or host information system.

Indications

The DINAMAP Compact Monitor is intended to monitor a single patient's vital signs at the bedside. The patient populations include adult, pediatric and neonatal.

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Technological Characteristics

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

- Noninvasive Blood Pressure & Heart Rate: Oscillometry
 - Pulse Oximetry & Heart Rate: Nellcor®, Inc., red & infrared spectroscopy
 - Thermometry: Thermistor with predictive algorithm
-

Nonclinical Tests

Several bench studies were conducted which demonstrate safety and effectiveness of the Compact Monitor and monitoring parameters:

- Pulse Oximetry
 - Environmental
 - Electromagnetic Compatibility
-

Clinical Tests

Several clinical studies were conducted which demonstrate safety and effectiveness of the Compact Monitor and monitoring parameters:

- Predictive Thermometry Accuracy
 - Adult Noninvasive Blood Pressure Accuracy
 - Pediatric Noninvasive Blood Pressure Accuracy
 - Neonatal Noninvasive Blood Pressure Accuracy
-

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 Compact Monitor 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



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

AUG 18 1997

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

Re: K970182
DINAMAP* Compact Monitor
Regulatory Class: II (two)
Product Code: 74 MHX
Dated: May 19, 1997
Received: May 20, 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 (Pre-market 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.

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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, 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: K970182

Device Name: DINAMAP* Compact Monitor

Indications for Use:

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

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IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Christy Bowman for A/C
Division Sign-Off)

Division of Cardiovascular, Respiratory,
and Neurological Devices

Prescription Use
(Per 21 CFR 801.109)

510(k) Number K970182
OR Over-The-Counter Use _____

(Optional Format 1-2-96)