Attachment B
3/29/99

K982641

510(k) Summary

Date

March 11, 1999

Contact

Darlene T. Korab, Manager
Regulatory Affairs
Critikon, LLC
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Tampa, FL 33634
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Device Name

- Advanced NIBP Module

The subject of this premarket notification is a software modification of the currently marketed DINAMAP MPS™ *Select*™ NIBP Module used with the DINAMAP MPS *Select* Family of Monitors, including the currently marketed DINAMAP MPS *Select Portable* Monitor and the currently marketed DINAMAP MPS *Select* Multiparameter System. In this premarket notification, the terms new device, new module and new NIBP module are used interchangeably with Advanced NIBP Module; and the terms predicate device, standard module and standard NIBP module are used interchangeably with DINAMAP MPS *Select* NIBP Module.

Common Name

- Non-Invasive Blood Pressure Module

Classification

The classification name, 21 Code of Federal Regulations (CFR) Part and Paragraph number and classification of the Advanced NIBP Module 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 Section	Class	Tier
Noninvasive blood pressure measurement system	870.1130	II	2

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510(k) Summary, Continued

Predicate Devices

The Advanced NIBP Module is substantially equivalent to the currently marketed DINAMAP MPS *Select* NIBP Module used with DINAMAP MPS *Select* Monitors, including the DINAMAP MPS *Select Portable* Monitor and the DINAMAP MPS *Select* Multiparameter System. The DINAMAP MPS *Select Portable* Monitor received market clearance on September 19, 1997 via Critikon, a Division of Johnson & Johnson Medical, Inc. 510(k) K971569. The DINAMAP MPS *Select* Multiparameter System received market clearance on August 15, 1996 via Johnson & Johnson Medical, Inc. 510(k) K955113.

Device	Manufacturer	510(k)
DINAMAP MPS *Select* Multiparameter System	Johnson & Johnson Medical, Inc.	K955113
DINAMAP MPS *Select Portable* Monitor	Johnson & Johnson Medical, Inc.	K971569

Device Description

Used with the DINAMAP MPS *Select* Family of Monitors, the Advanced NIBP Module obtains systolic, diastolic and mean arterial pressures and pulse rate via the oscillometric method. The Advanced NIBP Module optimizes performance in the presence of artifact due to vibration and patient motion. Reduced measurement time, a message for values that may be affected by artifact and greater patient comfort differentiate Advanced NIBP Module performance.

Indications

The Advanced NIBP Module is designed for use with the DINAMAP MPS *Select* Family of Monitors, including the DINAMAP MPS *Select Portable* Monitor and the DINAMAP MPS *Select* Multiparameter System. The Advanced NIBP Module is intended to obtain a single patient's systolic, diastolic and mean arterial blood pressures and pulse rate in the same intended use environment as the DINAMAP MPS *Select* Family of Monitors: hospital, outpatient surgery and healthcare practitioner facilities. The Advanced NIBP Module optimizes performance in the presence of artifact. The Module combines Advanced NIBP for use with small adult, adult, large adult and thigh cuffs with standard, currently marketed NIBP for use with neonatal cuffs. The device is intended for use by qualified healthcare personnel trained in its use.

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510(k) Summary, Continued

Technological Characteristics

The Advanced NIBP Module has the same technological characteristics as the predicate device, the DINAMAP MPS *Select* NIBP Module used in the DINAMAP MPS *Select* Monitors – the DINAMAP MPS *Select Portable* and the DINAMAP MPS *Select* Multiparameter System. Differences between the modules are limited to the NIBP software algorithm for the population whose cuff sizes include small adult, adult, large adult, and thigh. The neonatal application of the Advanced NIBP Module remains the same as the DINAMAP MPS *Select* NIBP Module.

There are no new technological characteristics. Both modular devices are utilized in software-driven electronic systems.

Testing

Clinical and bench studies were conducted to demonstrate performance (safety and effectiveness) of the Advanced NIBP Module Software Algorithm. The module from a hardware perspective, including environmental and EMC testing, was cleared for marketing with the previously mentioned, currently marketed DINAMAP MPS *Select Portable* and the DINAMAP MPS *Select* Multiparameter System.

Clinical studies consistent with the recommendations of ANSI/AAMI SP10 (10/92) American National Standard for Electronic or Automated Sphygmomanometers were conducted with Advanced NIBP Module Software. Results demonstrated the recommended accuracy (mean ± 5 mmHg, standard deviation ≤ 8 mmHg).

Bench testing demonstrated that:

1. average measurement time is reduced in the Advanced NIBP module when compared to the standard NIBP module; and that
2. displayed NIBP values are properly managed in the presence of artifact on the basis of Quality Factor Groups

Other Information

Critikon, LLC 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

MAR 29 1999

Ms. Darlene T. Korab
Manager, Regulatory Affairs
Johnson & Johnson Medical, Inc.
Critikon
4110 George Road
Tampa, FL 33634

Re: K982641
Advanced NIBP Module
Regulatory Class: II (Two)
Product Code: 74 DXN
Dated: February 26, 1999
Received: March 1, 1999

Dear Ms. Korab:

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,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment A

INDICATIONS FOR USE

510(k) Number (if known): K982641

Device Name: Advanced NIBP Module

Indications for Use:

The Advanced NIBP Module is designed for use with the DINAMAP MPS™ *Select*™ Family of Monitors, including the DINAMAP MPS *Select Portable* Monitor and the DINAMAP MPS *Select* Multiparameter System. The Advanced NIBP Module is intended to obtain a single patient's systolic, diastolic and mean arterial blood pressures and pulse rate in the same intended use environment as the DINAMAP MPS *Select* Family of Monitors: hospital, outpatient surgery and healthcare practitioner facilities. The Advanced NIBP Module optimizes performance in the presence of artifact. The Module combines Advanced NIBP for use with small adult, adult, large adult and thigh cuffs with standard NIBP for use with neonatal cuffs. The device is intended for use by qualified healthcare personnel trained in its use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(signature)
(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K982641

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