

510(K) SUMMARY

JUL 03 2013

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: _____.

Submitter:

Shenzhen Mindray Bio-medical Electronics Co., LTD
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park,
Nanshan, Shenzhen, 518057, P. R. China

Tel: +86 755 2658 2888

Fax: +86 755 2658 2680

● **Contact Person:**

Ms. Susan D. Goldstein-Falk
Official Correspondent for Shenzhen Mindray
Bio-Medical Electronics Co., Ltd
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, NY 10021

IN CALIFORNIA:

TEL: (949) 706-7456

FAX: (949) 706-7457

EMAIL: sgoldstein@mdiconsultants.com

Alternate Only:

Mr. Rong Liang
Product Approval Engineer of Technical Regulation Dept.
Shenzhen Mindray Bio-Medical Electronics Co., Ltd
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park,
Nanshan, Shenzhen, 518057, P.R. China

TEL: (86)-0755-8188 5637

FAX: (86)-0755-2658 2680

EMAIL: rongliang@mindray.com

● **Date Prepared:**

Sep 21, 2012

Name of the devices:

- **Trade/Proprietary Name:**

iMEC, iPM and BeneView T1 Patient Monitors (including models iMEC8, iMEC10, iMEC12, iPM 8, iPM 10, iPM 12, and BeneView T1)

- **Common Name:** Patient Monitor

- **Classification**

21 CFR 870.1025	Arrhythmia detector and alarm (including ST-segment measurement and alarm)	Class II
21 CFR 870.1025	Detector and Alarm, Arrhythmia	Class II
21 CFR 870.1025	Monitor, ST Segment with Alarm	Class II
21 CFR 870.2300	Cardiac monitor (including cardiometer and rate alarm)	Class II
21 CFR 870.1130	Non-Invasive blood pressure measurement System	Class II
21 CFR 870.1110	Blood pressure computer	Class II
21 CFR 880.2910	Clinical Electronic Thermometers – Temperature Monitor with Probe	Class II
21 CFR 870.2700	Oximeter, Pulse	Class II
21 CFR 870.2710	Ear Oximeter, Pulse	Class II
21 CFR 868.1400	Carbon Dioxide Gas Analyzer	Class II
21 CFR 868.1500	Enflurane gas analyzer	Class II
21 CFR 868.1620	Halothane gas analyzer	Class II
21 CFR 868.1700	Nitrous Oxide gas analyzer	Class II
21 CFR 868.1720	Oxygen gas analyzer	Class II
21 CFR 870.1435	Single-function, preprogrammed diagnostic computer.	Class II

Legally Marketed Predicate Devices:

K092449. BeneView T Series patient monitors (Including Models BeneView T8, BeneView T6 and BeneView T5), Shenzhen Mindray Bio-medical Electronics Co., LTD

Device Description:

The iMEC Series Patient Monitors (including iMEC8, iMEC10 and iMEC12), iPM Series Patient Monitors (including iPM 8, iPM 10 and iPM 12) and BeneView T1 Patient Monitor are the developed new series based on the technical platform of the BeneView T Series patient monitors. The new series, much more compact and flexible with the appearance changes, are the sub-configuration models of the BeneView T Series patient monitors by reducing some parameters monitoring functions such as impedance cardiograph (ICG), bispectral index (BIS) and respiration mechanics (RM) monitoring.

And comparing with the cleared BeneView T Series Patient Monitors using Mortara ECG algorithm, the subject patient monitors adopt Mindray Monitoring ECG Algorithm as an optional ECG algorithm to implement ECG monitoring, arrhythmia detection, and ST Segment Analysis.

Statement of intended Use:

The iMEC Series Patient Monitors, including iMEC8, iMEC10 and iMEC12, are intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters including ECG (3-lead or 5-lead selectable), arrhythmia detection and ST Segment analysis, heart rate (HR), respiration (Resp), temperature (Temp), pulse oxygen saturation (SpO₂), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), cardiac output (C.O.), and carbon dioxide (CO₂). All the parameters can be applied to single adult, pediatric and neonatal patients with the exception of the following: C.O. monitoring is restricted to adult patients only, and PAWP monitoring, arrhythmia detection and ST Segment analysis are not intended for neonatal patients.

The iPM Series Patient Monitors, including iPM 8, iPM 10 and iPM 12, are intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters including ECG (3-lead, or 5-lead, or 12-lead selectable), arrhythmia detection and ST Segment analysis, heart rate (HR), respiration (Resp), temperature (Temp), pulse oxygen saturation (SpO₂), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), cardiac output (C.O.), carbon dioxide (CO₂), and anesthetic gas (AG). All the parameters can be applied to single adult, pediatric and neonatal patients with the exception of the following: C.O. monitoring is restricted to adult patients only, and PAWP monitoring, arrhythmia detection and ST Segment analysis are not intended for neonatal patients. 12-lead monitoring and AG monitoring are available for iPM 10 and iPM 12 Patient Monitors only.

The BeneView T1 Patient Monitor is intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters including ECG (3-lead, or 5-lead, or 12-lead selectable), arrhythmia detection and ST Segment analysis, heart rate (HR), respiration (Resp), temperature (Temp), pulse oxygen saturation (SpO₂), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), cardiac output (C.O.), and carbon dioxide (CO₂). All the parameters can be applied to single adult, pediatric and neonatal patients with the exception of the following: C.O. monitoring is restricted to adult patients only, and PAWP monitoring, arrhythmia detection and ST Segment analysis are not intended for neonatal patients.

The monitors are to be used in healthcare facilities by clinical physicians or appropriate medical staff under the direction of physicians.

Technology:

The iMEC Series Patient Monitors (including iMEC8, iMEC10 and iMEC12), iPM Series Patient Monitors (including iPM 8, iPM 10 and iPM 12) and BeneView T1 Patient Monitor are substantially equivalent to the predicate devices BeneView T Series Patient Monitors (K092449).

Test Summary:

The iMEC Series Patient Monitors (including iMEC8, iMEC10 and iMEC12), iPM Series Patient Monitors (including iPM 8, iPM 10 and iPM 12) and BeneView T1 Patient Monitor comply with the recognized safety, performance and electromagnetic compatibility standards. A risk analysis has been developed to identify potential hazards and document the mitigation of the hazards. Mindray's product development process required that the following activities be completed during the development of those patient monitors:

- Requirements specification review
- Hardware and Software testing
- Code design and code reviews
- Environmental EMC testing
- Safety testing
- Performance testing
- Hardware and Software validation

Conclusion:

The results of all testing demonstrate that the iMEC Series Patient Monitors, iPM Series Patient Monitors and BeneView T1 Patient Monitor are as safe, as effective, and perform as well as the predicate devices.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

July 3, 2013

Shenzhen Mindray Bio-Medical Electronics Co., Ltd
Susan Goldstein-Falk
55 Northern Blvd., Suite 200
Great Neck, NY 11021 US

Re: K123074
Trade/Device Name: iMEC, iPM and BeneView T1 Patient Monitors (including models iMEC8, iMEC10, iMEC12, iPM 8, iPM 10, iPM 12, and BeneView T1)
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm
Regulatory Class: Class II
Product Code: MHX
Dated: May 24, 2013
Received: June 6, 2013

Dear Susan Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

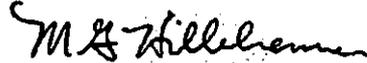
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, Misbranding by reference to premarket notification (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123074

Device Name: **iMEC, iPM and BeneView T1 Patient Monitors**

Indications for Use:

- **iMEC**

The iMEC Series Patient Monitors, including iMEC8, iMEC10 and iMEC12, are intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters including ECG (3-lead or 5-lead selectable), arrhythmia detection and ST Segment analysis, heart rate (HR), respiration (Resp), temperature (Temp), pulse oxygen saturation (SpO₂), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), cardiac output (C.O.), and carbon dioxide (CO₂).

All the parameters can be applied to single adult, pediatric and neonatal patients with the exception of the following:

- C.O. monitoring is restricted to adult patients only;
- PAWP monitoring is not intended for neonatal patients;
- The Mindray ECG Algorithm arrhythmia detection is intended for adult and pediatric patients, and the Mindray ECG Algorithm ST Segment analysis is intended for adult patients only.

- **iPM**

The iPM Series Patient Monitors, including iPM 8, iPM 10 and iPM 12, are intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters including ECG (3-lead, or 5-lead, or 12-lead selectable), arrhythmia detection and ST Segment analysis, heart rate (HR), respiration (Resp), temperature (Temp), pulse oxygen saturation (SpO₂), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), cardiac output (C.O.), carbon dioxide (CO₂), and anesthetic gas (AG).

All the parameters can be applied to single adult, pediatric and neonatal patients with the exception of the following:

- C.O. monitoring is restricted to adult patients only;
- PAWP monitoring is not intended for neonatal patients;
- The Mortara ECG Algorithm arrhythmia detection and ST Segment analysis is intended for adult and pediatric patients. The Mindray ECG Algorithm arrhythmia detection is intended for adult and pediatric patients, and the Mindray ECG Algorithm ST Segment analysis is intended for adult patients only.
- 12-lead monitoring and AG monitoring are available for iPM 10 and iPM 12 Patient Monitors only.

- **BeneView T1**

The BeneView T1 Patient Monitor is intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters including ECG (3-lead, or 5-lead, or 12-lead selectable), arrhythmia detection and ST Segment analysis, heart rate (HR), respiration (Resp), temperature (Temp), pulse oxygen saturation (SpO₂), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), cardiac output (C.O.), and carbon dioxide (CO₂).

All the parameters can be applied to single adult, pediatric and neonatal patients with the exception of the following:

- C.O. monitoring is restricted to adult patients only;
- PAWP monitoring is not intended for neonatal patients;
- The Mortara ECG Algorithm arrhythmia detection and ST Segment analysis is intended for adult and pediatric patients. The Mindray ECG Algorithm arrhythmia detection is intended for Adult and Pediatric patients, and the Mindray ECG Algorithm ST Segment analysis is intended for adult patients only.

The monitors are to be used in healthcare facilities by clinical physicians or appropriate medical staff under the direction of physicians.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)