

JUL 20 2011

Patient Monitor
Traditional 510K Submission

Section 1

510(k) Summary of Safety and Effectiveness

This summary of 510k safety and effectiveness is being submitted in according with 21CFR part 807.92

Submitter: Edan Instruments, Inc
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Contact person: Randy Jiang

Date of Preparation: 2011-03-20

Proprietary Name: Patient Monitor (Models M50 and M80)

Classification:

Description	Classification	Product code
21 CFR 870.1025 Arrhythmia detector and alarm (Including ST-segment measurement and alarm)	II	MHX
21 CFR 870.2300 Cardiac monitor (including cardiachoment and rate alarm)	II	DRT
21 CFR 870.1130 Non-Invasive blood pressure measurement System	II	DXN
21 CFR 870.1110 Blood pressure computer	II	DSK
21 CFR 880.2910 Clinical Electronic Thermometers-Temperature Monitor with Probe	II	FLL
21 CFR 870.2700 Oximeter, Pulse	II	DQA
21 CFR 870.1400 Carbon Dioxide Gas Analyzer	II	CCK
21 CFR 868.1500 Enflurane gas analyzer	II	CBQ
21 CFR 868.1620 Halothane gas analyzer	II	CBS
21 CFR 868.1700 Nitrous Oxide gas analyzer	II	CBR
21 CFR 868.1720 Oxygen gas analyzer	II	CCL
21 CFR 868.2900 cable, transducer and electrode, patient, (including connector)	II	DSA
21 CFR 870.2300 monitor, cardiac (incl. cardiachometer & rate alarm)	II	DRT
21 CFR 870.1025 Detector and Alarm, Arrhythmia	II	DSI
21 CFR 870.1025 Monitor, ST Segment with Alarm	II	MLD

Regulatory Class: Class II

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Legally Marketed Predicate Devices::

Manufacturer	Predicate Device	510(k) number	Cleared date
Shenzhen Mindray Bio-medical Electronics co., LTD	PM-8000 Express	K053193	Oct.25.2005
Edan Instruments, Inc	M3B	K083821	May.14.2009
Colin Medical Instruments Corp	BX-10	K032857	April.21.2003
Shenzhen Mindray Bio-medical Electronics co., LTD	BeneView T5	K073280	Nov.8.2007

Device Description: M50/M80 Patient Monitor provides the following primary features:

M50/M80 Patient Monitor can perform long-time continuous monitoring of multiple physiological parameters. Also, it is capable of storing, displaying, analyzing and controlling measurements, and it will indicate alarms in case of abnormality so that doctors and nurses can deal with them in time.

M50 Patient Monitor can monitor parameters including SpO₂, NIBP, ECG, RESP, TEMP, CO₂, IBP.

M80 Patient Monitor can monitor parameters including SpO₂, NIBP, ECG, RESP, TEMP, CO₂, IBP, C.O. and AG.

M50 is outfitted with a 8.4-inch display screen, M80 is 15-inch, as well as an equal large touch screen, which enables the operation by touching the screen, thus offering convenience for doctors and nurses.

M50 Patient Monitor has parameter modules including SpO₂ (pulse oxygen saturation, pulse rate and SpO₂ plethysmogram) with EDAN SpO₂ module or Nellcor SPO₂ module, NIBP (systolic pressure, diastolic pressure, mean pressure and pulse rate), TEMP, ECG, RESP, CO₂, IBP and Quick Temp.

M80 Patient Monitor has parameter modules including SpO₂ with EDAN SpO₂ module or Nellcor SPO₂ module, NIBP with EDAN NIBP module or Omron M3600, TEMP, ECG, RESP, CO₂, CO, IBP, AG.

The EDAN SpO₂ module used in M80 and M50 is also used by H100B Pulse Oximeter which has been cleared by FDA under K092727. The CO₂ module and Nellcor SpO₂ module used in M80 are the same to those used in M3B, which has been cleared by K083821 in May 14, 2009.

M80 could be configured with two different NIBP modules, one is EDAN NIBP module, the other one is Omron M3600 NIBP module; M3600 module used in M80 is the same to that used in BX-10, which has been cleared by K032857 in April.21.2003.

CO2 module and Nellcor SpO2 module used in M50 are the same to those used in M3B, which has been cleared by K083821 in May 14, 2009.

Arrhythmia and ST Analysis used in M80 is the same to that in PC ECG which has been cleared by FDA under K102854 and K092010

Comparison with predicate device

The M50 and M80 Patient Monitors have the following similarities to that which previously received 510(k) concurrence:

- have the same indications for use,
- use the similar operating principle,
- have the same testing module, e.g. EDAN SpO2 module and Nellcor NELL-1 module.
- have the same or similar performance specifications

In summary, the M50 and M80 Patient Monitor described in this submission is, in our opinion, substantially equivalent to the predicate device

Intended Use:

M80:

The monitor monitors parameters such as ECG (3-lead, 5-lead, 12-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO2), Invasive or noninvasive blood pressure (2/4 channels IBP NIBP), Cardiac Output (CO), Temperature (dual-TEMP), Expired CO2 and Anesthetic gas (AG). The monitor is equipped with alarms that indicate system faults (such as loose or defective electrodes), physiologic parameters that have exceeded the limits set by the operator, or both.

M50:

The monitor monitors parameters such as ECG (3-lead, 5-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO2), Invasive or noninvasive blood pressure (dual-IBP, NIBP), Temperature (dual-TEMP), Expired CO2 and Quick Temperature (Quick TEMP). The monitor is equipped with alarms that indicate system faults (such as loose or defective electrodes), physiologic parameters that have exceeded the limits set by the operator, or both. The arrhythmia detection and ST Segment analysis are not intended for neonatal patients.

Contraindications:

It is not intended for use in patient's home or residence, or when it has not been ordered by a physician.

Test Summary:

The following quality assurance measures were applied to the development of the Patient Monitor

- Software testing
- Hardware testing
- Safety testing
- Environment test
- Risk analysis
- Final validation

Conclusion:

Verification and validation testing was done on the Patient Monitor. This premarket notification submission demonstrates that Patient Monitor is substantially equivalent to the predicate device.



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JUL 20 2011

Re: K110922
Trade/Device Name: Patient Monitor Models M50 and M80
Regulatory Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor (with arrhythmia detection or alarms)
Regulatory Class: II (two)
Product Code: MHX, DRT, DXN, DSK, FLL, DQA, CCK, CBQ, CBS, CBR, CCL, DSA,
DRT, DSF, and MLD
Dated: June 25, 2011
Received: June 27, 2011

Dear Mr. Jiang:

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.

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

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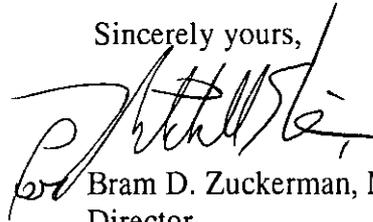
found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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,



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

Enclosure

Indication for Use

510(k) Number (if known):

Device Name: Patient Monitor Models M50 and M80

M80:

The monitor monitors parameters such as ECG (3-lead, 5-lead, 12-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO2), Invasive or noninvasive blood pressure (2/4 channels IBP NIBP), Cardiac Output (CO), Temperature (dual-TEMP), Expired CO2 and Anesthetic gas (AG). The monitor is equipped with alarms that indicate system faults (such as loose or defective electrodes), physiologic parameters that have exceeded the limits set by the operator, or both.

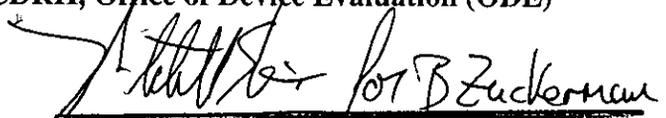
M50:

The monitor monitors parameters such as ECG (3-lead, 5-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO2), Invasive or noninvasive blood pressure (dual-IBP, NIBP), Temperature (dual-TEMP), Expired CO2 and Quick Temperature (Quick TEMP). The monitor is equipped with alarms that indicate system faults (such as loose or defective electrodes), physiologic parameters that have exceeded the limits set by the operator, or both.

The arrhythmia detection and ST Segment analysis are not intended for neonatal patients.

Prescription Use (21 CFR Part 801 Subpart D) And/Or Over the Counter Use (21 CFR Part 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off) 7/20/2011
Division of Cardiovascular Devices
510(k) Number K110922