OCT 15 2004

K041918

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510(k) Summary of Safety and Effectiveness

Submitter Information:

Invivo Research Inc.
12601 Research Parkway
Orlando, FL 32826
407-275-3220
Contact: Mr. Neil Battiste

Device Name

Integrated Patient Monitor System

Common Name

Multiparameter Patient Monitor

Classification Names	Codes	Reference
1. Monitor, Physiological Patient	MWI	870.2300
2. System, Measurement, Blood Pressure, Non Invasive	DXN	870.1130
4. Oximeter	DQA	870.2700
3. Monitor, Breathing Frequency	BZQ	868.2375
5. Thermometer, Electronic, Clinical	FFL	880.2910

Predicate Devices:

Invivo Research Omni-Trak™ 3150/3155 Series Patient Monitoring System.

510(k) Number: K002030
Device Classification Name: Monitor, Physiological Patient (w/o Arr. Detector or Alarms)
Regulation Number: 870.2300, 74 MWI

Invivo Research Millennia 3500 Series Monitor

510(k) Number: K974581
Device Classification Name: Monitor, Cardiac (incl. cardiotachometer & rate alarm)
Regulation Number: 870.2300, 74 DRT

Device Description:

The Philips Medical Systems Integrated Patient Monitoring System (IPMS) is a significant modification of the Invivo Research Omni-Trak™ 3150/3155 Series Patient Monitoring System. This device has been repackaged to integrate into the Phillips Physiotrak patient gurney used with the Philips MRI System.

The Philips Medical Systems Integrated Patient Monitoring System is intended to monitor the heart rhythm and other vital signs for a patient undergoing an MRI procedure and to provide signals for synchronization for the MRI scanner. The monitor runs on DC (battery) power supplies and monitors the patient's heart rate, (non invasive) blood pressure, SPO_2, respiration and temperature. This information can be displayed either at the monitor or remotely.

The monitor sounds an alarm if any monitored parameter falls outside the range indicated by the programmable MAX and MIN alarm limits. The alarm limits is programmable either manually or automatically based on the current value of the parameter(s).

This monitoring system is MRI-compatible. It utilizes technology from the Invivo Research Omni-Trak™ 3150/3155 Series Patient Monitoring System and the Invivo Research Millennia Patient Monitor. The IPMS consists of three major component parts; the MCB (Patient Connector Box), MEB (Monitoring Electronics Box), and MDCU (Monitoring Display and Control Unit) which are integrated into the Phillips Physiotrak patient gurney

Intended Use

The Philips Medical Systems Integrated Patient Monitoring System (IPMS) is intended to monitor the heart rhythm and other vital signs for a patient undergoing an MRI procedure and to provide signals for synchronization for the MRI scanner.

Summary of Performance Testing:

Validation and Verification Testing confirmed that this device operates as designed and intended:

Parameter	Specification
ELECTRICAL AND MECHANICAL CHARACTERISTICS	
Line Voltage	115 VAC +/- 10%, 50/60 Hz
Power Sources Available	AC Power, or internal battery power with remote charger
Power Consumption	< 30 Volt-Amperes @ 120 VAC nominal (< 60 VA maximum during charging)
Battery	Lead-Acid Gel Cell (x4), Capacity > 8 hours with 4 batteries
Electrical Safety	Per EN 60601-1
Electromagnetic Compatibility	Per EN 60601-1-2
PERFORMANCE REQUIREMENTS	
Heart Rate Monitor	
Range/Resolution	0 to 250 BPM / 1 BPM
Rate Accuracy	0.5% of reading, +/- 1BPM
Defibrillator Protection	Accepts and recovers from a defibrillator discharge up to 5 KV
Non-Invasive Blood Pressure Monitoring	
Auto Mode Set Intervals	OFF, 1, 2, 2.5, 3, 5, 10, 15, 20, 30, 45 Min, or 1,2, 4 Hrs
Pop-Off Pressure Level	270 +/- 14 mmHg
Cuff Inflation Time	3 to 20 seconds
Pulse Oximetry	
Range	0 to 100% saturation
Accuracy	< 3.0% (60% to 100%)
Averaging Period	3, 6, or 12 seconds
Respiration Monitoring	
Range	4 to 150 RPM
Resolution	1 RPM
Accuracy	2% up to 60 RPM, 3.4% at 87 RPM, 5.6% at 142 RPM
Temperature	
Range	20°C to 44°C
Accuracy	0.3°C (32°C to 44°C)
Time Constant	15 seconds
MRI COMPATIBILITY	
Maximum RF Emissions	Maximum –100dB RF noise at MRI Larmor Frequencies
MRI In-Bore Materials Used	All materials are non- magnetic, and do not produce proton-signal emissions during MRI

Conclusion

The Integrated Patient Monitoring System is safe, effective and substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2004

Invivo Research, Inc.
c/o Mr. Neil Battiste
Director of Regulatory Affairs
12601 Research Parkway
Orlando, FL 32826

Re: K041918
Trade Name: Integrated Patient Monitor System (IPMS)
Regulation Number: 21 CFR 870.2300
Regulation Name: Physiological Patient Monitor
Regulatory Class: Class II (two)
Product Code: MWI
Dated: September 16, 2004
Received: September 20, 2004

Dear Mr. Battiste:

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 such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Bram D. Zuckerman, M.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): K04/198

Device Name: Integrated Patient Monitoring System

Indications For Use:

The Philips Medical Systems Integrated Patient Monitoring System (IPMS) is intended to monitor the heart rhythm and other vital signs for a patient undergoing an MRI procedure and to provide signals for synchronization for the MRI scanner.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K04/198