K050399

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTER INFORMATION

A.	Company Name:	Invivo Research, Inc.
B.	Company Address:	12601 Research Parkway Orlando, FL 32826
C.	Company Phone: Company Fax:	(407) 275-3220 (407) 249-2022
D.	Contact Person:	Neil Battiste Director of Regulatory Affairs (acting) Invivo Research, Inc.
E.	Date Summary Prepared:	February 10, 2004

DEVICE IDENTIFICATION

A.	Generic Device Name:	3160 MRI Patient Monitor
B.	Trade/Proprietary Name:	3160 Series MRI Compatible Patient Monitoring System
C.	Classification:	Class II
D.	Product Codes:	DRT, DXN, DQA, CCK, CBQ, CBS, CBR, CCL, MWI

DEVICE DESCRIPTION

The 3160 MRI Patient Monitoring System is intended to monitor vital signs for patients undergoing MRI procedures and to provide signals for synchronization for the MRI scanner. It is designed to assist clinicians in monitoring patient vital signs in the midst of the dynamic and evolving Magnetic Resonance environment. A combination of wireless communication, radio frequency (RF) shielding, digital signal processing (DSP), and adaptable mounting technologies address the challenges associated with patient monitoring in the MRI area. Built on Invivo's strong heritage in MRI patient vital signs monitoring, the 3160 provides accurate, continuous, and reliable performance during all phase of MRI applications.

K050399

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SUBSTANTIAL EQUIVALENCE

The Invivo Research System is of comparable type and is substantially equivalent to the following predicate devices:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
Magnitude ™ 3150/3155 MRI Patient Monitoring System	Invivo Research, Inc.	K040915	09/22/04
Integrated Patient Monitoring System	Invivo Research, Inc.	K041918	10/15/04

INTENDED USE

The 3160 MRI Patient Monitoring System is intended to monitor vital signs for patients undergoing MRI procedures and to provide signals for synchronization for the MRI scanner.

The 3160 MRI Patient Monitoring System is intended for use by health care professionals.

COMPARISON TO PREDICATE DEVICE:

The MRI Compatible Patient Monitoring System and the predicate devices (Magnitude 3150/3155 and the Integrated Patient Monitoring System) are all portable monitors which are used to transmit vital sign information to a patient monitor during MRI procedures.

The systems differ in that the MRI Compatible Patient Monitor has been enhanced by providing wireless technology for the ECG leads and the pulse oximeter function, and by moving to a lithium battery for longer battery life.

K050394

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TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the 3160 MRI Compatible Patient Monitoring System and the predicate devices has been performed. The results of this comparison demonstrate that the 3160 MRI Compatible Patient Monitoring System is equivalent to the marketed predicate devices in technological characteristics.

ENVIRONMENTAL AND NON-CLINICAL TESTING:

Applicable environmental and non-clinical testing was performed per UL-2601-1 and IEC 60601-1-2 as well as other applicable standards and procedures. The 3160 MRI Compatible Monitoring System passed all tests.

PERFORMANCE DATA

The performance data included in this submission to compare equivalency of the Magnitude 3150/3155 and the Integrated Patient Monitor System 510(k) cleared devices to the modified 3160 MRI Compatible Patient Monitoring System met the performance requirements for accuracy and precision and indicates substantial equivalence to the predicate devices. Equivalent performance in meeting user requirements was also determined.

Summary of Performance Testing:

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

Parameter	Specification
ELECTRICAL AND MECHANICAL CHARACTERISTICS	
Operating Voltage	90 to 264 VAC
Power Consumption	30 Volt-Amperes with Charged batteries (48 VA maximum during charging)
Battery	Lithium Ion, Capacity > 8 hours
Electrical Safety	Per EN 60601-1
Electromagnetic Compatibility	Per EN 60601-1-2

PERFORMANCE REQUIREMENTS

Heart Rate Monitor	
Range/Resolution	Adult: 30 to 249 BPM Neonate: 30 to 300 BPM / 1 BPM
Rate Accuracy	±1% from 30 to 200 BPM ±1.5% from 201 to 250 BPM ±2% from 251 to 300 BPM (Neonate only)
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 and 4 Hrs
Pop-Off Pressure Level	285 +/- 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	+/- 5% or 2rpm (whichever is greater)

Anesthetic Agents		
Halothane	Range: 0.15 to 6.0 Vol.%	Accuracy: ±0.15 Vol.% +15% relative
Enflurane	Range: 0.15 to 8.0 Vol %	Accuracy: (0.15-7 %)±0.15 Vol% + 15% relative
Isoflurane	Range: 0.15 to 6.0 Vol %	Accuracy: ±0.15 Vol.% +15% relative
Sevoflurane	Range: 0.15 to 9.0 Vol%	Accuracy: (0.15-8%) ±0.15 Vol% + 15% relative
Desflurane	Range: 0.15 to 20 Vol%	Accuracy: ±0.15 Vol.% +15% relative
Carbon Dioxide	Range: 0 to 10 Vol%	Accuracy: (measured with agent option) ±4mmHG or 12%, whichever is greater
Nitrous Oxide	Range: 0 to 99 Vol %	Accuracy: (measured with agent option) ±2% Vol + 8% relative

MRI COMPATIBILITY	
Maximum RF Emissions	Maximum –150dB 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 test results demonstrate the 3160 MRI Compatible Patient Monitoring System is substantially equivalent to the Magnitude 3150/3155 Series Patient Monitoring System and the Integrated Patient Monitoring System devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 26 2005

Invivo Resarch, Inc.
c/o Eduardo Rey
Regulatory Compliance Engineer
12601 Research Parkway
Orlando FL 32826

Re: K050399
Trade/Device Name: Patient Monitor System, Model 3160
Regulation Number: 21 CFR 870.
Regulation Name:
Regulatory Class: Class II
Product Code: MWI
Dated: August 22, 2005
Received: August 23, 2005

Dear Mr. Rey:

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) 594-4648. 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 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): K050399

Device Name: **3160 MRI Patient Monitoring System**

Indications for Use:

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Prescription Use ✓ (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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K050399