K090785 pg 1 of 8

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTER INFORMATION

Establishment / Sponsor Name:	Invivo Corporation
Establishment / Sponsor Address:	12501 Research Parkway Orlando, FL 32826 USA
Manufacturer Name:	Philips Medical Systems
Manufacturer Address:	3000 Minuteman Road Andover, MA 01810
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Establishment Registration Number:	1051786 (Sponsor) 1217116 (Manufacturer)
Date Summary Prepared:	March 18, 2009

DEC 1 5 2009

DEVICE IDENTIFICATION

Generic Device Name:	MRI multi-parameter patient monitor
Trade / Proprietary Name:	Expression MRI Patient Monitoring System (Model 865214)
Classification:	Class II

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

CLASSIFICATION

Device Panel	Description	Product Code	CFR Section	Classification
Cardiovascular	Monitor, Physiological, Patient (without arrhythmia detection or alarms)	MWI	870.2300	II
	Alarm, Blood Pressure	DSJ	870.1100	II
	Computer, Blood Pressure	DSK	870.1110	II
	System, Measurement, Blood Pressure, Non-Invasive	DXN	870.1130	II
	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm)	DRT	870.2300	II
	Cable, Transducer and Electrode, Patient (including connector)	DSA	870.2900	II
Anesthesiology	Oximeter	DQA	870.2700	II
	Analyzer, Gas, Carbon-dioxide, Gaseous-phase	CCK	868.1400	II
	Monitor, Breathing Frequency	BZQ	868.2375	II
	Analyzer, Gas, Enflurane, Gaseous Phase (anesthetic concentration)	CBQ	868.1500	II
	Analyzer, Gas, Halothane, Gaseous Phase (anesthetic concentration)	CBS	868.1620	II
	Analyzer, Gas, Nitrous Oxide, Gaseous Phase (anesthetic concentration)	CBR	868.1700	II
	Analyzer, Gas, Oxygen, Gaseous Phase	CCL	868.1720	II
	Analyzer, Gas, Desflurane, Gaseous-Phase (anesthetic concentration)	NHO	868.1500	II
	Analyzer, Gas, Isoflurane, Gaseous-Phase (anesthetic concentration)	NHQ	868.1500	II
	Analyzer, Gas, Sevoflurane, Gaseous-Phase (anesthetic concentration)	NHP	868.1500	II
General Hospital	Thermometer, Electronic, Clinical	FLL	880.2910	II

INTENDED USE

The Expression MRI Patient Monitoring System (Model 865214) is intended to monitor vital signs for patients undergoing MRI procedures and to provide signals for synchronization for the MRI scanner. The Expression MRI Patient Monitoring System (Model 865214) is intended for use by healthcare professionals.

· 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

DEVICE DESCRIPTION

The device description of the modified device has not changed from that of the predicate device as a result of the modification.

The Expression MRI Patient Monitoring System (Model 865214) is designed to assist clinicians in monitoring patient vital signs in the midst of the dynamic and evolving magnetic resonance (MR) 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 MR environment.

The Expression MRI Patient Monitoring System (Model 865214) includes monitoring capabilities for wireless electrocardiogram (ECG), wireless pulse oximetry (SpO2), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), temperature, respiration, end-tidal CO2 (EtCO2), oxygen, and anesthetic agents.

SUBSTANTIAL EQUIVALENCE

The Expression MRI Patient Monitoring System (Model 865214) is of comparable type and is substantially equivalent to the following predicate devices:

Predicate Device	Manufacturer	510(K) No.	Clearance Date
3160 MRI Patient Monitoring System	Invivo Corporation	K053462	January 18, 2006
PICOSAT II SpO2 Pulse Oximetry Module	Philips Medical Systems	K081937	August 29, 2008

COMPARISON TO PREDICATE DEVICE

The Expression MRI Patient Monitoring System (Model 865214) and the primary predicate device, the 3160 MRI Patient Monitoring System which received clearance to market under 510(k) K053462 on January 18, 2006, are identical with respect to indications for use, intended use, and fundamental scientific technology. Both devices are multi-parameter patient monitors intended to monitor vital signs for patients undergoing MRI procedures and to provide signals for synchronization for the MRI scanner.

The primary differences between the Expression MRI Patient Monitoring System (Model 865214) and the predicate device are listed below:

- Minor hardware and cosmetic modifications were implemented to the external appearance of the device.
- SpO2 detection and measurement is completed with the Philips Medical Systems PICOSAT II SpO2 Pulse Oximetry Module, which was cleared to market under 510(k) K081937 on August 29, 2008.
- Body temperature measurement is completed with the Lumasense Technologies, Inc. Multichannel Fluoroptic Thermometer.
- Labeling was modified to instruct the user of the proper patient application of the Multichannel Fluoroptic Thermometer.
- Anesthetic agents monitoring parameters were improved.
- Oxygen (O2) monitoring parameters were improved.
- Labeling was modified to include the improved performance specifications of pulse oximetry, temperature monitoring, anesthetic agents monitoring, and oxygen monitoring.

Additional modifications to the predicate device that have been implemented since the predicate device's clearance to market in 510(k) K053462 on January 18, 2006 are listed below. All modifications were documented in the Invivo Corporation Quality System and are implemented in the modified Expression MRI Patient Monitoring System (Model 865214).

- Minor software modifications were implemented to permit the operator to choose a distinct Pediatric menu option for non-invasive blood pressure monitoring. (The predicate device was cleared to market on January 18, 2006 with the ability to measure NIBP for adult, pediatric, and neonatal patients using adult mode with an adult cuff, or neonatal mode with a neonatal cuff.) The modification added a distinct menu option for "pediatric" patients. The pediatric mode is intended for use on patients who have low pulse amplitude sensitivity and therefore, cannot achieve NIBP detection in adult mode, as described in the operations manual. Pediatric mode uses the same measurement algorithm and technology as adult mode, but improves the measurement acquisition consistency on this patient population with low pulse amplitude sensitivity. Verification and validation testing completed on patient simulators did not raise any issues regarding the safety and effectiveness of the device and clinical data was not required to substantiate claims of safety and effectiveness.
- A non-invasive blood pressure cuff measuring 9-25cm was introduced. The cuff is available for use on patients that are categorized by the FDA as part of the pediatric population. However, final determination of whether the cuff should be used on a particular patient is dependent on the trained clinician who should consider the patient's limb size and body weight per the instructions in the operations manual. The cuff is constructed of the same material as the adult and neonatal cuffs which were distributed with the predicate device and have been in marketing distribution since 1994 by the cuff manufacturer. Therefore, biocompatibility testing to ISO 10993 was not required. Verification and validation testing completed on patient simulators did not raise any issues regarding the safety and effectiveness of the predicate device and clinical data was not required to substantiate claims of safety and effectiveness.

- Minor modifications to the operations manual were implemented to define and explain the pediatric mode for non-invasive blood pressure.
- Minor modifications were implemented to the off-the-shelf radio in the Display Control Unit and Wireless Processing Unit to reduce ferrous materials for improved communication in the MRI environment, permitting closer proximity of the device to the magnet bore.

FUNDAMENTAL SCIENTIFIC TECHNOLOGY

The fundamental scientific technology employed in the operation of the Expression MRI Patient Monitoring System (Model 865214) as modified, has not changed from that of the predicate device as a result of the modification.

PERFORMANCE DATA

The performance data included in this notification establishes substantial equivalence of the modified device, the Expression MRI Patient Monitoring System (Model 865214), to the predicate device which received market clearance in 510(k) K053462 on January 18, 2006. The modified device was evaluated to the following safety and performance tests:

- Voluntary standards
- Verification and validation of performance specifications
- Verification and validation of MR compatibility
- Validation of SpO2 Accuracy
- Quality demonstration through HALT

In all testing, the device was verified using a worst-case environment.

Voluntary Standards

The Expression MRI Patient Monitoring System (Model 865214) was evaluated to the following voluntary standards where applicable per FDA Guidance titled *"Use of Standards in Substantial Equivalence Determination."*

General Requirements for Safety

- IEC 60601-1
- IEC 60601-1-1
- IEC 60601-1-2
- IEC 60601-1-4
- IEC 60601-1-8

Particular Requirements for Safety and Performance

- ANSI / AAMI BP22
- ANSI / AAMI EC13

- ANSI / AAMI EC38
- ANSI / AAMI EC53
- ANSI / AAMI SP10
- ASTM E1112
- ASTM F1456
- IEC 60601-2-27
- IEC 60601-2-30
- IEC 60601-2-34
- ISO 9919
- ISO 21647

Hazard Analysis / Risk Management

- ISO 14971

Verification and Validation of Performance Specifications

All patient monitoring parameters of the Expression MRI Patient Monitoring System (Model 865214) were verified according to the performance specifications. The conclusions of all test results indicate "pass"; the device operates as intended within the performance specifications. Results of design verification and validation do not raise issues regarding the safety and effectiveness of the device and clinical data was not required to substantiate claims of safety and effectiveness.

A summary of the verification and validation protocol and conclusion for parameters which represented modifications from the predicate device are included in the following tables:

Pulse Oximetry (SpO2)		
Parameter	**Specification**	**Conclusion**
Saturation Range	1-100%	Pass
Saturation Accuracy	±3% at 70-100%	Pass
Pulse Rate Range	30-250 BPM	Pass
Pulse Rate Accuracy	±2% or 1 BPM, whichever is greater	Pass

Temperature		
Parameter	**Specification**	**Conclusion**
Measurement Range	20-44°C	Pass
Accuracy	±0.5°C	Pass

Anesthetic Agents Monitoring		
Parameter	**Specification**	**Conclusion**
Measurement Range	Halothane: 0.50 Vol%	Pass
	Enflurane: 0-5.0 Vol%	Pass
	Isoflurane: 0-5.0 Vol%	Pass
	Sevoflurane: 0-8.0 Vol%	Pass

Anesthetic Agents Monitoring		
	Desflurane: 0-18.0 Vol%	Pass
	CO2: 0-10.0 Vol%	Pass
	Nitrous Oxide: 0-100%	Pass
Accuracy	Halothane: ±0.15 Vol% at 0-1.00 Vol%	Pass
	Halothane: ±0.20 Vol% at 1.00-5.00 Vol%	Pass
	Enflurane: ±0.15 Vol% at 0-1.00 Vol%	Pass
	Enflurane: ±0.20 Vol% at 1.00-5.00 Vol%	Pass
	Isoflurane: ±0.15 Vol% at 0-1.00 Vol%	Pass
	Isoflurane: ±0.20 Vol% at 1.00-5.00 Vol%	Pass
	Sevoflurane: ±0.15 Vol% at 0-1.00 Vol%	Pass
	Sevoflurane: ±0.20 Vol% at 1.00-5.00 Vol%	Pass
	Sevoflurane: ±0.40 Vol% at 5.00-8.00 Vol%	Pass
	Desflurane: ±0.15 Vol% at 0-1.00 Vol%	Pass
	Desflurane: ±0.20 Vol% at 1.00-5.00 Vol%	Pass
	Desflurane: ±0.40 Vol% at 5.00-10.00 Vol%	Pass
	Desflurane: ±0.60 Vol% at 10.0-15.0 Vol%	Pass
	Desflurane: ±1.0 Vol% at 15.0-18.0 Vol%	Pass
	CO2: ±0.10 Vol% at 0-1.00 Vol%	Pass
	CO2: ±0.20 Vol% at 1.00-5.00 Vol%	Pass
	CO2: ±0.30 Vol% at 5.00-7.00 Vol%	Pass
	CO2: ±0.50 Vol% at 7.00-10.00 Vol%	Pass
Flow rate	Adult mode: 200mL/min (+/-20mL/min)	Pass
	Neonatal mode: 150mL/min (+/-15mL/min)	Pass
Respiration Rate	2 - 60 rpm (+/-1 rpm)	Pass
Auto ID Threshold	(Primary agent ID) 0.15%	Pass
Zero Drift Rate	Automatically zeroes at least every four hours or for every ±1°C temperature change from the last stored stable operating temperature	Pass
Display Resolution	0.1% Volume	Pass
Multiple Agents Alarm Threshold	Upon detection of more than one agent of >0.15 Vol%	Pass

Verification and Validation of MR Susceptibility

The Expression MRI Patient Monitoring System (Model 865214) was verified using a 3.0T MRI system and a 1.5T MRI system. These devices were verified by documenting proper operation within the performance specifications while being subjected to 3.0T and 1.5T magnetic fields using simulators and test equipment under actual use conditions. The following scans were used to simulate normal and worst-case scenario conditions:

1.5T MR Imaging System

- T1W_FFE

- T1W_IR
- T2W_SE_EPI

3.0T MR Imaging System

- T1W_FFE
- T1W_IR_TSE
- T2W_SE_EPI

All test results indicate "pass"; the Expression MRI Patient Monitoring System (Model 865214) met the performance specifications as stated in the device labeling for use in the 1.5T and 3.0T MRI environments.

Additional testing to verify the performance of the Expression MRI Patient Monitoring System in the following conditions of use was also completed:

- static magnetic field strength
- specific absorption rate
- scan duration
- gradient field switching rate
- device proximity to the magnet bore

All test results indicate "pass"; the Expression MRI Patient Monitoring System (Model 865214) met the MR conditions of use as stated in the device labeling.

Validation of SpO2 Accuracy

Pulse oximetry (SpO2) accuracy of the Expression MRI Patient Monitoring System (Model 865214) was validated over the specified measurement range of 70-100% of arterial blood oxygen saturation as compared to arterial blood CO-oximetry for validation. Test results show that the Expression MRI Patient Monitoring System (Model 865214) passes an A_{RMS} specification of 3 for the range of 70-100% oxygen saturation.

Quality Demonstration Through HALT

Quality demonstration testing is being performed using highly accelerated life tests to show conformance to customer requirement specifications and ensure longevity of the Expression MRI Patient Monitoring System (Model 865214) within the use model. Preliminary test results demonstrate that the device meets the mechanical customer requirement specifications over the use life of the device.

Conclusion

The conclusion of all safety and performance testing confirms that all identified risks have been mitigated and the Expression MRI Patient Monitoring System (Model 865214) operates as designed and intended within the performance specifications.

The test results demonstrate that the modified Expression MRI Patient Monitoring System (Model 865214) is substantially equivalent to the predicate device cleared to market via 510(k) K053462 on January 18, 2006.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Invivo Corporation
c/o Mr. Rusty Kelly
Quality & Regulatory Manager
12501 Research Parkway
Orlando, FL 32826

DEC 15 2009

Re: K090785
Trade/Device Name: MRI Patient Monitoring System, Model 865214
Regulatory Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II (Two)
Product Code: MWI
Dated: November 18, 2009
Received: November 20, 2009

Dear Mr. Kelly:

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 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, 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): K090785

Device Name: MRI Patient Monitoring System (Model 865214)

Indications for Use: The MRI Patient Monitoring System (Model 865214) is intended to monitor vital signs for patients undergoing MRI procedures and to provide signals for synchronization for the MRI scanner.

The MRI Patient Monitoring System (Model 865214) is intended for use by healthcare professionals.

Prescription Use: X AND/OR Over-the Counter Use:
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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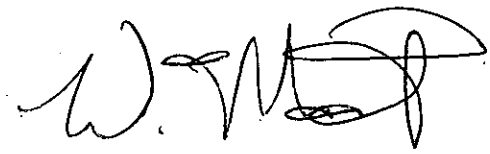
Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K090785