Invivo™

K103700

MAR 15 2011

510(K) SUMMARY

2.1 SUBMITTER INFORMATION

Establishment / Sponsor Name:	Invivo Corporation
Establishment / Sponsor Address:	12151 Research Parkway Orlando, FL 32826 USA
Manufacturer Name:	Sanmina- SCI Systems Singapore PTE.LTD.
Manufacturer Address:	2 Chai Chee Dr Singapore, SG-NOTA 469044, Singapore
Company Phone:	(407) 275-3220
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Person to contact regarding questions:	Rusty Kelly Quality & Regulatory Manager, Invivo Corporation (407) 455-6166 Rusty.Kelly@philips.com
Establishment Registration Number:	1051786 (Sponsor) 3006606827 (Manufacturer)
Date Summary Prepared:	December 17, 2010

2.2 DEVICE IDENTIFICATION

Trade name:	Essential MRI Patient Monitor (Model 865353)
Common name:	MRI patient monitor
Classification name:	Oximeter (21 CFR 870.2700, Product Code DQA)

2.3 IDENTIFICATION OF LEGALLY MARKETED CLEARED DEVICE

The MRI Patient Monitor (Model 865353) is substantially equivalent to the following cleared device:

Cleared Device	Manufacturer	510(k) No.	Clearance Date
MRI Patient Monitoring System (Model 865214)	Invivo Corporation	K090785	Dec 15, 2009

2.4 MODIFIED DEVICE DESCRIPTION

The MRI Patient Monitor (Model 865353) is substantially equivalent to the cleared device.

Invivo has marketed a stand-alone pulse oximeter for the last 20 years as cleared to market in K864730 (Invivo Pulse Oximeter, Model 4500). This technology is over 20 years old and has not changed in design or fundamental technology since cleared to market. Invivo has identified the need to market an improved stand-alone pulse oximeter as a replacement for this device.

The modified device is predicated from the MRI Patient Monitoring System (Model 865214) which received clearance to market under 510(k) K090785 on December 15, 2009. The cleared device consists of a processing unit, display, and wireless SpO_2 module which is directly connected to the patient by a fiber optic sensor, clip, and grip. All oximetry data collection and processing is completed by the wireless SpO_2 module and fiber optic sensor. The module transmits the patient data to the processing unit using telemetry, and the processing unit transmits the data to the display using telemetry. The modified device incorporates the same wireless SpO_2 module and fiber optic sensor that is currently used with the cleared device. In the modified device, the module transmits the data directly to the display using telemetry.

The following modifications have been incorporated to create the modified device:

- The display was reduced in size and weight.
- The operator interface is a touch screen (instead of a rotary knob and keypad).
- SpO_2, pulse rate (derived from SpO_2), and perfusion index parameters only are measured and displayed. The following parameters are no longer measured and displayed: ECG, non-invasive blood pressure, invasive blood pressure, respiration, temperature, end-tidal CO_2, and anesthetic agents concentrations.

- The device does not provide signals for synchronization for the MRI scanner ("gating"). "Gating", or lack thereof, has no effect on patient monitoring ability or quality.
- The display is battery-operated only. The display does not offer connections to AC mains.
- The radio printed circuit board layout was reduced in size to accommodate the smaller display size.
- The display radio antenna was reduced in size to accommodate the smaller display size and the antenna was concealed in the device handle.
- The module used with the device also communicates with the existing cleared MRI Patient Monitoring Systems, Models 865214 and 3160.
- The operating platform was modified to the MicroBlaze soft-core microprocessor running on the Spartan 6LX45 FPGA. The operational system was modified to the uC ("micro C") from company Micrium.
- The display was modified to provide unlatched alarms only. Latched alarms are no longer provided.
- The intelligent battery charger is located in the battery (instead of in the device).

The modified device has the same performance specifications (SpO_2 operating range and accuracy) and uses the same patient applied parts (wireless SpO_2 module, fiber optic sensor, clips, and grips) as the cleared device.

The MRI Patient Monitor consists of the following primary components:

- Display ("Vital Signs Viewer")
- Wireless SpO_2 Module
- SpO_2 Sensor
- SpO_2 Grips and Clips

The display and SpO_2 module enclose the transceiver and antennas that support bi-directional 2.4 GHz wireless communication. The modified device's operator interface consists of a color 5.7-inch LCD display and touch screen. The modified device's display provides the same vital sign information regarding SpO_2, generates the same types of alarms (audible, lights, and text), and controls the same functions (alarm limits, patient type, display setup, and network selection) as the cleared device.

2.5 INTENDED USE

The intended use of the modified device as described in its labeling has not changed from that of the cleared device as a result of the modification.

The MRI Patient Monitor (Model 865353) is intended to monitor vital signs for patients undergoing MRI procedures. The MRI Patient Monitor (Model 865353) is intended for use by healthcare professionals.

2.6 SUBSTANTIAL EQUIVALENCE COMPARISON

The modified device, the MRI Patient Monitor (Model 865353), and the cleared device, the MRI Patient Monitoring System (Model 865214) which received clearance to market under 510(k) K090785 on December 15, 2009, 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. Details of all modifications are listed in the following table:

Table 2-1: Substantial Equivalence Comparison

	Cleared Device **MRI Patient Monitoring System** **(Model 865214)**	**Modified Device** **MRI Patient Monitor** **(Model 865353)**
510(k) Number	K090785, Cleared on December 15, 2009	Pending
General Safety	Compliant to IEC 60601-1, IEC 60601-1-2, IEC 60601-1-4, IEC 60601-1-6, and IEC 60601-1-8 Defibrillator protection up to 5kV	IDENTICAL TO CLEARED DEVICE
Power Requirements	Battery Type: Lithium-ion Battery Operation Time: At least 8 hours Also uses AC mains to AC-DC power converter	Battery Type: IDENTICAL TO CLEARED DEVICE Battery Operation Time: IDENTICAL TO CLEARED DEVICE No AC power available
Environmental	Operating Temperature: 10-44°C Relative Humidity: 0-80% non-condensing Storage Temperature: -40 – 75°C	IDENTICAL TO CLEARED DEVICE
Display	Type: Color LCD with 800 x 600 resolution Size: 12.25-inch diameter Weight: 17 lbs (7.7 Kg) Dimensions: Height: 11.5 inches (29.2 cm) Width: 15.4 inches (39.1 cm) Depth: 5.5 inches (14.0 cm)	Type: Color LCD with 640 x 480 resolution Size: 5.7-inch diameter Weight: 3.3 lbs (1.5 Kg) Dimensions: Height: 6.1 inches (15.5 cm) Width: 6.9 inches (17.5 cm) Depth: 3.7 inches (9.4 cm)
Operator Interface	Rotary knob and keypad	Touch screen The layout of menus and patient data is IDENTICAL TO CLEARED DEVICE
Mounting Configurations	Traditional roll around cart Mounting options able to be mounted permanently to various surfaces	IDENTICAL TO CLEARED DEVICE

	Cleared Device **MRI Patient Monitoring System** **(Model 865214)**	**Modified Device** **MRI Patient Monitor** **(Model 865353)**
Wireless Communication	RF Output Power: +20 dBm Frequency Range: 2.4GHz band Radios have FCC approval under the following identification numbers: • SpO_2 Module: S6W2GMOD • Processing Unit: S6WDR3160BAS • Display: HSW-2410NF	The functionality, technology, and operating performance of the wireless communication is IDENTICAL TO CLEARED DEVICE. The wireless SpO_2 module including its radio is IDENTICAL TO CLEARED DEVICE. The cleared device radio in the Processing Unit was modified to create the radio in the display. The only modifications are as follows: • The radio printed circuit board layout was reduced in size to accommodate the smaller device size. • The radio antenna was reduced in size to accommodate the smaller device size and is concealed in the device handle. For these reasons, a new FCC evaluation was required for the radio in the display. Radios have FCC approval under the following identification numbers: • SpO_2 Module: IDENTICAL TO CLEARED DEVICE • Display: S6WESSENTIAL
Vital Signs Monitored	SpO_2, ECG, NIBP, pulse rate (derived from SpO_2, ECG, or NIBP), perfusion index, IBP, ETCO2, respiration, agents, and temperature	SpO_2, pulse rate (derived from SpO_2), and perfusion index
Pulse Oximetry (SpO2)	Saturation Range: 1-100% Saturation Accuracy: ±3% at 70-100% Pulse Rate Range: 30-250 BPM Pulse Rate Accuracy: ±2% or 1 BPM, whichever is greater	IDENTICAL TO CLEARED DEVICE
Patient Applied Parts	SpO_2 Fiber optic sensor, SpO_2 fiber optic grips and clips	IDENTICAL TO CLEARED DEVICE

	Cleared Device **MRI Patient Monitoring System** **(Model 865214)**	**Modified Device** **MRI Patient Monitor** **(Model 865353)**
Labeling	Device is MR Conditional according to ASTM F2503	Device is MR Conditional according to ASTM F2503 Labeling was modified as follows: • Added photographs and specifications showing dimensional modifications to display • Cited use of the touch screen display • Removed references to ECG, non-invasive blood pressure, invasive blood pressure, temperature, respiration, end-tidal CO_2, and anesthetic agents monitoring, and gating which were present on the cleared device • Cited that device is battery operated only • Added instructions for battery charging • Added description of communication between the modified device and existing cleared devices, MRI Patient Monitoring System Models 865214 and 3160
Battery Charger	Integral to patient monitor and separate charger	Integral to battery
Operating Platform	STPC 486 Processor	MicroBlaze soft-core microprocessor running on the Spartan 6LX45 FPGA
Operating System	Multitask	uC ("micro C")
Alarms	Provides latched and unlatched alarms. Alarm system compliant to IEC 60601-1-8.	Provides unlatched alarms only. Alarm system compliant to IEC 60601-1-8.

2.7 SUMMARY OF NON-CLINICAL PERFORMANCE DATA

The performance data included in this notification establishes substantial equivalence of the modified device, the MRI Patient Monitor (Model 865353), to the cleared device which received market clearance in 510(k) K090785 on December 15, 2009. The modified device was evaluated to the following safety and performance tests:

- FDA Guidance Documents
- Voluntary standards
- Verification and validation of performance specifications
- Verification and validation of MR conditions of use
- Environmental testing
- Evaluation of wireless technology

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

Verification and validation of SpO_2 accuracy in the modified device is not required because the SpO_2 module, technology, patient-applied parts, algorithm, and software is the same as the cleared device.

FDA Guidance Documents

The modified device, MRI Patient Monitor (Model 865353), was designed and evaluated in accordance with the following FDA Guidance Documents:

- Use of Standards in Substantial Equivalence Determination (Issued March 12, 2000)
- Pulse Oximeters – Premarket Notification Submission (Issued July 19, 2007)
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (Issued May 11, 2005)
- Radio-Frequency Wireless Technology in Medical Devices (Issued January 3, 2007)

Voluntary Standards

Standards Data Reports (Form FDA 3654 (09/07)) are provided in **Section 3** of this notification. The MRI Patient Monitor (Model 865353) was evaluated to the following voluntary standards where applicable:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety
- IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests
- IEC 60601-1-4, Medical electrical equipment - Part 1-4: General requirements for safety -- Collateral standard: Programmable electrical medical systems
- IEC 60601-1-6, Medical electrical equipment - Part 1-4: General requirements for safety -- Collateral standard: Usability

- IEC 60601-1-8, Medical electrical equipment - Part 1-8: General requirements for safety - Collateral Standard: Alarm Systems - Requirements, tests and guidance - General requirements and guidelines for alarm systems in medical equipment
- IEC 60601-2-33, Medical electrical equipment - Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis
- ISO 9919, Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use
- ISO 10993-1, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
- ISO 14971, Medical devices - Application of risk management to medical devices
- ASTM F2503-08, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
- ASTM F2052-06, Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment

The modified device, MRI Patient Monitor (Model 865353), was evaluated by a third party laboratory to IEC 60601-1, IEC 60601-1-2, IEC 60601-1-4, IEC 60601-1-6, IEC 60601-1-8, and ISO 9919 and complies to the requirements in these standards.

Compliance of the modified device to ISO 14971 is demonstrated by risk management summary provided in **Section 6.3**.

Compliance of the modified device to ISO 10993-1 is demonstrated through risk management analysis and evaluation of the modified device against a history of cleared devices provided in **Section 6.12**.

Compliance of the modified device to IEC 60601-2-33, ASTM F2503-08, and ASTM F2052-06 was demonstrated through validation testing performed by Invivo Corporation in the MR environment. The modified device complies to the applicable requirements of these standards.

A Standards Summary Report Table noting deviations, adaptations, or options used in demonstrating compliance of the modified device to the standards is provided in **Section 6.10**.

Verification and Validation of Performance Specifications

All performance specifications of the modified device, MRI Patient Monitor (Model 865353), were defined by Invivo Corporation according to national standards, international standards, market needs, risk management, and intended

use. The verification and validation protocol for the specifications which are modified from the cleared device are provided in **Section 6.4.**

Results of the complete verification and validation indicate that the device operates as intended within the performance specifications. The results 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.

Verification and Validation of MR Conditions of Use

The MR conditions of use of the modified device, MRI Patient Monitor (Model 865353), were defined by Invivo Corporation according to national standards, international standards, intended use, risk management, and market needs. The modified device was evaluated for proton emissions, image artifact, magnetically induced displacement force, RF heating, Specific Absorption Rate, and Peripheral Nerve Stimulation (PNS) using 3.0T and 1.5T magnetic fields, simulators, and test equipment under the most extreme use conditions within the intended use. Details are provided in **Sections 6.6, 6.7, and 6.8.**

Test results demonstrate that the MRI Patient Monitor (Model 865353) met the MR conditions of use as defined in the modified device labeling. Test results are provided in **Sections 6.6, 6.7, and 6.8.**

Environmental Testing

Environmental specifications for the modified device, MRI Patient Monitor (Model 865353) were defined by Invivo Corporation according to international standards, intended use, risk management, and market needs. Test results demonstrate conformity to customer requirement specifications over the device use life and ensure longevity of the modified device within the use model. Test data was not provided in this submission but is contained within the modified device's Design History File.

Evaluation of Wireless Technology

The modified device display was evaluated to FCC Part 15 for Low Power Communication Device Transmitters. Test results are provided in **Section 6.9.**

The modified device incorporates the same wireless SpO_2 module including radio that is currently used with the cleared device. Additional evaluation of the wireless SpO_2 module was not required.

Integrity of the wireless communication between the modified device display and cleared wireless SpO_2 module was validated to operate as intended. Results are provided in **Section 6.9.**

Conclusion

The conclusion of all testing confirms that all identified risks have been mitigated, the device operates as designed and intended within the performance specifications, and the device meets the labeling claims.

The results 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Rusty Kelly
Quality & Regulatory Manager
Invivo Corporation
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Orlando, Florida 32826

MAR 15 2011

Re: K103700
Trade/Device Name: MRI Patient Monitor (Model 865353)
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: February 11, 2011
Received: February 14, 2011

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. 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.

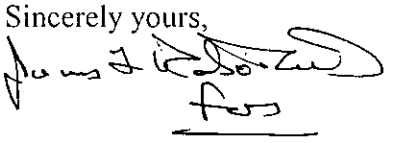
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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



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Enclosure

Indications for Use

510(k) Number (if known): K103700

Device Name: MRI Patient Monitor (Model 865353)

Indications For Use: The MRI Patient Monitor (Model 865353) is intended to monitor vital signs for patients undergoing MRI procedures. The MRI Patient Monitor (Model 865353) is intended for use by healthcare professionals.

Prescription Use ___X___ 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 Anesthesiology, General Hospital
Infection Control, Dental Devices

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