K121424

Invivo

JUN 13 2012

510(K) SUMMARY

2.1 SUBMITTER INFORMATION

Establishment / Sponsor Name:	Invivo Corporation
Establishment / Sponsor Address:	12151 Research Parkway Orlando, FL 32826 USA
Manufacturer Name:	Philips Medical Systems
Manufacturer Address:	3000 Minuteman Road Andover, MA 01810 USA
Company Phone:	(407) 275-3220
Company Fax:	(407) 249-2022
Person to contact regarding questions:	Rusty Kelly Quality & Regulatory Manager, Invivo Corporation (407) 455-6166 Rusty.Kelly@philips.com
Establishment Registration Number:	1051786 (Sponsor) 1217116 (Manufacturer)
Date Summary Prepared:	May 9, 2012

2.2 DEVICE IDENTIFICATION

Trade name:	Expression Information Portal (Model IP5)
Common name:	MRI patient monitoring display
Classification name:	Cardiac monitor (including cardiotachometer and rate alarm) (21 CFR 870.2300, Product Code MWI)

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2.3 IDENTIFICATION OF LEGALLY MARKETED CLEARED DEVICE

The Expression Information Portal (Model IP5) 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 Expression Information Portal (Model IP5) is substantially equivalent to the cleared device.

Invivo has marketed the cleared device, MRI Patient Monitoring System (Model 865214), since 2009. Invivo has identified the need to market a secondary patient monitoring display for use outside the MR system room as a supplement or alternate for the cleared device's display.

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 within a "Cart", detachable wireless display, wireless ECG module, and wireless SpO2 module. The cleared device provides patient monitoring data for ECG, SpO2, respiration, non-invasive blood pressure (NIBP), invasive blood pressure (IBP), temperature, oxygen (O_2), end-tidal carbon dioxide ($EtCO_2$), and anesthetic agents.

The modified device is a supplement or alternate for the cleared device's display. In this way, the modified device is a "repeater" display. The modified device does not perform any data collection or processing as a stand-alone patient monitoring system. The modified device relies upon the cleared device's processing unit within a transportable roll-around "Cart", wireless modules, and patient applied parts to complete data collection and processing. The cleared wireless ECG module collects and processes all ECG data and transmits the data to the cleared processing unit. Likewise, the wireless SpO_2 module collects and processes all SpO_2 and bellows-derived respiration data and each transmits the data to the cleared processing unit. The cleared processing unit transmits the data from the wireless modules to the cleared and/or modified display using telemetry. The processing unit collects and processes NIBP, IBP, temperature, O_2, $EtCO_2$, CO_2-derived respiration, and anesthetic agents, and transmits the data to the cleared and/or modified display using telemetry. All data transmission occurs simultaneously.

The cleared and modified displays have no contact with the patient. The cleared display incorporates an LCD display for viewing, and keypad and rotary knob for navigation. The cleared display may be docked upon the Cart or detached from the Cart and placed in a remote location such as the MR control room, MR induction room, or MR recovery room. When located within the MR control, induction, or recovery rooms, the cleared display may be connected to the Hospital Information System (HIS) via the third-party serial-to-Ethernet adapter provided by Lantronix UDS-1100 and wired to the RS232 port on the rear of the display. The cleared display's HIS-interface data output is in ASCII character format, whether the data is textual or numeric, and output at the rate specified by the user. No data is input from the HIS to the cleared display or modified display.

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

- The display dimensions are increased to enable improved visibility.
- The carrying handle is removed because the modified display is not intended to be a transportable device.
- The display is unable to be docked to the Cart because the display is not intended to be used in the MR system room.
- The operator interface is a touch screen with optional USB connection of wireless keyboard and wireless mouse.
- The display is AC mains powered only. The display does not provide battery power.
- The radio, which was enclosed within the display enclosure in the cleared device, is included now in a wireless radio module that is docked in the display's radio bay located on the top back of the display enclosure.
- The operating platform is PC-based running QNX Neutrino 6.5 (rather than STPC 486 Processor running Multitask "MT").
- The audible alarm tone, pulse, and burst characteristics of high priority alarms are consistent with those defined in the international standard, IEC 60601-1-8, Medical Electrical Equipment – Part 1-8: General Requirements for Basic Safety and Essential Performance – Collateral Standard: General Requirements, Tests, and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems.
- The alarm light located on the top of the display is removed. (Other visual alarm indicators consistent with IEC 60601-1-8 and error messages are still provided identical to the cleared device. Audible alarms consistent with IEC 60601-1-8 are also provided. Note that the alarm light is an optional visual indication per IEC 60601-1-8.)
- The visual indications of wireless ECG module and wireless SpO_2 module communication status are modified from that of the cleared device.
- The printer is provided as separate USB-connected peripheral equipment (rather than permanently installed within the display enclosure).
- The labeling on the display is revised to indicate the device is MR Unsafe (rather than MR Conditional as previously cleared), and that the device

must be used outside the MR system room. Additional labeling regarding MR Conditions of Use are added for the peripheral equipment.

- The display is enabled to receive patient identification information (i.e., name and patient ID) from a wireless barcode scanner or from the operator's manual entry.
- When located within the MR control, induction, or recovery rooms, the display may be connected to the Hospital Information System (HIS) via a standard Ethernet connection on the rear of the display, or optionally via the RS232 port on the rear of the display.
- The data output is in HL7 format, compliant to HL7 Messaging Standard Version 2.6.

The layout of displayed information on the modified display is identical to the cleared display with the exceptions of the following items:

- Communication status indicators are located in the bottom right corner of the display (rather than across the bottom of the display).
- Patient information bar is located across the top of the display.
- The Alarms Setup, Printer Setup, and Monitor Setup functions are collapsed under a Setup key on the virtual keypad (rather than each function having its own key).

The Expression Information Portal (Model IP5) consists of the following primary components:

- Display
- AC-DC power supply
- Radio module

The Expression Information Portal (Model IP5) is also provided with the following optional peripheral equipment:

- Printer
- Wireless keyboard and mouse
- Wireless barcode scanner
- Uninterruptible power supply
- Desk stand
- Wall mounting arm

The modified device's radio module includes the transceiver and antenna that support bi-directional 2.4 GHz wireless communication identical to the cleared device. The cleared and modified devices use the same radio transceiver and antenna, and operate within the same frequency band reserved for industrial, scientific, and medical (ISM) equipment. Because the Expression Information Portal (Model IP5) is intended to supplement or act as an alternate for the existing cleared display, the IP5 transceiver, antenna, and radio performance specifications have not been modified from that of the cleared device and the modified device cites the same FCC certification as the cleared device.

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The modified device's operator interface consists of a color 19-inch LCD display and touch screen. Identical to the cleared device, the modified device's display has no contact with the patient. Similar to the cleared device, the modified device enables printing, mounting, operation, and HIS connection within the MR control room, MR induction room, or MR recovery room. The modified device displays all of the same patient vital sign information, generates the same types of alarms (priority level, audible, color-coded, and visual 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 Expression Information Portal (Model IP5) is intended to monitor vital signs for patients undergoing MRI procedures. The Expression Information Portal (Model IP5) is intended for use by healthcare professionals.

2.6 SUBSTANTIAL EQUIVALENCE COMPARISON

The modified device, the Expression Information Portal (Model IP5), 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, fundamental scientific technology, and RF communication. Both devices are intended for use by healthcare professionals to monitor vital signs for patients undergoing MRI procedures.

The modified device is a supplement or alternate for the cleared device's display. The modified device does not perform any data collection or processing as a stand-alone patient monitoring system. The modified device relies upon the cleared device's processing unit within the "Cart", wireless modules, and patient applied parts to complete data collection and processing. Details of all modifications to the display are listed in **Table 2-1**. No modifications were made to the cleared device's processing unit / "Cart", wireless ECG module, or wireless SpO_2 module.

Table 2-1: Substantial Equivalence Comparison

	Cleared Device **MRI Patient Monitoring System** **(Model 865214)**	**Modified Device** **Expression Information Portal** **(Model IP5)**
510(k) Number	K090785, Cleared on December 15, 2009	Pending
General Safety	Compliant to IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-1-4, IEC 60601-1-6, and IEC 60601-1-8	IDENTICAL TO THE CLEARED DEVICE
Display Power Requirements	AC mains to AC-DC power converter Battery Type: Lithium-ion Battery Operation Time: At least 8 hours The display provides visual indicators of power status (AC mains connection and/or battery life) for the following components: • display, • processing unit / "Cart", • wireless ECG module, and • wireless SpO_2 module.	AC mains to AC-DC power converter No battery power available The display provides visual indicators of power status IDENTICAL TO THE CLEARED DEVICE.
Display Environmental Specifications	Operating Temperature: 10-44°C Relative Humidity: 0-80% non-condensing Storage Temperature: -40 – 75°C	Operating Temperature: 15-35°C Relative Humidity: 15-80% non-condensing Storage Temperature: -20 – 60°C The modified environmental specifications are still compliant with the intended use in a climate-controlled clinical setting. Testing and risk assessment have verified that the modifications do not pose any new concerns regarding the safety and effectiveness of the device.
Display Dimensions	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 1440 x 900 resolution Size: 19-inch diameter Weight: 18.6 lbs (8.4 Kg) Dimensions (including docked radio module): Height: 17.34 inches (44.04 cm) Width: 18.75 inches (47.63cm) Depth: 6.45 inches (16.38 cm)

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	Cleared Device MRI Patient Monitoring System (Model 865214)	Modified Device Expression Information Portal (Model IP5)
Display Operator Interface	Rotary knob and keypad One speaker (top front of display) Communication status indicators are lined across the lower portion of the display. Patient information bar is not provided. Alarms Setup, Printer Setup, and Monitor Setup functions each have a separate key on the keypad which is visible to the operator at all times.	Touch screen with optional USB connection of wireless keyboard and wireless mouse Two speakers (one on each side of the display) Communication status indicators are located in the bottom right corner of the display. Patient information bar is located across the top of the display. Alarms Setup, Printer Setup, and Monitor Setup are collapsed within one Setup key on the virtual keypad that is visible to the operator at all times. When the Setup key is selected, a submenu displaying Alarm Setup, Printer Setup, and Monitor Setup appears. All other aspects of the layout and patient data are IDENTICAL TO THE CLEARED DEVICE.
Display Mounting Configurations	Cart-mounted Desktop Wall mounted	Desktop Wall mounted

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	Cleared Device MRI Patient Monitoring System (Model 865214)	Modified Device Expression Information Portal (Model IP5)
Wireless Communication Between the Processing Unit and Display	RF Output Power: +20 dBm Frequency Range: 2.4GHz band	The functionality, technology, and operating performance of the wireless communication are IDENTICAL TO THE CLEARED DEVICE.
	The display radio module has FCC approval under identification number HSW-2410NF.	Uses the same radio module with the same FCC approval as THE CLEARED DEVICE.
	The radio transceiver is located within the display enclosure and the antenna is mounted to the top of the display.	The radio transceiver is located within a radio module and the antenna is mounted to the top of the radio module. The radio module is docked within the display's radio bay on the top rear of the display. The transceiver and antenna are IDENTICAL TO THE CLEARED DEVICE.
	The display provides visual indicators of communication status between the following components: • display and processing unit, • processing unit and wireless ECG module, and • processing unit and wireless SpO_2 module.	The display provides visual indicators of the communication status IDENTICAL TO THE CLEARED DEVICE.
	Communication status is established within a few seconds upon power on if the display, processing unit, wireless ECG module, and wireless SpO_2 module are each set to the same network (A, B, C, D, or E).	Communication status is established within a few seconds, IDENTICAL TO THE CLEARED DEVICE.

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	Cleared Device MRI Patient Monitoring System (Model 865214)	Modified Device Expression Information Portal (Model IP5)
Vital Signs Monitored	SpO_2, ECG, NIBP, pulse rate (derived from SpO_2, ECG, or NIBP), perfusion index, IBP, ETCO2, respiration, anesthetic agents, and temperature. Vital signs are measured by and processed in the processing unit, wireless ECG module, and wireless SpO_2 module. The processing unit transmits data to the display for viewing. The time for making patient vital sign information available between processing and viewing at the display is less than 1 second.	IDENTICAL TO THE CLEARED DEVICE Vital sign performance specifications are not affected. The modified device is a supplemental or alternate display only. All vital signs are measured by and processed in the host system's processing unit, wireless ECG module, and wireless SpO_2 module. The host system's processing unit transmits the data to the modified display for viewing. The time for making patient vital sign information available between processing viewing at the modified display is IDENTICAL TO THE CLEARED DEVICE.
Patient Applied Parts of the Display	No patient applied parts	IDENTICAL TO THE CLEARED DEVICE

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	Cleared Device MRI Patient Monitoring System (Model 865214)	Modified Device Expression Information Portal (Model IP5)
Display Labeling	Display is MR Conditional according to ASTM F2503. Display is intended for use within the MR environment including the MR system room, control room, induction room, and recovery room.	Device is MR Unsafe according to ASTM F2503. Display is intended for use within the MR environment, outside the MR system room (i.e., within the MR control room, MR induction room, or MR recovery room). Labeling was modified as follows: • Added photographs and specifications showing dimensional modifications to display • Cited use of the touch screen display • Cited the modifications to the screen layout • Cited that device is AC-powered only • Added warnings associated with MR Unsafe components and MR Conditional barcode scanner • Added instructions for printer functionality • Added instruction for HIS interface • Added instructions for patient Case Management • Added description of communication between the modified device and existing cleared device, MRI Patient Monitoring System (Model 865214)
Display Operating Platform	STPC 486 Processor	PC-based
Display Operating System	Multitask "MT"	QNX Neutrino 6.5
Alarms	Provides latched and unlatched alarms. Provides visual (flashing text, numerics, and waveforms) and audible alarms. Alarm system compliant to IEC 60601-1-8. Alarm light is provided on the top of the display. The time for making alarm conditions available between processing and viewing at the display is 2 seconds.	IDENTICAL TO THE CLEARED DEVICE No alarm light is provided. The time for making alarm conditions available between processing and viewing at the display is IDENTICAL TO THE CLEARED DEVICE.

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	Cleared Device MRI Patient Monitoring System (Model 865214)	Modified Device Expression Information Portal (Model IP5)
Hospital Information System (HIS) Interface	HIS interface is available when operating outside the MR system room. Display is connected to HIS via a third-party serial-to-Ethernet adapter provided by Lantronix UDS-1100 and wired to the RS232 port on the rear of the display. Data output is in ASCII character format, regardless of whether the data is textual or numeric, and is output at the rate specified by the user. No data is input from the HIS to the display.	HIS interface is available when operating outside the MR system room (IDENTICAL TO THE CLEARED DEVICE). Display is connected to HIS via standard Ethernet cable connected to the Ethernet port on the rear of the display, or optionally via the RS232 port on the rear of the display. Data output is in HL7 format and output at a rate specified by the user. Data output is compliant to HL7 Messaging Standard Version 2.6. No data is input from the HIS to the display (IDENTICAL TO THE CLEARED DEVICE).

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2.7 SUMMARY OF NON-CLINICAL PERFORMANCE DATA

The performance data included in this notification establishes substantial equivalence of the modified device, the Expression Information Portal (Model IP5), 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 vital sign algorithms, measurement range, and accuracy in the modified device are not required because the modified device is a "repeater" display only. All vital signs are measured by and processed in the cleared device's processing unit, wireless ECG module, and wireless SpO_2 module. The cleared device's processing unit transmits the data to the modified display for viewing.

FDA Guidance Documents

The modified device, Expression Information Portal (Model IP5), is designed and evaluated in accordance with the following FDA Guidance Documents:

- Use of Standards in Substantial Equivalence Determination (Issued March 12, 2000)
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (Issued May 11, 2005)
- Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices (Issued September 9, 1999)
- Radio-Frequency Wireless Technology in Medical Devices (Issued January 3, 2007)
- Draft Guidance for Industry and Food and Drug Administration Staff – Applying Human Factors and Usability Engineering to Optimize Medical Device Design (Issued June 22, 2011)

The modified device, Expression Information Portal (Model IP5), is designed and evaluated in accordance with the following FDA Guidance Documents where applicable to display and printers used for patient monitoring:

- Cardiac Monitor Guidance (including Cardiotachometer and Rate Alarm) (Issued November 5, 1998)
- Draft Guidance for Industry and FDA Staff - Pulse Oximeters - Premarket Notification Submissions [510(k)s] (Issued July 19, 2007)
- Non-Invasive Blood Pressure (NIBP) Monitor Guidance (Issued March 10, 1997)

Voluntary Standards

Standards Data Reports (Form FDA 3654 (06/11)) are provided in **Section 3** of this notification. The Expression Information Portal (Model IP5) and its peripheral equipment were evaluated to the following voluntary standards where applicable to displays and printers:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety
- IEC 60601-1-1, Medical Electrical Equipment – Part 1-1: General Requirements for Safety: Collateral Standard: Safety Requirements for Medical Electrical Systems
- 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 60601-2-27, Medical electrical equipment – Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiograph monitoring equipment
- IEC 60601-2-30, Medical electrical equipment – Part 2-30: Particular requirements for the safety, including essential performance, of automated cycling non-invasive blood pressure monitoring equipment
- IEC 60601-2-34, Medical electrical equipment – Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment
- IEC 60601-2-49, Medical electrical equipment – Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
- ISO 9919, Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use
- ISO 21647, Medical electrical equipment – Particular requirements for the basic safety and essential performance of respiratory gas monitors
- ISO 14971, Medical devices – Application of risk management to medical devices
- ANSI/AAMI EC13, Cardiac monitors, heart rate meters and alarms
- ANSI/AAMI SP10, Manual, electronic, or automated sphygmomanometers

- ASTM E1112-00, Standard specification for electronic thermometer for intermittent determination of patient temperature
- 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
- UL 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety

The modified device, Expression Information Portal (Model IP5), was evaluated by a third party laboratory to IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-1-4, IEC 60601-1-6, IEC 60601-1-8, and UL 60601-1. The modified device and its peripheral equipment comply with the applicable requirements of these standards. The complete IEC 60601-1-2 test report is provided in **Appendix A**.

Compliance of the modified device to IEC 60601-2-27, IEC 60601-2-30, IEC 60601-2-34, IEC 60601-2-49, ISO 9919, ISO 21647, ANSI/AAMI EC13, ANSI/AAMI SP10, and ASTM E1112 as they pertain to displays and printers was demonstrated through verification testing performed by Invivo Corporation. The modified device and its peripheral equipment comply with the applicable requirements of these standards.

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

Compliance of the modified device to ASTM F2503 and ASTM F2052 was demonstrated through validation testing performed by Invivo Corporation in the MR environment. The modified device and its peripheral equipment comply with the applicable requirements of these standards. Labeling is provided in **Sections 5.6 and 5.8**. Test results are provided in **Section 6.6**.

A Standards Summary Report Table noting deviations, adaptations, or options used in demonstrating compliance of the modified device and its peripheral equipment to the standards is provided in **Section 6.9**.

Compliance of the modified device to ISO 10993-1 is not required as the modified device has no contact with the patient. Additional justification is provided in **Section 6.10**.

Verification and Validation of Performance Specifications

All performance specifications of the modified device, Expression Information Portal (Model IP5), 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 modified 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 vital sign algorithms, measurement range, and accuracy in the modified device are not required because the modified device is a "repeater" display only. All vital signs are measured by and processed in the cleared device's processing unit, wireless ECG module, and wireless SpO_2 module. The cleared device's processing unit transmits the data to the modified display for viewing.

Verification and Validation of MR Conditions of Use

The MR conditions of use of the modified device, Expression Information Portal (Model IP5), are defined by Invivo Corporation according to national standards, international standards, intended use, risk management, and market needs. The modified device's barcode scanner was evaluated for magnetically induced displacement force. Details are provided in **Section 6.6**. The modified device's display, power supply, radio module, and printer were not evaluated for magnetically induced displacement force because they labeled as MR Unsafe and only intended for use outside the MR system room (in other words, within the MR control room, MR induction room, or MR recovery room). None of the modified device's components were evaluated for proton emissions, image artifact, RF heating, Specific Absorption Rate, or proper functioning in worst-case Peripheral Nerve Stimulation (PNS) settings because the display and printer are not intended for use inside the MR system room, and the barcode scanner is not intended for use inside the MR system bore or in direct contact with the patient during active scanning. Details are provided in **Section 6.6**.

Test results demonstrate that the Expression Information Portal (Model IP5) meets the MR conditions of use as defined in the modified device labeling. Test results are provided in **Section 6.6**.

Environmental Testing

Environmental specifications for the modified device, Expression Information Portal (Model IP5), are defined by Invivo Corporation according to international standards, intended use, risk management, and market needs. Testing was completed for temperature and humidity per the storage and operating specifications. 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 radio module used in the cleared and modified devices was evaluated to FCC Part 15 for Low Power Communication Device Transmitters. Test results are summarized in **Section 6.7**.

The modified device incorporates the same radio (transceiver, antenna, and performance specifications) that is currently used with the cleared device.

Integrity of the wireless communication between the modified device display and cleared processing unit was validated to operate as intended. Results are provided in **Appendix B**.

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

Invivo Corporation
c/o Mr. Rusty Kelly
Quality & Regulatory Manager
12151 Research Parkway
Orlando, FL

JUN 13 2012

Re: K121424
Trade/Device Name: Expression Information Portal
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II (two)
Product Code: MWI
Dated: May 9, 2012
Received: May 14, 2012

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,

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): K121424

Device Name: Expression Information Portal (Model IP5)

Indications For Use: The Expression Information Portal (Model IP5) is intended to monitor vital signs for patients undergoing MRI procedures. The Expression Information Portal (Model IP5) 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 Cardiovascular Devices

510(k) Number K121424