



Food and Drug Administration  
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December 23, 2015

Invivo Corporation  
c/o Christine Trefethen  
Regulatory Manager  
Philips Medical Systems  
3000 Minuteman Rd.  
Andover, MA 01801

Re: K152330

Trade/Device Name: Expression MR400 MRI Patient Monitoring System (Model MR400)  
Regulation Number: 21 CFR 870.2300  
Regulation Name: Cardiac Monitor (Including Cardiometer and Rate Alarm)  
Regulatory Class: Class II  
Product Code: MWI  
Dated: November 24, 2015  
Received: November 25, 2015

Dear Christine Trefethen:

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 contact the Division of Industry and Consumer Education 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a faint, light-colored FDA logo watermark.

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) K152330

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Device Name

Expression MR400 MRI Patient Monitoring System (Model MR400)

Indications for Use (Describe)

The Expression MR400 MRI Patient Monitoring System (Model MR400) is intended to monitor vital signs for patients undergoing MRI procedures and to provide signals for synchronization for the MRI scanner.

The Expression MR400 MRI Patient Monitoring System (Model MR400) is intended for use by healthcare professionals.

The Expression MR400 MRI Patient Monitoring System (Model MR400) provides monitoring for the following vital sign parameters: ECG, pulse oximetry (SpO<sub>2</sub>), non-invasive blood pressure (NIBP), and optionally, invasive blood pressure (IBP), carbon dioxide (CO<sub>2</sub>) and respiration rate, anesthetic agents, nitrous oxide (N<sub>2</sub>O), oxygen (O<sub>2</sub>), and/or temperature.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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## SPECIAL 510(K) SUMMARY

### SUBMITTER INFORMATION

Establishment Name: Invivo Corporation  
Establishment Address: 12151 Research Parkway  
Orlando, FL 32826 USA

Company Phone: (407) 252-0414

Company Fax: (407) 249-2022

Person to contact  
regarding questions: Rusty Kelly  
Sr. Manager Quality and Regulatory  
(407)-252-0414  
Rusty.Kelly@philips.com

Establishment  
Registration Number: 1051786

Date Summary Prepared: August 11, 2015

### DEVICE IDENTIFICATION

Trade name: Expression MR400 MRI Patient Monitoring  
System (Model MR400)

Common name: MRI patient monitoring system

Classification name: Cardiac monitor (including cardiometer and  
rate alarm)  
(21 CFR 870.2300, Product Code MWD)

## IDENTIFICATION OF LEGALLY MARKETED PREDICATE DEVICE

The Expression MR400 MRI Patient Monitoring System also referred to as the Expression MR400 or MR400, is substantially equivalent to the following predicate device:

Predicate Device	Manufacturer	510(k) No.	Clearance Date
MRI Patient Monitoring System (Model 865214)	Invivo Corporation	K124061	Feb 22, 2013

## DEVICE DESCRIPTION

The Expression MR400 is a multi-parameter patient monitoring system used to monitor the vital signs of patients in an MRI magnet room and throughout an MRI suite. The MR400's software simultaneously processes and displays multiple parameters, waveforms, measurement numeric values and alarms. All patient information is provided on a wheeled cart which consists of a patient monitor with a touch screen display. The device is powered by either AC line power or its internal battery. The standard and optional parameters which can be monitored by the MR400 include:

- Electrocardiogram (ECG)
- Heart rate (HR, ECG and SPO2 derived)
- Blood oxygen saturation/pulse oximetry (SPO2)
- End-tidal and fractional inspired CO2 (EtCO2 and FiCO2)
- Invasive blood pressure (IBP) (P1 and P2)
- Anesthetic agents (AGENT)
  - Desflurane (DES)
  - Enflurane (ENF)
  - Halothane (HAL)
  - Isoflurane (ISO)
  - Sevoflurane (SEV)
- Fractional inspired O2 (FiO2), and end-tidal and fractional inspired N2O (EtN2O and FiN2O)
- Temperature (TEMP)
- Non-invasive blood pressure (NIBP)
- Respiration rate (CO2-derived and/or bellows-derived)

The MR400 consists of the following key components:

- Cart with touchscreen display
- Wireless ECG module
- Wireless SpO<sub>2</sub> module
- Batteries for both the Cart and Wireless Modules
- Battery charger
- Power cord

Accessories to the MR400 are offered to accommodate various patient sizes—neonatal, infant, pediatric, adult, and large adult. Key accessories include:

- ECG lead cables and electrodes
- SPO<sub>2</sub> probes and clips
- NIBP cuffs and hoses
- IBP transducer
- Temperature probe and sheath
- Cannulas
- Water traps
- Chest pneumograph
- Expression IP5 (optional secondary display for control room w/printer)

## **INDICATIONS FOR USE**

The Expression MR400 MRI Patient Monitoring System (Model MR400) is intended to monitor vital signs for patients undergoing MRI procedures and to provide signals for synchronization for the MRI scanner.

The Expression MR400 MRI Patient Monitoring System (Model MR400) is intended for use by healthcare professionals.

The Expression MR400 MRI Patient Monitoring System (Model MR400) provides monitoring for the following vital sign parameters: ECG, pulse oximetry (SpO<sub>2</sub>), non-invasive blood pressure (NIBP), and optionally, invasive blood pressure (IBP), carbon dioxide (CO<sub>2</sub>) and respiration rate, anesthetic agents, nitrous oxide (N<sub>2</sub>O), oxygen (O<sub>2</sub>), and/or temperature.

## **TECHNOLOGICAL CHARACTERISTICS**

The modified device has the same fundamental scientific technology as the predicate device.

<b>Technological Characteristic</b>	<b>Predicate: MRI Patient Monitoring System (K124061)</b>	<b>Modified Device: Expression MR400 MRI Patient Monitoring System</b>	<b>Comparison</b>
<b>Cart</b>			
Display	Detachable, located on top front of display	Permanently installed, located on the rear of the display	Substantially Equivalent
Expression IP5	Software is compatible with the predicate device	Software was updated to be compatible with the predicate device and the Expression MR400	Substantially Equivalent
Printer	Integrated on side of display	No printer permanently installed on display.	Substantially Equivalent
Alarms Set Up, Printer Set Up and Monitor Set Up	Separate key on the keypad which is visible to the operator at all times	Collapsed within one Setup key on the virtual keypad that is visible to the operator at all times	Substantially Equivalent
Power Supply	External	Integrated	Substantially Equivalent
Internal Batteries	Four User-replaceable	Two Permanently installed and two User-replaceable	Substantially Equivalent
Alarms	Vital Sign Alarms	Added user adjustable alarms for extreme bradycardia, extreme tachycardia, apnea and desaturation	Substantially Equivalent
<b>Non-Invasive Blood Pressure</b>			
NIBP Connector	Connector ports are for unique predicate accessories	Accommodate locking connectors unique to the modified device accessories	Substantially Equivalent
NIBP Hose	3 meters in length	5 meters in length	Substantially Equivalent
NIBP Data Collection & Measurement	Performed in the processing unit within the cart.	Performed in the processing unit within the cart using the picoNIBP OEM Module	Substantially Equivalent
<b>CO2</b>			
CO2 Connector	Connector ports are for unique predicate accessories	Accommodate locking connectors unique to the modified device accessories	Substantially Equivalent
CO2 Collection & Measurement	Completed using Excelitas CO2 Sensor	Completed using LoFloC5 Co2 Sensor	Substantially Equivalent
CO2 cannula	22 ft. in length	17ft. in length	Substantially Equivalent
<b>ECG</b>			
ECG Cable Cover	Wire bundle enclosed in a silicone foam trunk	Flat wire assembly enclosed in Azote foam	Substantially Equivalent
Wireless ECG Module- communication	5 user-selectable networks	10 user-selectable networks. (only 5 per module, either 1-5 or 6-10)	Substantially Equivalent

Wireless ECG Module- battery	Operates on one (1) 3.7 VDC user-replaceable lithium battery	Operates on two (2) 3.7 VDC user-replaceable lithium batteries	Substantially Equivalent
Wireless ECG Module- housing	Plastic covering, single battery slot, Ingress Protection IPX1	Plastic housing made of same materials as predicate, supports two batteries, has eject buttons for batteries, improved Ingress Protection rating of IP21	Substantially Equivalent
<b>SPO2</b>			
Wireless SPO2 Module- communication	5 user-selectable networks	10 user-selectable networks. (only 5 per module, either 1-5 or 6-10)	Substantially Equivalent
Wireless SPO2 Module- housing	Plastic covering, single battery slot, Ingress Protection IPX1	Plastic housing made of same materials as predicate, has eject button for battery, improved Ingress Protection rating of IP21	Substantially Equivalent

### SUMMARY OF NON-CLINICAL PERFORMANCE DATA

Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the modified device with respect to the predicate. Testing involved system level tests, performance tests, and safety testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate device and the specifications of the modified device. Results of the non-clinical testing demonstrate that the modified device operates as intended within the performance specifications and is substantially equivalent to the cleared device. The results do not raise issues regarding the safety and effectiveness of the device. Clinical data was not required to substantiate claims of safety and effectiveness. The modified device, the Expression MR400 MRI Patient Monitoring System, described in this submission is substantially equivalent to the cleared device, the MRI Patient Monitoring System (Model 865214).