September 30, 2021

Invivo Corporation
Maria Keelan
Regulatory Operations Specialist
12151 Research Parkway
Orlando, Florida 32826

Re: K212227
Trade/Device Name: Philips MR Patient Care Portal 5000
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, DSF, DPS, DSJ, DXN, DSK, FLL, CBQ, CBR, CBS, CCL, NHO, NHP, NHQ, DQA, FLS
Dated: July 15, 2021
Received: July 16, 2021

Dear Maria Keelan:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology, Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K212227

Device Name
Philips MR Patient Care Portal 5000

Indications for Use *(Describe)*

The MR Patient Care Portal 5000 is intended for use by healthcare professionals. The device is indicated for use to monitor vital signs of patients undergoing MRI procedures including ECG, pulse oximetry (SpO2), non-invasive blood pressure (NIBP), and optionally, invasive pressure (IP), carbon dioxide (CO2) and respiration rate, anesthetic agents, nitrous oxide (N2O), oxygen (O2), and/or temperature based on the configurations of the host patient monitor with which the MR Patient Care Portal 5000 is wirelessly communicating. The target patient population includes adult, pediatric, and neonatal patients that require monitoring during MRI procedures.

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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510(K) SUMMARY

The 510(k) summary was prepared in accordance with the requirements with CFR 807.92.

I. SUBMITTER

DATE PREPARED	July 15, 2021
APPLICANT	Invivo Corporation (Invivo, a division of Philips Medical Systems) 12151 Research Parkway, Orlando, FL 32826 Tel.: 407-473-5510 Fax: 407-382-2707
OFFICIAL CORRESPONDENT	Maria Keelan Regulatory Operations Specialist 12151 Research Parkway, Orlando, FL 32826 Tel.: 407-473-5510 Fax: 407-382-2707 maria.keelan@philips.com

II. DEVICE INFORMATION

TRADE NAME	Philips MR Patient Care Portal 5000
COMMON NAME	Remote Display
CLASSIFICATION	Class II 21 CFR 870.2300 Cardiac monitor (including cardiotachometer and rate alarm)
PRODUCT CODE	MWI: Monitor, physiological, patient (without arrhythmia detection or alarms)
SUB PRODUCT CODE	DSF; DRT; DPS; DSJ; DXN; DSK; FLL; CBQ; CBR; CBS; CCL; NHO; NHP; NHQ; DQA; FLS.

III. PREDICATE INFORMATION

PREDICATE DEVICE	Primary Predicate: Expression Information Portal (Model IP5) (K121424)

IV. DEVICE DESCRIPTION

The Philips MR Patient Care Portal 5000 is an information portal that serves as a remote monitor and remote control with electronic medical records capabilities outside the MR Scanner room (i.e. Control Room, Induction Room, or Recovery Room). The Philips MR Patient Care Portal 5000 displays the vital signs of a single patient monitoring system with which the device is communicating with from the MR control room.

The Philips MR Patient Care Portal 5000 is intended to replace the substantially equivalent device, the Expression Information Portal (Model IP5), cleared under 510(k) K121424 as a remote display and remote control for host patient monitoring systems, the Expression Model MR400 MRI Patient Monitoring System and Expression MR200 MRI Patient Monitoring System.

The Philips MR Patient Care Portal 5000 is not designed to be used in the MR Scanner room, does not perform any data collection or processing of data as stand-alone patient monitoring system, and it is not a central station.

The Philips MR Patient Care Portal 5000 system consists of the following primary components:

- Desktop unit;
- Radio Kit, USB;
- Radio Cradle;
- Display, 18.5 inch;

V. INTENDED USE

The MR Patient Care Portal 5000 is intended to be used outside the MR Scanner room (i.e. Control Room, Induction Room, or Recovery Room) by healthcare professionals to monitor vital signs of a patient undergoing a MRI procedure. The device remotely monitors a patient's vital signs by wirelessly communicating with a patient monitoring system.

Indications for Use:

The MR Patient Care Portal 5000 is intended for use by healthcare professionals. The device is indicated for use to monitor vital signs of patients undergoing MRI procedures including ECG, pulse oximetry (SpO2), non-invasive blood pressure (NIBP), and optionally, invasive pressure (IP), carbon dioxide (CO2) and respiration rate, anesthetic agents, nitrous oxide (N2O), oxygen (O2), and/or temperature based on the configurations of the host patient monitor with which the MR Patient Care Portal 5000 is wirelessly communicating. The target patient population includes adult, pediatric, and neonatal patients that require monitoring during MRI procedures.

VI. Comparison of Technological Characteristics with the Predicate Device

The Philips MR Patient Care Portal 5000 has the following similarities to the legally marketed predicate device, the Expression Information Portal (Model IP5).

- Same intended use and indications for use
- Same operating principle
- Same conditions of use

Table 5-1 provides a high-level comparison of the technological characteristics between the Philips MR Patient Care Portal 5000 and the Expression Information Portal (Model IP5).

Table 5-1. Comparison of Technological Features with the Primary Predicate Device

Similarities	
General Safety	Both the Philips MR Patient Care Portal 5000 and the Expression Information Portal (Model IP5) comply with FDA recognized consensus standards and industry recognized standards.
Lifetime (aka Service Life)	Both the subject device and predicate device expected service life is "7" years from the date of manufacture.
Host patient compatibility	Both the subject device and predicate device support the same host patient monitoring systems, the Expression Model MR400 MRI Patient Monitoring System or the Expression MR200 MRI Patient Monitoring System.
Dimensions	The radio module dimensions are the same .
Power requirements	AC mains to AC/DC power adapter rated 100-240 VAC at 50-60 Hz
Operating Temperature range:	15 to 35ºC (59°F to 95°F)
Material composition of radio and optional accessories and components	The material composition of the radio and optional accessories and components for both devices are the same.
Mounting Configurations	Desktop mounted or Wall mounted

Wireless Communication with the Host Patient monitor	• RF Output Power: +20 dBm
	• Frequency Range: 2.4GHz band
	• The radio module has FCC approval under identification number HSW-2410NF.
	• Radio frequency (RF) transceiver is the same
	• The display provides visual indicators of communication status between the following components:
	  • Subject and predicate device and host patient monitor,
	  • Host patient monitor and its wireless ECG module, and
	  • Host patient monitor and its wireless SpO2 module.
	• Communication status is established within a few seconds upon power on if the subject and predicate device, host patient monitor, wireless ECG module, and wireless SpO2 module are each set to the same network (A, B, C, D, or E (for MR200) or 1-10 (for MR400)).

Vital signs monitored	All vital signs are measured by and processed in the host patient monitoring system. The host patient monitoring systems, either the Expression Model MR400 MRI Patient Monitoring System or Expression MR200 MRI Patient Monitoring System, transmit the following data to the subject or predicate device for viewing: ECG (MR200 and MR400) SPO2 (MR200 and MR400) NIBP (MR200 and MR400) IP (MR400 only) CO2 (MR200 and MR400) O2 (MR400 only) Anesthetic agents (MR400 only) N2O (MR400 only) Respiration (MR200 and MR400) The time for making patient vital sign information available between processing viewing at the modified display is less than one second.
Patient applied parts	No patient applied parts
Environment of Use	Both the subject device and the predicate device optional accessories and components are intended for use outside the MR Scanner room (i.e., within the MR control room, MR induction room, or MR recovery room). The Bar Code Scanner handheld, the same optional component used with both the subject device and predicate device may be taken into the MR scanner room in a location at or outside the 2,000 (2,000 or less)

	Gauss (0.2T) field line, as measured from the center line of the MR bore, but in no case closer than 3 feet (1 meter) from the MR system.
Display operating platform	PC based
Alarms	Both the subject device and the predicate device provide: • latched and unlatched alarms. • visual (flashing text, numerics, and waveforms) and audible alarms. • alarm system compliant to IEC 60601-1-8. • time for making alarm conditions available between processing and viewing at the display is two seconds
Hospital Information System (HIS) Interface	Both the subject device and predicate device can interface with the Hospital Information System (HIS) as follows: • HIS interface is available when operating outside the MR System room. • Connect 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 device. • 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. • Data output via the RS232 port is serial • No data input from the HIS to the subject and predicate device with the exception of time sync. • No internet connection
System optional accessories and components	Optional medical device accessories: • Thermal Printer, USB Optional non-medical accessories and components: • Bar code scanner with base • Wireless keyboard and mouse • Wall Arm, 16” • Wall Channel, Polymount, 19” • Arm Extension, Strip Chart Printer
Differences	
Assembly	The difference in assembly between the subject device and the predicate device is that the subject device is designed in a modular fashion where the display/touch screen is separate from the processing unit while the predicate device is designed in an integrated fashion where the display/touch screen and processing unit are one. This difference in modular construction does not affect the substantial equivalence of the subject device relative to the predicate since both

	devices have the SAME principle and mode of operation and conditions of use.
Dimensions	The difference in configuration (modular versus integrated) design and dimensions between the subject device and the predicate device system configuration does not affect the substantial equivalence of the device. Both devices have the SAME principle and mode of operation and condition of use.
Environmental Specifications	While the subject device and predicate device have slight differences in operating humidity ranges, transport and storage, and atmospheric pressure temperatures the slight differences in environmental specifications do not affect the substantial equivalence of the subject device relative to the predicate. Both devices have the SAME principle and mode of operation and condition of use.
Material composition primary components	Although the material composition of the main components of the subject device—Desktop Unit, Radio Cradle, and Display—and predicate device (integrated touch screen display/ processing unit) differ, neither device requires biocompatibility testing of the materials since neither the subject nor predicate device come in direct or indirect contact with the patient's body during use and the devices are not intended by the user to be protective devices. The differences in material composition do not affect the substantial equivalence of the subject device relative to the predicate.
Operator Interface (Touch screen display)	There are some differences in technological characteristics of the operator interface between the subject device and predicate device. The technological characteristics remain the SAME with the exception of the improved screen resolution, configuration with respect to the processing unit (modular versus integrated), and the speaker. The subject device Display has been evaluated by DIVA Laboratories and certified to IEC 60601-1 Edition 3.1 as a medical device component, and verified and certified again to IEC 60601-1 Edition 3.1 as part of the completed Portal 5000 system. Although the subject device includes one speaker, the subject device incorporates a built-in diagnostic speaker test, power up tone, alarm plays during volume adjustment, and visual alarm for redundancy. Performance testing and risk assessment have verified the difference does not affect the directional or average sound pressure level and does not affect the substantial equivalence of the subject device relative to the predicate.

	The graphical user interface of the subject device was updated to better align with other Philips patient monitors to provide a common look, and feel, to improve clinician familiarity and ease of use. Caregivers come from other areas of the hospital to monitor their patient undergoing an MRI, so having a common graphical user interface improves usability. The graphical user interface differences do not affect the substantial equivalence of the subject device relative to the predicate.

Radio Module	The subject device uses a radio module with the SAME radio frequency (RF) transceiver as the predicate device. The difference in the radio module is as follows:
	• an improved digital interface board that provides enhanced electrical fast transient (EFT) and
	• a coated housing that provides enhanced electromagnetic compatibility (EMC) performance per the requirements of IEC 60601-1-2 Edition 4.0.
	• The 3 dBi antenna has been replaced with a 2 dBi antenna.
	• In addition, there are two optional accessories that are intended to mitigate any signal integrity issues:
	  • Control room flex antenna and
	  • Advanced Communications Option (ACO) passive antenna.
	The additional antennas are also permitted under the FCC certification HSW-2410NF. The differences do to not affect the substantial equivalence of the subject device relative to the predicate.
	
	• The radio frequency (RF) transceiver is located within a radio module and the 2 dBi antenna is mounted to the top of the radio module. Although the radio module of the subject device is docked on a radio cradle, and the radio module of the predicate device is docked within the display's radio bay on the top rear of the display, the subject device configuration has been tested for operating performance and IEC 60601-1-2 Edition 4.0. The difference does not affect the substantial equivalence of the subject device relative to the predicate. The functionality, technology, and operating performance of the wireless communication with the host patient monitor are the SAME as the predicate device.

Display operating system	Although the display operating system (software) is different between the predicate and subject device, both the subject device and predicate device implement a common system watchdog to identify processing faults. Both devices have the SAME principle and mode of operation.

	The operating system differences do not affect the substantial equivalence of the subject device relative to the predicate.
System optional component	The "Mount, remote desktop wall" is an optional component for use with the subject device only. The Desktop Unit Wall Mount is evaluated for safety as part of the Philips MR Patient Care Portal 5000 system. The introduction of this optional component does not affect the performance and substantial equivalence of the device relative to the predicate. The Control room flex antenna and the advance communication option (ACO) antenna are optional non-medical components of the Radio Kit, USB and are intended to mitigate any signal integrity issue. The use of these antennas does not affect the substantial equivalence and performance of the subject device relative to the predicate.

VII. NON-CLINICAL PERFORMANCE DATA

The following non-clinical performance data is not applicable:

- Sterilization
- Biocompatibility
- Performance testing-Animal

The following non-clinical performance data was provided in support of the substantial equivalence determination:

Cleaning & Disinfecting

The Philips MR Patient Care Portal 5000 is designed to be cleaned and disinfected as encountered in the intended use environment. A list of disinfectants and cleaners were compiled using input from customer surveys and complaint data based on legacy devices. The accelerated cleaning test utilized worst-case scenario of daily and monthly cleaning cycles. Results of the test support the use of the listed cleaners and disinfectants during the lifetime of the device.

Shelf-Life

The Philips MR Patient Care Portal 5000 does not have a defined shelf life. Tests were conducted against these extreme conditions as worst-case usage scenario for the subject device, its components, and/or accessories. Although these tests were performed as part of the lifetime of the device, the results are applicable to transport and storage conditions that may be encountered when the device is not in use. Tests results support the storage conditions necessary to maintain the performance, safety and intended use of the subject device.

Lifetime

The lifetime (also referred to as service life) of the device has been defined as "7" years. This is based on the combination of worst-case usability scenario and cleaning durability testing using accelerated testing under extreme conditions. Although tests were conducted under extreme environmental conditions, these test results are still applicable. The intended environmental usage conditions will not exceed test ranges that were used to challenge the subject device. The extreme testing conditions encompassed actual use environmental conditions that would be encountered in the intended use environment. Test results support the lifetime claim of "7" years for the Philips MR Patient Care Portal 5000 when used within operating conditions and as defined by the manufacturer.

Performance Testing - Bench

To establish substantial equivalence of the Philips MR Patient Care Portal 5000, functional and system level testing was conducted to validate the safety and performance of the device. The use of mechanical and engineering testing supports the safety and performance of the subject device under the intended use environment. Tests were performed according to applicable consensus standards and internal procedures/protocols. Conducted tests focused on the integrity and durability of the device to meet specific design requirements to ensure its safety and efficacy.

Performance Testing - Clinical *(Human Factors and Usability)*

The Philips MR Patient Care Portal 5000 is designed to be used in a controlled environment. Tests were performed to ensure implemented risk management measures were effective. Conducted tests focused on the interactions between the user and the Philips MR Patient Care Portal 5000 and its proposed labeling (i.e. IFU, Quick Reference Guide) under 'simulated-use' and were completed according to recognized consensus standards, industry standards, and FDA guidance documents regarding Human Factors/Usability. User specific data collected included the user receiving information from the device, user interpretation of information to make decisions, and user manipulation of the device/component or controls. Conducted usability tests support the safety and efficacy of the Philips MR Patient Care Portal 5000. The subject device met performance, usability, and safety test acceptance criteria.

Software Verification and Validation

Software verification and validation testing was conducted and documentation was provided per FDA's Guidance for Industry and FDA Staff "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. The Philips MR Patient Care Portal 5000 Software Level of Concern was determined to be Major since the Philips MR Patient Care Portal 5000 provides vital signs monitoring and alarms for potentially life-threatening situations in which medical intervention is necessary.

Electromagnetic Compatibility and Electrical Safety

Electrical safety and electromagnetic compatibility (EMC) testing was conducted on the Philips MR Patient Care Portal 5000. The device complies with the applicable requirements within the ANSI AAMI ES60601-1 standard for safety and the IEC 60601-1-2 standard for EMC. Additional wireless and co-existence testing per US FCC CFR 47 Part 15 and FDA guidance was conducted to ensure safe and effective use of the Philips MR Patient Care Portal 5000 radio frequency wireless technology features.

VIII. SUMMARY/CONCLUSIONS

The results of the substantial equivalence assessment, taken together with non-clinical bench testing, electrical safety and electromagnetic compatibility, software verification and validation, human factors and usability demonstrate that the Philips MR Patient Care Portal 5000 does not raise different questions of safety and effectiveness when compared to the predicate, performs as intended, and has performance characteristics that are substantially equivalent to the Expression Information Portal (Model IP5) predicate device.