December 14, 2018

Iradimed Corporation
Francis Casey
Vice-President, QA & Regulatory Affairs
1025 Willa Springs Drive
Winter Springs, Florida 32708

Re: K182900
Trade/Device Name: 3880 MRI Patient Monitoring System
Regulation Number: 21 CFR 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alar)
Regulatory Class: Class II
Product Code: MWI
Dated: October 12, 2018
Received: October 16, 2018

Dear Francis Casey:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Stephen C. Browning -S5

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*
K182900

Device Name
3880 MRI Patient Monitoring System

Indications for Use *(Describe)*
The IRadimed Corporation's 3880 MRI Patient Monitoring System is intended to monitor a single patient's vital signs for patients undergoing Magnetic Resonance Imaging (MRI) procedures. The 3880 MRI Patient Monitoring System is intended for use by healthcare professionals. The 3880 MRI Patient Monitoring System is intended for use in Adult and Pediatric, including Neonatal populations, for monitoring of Electrocardiogram (ECG), Non-Invasive Blood Pressure (NIBP), Invasive Blood Pressure (IBP) and Temperature. The 3880 MRI Patient Monitoring System is also intended for use in Adult and Pediatric, not including Neonatal populations, for monitoring of Pulse Oximetry (SpO2), Anesthetic Agents, Respiration, Capnography (CO2) and Oxygen (O2). The 3880 MRI Patient Monitoring System provides monitoring for three distinct patient types as defined below (Note: Pediatric group excludes Neonates):
1 - Adult (greater than 22 years),
2 - Pediatric (Infant 29 days - 2 years), Child (2 - 12 years), Adolescent (12 - 21 years),
3 - Neonate (28 days).

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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05 510(k) Summary

SUBMITTER INFORMATION:

Establishment Name: IRadimed Corporation
Establishment Address: 1025 Willa Springs Drive
Winter Springs, FL 32708

Contact Name: Mr. Francis Casey
Contact E-mail: fcasey@iradimed.com
Contact Phone: 407-677-8022 x106
Contact Fax: 407-677-5037

Date Prepared: October 12, 2018

DEVICE IDENTIFICATION:

Trade name: 3880 MRI Patient Monitoring System
Common name: MRI multi-parameter patient monitoring system
Classification name: Monitor, Physiological, Patient (Without Arrhythmia Detection or Alarms)
Regulation number: 21 CFR 870.2300
Regulatory class: 2
Product code: MWI

PRIMARY LEGALLY MARKETED PREDICATE DEVICE TO WHICH EQUIVALENCE CLAIMED:

Primary Predicate Device: 3880 MRI Patient Monitoring System
Manufacturer: IRadimed Corporation
510(k) #: K172200
Clearance date: October 25, 2017

OTHER LEGALLY MARKETED PREDICATE DEVICES TO WHICH EQUIVALENCE CLAIMED:

IBP Predicate Device: Expression MR400 MRI Patient Monitoring System
Manufacturer: Invivo Corp., a division of Philips Medical Systems
510(k) #: K152330
Clearance date: December 23, 2015

DEVICE DESCRIPTION:

The 3880 MRI Patient Monitoring System, also referred to as the 3880, is a multi-parameter vital signs monitor designed for use in the Magnetic Resonance Imaging (MRI) environment by trained healthcare professionals. The 3880 processes and displays multiple parameters, waveforms, measurement numeric values and alarms. The device is powered by either AC line power or its internal battery. It is light weight making it a practical intra-department patient transportation monitor for use within the MRI suite. The device can be carried by its handle, mounted to a wheeled cart/stand, or attached to a patient bed. The 3880 provides monitoring for the following parameters:

- Electrocardiogram (ECG)
- Heart rate (HR- ECG, SpO_2, IBP and NIBP derived)
- Blood oxygen saturation/pulse oximetry (SpO_2)
- Non-invasive blood pressure (NIBP)
- Invasive blood pressure (IBP)
- End-tidal and fractional inspired CO_2 ($EtCO_2$ and $FiCO_2$)
- Anesthetic agents (AGENTS) (requires 3886 Multi-Gas Unit)
  - Desflurane (DES)
  - Enflurane (ENF)
  - Halothane (HAL)
  - Isoflurane (ISO)
  - Sevoflurane (SEV)
- Fractional inspired O_2 (FiO_2), and end-tidal and fractional inspired N_2O (EtN_2O and FiN_2O) (requires 3886 Multi-Gas Unit)
- Temperature (TEMP)
- Respiration rate (CO_2-derived)

The 3880 MRI Patient Monitoring System can be ordered with the following configurations:

Standard Configuration:

	3880 MRI Patient Monitor				
Configuration	ECG	SpO_2	NIBP	CO_2	Temp
3880	X	X	X	X	X

Optional Configurations:

Anesthetic Agents (Requires 3880 Monitor and 3886 Multi-Gas Unit)**:**

	3886 Multi-Gas Unit		
Optional Configuration	AGENTS	CO_2	O_2
3886	X	X	X

Invasive Blood Pressure (IBP) (Requires 3880 Monitor and 3883 ipPOD)**:**

	3883 ipPOD
Optional Configuration	IBP
3883	X

The 3880 consists of the following key components:

- Patient monitor with buttons and touch screen display
- Wireless ECG POD, "ePOD"
- Wireless SpO_2 POD, "oPOD"
- Battery for patient monitor
- Power supply and cables
- Operations Manual

Accessories to the 3880 are offered to accommodate various patient sizes. Key standard and optional accessories include:

- ECG cables and electrodes
- SpO_2 sensors and grips
- NIBP cuffs and hoses
- Invasive blood pressure ipPOD (3883)
- Invasive blood pressure cable adapters (transducers sold separately)
- Temperature sensor
- Cannulas and Sample Lines
- Remote monitoring tablet (3885T)
- Remote monitoring tablet docking base, including printer (3885B)
- Multi-Gas Unit (3886)
- Mounting hardware and stand

INDICATIONS FOR USE:

The IRadimed Corporation's 3880 MRI Patient Monitoring System is intended to monitor a single patient's vital signs for patients undergoing Magnetic Resonance Imaging (MRI) procedures.

The 3880 MRI Patient Monitoring System is intended for use by healthcare professionals.

The 3880 MRI Patient Monitoring System is intended for use in Adult and Pediatric, including Neonatal populations, for monitoring of Electrocardiogram (ECG), Non-Invasive Blood Pressure (NIBP), Invasive Blood Pressure (IBP) and Temperature.

The 3880 MRI Patient Monitoring System is also intended for use in Adult and Pediatric, not including Neonatal populations, for monitoring of Pulse Oximetry (SpO_2), Anesthetic Agents, Respiration, Capnography (CO_2) and Oxygen (O_2).

The 3880 MRI Patient Monitoring System provides monitoring for three distinct patient types as defined below (Note: Pediatric group excludes Neonates):

Patient Type	**Age**
1 Adult	greater than 22 years
2 Pediatric (Includes: Infant, Child and Adolescent)	
-Adolescent	aged 12 through 21 (up to but not including the 22nd birthday)
-Child	2 years to less than 12 years
-Infant	29 days to less than 2 years
3 Neonate	from birth through the first 28 days of life

TECHNOLOGICAL CHARACTERISTICS:

IRadimed Corporation's 3880 MRI Patient Monitoring System is equivalent to the following predicate devices: the 3880 MRI Patient Monitoring System (K172200) and the Expression MR400 MRI Patient Monitoring System (K152330). The purpose of this submission is to add the Invasive Blood Pressure (IBP) vital sign monitoring parameter to the 3880 MRI Patient Monitoring System. The technological characteristics of the proposed device are compared to both the primary predicate device (K172200) and the IBP parameter-specific predicate device (K152330) in Tables 5-1 and 5-2, respectively.

Table 5-1, Technological Characteristics Comparison Table of Primary Predicate:

Technological Characteristic	**Primary Predicate Device:** IRadimed Corporation's 3880 MRI Patient Monitoring System (K172200)	**Proposed Device:** IRadimed Corporation's 3880 MRI Patient Monitoring System (Pending 510(k))	**Comparison**
MONITOR			
Intended Use/ Indication for Use	The IRadimed Corporation's 3880 MRI Patient Monitoring System is intended to monitor a single patient's vital signs for patients undergoing Magnetic Resonance Imaging (MRI) procedures.	The IRadimed Corporation's 3880 MRI Patient Monitoring System is intended to monitor a single patient's vital signs for patients undergoing Magnetic Resonance Imaging (MRI) procedures.	Same
	The 3880 MRI Patient Monitoring System is intended for use by healthcare professionals.	The 3880 MRI Patient Monitoring System is intended for use by healthcare professionals.	Same
	The 3880 MRI Patient Monitoring System is intended for use in Adult and Pediatric, including Neonatal populations, for monitoring of Electrocardiogram (ECG), Non-Invasive Blood Pressure (NIBP) and Temperature.	The 3880 MRI Patient Monitoring System is intended for use in Adult and Pediatric, including Neonatal populations, for monitoring of Electrocardiogram (ECG), Non-Invasive Blood Pressure (NIBP), Invasive Blood Pressure (IBP) and Temperature.	Substantially Equivalent
	The 3880 MRI Patient Monitoring System is also intended for use in Adult and Pediatric, not including Neonatal populations, for monitoring of Pulse Oximetry (SpO_2), Anesthetic Agents, Respiration, Capnography (CO_2) and Oxygen (O_2).	The 3880 MRI Patient Monitoring System is also intended for use in Adult and Pediatric, not including Neonatal populations, for monitoring of Pulse Oximetry (SpO_2), Anesthetic Agents, Respiration, Capnography (CO_2) and Oxygen (O_2).	Same
	The 3880 MRI Patient Monitoring System provides monitoring for three distinct patient types as defined below (Note: Pediatric group excludes Neonates):	The 3880 MRI Patient Monitoring System provides monitoring for three distinct patient types as defined below (Note: Pediatric group excludes Neonates):	Same
	Patient Types/Ages: **1_Adult**/ Greater than 22 years **2_Pediatric/** (Includes: Infant, Child and Adolescent) - Adolescent/ aged 12 through 21 (up to but not including the 22nd birthday) - Child/ 2 years to less than 12 years - Infant/ 29 days to less than 2 years **3_Neonate**/ from birth through the first 28 days of life	**Patient Types/Ages:** **1_Adult**/ Greater than 22 years **2_Pediatric/** (Includes: Infant, Child and Adolescent) - Adolescent/ aged 12 through 21 (up to but not including the 22nd birthday) - Child/ 2 years to less than 12 years - Infant/ 29 days to less than 2 years **3_Neonate**/ from birth through the first 28 days of life	Same

Technological Characteristic	**Primary Predicate Device:** IRadimed Corporation's 3880 MRI Patient Monitoring System (K172200)	**Proposed Device:** IRadimed Corporation's 3880 MRI Patient Monitoring System (Pending 510(k))	Comparison
Monitor Materials	Housing mainly coated aluminum, antimagnetic stainless steel, plastics	Housing mainly coated aluminum, antimagnetic stainless steel, plastics	Same
Display	No cart required, (optional mounting accessory for attachment to wheeled stand or patient bed), Touchscreen	No cart required, (optional mounting accessory for attachment to wheeled stand or patient bed), Touchscreen	Same
Remote Monitoring capabilities (optional for both)	Remote Monitoring Tablet (3885T), operates on battery power, can be docked for charging and desktop use in the Base Station (3885B) which is plugged into AC mains power	Remote Monitoring Tablet (3885T), operates on battery power, can be docked for charging and desktop use in the Base Station (3885B) which is plugged into AC mains power	Same
MRI Conditions of Use	Monitor: < 30,000 gauss Wireless PODS: < 30,000 gauss Multi-Gas Unit: < 600 gauss Secondary Display (two pieces): • Tablet < 15,000 gauss, except during the course of an MRI scan • Base Station: MR Unsafe	Monitor: < 30,000 gauss Wireless PODS: < 30,000 gauss Multi-Gas Unit: < 600 gauss Secondary Display (two pieces): • Tablet < 15,000 gauss, except during the course of an MRI scan • Base Station: MR Unsafe	Same
Printer	Integrated into secondary display- Base Station (3885B)	Integrated into secondary display- Base Station (3885B)	Same
Energy Source	External power supply connected to AC mains power or lithium polymer internal battery power	External power supply connected to AC mains power or lithium polymer internal battery power	Same
Wireless Communication	Via 2.4 GHz wireless radios	Via 2.4 GHz wireless radios	Same
Alarms Capability	Audible and Visual Alarms on monitor and remote display, Compliant to IEC 60601-1-8	Audible and Visual Alarms on monitor and remote display, Compliant to IEC 60601-1-8	Same
Biocompatibility	Complies with ISO 10993-1, 10993-5, 10993-10	Complies with ISO 10993-1, 10993-5, 10993-10	Same
Sterility	Not Applicable	Not Applicable	Same
ECG			
Wireless ECG Materials	Plastic housing with enclosed battery, ECG Lead Wires and Electrodes	Plastic housing with enclosed battery, ECG Lead Wires and Electrodes	Same
Module Energy Source	Lithium polymer battery	Lithium polymer battery	Same
ECG Information Displayed	Waveform and Numeric	Waveform and Numeric	Same
ECG Accuracy during MRI Scan	May be Affected by MRI gradients	May be Affected by MRI gradients	Same
SpO_2			
Wireless SpO_2 Materials	Module is enclosed in a plastic housing with enclosed battery, SpO_2 sensor cable and grip(s)	Module is enclosed in a plastic housing with enclosed battery, SpO_2 sensor cable and grip(s)	Same
Operating Principle	Red & Infrared Light Absorption	Red & Infrared Light Absorption	Same

Technological Characteristic	**Primary Predicate Device:** IRadimed Corporation's 3880 MRI Patient Monitoring System (K172200)	**Proposed Device:** IRadimed Corporation's 3880 MRI Patient Monitoring System (Pending 510(k))	Comparison
Module Energy Source	Lithium ion battery	Lithium ion battery	Same
SPO_2 Information Displayed	Waveform and Numeric	Waveform and Numeric	Same
NIBP			
NIBP Materials	NIBP Hose- Medical Grade, Class IV PVC (non-latex) NIBP Cuffs for Adults and pediatric patients- medical grade urethane NIBP Cuffs for neonatal patients- medical grade soft fabric	NIBP Hose- Medical Grade, Class IV PVC (non-latex) NIBP Cuffs for Adults and pediatric patients- medical grade urethane NIBP Cuffs for neonatal patients- medical grade soft fabric	Same
Operating Principle	Oscillometric technology (with an inflatable cuff) determines systolic and diastolic pressures	Oscillometric technology (with an inflatable cuff) determines systolic and diastolic pressures	Same
NIBP Information Displayed	Numeric	Numeric	Same
CO_2			
Materials	Various sized nasal and oral cannulas for different patient types- Medical Grade Co-extruded PVC	Various sized nasal and oral cannulas for different patient types- Medical Grade Co-extruded PVC	Same
Operating Principle	Side stream, NDIR (non-dispersive infrared absorption) technique	Side stream, NDIR (non-dispersive infrared absorption) technique	Same
CO_2 Information Displayed	Waveform and Numeric	Waveform and Numeric	Same
ANESTHETIC AGENTS, O_2			
Materials	Scavenge Hose- Medical Grade PVC O_2 Oxygen Cell- Paramagnetic Co-Extruded Sample Line	Scavenge Hose- Medical Grade PVC O_2 Oxygen Cell- Paramagnetic Co-Extruded Sample Line	Same
Operating Principle	Side Stream, non-dispersive infrared (NDIR) absorption technique	Side Stream, non-dispersive infrared (NDIR) absorption technique	Same
Anesthetic Agents Monitored	Desflurane (DES) Enflurane (ENF) Halothane (HAL) Isoflurane (ISO) Sevoflurane (SEV) Nitrous Oxide (N_2O)	Desflurane (DES) Enflurane (ENF) Halothane (HAL) Isoflurane (ISO) Sevoflurane (SEV) Nitrous Oxide (N_2O)	Same
Anesthetic Agents Information Displayed	Waveform and Numeric	Waveform and Numeric	Same
TEMP			
Materials	Fiber-optic Temperature Sensor, Medical Grade PVC	Fiber-optic Temperature Sensor, Medical Grade PVC	Same

Technological Characteristic	**Primary Predicate Device:** IRadimed Corporation's 3880 MRI Patient Monitoring System (K172200)	**Proposed Device:** IRadimed Corporation's 3880 MRI Patient Monitoring System (Pending 510(k))	Comparison
Operating Principle	Fiber-optic Technology	Fiber-optic Technology	Same
TEMP Information Displayed	Numeric, Celsius (°C) or Fahrenheit (°F)	Numeric, Celsius (°C) or Fahrenheit (°F)	Same

Table 5-2, Technological Characteristics Comparison Table of Invasive Blood Pressure Predicate Device:

Technological Characteristic	**IBP Predicate Device:** Invivo Corporation (Philips) Expression MR400 MRI Patient Monitoring System (K152330)	**Proposed Device:** IRadimed Corporation 3880 MRI Patient Monitoring System (Pending 510(k))	Comparison
Intended Use/ Indication 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 (SpO2), non-invasive blood pressure (NIBP), and optionally, invasive blood pressure (IBP), carbon dioxide (CO2) and respiration rate, anesthetic agents, nitrous oxide (N2O), oxygen (O2), and/or temperature.	The IRadimed Corporation's 3880 MRI Patient Monitoring System is intended to monitor a single patient's vital signs for patients undergoing Magnetic Resonance Imaging (MRI) procedures. The 3880 MRI Patient Monitoring System is intended for use by healthcare professionals. The 3880 MRI Patient Monitoring System is intended for use in Adult and Pediatric, including Neonatal populations, for monitoring of Electrocardiogram (ECG), Non-Invasive Blood Pressure (NIBP), Invasive Blood Pressure (IBP) and Temperature. The 3880 MRI Patient Monitoring System is also intended for use in Adult and Pediatric, not including Neonatal populations, for monitoring of Pulse Oximetry (SpO2), Anesthetic Agents, Respiration, Capnography (CO2) and Oxygen (O2). The 3880 MRI Patient Monitoring System provides monitoring for three distinct patient types as defined below (Note: Pediatric group excludes Neonates): Patient Type /Age 1 Adult/ greater than 22 years 2 Pediatric (Includes: Infant, Child and Adolescent) -Adolescent / aged 12 through 21 (up to but not including the 22nd birthday) -Child/ 2 years to less than 12 years -Infant/ 29 days to less than 2 years 3 Neonate/ from birth through the first 28 days of life	Substantially equivalent
Operating Principle	Conversion of intra-arterial blood pressure measurements into electrical signals (via transducer)	Conversion of intra-arterial blood pressure measurements into electrical signals (via transducer)	Same
Materials	IBP signal processing board housed in MR400 Cart with connection ports for P1 or P2 channels.	IBP signal processing board housed in 3883 ipPOD with connection ports for P1 and P2 channels.	Substantially equivalent
IBP Information Displayed	Waveform and Numeric	Waveform and Numeric	Same

SIMILARITIES AND DIFFERENCES

The proposed device is the same as the primary predicate device (K172200) except for the addition of Invasive Blood Pressure (IBP) monitoring. The proposed device is the same or similar to the IBP parameter specific predicate device (K152330) in the following ways: it utilizes the same fundamental operating principle, it displays IBP vital sign information for up to two channels in waveform and numerics, and it is intended for the same population of Adults to Neonatal patients.

The proposed device differs from the primary predicate device in the following way: the software of the primary predicate device (K172200) has been modified to include monitoring of Invasive Blood Pressure. The proposed device differs from the IBP parameter specific predicate device (K152330) in the following ways: the proposed device utilizes a Wireless IBP Pod (module) to send data to the monitor for display whereas the IBP parameter specific device is hardwired to the monitor.

A detailed comparison of the differences is provided in Section 12, the Substantial Equivalence Discussion.

SUMMARY OF NON-CLINICAL PERFORMANCE DATA:

Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the proposed device with respect to the predicates. Testing involved system level tests, performance tests, safety testing identified during hazard analysis and testing to the FDA Recognized Consensus Standards listed in Table 5-2 below. Results of the performance testing (see Section 18) demonstrate that the proposed device operates as intended within the performance specifications and is substantially equivalent to the predicate devices. The results do not raise issues regarding the safety and effectiveness of the proposed device. The proposed device is in compliance with the following standards:

Table 5-2, FDA Recognized Consensus Standards Summary Table:

FDA Recognition #	Standard #	Standard Development Organization / Title of Standard	Revision/Year	Results
19-4	60601-1*	IEC/ Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance	Edition 3.1 2005/(R)2012 And A1:2012	Pass
19-5	60601-1-2*	IEC/ Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests	Edition 4: 2015	Pass
5-76	60601-1-8	IEC/ 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	Edition 2.1 2012	Pass
3-126	60601-2-27	IEC/ Medical Electrical Equipment – Part 2-27: Particular Requirements For The Basic Safety And Essential Performance Of Electrocardiographic Monitoring Equipment [Including: Corrigendum 1 (2012)]	Edition 3.0 2011	Pass
3-115	60601-2-34*	IEC/ Medical Electrical Equipment - Part 2-34: Particular Requirements For The Basic Safety, Including Essential Performance, Of Invasive Blood Pressure Monitoring Equipment	Edition 3.0 2011	Pass

FDA Recognition #	Standard #	Standard Development Organization / Title of Standard	Revision/Year	Results
3-123	80601-2-30	ISO/ Medical Electrical Equipment – Part 2-30: Particular Requirements For The Basic Safety And Essential Performance Of Automated Non-Invasive Sphygmomanometers	Edition 1.1 2013	Pass
1-96	80601-2-55	ISO/ Medical Electrical Equipment – Part 2-55: Particular Requirements For The Basic Safety And Essential Performance Of Respiratory Gas Monitors	Edition 1.0 2011	Pass
6-232	80601-2-56	ISO/ Medical Electrical Equipment – Part 2-56: Particular Requirements For Basic Safety And Essential Performance Of Clinical Thermometers For Body Temperature Measurement	Edition 1.0 2009	Pass
1-85	80601-2-61	ISO/ Medical Electrical Equipment – Part 2-61: Particular Requirements For Basic Safety And Essential Performance Of Pulse Oximeter Equipment	Edition 1.0 2011	Pass
5-40	14971*	ISO/ Medical Devices – Application Of Risk Management To Medical Devices	Edition 2.0 2007	Pass
2-220	10993-1	ISO/ Biological Evaluation Of Medical Devices – Part 1: Evaluation And Testing Within A Risk Management Process	Edition 4.0 2009	Pass
2-245	10993-5	ISO/ Biological Evaluation Of Medical Devices – Part 5: Tests For In Vitro Cytotoxicity	Edition 3.0 2009	Pass
2-174	10993-10	ISO/ Biological Evaluation Of Medical Devices – Part 10: Tests For Irritation And Skin Sensitization	Edition 3.0 2010	Pass
8-422	F2052-15*	ASTM/ Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Device in MR Environment	2015	Pass
8-128	F2213-11*	ASTM/ Standard Test Method For Measurement Of Magnetically Induced Torque On Medical Devices In The Magnetic Resonance Environment	2011	Pass
19-13	62133	IEC/ Secondary Cells And Batteries Containing Alkaline Or Other Non-Acid Electrolytes - Safety Requirements For Portable Sealed Secondary Cells, And For Batteries Made From Them, For Use In Portable Applications [Including: Corrigendum 1 (2013)]	Edition 2.0 2012	Pass
5-114	62366	IEC/ Medical Devices - Part 1: Application Of Usability Engineering To Medical Devices [Including CORRIGENDUM 1 (2016)]	Edition 1.0 2015	Pass

* Standards identified with an asterisk in the table above have corresponding test reports supplied in Section 18 to support the addition of Invasive Blood Pressure monitoring with the 3880 MRI Patient Monitoring System. Compliance with all other applicable standards was provided and reviewed with the primary predicate device, which was cleared to market under K172200.

SUMMARY OF CLINICAL PERFORMANCE DATA:

Clinical data is not required to substantiate claims of safety and effectiveness for the modification of the proposed device to include invasive blood pressure monitoring.

STATEMENT OF SUBSTANTIAL EQUIVALENCE:

The proposed 3880 MRI Patient Monitoring System with the addition of invasive blood pressure monitoring capabilities utilizes the same fundamental scientific technology as the predicate devices on the market. It has passed all performance and verification/validation testing and complies with the applicable standards. Therefore, IRadimed Corporation's 3880 MRI Patient Monitoring System, as described in this submission, is substantially equivalent to the primary predicate devices, the Iradimed 3880 MRI Patient Monitoring System

(K172200) and the IBP parameter-specific predicate device, Invivo's Expression MR400 MRI Patient Monitoring System (K152330).