October 25, 2017

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

Re: K172200
Trade/Device Name: 3880 MRI Patient Monitoring System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI
Dated: September 26, 2017
Received: September 27, 2017

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. 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 (DICE) 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 (DICE) 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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172200

Device Name
3880 MRI Patient Monitoring System

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), 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

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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IRADIMED CORPORATION
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05 510(k) Summary

SUBMITTER INFORMATION:

Establishment Name:	IRadimed Corporation
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Contact Name:	Mr. Francis Casey
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Contact Phone:	407-677-8022 x106
Contact Fax:	407-677-5037
Date Prepared:	September 25th, 2017

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:

Predicate device:	Tesla M3 MRI Patient Monitoring System
Manufacturer:	MIPM (Mammendorfer Institut für Physik und Medizin)
510(k) #:	K142032
Clearance date:	May 7th, 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 (MR) 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 patient bed. The 3880 provides monitoring for the following parameters:

- Electrocardiogram (ECG)
- Heart rate (HR- ECG, SpO_2, and NIBP derived)

- Blood oxygen saturation/pulse oximetry (SpO_2)
- Non-invasive blood pressure (NIBP)
- End-tidal and fractional inspired CO_2 (EtCO2 and $FiCO_2$)
- Anesthetic agents (AGENT) (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 Configuration (Requires 3880 and 3886)**:**

	3886 Multi-Gas Unit		
Configuration	AGENTS	CO_2	O_2
3886	X	X	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
- Operation 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
- Temperature sensor
- Cannulas
- Remote monitoring tablet (3885-T)
- Remote monitoring tablet docking base, including printer (3885-B)
- 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), 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 its primary predicate, MIPM Tesla M3, in both functionality and technology. See table 5-1 below for details:

Table 5-1, Technological Characteristics Comparison Table:

Technological Characteristic	**Predicate Device:** MIPM's Tesla M3 MRI Patient Monitoring System (K142032)	**Proposed Device:** IRadimed Corporation's 3880 MRI Patient Monitoring System (Pending 510(k))	**Comparison** (see Section 12 for detailed discussion of Substantial Equivalence)
MONITOR			
Intended Use	The MRI Patient Monitoring System Tesla M3 is intended for monitoring of vital signs during MRI examinations (MRI procedures) of patients. The Tesla M3 is intended for use in the	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.	Substantially equivalent

Technological Characteristic	**Predicate Device:** MIPM's Tesla M3 MRI Patient Monitoring System (K142032)	**Proposed Device:** IRadimed Corporation's 3880 MRI Patient Monitoring System (Pending 510(k))	**Comparison** (see Section 12 for detailed discussion of Substantial Equivalence)
	Adult, Pediatric and Neonatal populations for the continuous monitoring of Electrocardiogram (ECG), Non-Invasive Blood Pressure (NIBP), Invasive Blood Pressure (IBP), Temperature, Respiration, Capnography ($etCO_2$), Oxygen and Anesthetic Agents. The Tesla M3 is intended for use in the Adult and Pediatric populations for the continuous monitoring of Pulse Oximetry (SpO_2). The Tesla M3 is intended for use by health care professionals.	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), 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): **<u>Patient Types/Ages:</u>** **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	
Monitor Materials	Housing mainly coated aluminum, antimagnetic stainless steel, plastics	Housing mainly coated aluminum, antimagnetic stainless steel, plastics	Substantially equivalent
Display	Permanently installed on wheeled cart, Touchscreen	No cart required, (optional mounting accessory for attachment to wheeled stand or patient bed), Touchscreen	Substantially equivalent

Technological Characteristic	**Predicate Device:** MIPM's Tesla M3 MRI Patient Monitoring System (K142032)	**Proposed Device:** IRadimed Corporation's 3880 MRI Patient Monitoring System (Pending 510(k))	**Comparison** (see Section 12 for detailed discussion of Substantial Equivalence)
Remote Monitoring capabilities (optional for both)	Desktop use only, must be plugged into AC mains power	Remote Monitoring Tablet (3885-T), operates on battery power, can be docked for charging and desktop use in the Base Station (3885-B) which is plugged into AC mains power	Substantially equivalent
MRI Conditions of Use	Monitor: < 200 gauss Wireless modules: < 30,000 gauss Multi-Gas Module: < 200 gauss Secondary Display (single piece): 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	Substantially equivalent
Printer	Integrated into secondary display	Integrated into secondary display- Base Station (3885-B)	Substantially equivalent
Energy Source	External power supply connected to AC mains power or lithium ion internal battery power	External power supply connected to AC mains power or lithium polymer internal battery power	Substantially equivalent
Wireless Communication	ECG and SpO_2 patient modules link to the Monitor via wireless 2.4 GHz link.	ECG and SpO_2 patient PODS link to the Monitor via wireless 2.4 GHz link.	Substantially equivalent
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	Substantially equivalent
Biocompatibility	Complies with ISO 10993-1	Complies with ISO 10993-1, 10993-5, 10993-10	Substantially equivalent
Sterility	Not Applicable	Not Applicable	Substantially equivalent
ECG			
Wireless ECG Materials	Plastic housing with enclosed battery, ECG Lead Wires and Electrodes	Plastic housing with enclosed battery, ECG Lead Wires and Electrodes	Substantially equivalent
Module Energy Source	Lithium ion battery	Lithium polymer battery	Substantially equivalent
ECG Information Displayed	Waveform and Numeric	Waveform and Numeric	Substantially equivalent
ECG Accuracy during MRI Scan	Affected by MRI gradients	Affected by MRI gradients	Substantially equivalent
SpO_2			
Wireless SpO_2 Materials	Module is enclosed in a plastic housing with enclosed battery, SpO2 sensor cable and grip(s)	Module is enclosed in a plastic housing with enclosed battery, SpO_2 sensor cable and grip(s)	Substantially equivalent
Operating Principle	Red & Infrared Light Absorption	Red & Infrared Light Absorption	Substantially equivalent
Module Energy Source	Lithium ion battery	Lithium polymer battery	Substantially equivalent
SPO2 Information Displayed	Waveform and Numeric	Waveform and Numeric	Substantially equivalent

Technological Characteristic	**Predicate Device:** MIPM's Tesla M3 MRI Patient Monitoring System (K142032)	**Proposed Device:** IRadimed Corporation's 3880 MRI Patient Monitoring System (Pending 510(k))	**Comparison** (see Section 12 for detailed discussion of Substantial Equivalence)
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	Substantially equivalent
Operating Principle	Oscillometric technology (with an inflatable cuff) determines systolic, diastolic and mean arterial pressures	Oscillometric technology (with an inflatable cuff) determines systolic, and diastolic pressures	Substantially equivalent
NIBP Information Displayed	Numeric	Numeric	Substantially equivalent
CO_2			
Materials	Various sized nasal and oral cannulas for different patient types- Medical Grade PVC	Various sized nasal and oral cannulas for different patient types- Medical Grade PVC	Substantially equivalent
Operating Principle	Side stream, NDIR (non-dispersive infrared absorption) technique.	Side stream, NDIR (non-dispersive infrared absorption) technique.	Substantially equivalent
CO2 Information Displayed	Waveform and Numeric	Waveform and Numeric	Substantially equivalent
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	Substantially equivalent
Operating Principle	Side Stream, non-dispersive infrared (NDIR) absorption technique	Side Stream, non-dispersive infrared (NDIR) absorption technique	Substantially equivalent
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)	Substantially equivalent
Anesthetic Agents Information Displayed	Waveform and Numeric	Waveform and Numeric	Substantially equivalent
TEMP			
Materials	Fiber-optic Temperature Sensor, Medical Grade PVC	Fiber-optic Temperature Sensor, Medical Grade PVC	Substantially equivalent
Operating Principle	Fiber-optic Technology	Fiber-optic Technology	Substantially equivalent
TEMP Information Displayed	Numeric, Celsius (°C) only	Numeric, Celsius (°C) or Fahrenheit (°F)	Substantially equivalent

SUMMARY OF NON-CLINICAL PERFORMANCE DATA:

Verification, validation, and testing activities establish the performance, functionality, usability and reliability characteristics of the device with respect to the predicate. Testing involved system level tests, biocompatibility, performance, and safety testing resulting from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate device and the specifications of the 3880 MRI Patient Monitoring System as well as the requirements from FDA Recognized Consensus Standards (see Table 5-2 below for a list of the FDA Recognized Consensus Standards the device claims conformance to including a summary of the results of testing). Section 18 of this submission includes a complete list of all testing performed to demonstrate substantial equivalence to the predicate device). Results of the non-clinical testing demonstrate that the device operates as intended within its performance specifications and is substantially equivalent to the predicate device. The results do not raise issues regarding the safety and effectiveness of the device.

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

FDA Recognition #	Standard #	Title of Standard	Revision/Year	Results
19-4	60601-1	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	Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests	Edition 3: 2007	Pass
5-76	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	Edition 2.1 2012	Pass
3-126	60601-2-27	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
3-123	80601-2-30	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	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	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	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	Medical Devices – Application Of Risk Management To Medical Devices	Edition 2.0 2007	Pass
2-220	10993-1	Biological Evaluation Of Medical Devices – Part 1: Evaluation And Testing Within A Risk Management Process	Edition 4.0 2009	Pass
2-245	10993-5	Biological Evaluation Of Medical Devices – Part 5: Tests For In Vitro Cytotoxicity	Edition 3.0 2009	Pass
2-174	10993-10	Biological Evaluation Of Medical Devices – Part 10: Tests For Irritation And Skin Sensitization	Edition 3.0 2010	Pass
8-422	F2052-15	Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Device in MR Environment	2015	Pass
3-349	F2503-13	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	2013	Pass
8-128	F2213-11	Standard Test Method For Measurement Of Magnetically Induced Torque On Medical Devices In The Magnetic Resonance Environment	2011	Pass
19-13	62133	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

SUMMARY OF CLINICAL PERFORMANCE DATA:

Non-invasive Blood Pressure (NIBP) clinical performance data provided in Section 20 demonstrates that the device meets the requirements of ISO 81060-2 (2013) *"Non-Invasive Sphygmomanometers - Part 2: Clinical Validation Of Automated Measurement Type"*, operates as intended within the performance specifications and is safe and effective for clinical use. The results do not raise issues regarding the safety and effectiveness of the device.

STATEMENT OF SUBSTANTIAL EQUIVALENCE:

IRadimed Corporation's 3880 MRI Patient Monitoring System, described in this submission is substantially equivalent to the cleared device, the Tesla M3 MRI Patient Monitoring System (K142032).