DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 29, 2019

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

Re: K180903
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: February 15, 2019
Received: February 19, 2019

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 and Part 809); 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 and Part 809), 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,

Shawn W. Forrest -S
2019.03.29 11:11:31 -04'00'

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)*
K180903

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), Pulse Oximetry (SpO2), Non-Invasive Blood Pressure (NIBP), Temperature, Anesthetic Agents, Respiration, Capnography (CO2), and Oxygen (O2).

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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IRADIMED CORPORATION
1025 Willa Springs Drive
Winter Springs, FL 32708
PH: 407-677-9022
FX: 407-677-5037

005 510(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: March 21, 2019

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 25th, 2017

OTHER LEGALLY MARKETED PREDICATE DEVICES TO WHICH EQUIVALENCE CLAIMED:

SpO_2 Predicate Device: 3160 Precess MRI Patient Monitoring System
Manufacturer: Invivo Corporation
510(k) #: K050399
Clearance date: August 25th, 2005

SpO_2 Reference Device: MASIMO SET® RAD-8 PULSE OXIMETER
Manufacturer: Masimo Corporation
510(k) #: K053269
Clearance date: December 21st, 2005

CO_2/AGENTS Predicate Device:	Root Monitoring System and Accessories (ISA OR+ & Nomoline Accessories)
Manufacturer:	Masimo Corporation
510(k) #:	K171121
Clearance date:	November 11th, 2017

DEVICE DESCRIPTION:

The 3880 MRI Patient Monitoring System, also referred to as the 3880, cleared October 25th, 2017, 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 attached to a 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 ($EtCO_2$ 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 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
- Nomoline: Adapters, Cannulas, Airway Adapter 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), Pulse Oximetry (SpO_2), Non-Invasive Blood Pressure (NIBP), Temperature, Anesthetic Agents, Respiration, Capnography (CO_2), and Oxygen (O_2).

TECHNOLOGICAL CHARACTERISTICS:

IRadimed Corporation's 3880 MRI Patient Monitoring System is equivalent to the predicate devices identified: the 3880 MRI Patient Monitoring System (K172200), the 3160 Precess MRI Patient Monitoring System (K050399), the Masimo SET® Rad-8 Pulse Oximeter (K053629) and the Masimo Root Monitoring System and Accessories (K171121) in both functionality and technology. The purpose of this submission is to add neonatal indications for use for the pulse oximeter (SpO_2), capnography (CO_2) and Anesthetic Agents (AGENTS) vital sign monitoring parameters to the primary predicate 3880 MRI Patient Monitoring System, cleared October 25th, 2017. See Tables 5-1, 5-2 and 5-3 below for comparisons of the technological characteristics between the proposed and predicate devices:

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 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 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	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), Pulse Oximetry (SpO_2), Non-Invasive Blood Pressure (NIBP), Temperature, Anesthetic Agents, Respiration, Capnography (CO_2), and Oxygen (O_2).	Same Same Substantially Equivalent
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

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
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	ECG, SpO_2 and CO_2/AGENTS modules link to the Monitor via wireless 2.4 GHz link.	ECG, SpO_2 and CO_2/AGENTS modules link to the Monitor via wireless 2.4 GHz link.	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	Affected by MRI gradients	Affected by MRI gradients	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

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
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
TEMP			
Materials	Fiber-optic Temperature Sensor, Medical Grade PVC	Fiber-optic Temperature Sensor, Medical Grade PVC	Same
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 SpO2 Specific Predicate Device:

Technological Characteristic	**SpO_2 Predicate Devices:** Invivo Corporation's 3160 MRI Patient Monitoring System (K050399) and Masimo Corporation's Masimo SET® Rad-8 Pulse Oximeter (K053269)	**Proposed Device:** IRadimed Corporation's 3880 MRI Patient Monitoring System (Pending 510(k))	Comparison
Indications for Use	The 3160 MRI Patient Monitoring System is intended to monitor vital signs for patients undergoing MRI procedures and to provide signals for synchronization for the MRI scanner. The 3160 MRI Patient Monitoring System 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), Temperature, Pulse Oximetry (SpO2), Anesthetic Agents, Respiration, Capnography (CO2), and Oxygen (O2).	Substantially equivalent
Wireless SpO_2 Module Materials	(Invivo) Dolphin SpO_2 Module enclosed in plastic housing (K050399) (Masimo) Masimo SpO_2 MS Series Module enclosed in plastic housing (K053269)	Masimo SpO_2 MS Series Module enclosed in plastic housing	Substantially equivalent
Sensor Materials	(Invivo) fiber-optic glass SpO_2 sensor cable	fiber-optic glass SpO_2 sensor cable	Substantially equivalent
SpO_2 Reusable Accessories	(Invivo) Silicone rubber grips with receptacles for insertion of fiber-optic sensor heads from sensor cable. Various sizes to accommodate all patient types	Silicone rubber grips with receptacles for insertion of fiber-optic sensor heads from sensor cable. Various sizes to accommodate all patient types	Substantially equivalent
Operating Principle	Red & Infrared Light Absorption	Red & Infrared Light Absorption	Same
SpO_2 Information Displayed	Waveform and Numeric	Waveform and Numeric	Same

Table 5-3, Technological Characteristics Comparison Table of CO_2/AGENTS Specific Predicate Device:

Technological Characteristic	**CO_2/AGENTS Predicate Device:** Masimo Root Monitoring System and Accessories (ISA OR+ Module and Nomoline Accessories) (K171121)	**Proposed Device:** IRadimed Corporation's 3880 MRI Patient Monitoring System (Pending 510(k))	Comparison
Indications for Use	The Masimo Root Monitoring System and Accessories are indicated for use by healthcare professionals for the monitoring of multiple physiological parameters in healthcare environments. The optional ISA product family consists of sidestream gas analyzers (ISA OR+) and accessories including Nomoline, intended to be connected to other medical backboard devices for monitoring of breath rate [respiration] and the following breathing gases[anesthetic agents]: ISA OR+: CO_2, O_2, N_2O, Halothane, Enflurane, Sevoflurane and Desflurane The intended patient population is adult, pediatric, infant and neonatal patients. Note: the complete Indications for Use from K171121 can be found in Section 21 "Other". The excised portion above is relevant to establishing substantial equivalence with the CO_2/AGENTS parameters with the proposed device.	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), Temperature, Pulse Oximetry (SpO_2), Anesthetic Agents, Respiration, Capnography (CO_2), and Oxygen (O_2).	Substantially equivalent
Patient Population	Adult and Pediatric including Neonates	Adult and Pediatric including Neonates	Same
Multi-Gas Module Materials	Masimo ISA OR+ Multi-Gas Analyzer w/Paramagnetic O_2 Oxygen Cell	Masimo ISA OR+ Multi-Gas Analyzer w/Paramagnetic O_2 Oxygen Cell	Same
Enclosure Materials	Plastic Housing	Metal Housing	Substantially equivalent
Accessory Materials	Masimo Nomoline Accessories: • Sample line: Soft co-extruded PE/PVC • Cannula: Soft PVC • Airway adapters: Hard Plastic; methyl methacrylate-acrylonitrile-butadiene-styrene (MABS)	Masimo Nomoline Accessories: • Sample line: Soft co-extruded PE/PVC • Cannula: Soft PVC • Airway adapters: Hard Plastic; methyl methacrylate-acrylonitrile-butadiene-styrene (MABS)	Same
Operating Principle	Side Stream, non-dispersive infrared (NDIR) absorption technique	Side Stream, non-dispersive infrared (NDIR) absorption technique	Same
Anesthetic Agents/ Gases Monitored	Desflurane (DES) Enflurane (ENF) Halothane (HAL) Isoflurane (ISO) Sevoflurane (SEV) Nitrous Oxide (N_2O) Oxygen (O_2) Capnography (CO_2)	Desflurane (DES) Enflurane (ENF) Halothane (HAL) Isoflurane (ISO) Sevoflurane (SEV) Nitrous Oxide (N_2O) Oxygen (O_2) Capnography (CO_2)	Same
Respiration Rate Detection	CO_2 derived	CO_2 derived	Same
Information Displayed	Waveform and Numeric	Waveform and Numeric	Same

SIMILARITIES AND DIFFERENCES:

No changes have been made to the technological characteristics, specifications, operating principals, materials, system hardware or software of the proposed device; all are the same when compared to the primary predicate device (K172200). Both devices are intended to monitor patients vital signs while undergoing MRI procedures. Both devices provide the same vital sign monitoring parameters which are patient population specific ranging from adult to infant, or adult to neonatal patients.

The proposed and predicate devices differ in the following ways; the product labeling in the proposed device has been revised to include the application of pulse oximetry (SpO_2), Capnography (CO_2), Anesthetic Agents (AGENTS), and Oxygen (O_2) with neonatal patients.

SpO_2:
The sensors, hardware, SpO_2 sensor attachment accessories (sensor grips), and methods of attachment are substantially equivalent to those found in the SPO_2 specific predicate devices (Invivo's K050399 and Masimo's K053269). The proposed device's intended use / indications for use statement differs in that it includes more detail regarding the patient population the device is intended to be used with, as well as a listing of the parameters intended to be monitored.

CO_2/AGENTS:
The primary predicate (K172200) as well as the CO_2/AGENTS specific predicate (K171121) and the proposed device all use Masimo's ISA OR+ Multi-Gas Analyzer and Nomoline Accessories for monitoring of the CO_2/AGENTS parameters. However, Iradimed's primary predicate device was cleared to market one month prior to Masimo receiving clearance to market the ISA OR+ Gas Module and Nomoline Accessories for use with neonatal patients. This 510(k) is intended to clarify the indications for use statement to include neonatal monitoring of CO_2/AGENTS with the proposed device.

The risks identified in the modified device are identical to those provided in 510(k) K172200 and no new risks have been introduced as a result of the proposed modifications. Based on this information the differences between the modified and predicate devices do not affect the safety and effectiveness of the device when used as labeled. Therefore, the modified device as described in the submission is substantially equivalent to the predicate devices.

SUMMARY OF NON-CLINICAL PERFORMANCE DATA:

The proposed modifications to the 3880 MRI Patient Monitoring Systems labeling does not require non-clinical performance testing. The non-clinical performance testing provided in K172200 has not changed since the submission and is still applicable to the modified device (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). Based on this information, additional non-clinical performance data is not necessary to demonstrate substantial equivalence.

Table 5-4, FDA Recognized Consensus Standards Testing Summary Table:

FDA Recog. #	Standard #	Title of Standard	Rev/Year	Results
19-4	60601-1	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance	3.1 / 2005 +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	3.0 / 2007 4.0 / 2014	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	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)]	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	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	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	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	1.0 / 2011	Pass**
5-40	14971	Medical Devices – Application Of Risk Management To Medical Devices	2.0 / 2007	Pass
2-220	10993-1	Biological Evaluation Of Medical Devices – Part 1: Evaluation And Testing Within A Risk Management Process	4.0 / 2009	Pass
2-245	10993-5	Biological Evaluation Of Medical Devices – Part 5: Tests For In Vitro Cytotoxicity	3.0 / 2009	Pass
2-174	10993-10	Biological Evaluation Of Medical Devices – Part 10: Tests For Irritation And Skin Sensitization	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)]	2.0 / 2012	Pass

*All FDA Recognized Consensus Standards test reports listed above were provided and reviewed with the primary predicate device, which was cleared to market under K172200. The test reports provided in this submission, identified with asterisks in the table above, have been supplied in Section 18 to support substantial equivalence with the parameter specific predicates for the SpO_2 and CO_2/AGENTS parameters.

** Additional bench testing comparing performance of the Masimo SET Rad 8 was conducted to demonstrate equivalence of the subject device which integrates Masimo MS Series Module and sensor technology. The testing demonstrated equivalence of both systems when configured for use in neonates.

SUMMARY OF CLINICAL PERFORMANCE DATA:

The SpO_2 volunteer blood study testing results using ISO 80601-2-61:2011 were submitted with K172200. In accordance with the FDA guidance document titled "Pulse Oximeters-Premarket Notification Submissions [510(k)s]" and non-clinical performance data provided, no new clinical performance data is necessary to demonstrate substantial equivalence.

STATEMENT OF SUBSTANTIAL EQUIVALENCE:

The indications for use statement has been modified to include the application of the SpO_2 and CO_2/AGENTS parameters with neonatal patients. Although the neonate population was

not specifically indicated for use with the SpO_2 and CO_2/AGENTS parameters in the primary predicate device, the same technology and accessory types (SPO_2- fiber optic sensors, silicone grips and CO_2/AGENTS- ISA OR+ Multi-Gas Analyzer with Nomoline Accessories) were cleared for use with neonatal patients in the parameter specific predicate devices (SPO_2-Invivo's 510(k) K050399, Masimo's 510(k) K053269 and CO_2/AGENTS - Masimo's 510(k) K171121).

Therefore, IRadimed Corporation's 3880 MRI Patient Monitoring System, as described in this submission, is substantially equivalent to the primary predicate device, the Iradimed 3880 MRI Patient Monitoring System (K172200), and the parameter specific predicate devices, Invivo's 3160 Precess MRI Patient Monitoring System (SpO_2) (K050399), Masimo's Corporation's SET® Rad-8 Pulse Oximeter (K053629) and Masimo's Root Monitoring System and Accessories (CO_2/AGENTS), specifically the ISA OR+ Multi-Gas Module and the Nomoline Accessories (K171121).