DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 15, 2016

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

Re: K143369
Trade/Device Name: MRidium 3860+ MRI Infusion Pump/Monitoring System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: November 8, 2016
Received: November 9, 2016

Dear Mr. 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 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,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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)*
K143369

Device Name
MRidium 3860+ MRI Infusion Pump/Monitoring System

Indications for Use *(Describe)*
The Iradimed Corporation's MRidium 3860+ MRI Infusion Pump/Monitoring System is intended for:

- General hospital or clinical use by medical professionals whenever it is required to infuse patients with subcutaneous, intra-venous or intra-arterial fluids before, during, or after Magnetic Resonance Imaging (MRI) scans, functioning while either in a stationary or mobile position.
- The system is useful in the administration of fluids requiring precisely controlled infusion rates. The system can operate in either continuous, intermittent, or bolus delivery mode.
- The Infusion Pump can be used inside the MRI room mounted outside the 10,000 Gauss line (1 Tesla line), and with shielded magnets of field strength of 3.0 Tesla or less.
- This device is available for sale only upon the order of a physician or other related licensed medical professional, and not intended for any home use applications.
- The Pulse Oximeter is used to measure, display, and record functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult, pediatric, and infant patients in an MR environment. Testing of the oximeter was performed in MR conditional environments at 1.5T and 3T. It is indicated for spot checking and/or continuous monitoring of patients who are well or poorly perfused in the MRI.

The infusion pump is contraindicated for use on the inlet side of Extracorporeal Membrane Oxygenation (ECMO) systems where the negative pressure is greater than -100 mmHG as the high negative pressures can result in uncontrolled fluid flow.

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

IRadimed's MRidium 3860+ MRI Infusion Pump/Monitoring System

K143369

Submitter Information:

Iradimed Corporation
1025 Willa Springs Dr.
Winter Springs, FL 32708

407-677-8022 x106
Contact: Mr. Francis Casey

Date Prepared: December 7, 2016

Product Name:

Proprietary: MRidium 3860+ MRI Infusion Pump/Monitoring System
Common: Infusion Pump
Classification: Class II (see 21 CFR 880.5725)
Product Code: FRN

Primary Predicate/Legally Marketed Device to Which Equivalence is Claimed:
MRidium 3860 MRI Infusion Pump/Monitoring System: K090087 (Marketed as MRidium 3860+ MRI Infusion Pump/Monitoring System)

Device Description:
The MRidium 3860+ MRI Infusion Pump/Monitoring System with software version 3.5.3 is an MRI compatible IV pump intended for use within the MR Scan room. The device operates to full specification in magnetic fields of up to 10,000 Gauss and has RF emissions at Larmor frequencies up to and including 3.0 Tesla MR scanners (132 MHz) such that image signal to noise is not visibly affected with the pump within 1 foot from the MRI bore opening. The magnetic content of the device is such that there is no hazard of magnetic attraction.

The pump unit is designed with an integral single peristaltic pump channel utilizing an ultrasonic (non-magnetic) motor. This integral channel is vertically oriented to the right side of the unit. The main assembly of the pump unit shall contain the controls, display, power supply, battery, processor/memory functions suitable to meet the complete and expanded system requirements.

The left side of the unit is designed to accommodate attachment of an optional second peristaltic pump channel (Model 3861) which is controlled through the main pump assembly's display and controls. A remote display (Model 3865) is also available for independent viewing and control from the adjacent MRI Control areas.

The Dose Rate Calculator feature, allows the user to set up a patient's infusion rate based upon user selected parameters, including volume to be infused, dose, concentration, weight, and/or time.

The Dose Rate Calculator feature also provides a Drug Library, allowing the user to program a patient's infusion protocol from selected parameters, including volume to be infused, dose, concentration, weight and/or time.

The Drug Library includes a small drug library consisting of 5 drugs (four common medications most frequently infused during MRI procedures, and one customizable drug) and with the DERS library card, can hold up to 50 customizable drugs. The optional DERS library card also includes the ability of setting hard and soft limits for each drug. This Drug Library feature can only be activated/de-activated with a service-related, limited user access menu.

The Dose Error Reduction System (DERS) option (P/N 1145) to the Dose Rate Calculator feature allowing user facilities to program custom drug names, doses, and limits for use in the Dose Rate Calculator. A user programmable drug library memory card stores the specific infusion protocols established by the hospital facility. This library is accessed using the pump's Dose Rate Calculator Menu. The drug library card supports a number of separate user-programmed infusion protocols for either primary and/or primary/bolus infusions, retrievable by drug/protocol name. The library can be programmed with nominal starting values for: Dose, Concentration, and Time. Also, hard limits (maximum and minimum) and soft limits (high and low limits that require a user confirmation to exceed) for: Dose, Concentration, Time and Patient Weight can be programmed. Programming the custom medications and limits is performed with the pump and a dedicated drug library SD Memory Card in the limited access service mode.

The Pulse Oximeter feature of the 3860+ MRI Infusion Pump/Monitoring System is used in measuring, displaying, and recording functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult, pediatric, and infant patients in an MR environment. It is indicated for continuous monitoring of patients in the MRI who are well or poorly perfused. The 3860+ System displays the patient's pulse rate and SpO2 values, as well as applicable alarm limits. The 3860+ System includes adjustable audible and visual pulse rate and oxygen saturation (SpO2) alarms. It also includes a variety of additional features, including low battery alarms, status indicators and sensor-related alarms. The 3860+ System only uses fiberoptic SpO2 sensors. These fiber optic sensors, cables, and associated finger wrap accessories contain no conductive components; they can be applied safely to the patient while inside an MR (magnetic resonance) environment. The 3860 model number is used for the same infusion device with no SpO2 module.

Indications for Use:

General hospital or clinical use by medical professionals whenever it is required to infuse patients with subcutaneous, intra-venous or intra-arterial fluids before, during, or after Magnetic Resonance Imaging (MRI) scans, functioning while either in a stationary or mobile position.
The system is useful in the administration of fluids requiring precisely controlled infusion rates. The system can operate in either continuous, intermittent, or bolus delivery mode.

The Infusion Pump can be used inside the MRI room mounted outside the 10,000 Gauss line (1 Tesla line), and with shielded magnets of field strength of 3.0 Tesla or less.
This device is available for sale only upon the order of a physician or other related licensed medical professional, and not intended for any home use applications.

The Pulse Oximeter is used to measure, display, and record functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult, pediatric, and infant patients in an MR environment. Testing of the Oximeter was performed in MR conditional environments at 1.5T and 3T. It is indicated for spot checking and/or continuous monitoring of patients who are well or poorly perfused in the MRI.

The infusion pump is contraindicated for use on the inlet side of Extracorporeal Membrane Oxygenation (ECMO) systems where the negative pressure is greater than -100 mmHg as the high negative pressures can result in uncontrolled fluid flow.

Comparison to Primary Predicate/Reason for 510(k) Submission:

The Iradimed Corporation MRidium 3860+ MRI Infusion Pump/Monitoring System is the same as the primary predicate, which is the MRidium 3860 MRI Infusion Pump/Monitoring System (K090087) with the two modifications:

1. Updated version of software: The Infusion Pump in this submission includes software version 3.5.3, whereas the Infusion Pump in the K090087 submission included software version 2.0. The changes in the software include:
    - Addition of an optional Drug Error Reduction System library card. The primary predicate has a small drug library consisting of 5 drugs, with one of these being customizable; where the DERS library card can hold up to 50 customizable drugs.
    - The optional DERS library card includes the ability of setting hard and soft limits for each drug.
2. Pulse Oximeter: The subject device utilizes OEM Masimo Set Technology (K053269) for monitoring hemoglobin (SpO2) and Pulse Rate, with IRadimed 1170 fiberoptic SpO2 sensor. This employs the same fundamental scientific technology as the primary predicate, which utilized OEM Nonin Medical (K071415) for monitoring hemoglobin (SpO2) and Pulse Rate, with Nonin's fiberoptic SpO2 sensor. The differences between the two include:
    - Different OEM supplier for the pulse Oximeter monitor, however all performance specifications are identical between the two, and both have been cleared for market through a Premarket Notification.
    - Different manufacturer for fiberoptic cable; Nonin vs Iradimed. Both use fine diameter glass fibers arranged in two bundles, red/infrared Leds and photodiodes to transmit data to the monitoring unit within the pump.

Other than these two differences, the subject device is identical to the primary predicate device. The table below is a side-by-side comparison for the two modifications:

Characteristic	Subject Device MRidium 3860+ MRI Infusion Pump/Monitoring System with SW Version 3.5.3	Primary Predicate Device MRidium 3860 MRI Infusion Pump/Monitoring System with SW Version 2.0 K090087
Product Code	FRN	FRN
Regulation Number	21 CFR 880.5725	21 CFR 880.5725
Regulation Name	Infusion Pump	Infusion Pump
Regulatory Class	II	II
Indications for Use	General hospital or clinical use by medical professionals whenever it is required to infuse patients with subcutaneous, intra-venous or intra-arterial fluids before, during, or after Magnetic Resonance Imaging (MRI) scans, functioning while either in a stationary or mobile position. The system is useful in the administration of fluids requiring precisely controlled infusion rates. The system can operate in either continuous, intermittent, or bolus delivery mode. The Infusion Pump can be used inside the MRI room mounted outside the 10,000 Gauss line (1 Tesla line), and with shielded magnets of field strength of 3.0 Tesla or less. This device is available for sale only upon the order of a physician or other related licensed medical professional, and not intended for any home use applications. The Pulse Oximeter is used to measure, display, and record functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult, pediatric, and infant patients in an MR environment. Testing of the Oximeter was performed in MR conditional environments at 1.5T and 3T. It is indicated for spot checking and/or continuous monitoring of patients who are well or poorly perfused in the MRI. The infusion pump is contraindicated for use on the inlet side of Extracorporeal Membrane Oxygenation (ECMO) systems where the negative pressure is greater than -100 mmHg as the high negative pressures can result in uncontrolled fluid flow.	General hospital or clinical use by medical professionals whenever it is required to infuse patients with subcutaneous, intra-venous or intra-arterial fluids before, during, or after Magnetic Resonance Imaging (MRI) scans, functioning while either in a stationary or mobile position. The system is useful in the administration of fluids requiring precisely controlled infusion rates. The system can operate in either continuous, intermittent, or bolus delivery mode. The Infusion Pump can be used inside the MRI room mounted outside the 10,000 Gauss line (1 Tesla line), and with shielded magnets of field strength of 3.0 Tesla or less. This device is available for sale only upon the order of a physician or other related licensed medical professional, and not intended for any home use applications. The Pulse Oximeter is used to measure, display, and record functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult, pediatric, and infant patients in an MR environment. Testing of the Oximeter was performed in MR conditional environments at 1.5T and 3T. It is indicated for spot checking and/or continuous monitoring of patients who are well or poorly perfused in the MRI. The infusion pump is contraindicated for use on the inlet side of Extracorporeal Membrane Oxygenation (ECMO) systems where the negative pressure is greater than -100 mmHg as the high negative pressures can result in uncontrolled fluid flow.
Configuration	3860+ Infusion Pump 3861 Sidecar (Channel B) 3865 Remote	3860 Infusion Pump 3861 Sidecar (Channel B) 3865 Remote
Dose Rate Calculator	Yes	Yes
Drug Library	Yes	Yes
# Drugs in Library	up to 50 with DERS* Drug Library (customizable by customer)	5 (1 customizable by customer)
Ability to Set Hard/Soft Limits for Drugs	Yes*	No
Pulse Oximeter	Yes	Yes
Mfg of Pulse Oximeter	Masimo (K053269)	Nonin (K071415)
Mfg of Pulse Oximeter Cable (fiberoptic)	IRadimed p/n 1170	Nonin

*Only with addition of optional Dose Error Reduction System (DERS) Library Card; without optional DERS Library Card, there is no difference between the two software versions for the Drug Library

Performance Testing to Demonstrate Equivalence		
Characteristic	**Standard/Test/FDA Guidance**	**Result**
Human Factors/Usability	*"Applying Human Factors and Usability Engineering to Medical Devices: Guidance for Industry and Food and Drug Administration Staff"*, issued Feb 3, 2016	Pass
Software	Software Verification and Validation: • Code Review • Static Analysis • Unit Testing • Regression Testing • System Validation	Pass
Risk Management		
Safety Assurance Case	*"Infusion Pumps Total Product Life Cycle: Guidance for Industry and FDA Staff"*, issued Dec 2, 2014	Complete
Risk Analysis	ISO 14971	Complete

Summary of Performance Testing:

Verification and validation activities were performed to ensure that the MRidium 3860+ MRI Infusion Pump/Monitoring System with software version 3.5.3 meets design input and safety requirements. Verification and validation testing was conducted and confirmed that the new feature design requirements were met. Additionally, pre-existing design requirements were re-tested to confirm that all pre-existing requirements are met.

Human Factors studies and Risk Management methods have been used to assess the impact the modifications on the device, and a Safety Assurance Case has been generated to demonstrate substantial equivalence of the overall system to the predicate. The MRidium 3860+ MRI Infusion Pump/Monitoring System with software version 3.5.3 does not affect the indications for use/intended use as cleared with software version 2.0, or introduce any unacceptable risks.

Conclusion:

The MRidium 3860+ MRI Infusion Pump/Monitoring System with software version 3.5.3 is substantially equivalent to the MRidium 3860 MRI Infusion Pump/Monitoring System with software version 2.0 (primary predicate) with respect to indications for use, technological characteristics and principles of operation. There are slight technological differences that are related to the Pulse Oximeter and the Dose Rate Calculator (affecting the Drug Library using the optional DERS library card). These differences do not present any new issues with substantial equivalence to the predicate, as confirmed by performance testing and field data. Thus, the MRidium 3860+ MRI Infusion Pump/Monitoring System with software version 3.5.3 is substantially equivalent to the primary predicate device.