May 28, 2025

Iradimed Corporation
Daniel Bennett
Regulatory Affairs Director
1025 Willa Springs Drive
Winter Springs, Florida 32708

Re: K242752
Trade/Device Name: MRidium 3870 MRI Infusion Pump System (3870)
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion pump
Regulatory Class: Class II
Product Code: FRN, FOX, LHI
Dated: April 22, 2025
Received: April 25, 2025

Dear Daniel Bennett:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

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

Sincerely,

Jake K. Lindstrom -S

Jake Lindstrom, Ph.D.
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices, and
Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242752

Device Name
MRidium 3870 MRI Infusion Pump System

Indications for Use *(Describe)*
The Iradimed Corporation's MRidium 3870 MRI Infusion Pump System is indicated for general hospital or clinical use by medical professionals whenever it is required to infuse patients with intravenous fluids where a large magnetic field could be present such as Magnetic Resonance Imaging (MRI). The MRidium 3870 MRI Infusion pump can also be used during transport within the clinical environment as part of the periprocedural care before or after the MRI exam. The MRidium 3870 MRI Infusion Pump can be used with up to a 3.0 Tesla MRI system when placed as close as clinically possible to the MR system, without being placed within the magnet's bore, up to a 15,000 Gauss magnetic field line.

The pump and infusion sets are designed to deliver saline and IV medication. The system is useful in the administration of fluids requiring precisely controlled infusion rates. The system can operate in primary, loading, bolus, or KVO delivery mode.

The dedicated Iradimed 1056, 1058, and 1059 Infusion Sets for the MRidium 3870 MRI Infusion Pump are intended for single patient use up to 6 hours.

The device is intended for Adult and Pediatric patients, including Neonates. Careful clinical considerations involving drug and dosing should always be applied especially with regard to neonatal subpopulations (i.e., low and extremely low birth weight).

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.

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 MRidium® 3870 MRI Infusion Pump System

SUBMITTER INFORMATION:

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

Contact Name: Mr. Daniel L. Bennett
Contact E-mail: dbennett@iradimed.com
Contact Phone: 407-677-8022 x143
Contact Fax: 407-677-5037

Date Prepared: April 22, 2025

DEVICE IDENTIFICATION:

Trade name: MRidium® 3870 MRI Infusion Pump System
Common name: Infusion Pump
Classification name: Pump, Infusion
Regulation number: 21 CFR 880.5725
Regulatory class: II
Product code: FRN

PRIMARY PREDICATE DEVICE TO WHICH EQUIVALENCE CLAIMED:

Predicate Device: MRidium 3860+ MRI Infusion Pump/Monitoring System
Manufacturer: Iradimed Corporation
510(k) #: K143369
Clearance date: 12/15/2016

DEVICE DESCRIPTION:

The MRidium 3870 MRI Infusion Pump System is indicated for general hospital or clinical use by medical professionals whenever it is required to infuse patients with intravenous fluids where a large magnetic field could be present such as Magnetic Resonance Imaging (MRI). The MRidium 3870 MRI Infusion Pump can also be used during transport within the clinical environment as part of the periprocedural care before or after the MRI exam. The MRidium 3870 MRI Infusion Pump can be used with up to a 3.0 Tesla MRI system allowing placement as close as physically possible to the MRI scanner without being placed within the magnet's bore, up to a 15,000 Gauss magnetic field line. The magnetic content of the Pump is such that there is no hazard of magnetic attraction, up to 3T (30,000 gauss).

The pump unit is designed with an integral single peristaltic pump channel utilizing an ultrasonic (non-magnetic) motor. The integral infusion set mounting channel is horizontally oriented in the front of the pump with position detection sensors and graphical user feedback to aid the user in the correct infusion set loading process. The main assembly of the pump unit contains the controls, display, power supply, battery, and processor/memory functions suitable to meet all system requirements.

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A remote display (3875) is also available as an option for independent viewing and control from the adjacent MRI Control Room area (Zone III).

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 with soft and hard limits for each drug. These Drug Library inputs can only be created or modified by the Iradimed in-house clinical team based on input and validation from the healthcare facility. Once programmed, the library is digitally signed requiring proper verification by a software 'key' within the 3870 MR IV pump upon loading. Loading of the drug library requires access to the Password protected Service Menu.

The Dose Error Reduction System (DERS) feature allows user-facilities to provide input to custom names, and doses, with hard and soft limits for use in the Drug Library. The Drug Library supports care area specific infusion protocols for primary, bolus, loading dose, and KVO delivery modes, retrievable by drug/protocol name. The library, as prescribed by the healthcare facility, is programmed with nominal starting values for: Dose, Concentration, and Time. Also, hard limits (maximum and minimum allowable) and soft limits (high and low limits that require a user confirmation to exceed) for Dose, Concentration, Time and Patient Weight can be programmed.

INTENDED USE / INDICATIONS FOR USE:

The Iradimed Corporation's MRidium 3870 MRI Infusion Pump System is indicated for general hospital or clinical use by medical professionals whenever it is required to infuse patients with intravenous fluids where a large magnetic field could be present such as Magnetic Resonance Imaging (MRI). The MRidium 3870 MRI Infusion pump can also be used during transport within the clinical environment as part of the periprocedural care before or after the MRI exam. The MRidium 3870 MRI Infusion Pump can be used with up to a 3.0 Tesla MRI system when placed as close as clinically possible to the MR system, without being placed within the magnet's bore, up to a 15,000 Gauss magnetic field line.

The pump and infusion sets are designed to deliver saline and IV medication. The system is useful in the administration of fluids requiring precisely controlled infusion rates. The system can operate in primary, loading, bolus, or KVO delivery mode.

The dedicated Iradimed 1056, 1058, and 1059 Infusion Sets for the MRidium 3870 MRI Infusion Pump are intended for single patient use up to 6 hours.

The device is intended for Adult and Pediatric patients, including Neonates. Careful clinical considerations involving drug and dosing should always be applied especially with regard to neonatal subpopulations (i.e., low and extremely low birth weight).

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.

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SUMMARY OF SUBSTANTIAL EQUIVALENCE COMPARISON WITH PREDICATE DEVICE:

A side-by-side comparison of the Intended Use and Technological Characteristics of the predicate device and proposed device is provided in Table-1, below, which includes a summary of the technological characteristics of the device compared to the predicate device and why any differences do not impact substantial equivalence.

Table-1:

Summary of the Technological Characteristics of the Device Compared to the Predicate Device			
Characteristic	**Proposed Device:** Iradimed Corporation's MRidium 3870 MRI Infusion Pump System (Pending 510(k))	**Predicate Device:** Iradimed Corporation's MRidium 3860+ MRI Infusion Pump System (K143369)	**Comparison**
1.1.1 Classification Information			
Common Name	MRI Infusion Pump System	MRI Infusion Pump System	Same
Classification Name	Pump, Infusion	Pump, Infusion	Same
Regulation	21 CFR 880.5725	21 CFR 880.5725	Same
Class	II	II	Same
Product Code	FRN	FRN	Same
High Level Device Description	Volumetric Infusion Pump for use in the MRI environment. Used to deliver fluids into a patient's body in a controlled manner.	Volumetric Infusion Pump for use in the MRI environment. Used to deliver fluids into a patient's body in a controlled manner.	Same

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1.1.2 Intended Use / Indications for Use			
Intended Use / Indications for Use	The Iradimed Corporation's MRidium 3870 MRI Infusion Pump System is indicated for general hospital or clinical use by medical professionals whenever it is required to infuse patients with intravenous fluids where a large magnetic field could be present such as Magnetic Resonance Imaging (MRI). The MRidium 3870 MRI Infusion pump can also be used during transport within the clinical environment as part of the periprocedural care before or after the MRI exam. The MRidium 3870 MRI Infusion Pump can be used with up to a 3.0 Tesla MRI system when placed as close as clinically possible to the MR system, without being placed within the magnet's bore, up to a 15,000 Gauss magnetic field line. The pump and infusion sets are designed to deliver saline and IV medication. The system is useful in the administration of fluids requiring precisely controlled infusion rates. The system can operate in primary, loading, bolus, or KVO delivery mode. The dedicated Iradimed 1056, 1058, and 1059 Infusion Sets for the MRidium 3870 MRI Infusion Pump are intended for single patient use up to 6 hours. The device is intended for Adult and Pediatric patients, including Neonates. Careful clinical considerations involving drug and dosing should always be applied especially with regards to neonatal and neonatal subpopulations (i.e.: low and extremely low birth weight). 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.	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.	**Different:** The proposed device is capable of safely operating up to 15,000 (1.5T) Gauss field line in up to a 3T (3 Tesla) MRI system, which is an improvement over the predicate device which operates at up to the 10,000 Gauss (1T) field line in MRI systems up to 3T. The proposed device is indicated for only intravenous routes of administration, whereas the predicate is indicated for subcutaneous, intra-venous or intra-arterial fluids routes of administration. The proposed device route of administration is subset of the predicate device routes of administration and is consistent with the predicate use. In addition to infusion therapy, the predicate device also provided a pulse oximeter for monitoring the SpO2 vital sign. The proposed device does not include an SpO2 monitoring function, only providing infusion therapy. It is not necessary for an infusion pump to provide vital sign monitoring, as this can be achieved with a patient monitoring system, such as Iradimed's multi-parameter 3880 MRI Patient Monitoring System.
Contraindications for Use	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.	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.	Same

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Summary of the Technological Characteristics of the Device Compared to the Predicate Device			
Characteristic	**Proposed Device:** Iradimed Corporation's MRidium 3870 MRI Infusion Pump System (Pending 510(k))	**Predicate Device:** Iradimed Corporation's MRidium 3860+ MRI Infusion Pump System (K143369)	**Comparison**
1.1.3 Operating Principle			
Operating Principle	Non-magnetic ultrasonic motor driven linear peristaltic pump drive mechanism facilitates positive movement of fluids through an infusion line in a controlled manner.	Non-magnetic ultrasonic motor driven linear peristaltic pump drive mechanism facilitates positive movement of fluids through an infusion line in a controlled manner.	**Same**
1.1.4 Configurations and Accessories			
Number of Infusion Channels	1	1 (up to 2 with optional 3861 SideCar Pump attachment)	**Different:** The proposed device is a single channel infusion pump, whereas the predicate device could be configured with an optional secondary infusion channel which shared the same programming controls as the primary infusion channel. The proposed device can be configured with up to four infusion channels on an IV pole mount, each with their own controls. The proposed device provides an improvement over the predicate device in that it eliminates the need to share the controls and display while operating two infusion channels. The differences in the configurations of the proposed device do not raise any new questions of safety or effectiveness and are substantially equivalent to the predicate device
Max Infusion Channels Per IV Pole	4	4	**Same**
Remote Display Provided	Yes, optional 3875	Yes, optional 3865	**Different:** The predicate device (3860+) had an optional remote (3865) that can display and control a single system with up to 2 infusion channels. It used a wireless radio to communicate from the MRI scan room (Zone IV) to the control area (Zone III). The subject device (MRidium 3870 MRI Infusion Pump) has an optional remote (3875 Remote) that can display and control up to 4 infusion pumps at the same time. It uses the same proprietary point to point wireless radio to communicate from the MRI scan room (Zone IV) to the control area (Zone III). To improve security, the wireless point to point radio used with the 3875 Remote utilizes encryption, whereas the predicate device was not encrypted. The differences in the proposed device do not raise any new questions of safety or effectiveness and therefore it is substantially equivalent to the predicate device.
Range of wireless Remote communications	From MRI exam scan room to MR control room	From MRI exam scan room to MR control room	**Same**
IV Set Compatibility	1000 Series IV Sets (Iradimed Proprietary Design)	1000 Series IV Sets (Iradimed Proprietary Design)	**Same**
Non-magnetic IV Pole Provided	Yes, optional	Yes, optional	**Same**

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Drug Library	Included Feature	Optional Feature	**Different:** The predicate device (3860+) had an optional drug library (DERS) available but also operated in a rate/volume mode if no drug was selected, or if the drug library DERS option was not purchased. The subject device (MRidium 3870 MRI Infusion Pump) will only operate with the built in DERS drug library. Like the predicate, the drug library will be configured by the healthcare facility, but will be programmed at Iradimed before verification by the facility. Since the DERS drug library is no longer an option, including it on each pump should improve overall safety of the device. Therefore, the differences in the proposed device do not raise new questions of safety or effectiveness, and it is substantially equivalent to the predicate device.
1.1.5 Vital Signs Monitored			
Vital Signs Monitored	N/A	SpO2	**Different:** In addition to infusion therapy, the predicate device also provided a pulse oximeter for monitoring the SpO2 vital sign. The proposed device does not include an SpO2 monitoring function, only providing infusion therapy. It is not necessary for an infusion pump to provide vital sign monitoring, as this can be achieved with a patient monitoring system, such as Iradimed's multi-parameter 3880 MRI Patient Monitoring System. The difference in the proposed device does not raise any questions of safety or effectiveness regarding infusion therapy and therefore it is substantially equivalent to the predicate device.
1.1.6 Target Population Specification			
Target Population	Patients undergoing MRI procedures: • Adult • Pediatric, including Neonates	Patients undergoing MRI procedures: • Adult • Pediatric, including Neonates	**Same**
1.1.7 MRI System Range Specifications			
MRI Scanner Types	0.2 to 3.0 Tesla MRI Systems	0.2 to 3.0 Tesla MRI Systems	**Same**
Pump MRI Conditions: B0 Field / Gauss-Line Limit, full operation	3870 IV Pump: ≤ 15,000 gauss	3860+ IV Pump: ≤ 10,000 gauss	**Different:** The proposed device is capable of safely operating up to 15,000 (1.5T) Gauss field line in up to a 3T (3 Tesla) MRI system, which is an improvement over the predicate device which operates at up to the 10,000 Gauss (1T) field line in MRI

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			systems up to 3T. Therefore, the difference in the MR conditions of use does not affect the safety or effectiveness of the device and are substantially equivalent to the predicate device.
Power Supply MRI Conditions: B0 Field / Gauss-Line Limit	1120-19 Power Supply < 1,000 gauss	1120 Power Supply < 1,000 gauss	**Same**
Remote Display MRI Conditions: B0 Field / Gauss-Line Limit	3875 Remote Display System: MR Unsafe	3865 Remote Display: MR Unsafe	**Same**
1.1.8 Hardware Specifications			
Enclosure Materials	EMI shielded (aluminum) plastic, non-magnetic stainless steel.	Cast aluminum, non-magnetic stainless steel, and plastics.	**Different:** The predicate device's enclosure is comprised of cast aluminum, non-magnetic stainless steel, and plastics, whereas the proposed device's enclosure is comprised of EMI shielded plastics (aluminum shielding) and non-magnetic stainless steel. The differences in enclosure materials in the proposed device reduces the overall weight of the system. The materials in the proposed device are compliant with IEC 60601-1 and have been tested and found to perform as intended in the MRI environment without issue. Therefore, the proposed device's enclosure materials are substantially equivalent to the predicate device's enclosure materials.
IV Pump Motor	Non-magnetic ultrasonic motor	Non-magnetic ultrasonic motor	**Same**
Peristaltic Pump Mechanism	Cam driven, plastic mechanism with 12 fingers to move fluid. 250uLof fluid delivered per rotation.	Cam driven, plastic mechanism with 12 fingers to move fluid. 300uL of fluid delivered per rotation.	**Different:** The predicate device is provided with an ultrasonic motor driven peristaltic pump that uses a cam to drive 12 plastic mechanical pump fingers. The pump delivers 300uL of fluid for each rotation of the cam. The proposed device uses this same ultrasonic motor to drive 12 plastic mechanical pump fingers that are slightly narrower in width. Because of the narrower width, the proposed device pump delivers 250uL of fluid for each rotation of the cam. The difference in fluid movement has been taken into consideration in the motor drive profile, tested to TIR101 for fluid delivery accuracy, and therefore the pumping hardware and performance is substantially equivalent to the predicate device.
Mounting Bracket	Removable, for attachment to wheeled or stationary non-magnetic IV pole stand	Permanently installed on enclosure, for attachment to wheeled or stationary non-magnetic IV pole stand	**Different:** The predicate device is provided with a permanently installed mounting bracket that is part of its enclosure, whereas the proposed device utilizes a mounting bracket which is independent and can be installed onto an IV pole by itself. The proposed device is attached simply by sliding onto the bracket which locks it in place, and can then be removed from the pump with the press of a button. The quick release from the bracket provides users with the ability to swap a pump onto a different IV pole more quickly than the process in the predicate device

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			which required unscrewing of the mounting bracket using its handle. The strength and rigidity of the mounting bracket of the proposed device has been tested to IEC 60601-1 and found to be safe and effective for use. Therefore, the mounting bracket of the proposed device is substantially equivalent to the mounting bracket of the predicate device.
Free-Flow Prevention	Free Flow Preventor Clamp activated upon insertion of IV set and/or opening of IV Pump Door after closing.	Free Flow Preventor Clamp activated upon insertion of IV set and/or opening of IV Pump Door after closing.	**Same**
User Interface	Hard Keys and Soft Keys (Touchscreen)	Hard Keys	**Different:** The predicate device's user interface is comprised of hard-keys that are used to control data on a monochrome LCD display, whereas the proposed device's UI is comprised of soft-keys (touchscreen) and hard-keys for specific functions (start/stop infusion, audio alarm pause, home and power). The proposed device's display is provided on a multi-color LCD display. The UI of the proposed device has been tested for Human Factors (HF) and Usability (U) per IEC 60601-1-6 and IEC 62366 and found to be safe, effective and user friendly as documented elsewhere in this submission. The Summative HF/U study showed no issues related to safety or effectiveness of the user interface. Therefore, the UI of the proposed device is substantially equivalent to the UI in the predicate device.
Display	Liquid Crystal Touchscreen Display (LCD), Multi-Color	Liquid Crystal Display (LCD), monochrome	**Different:** The predicate device's information is provided on a monochrome LCD display, whereas the proposed device's display is provided on a multi-color LCD display. The ability in the proposed device to use multiple colors is an improvement over the monochrome display. The LCD display of the proposed device has been tested for Human Factors (HF) and Usability (U) per IEC 60601-1-6 and IEC 62366 and found to be safe, effective and user friendly as documented elsewhere in this submission. The Summative HF/U study showed no issues related to safety or effectiveness of the multi-color LCD display. Therefore, the display in the proposed device is substantially equivalent to the display in the predicate device.
Power Supply	1120-19 External power supply connected to AC mains power or lithium polymer internal battery power	1120 External power supply connected to AC mains power or lithium polymer internal battery power	**Different:** The predicate device's power supply (1120) can supply power to pumping channels, whereas the proposed device's power supply (1120-19) has enough power to supply power to up to 4 pumps at the same time. It also has a second connector output so that it could supply power to an Iradimed 3880 Patient Monitor at the same time as the infusion pumps. The addition of a second power output connector with the increase in power output has passed IEC 60601-1 testing and does not change how it is used. Therefore, the 1120-19 power supply in the proposed device is substantially equivalent to the 1120 power supply in the predicate device.
Alarm Light	Multi-color LED (Green, Red, Amber), 360° viewable	Dual-color LED (Green or Red), 180° viewable	**Different:** The predicate device's alarm light is a dual-color LED (red or green) which is viewable from 180-degrees (clinician must be on the same side as the LCD

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			display), whereas the proposed device's alarm light is a multi-color LED (red, green or amber) which is viewable from 360-degrees (clinician can see from all sides of the pump). The addition of a third color in the alarm light of the proposed device allows for a distinction between high priority alarms (red flashing light), medium priority alarms (amber flashing light), low priority alarms (amber static light), and infusion running (green flashing light). By adding an additional color, it allows for better alarm management than the predicate device. Additionally, the proposed device's 360-degree viewable alarm light ensures the clinician can see the alarm status even if not positioned in front of the pump, which is compliant with the IEC 60601-1-8 standard. Therefore, the alarm light in the proposed device is substantially equivalent to the alarm light in the predicate device.
Audio	Non-magnetic Piezo Speaker	Non-magnetic Piezo Speaker	**Same**
Dimensions	8.25 x 8.5 x 3.2 Inches (21 x 21.6 x 8.1 cm)	6 x 8 x 9.5 Inches (15.25 x 20.3 x 22.9 cm)	**Different:** The predicate device's dimensions are 6"x8"x9.5", whereas the proposed devices dimensions are 8.25"x8.5"x3.2". The difference in dimensions is due to the design of the proposed device being more compact from a height standpoint, allowing the units to stack on an IV pole while having their own display and controls. The differences in dimensions do not raise any questions of safety or effectiveness as both the predicate device and proposed device meet their performance requirements. Therefore, the proposed device's dimensions are substantially equivalent to the predicate device's dimensions.
Weight	6 LBS (2.7 kg) with Battery.	11.5 LBS (5.2 kg) with Battery.	**Different:** The predicate device weighs 11.5 lbs. with its battery installed, whereas the proposed device weighs approximately 6 lbs. with its battery installed. The difference in weight is primarily a result of the different materials used in their enclosures. The lighter weight materials are compliant with IEC 60601-1 and have been tested and found to perform as intended in the MRI environment without issue. Therefore, the proposed device's weight is substantially equivalent to the predicate device's weight.
Remote Display (optional)	Remote monitoring and control provided via the 3875 Remote Display.	Remote monitoring and control provided via the 3865 Remote Display.	**Different:** The predicate device's remote display (Part #: 3865) mirrors the display and controls of the predicate device and is comprised of plastics, a monochrome LCD, and ferrous materials. The proposed device's remote display (Part #: 3875) mirrors the display and controls of the MRidium 3870 MRI Infusion Pump and is comprised of plastic, a 10" multi-color LCD and non-ferrous materials and is intended for the MRI control area of the MRI (Zone III) and labeled MR UNSAFE just as the predicate 3865 is. Therefore, the differences in the Remote Display hardware do not affect the safety or effectiveness of the device and are substantially equivalent to the predicate device.

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1.1.9 Power Specifications			
Operating Voltage Range	100 – 240 VAC, ± 10 percent	100 – 240 VAC, ± 10 percent	**Same**
Frequency Range	50 – 60 Hz, single phase	50 – 60 Hz, single phase	**Same**
Power Consumption, Maximum	<36 watts maximum during charging	<36 watts maximum during charging	**Same**
Electrical Safety Classification	Class I, Type CF Defibrillator Proof	Class I, Type CF Defibrillator Proof	**Same**
Leakage Current, Chassis	< 100 uA RMS; < 500 uA RMS (Single Fault)	< 100 uA RMS; < 300 uA RMS (Single Fault)	**Different:** The predicate device specifies chassis leakage current of < 100 uA rms; < 300 uA rms (Single Fault), whereas the proposed device specifies chassis leakage current of < 100 uA rms; < 500 uA rms (Single Fault). The difference in chassis leakage current specification meets the requirements of IEC 60601-1 and does not raise any new questions of safety or effectiveness. Therefore, the proposed device is substantially equivalent to the predicate device.
Leakage Current, Patient	< 10 uA RMS; < 50 uA RMS (Single Fault)	< 10 uA RMS	**Different:** The predicate device specifies patient leakage current of < 10 uA rms, whereas the proposed devices specifies patient leakage current of < 10 uA rms; < 50 uA rms (Single Fault). The difference in patient leakage current specification is that the predicate did not identify the single fault limit in its labeling. The labeling in the proposed devices meets the requirements of IEC 60601-1 for TYPE CF devices and does not raise any new questions of safety or effectiveness. Therefore, the proposed device is substantially equivalent to the predicate device.
Pump Battery Type and Capacity	Rechargeable Lithium Polymer Pack, 14.8 V at 4.8 Ah	Rechargeable Lithium Polymer Pack, 14.8 V at 5.8 Ah	**Different:** The predicate device specifies Pump Battery Type and Capacity as Rechargeable Lithium Polymer Pack, 14.8 V at 5.8 Ah, whereas the proposed device specifies Pump Battery Type and Capacity as Rechargeable Lithium Polymer Pack, 14.8 V at 4.8 Ah. There is no difference in the type (rechargeable lithium polymer), only in the capacity. The predicate device could be supplying power to two infusion channels at the same time, while the proposed device has only a single channel per battery. The difference in battery capacity is provided in the labeling and does not raise any new questions of safety or effectiveness. Therefore, the proposed device is substantially equivalent to the predicate device.
Pump Battery Operating Time	> 8 Hours at 125 mL/hr Rate	> 12 Hours at 125 mL/hr Rate	**Different:** The predicate device specifies Pump Battery Operating Time of >12 Hours at 125 mL/hr Rate, whereas the proposed device specifies Pump Battery Operating Time of > 8 Hours at 125 mL/hr Rate. The Pump Battery Operating Time is provided in the labeling and does not raise any new questions of safety or

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			effectiveness as the battery has enough capacity. The system can also be operated while AC power is plugged in if the battery were to run low. Like the predicate device, the proposed device also provides alarms when "low" battery conditions exist. Therefore, the proposed device is substantially equivalent to the predicate device.
Pump Battery Charge Time	< 5 hours to 95% capacity	< 9 hours to 95% capacity	**Different:** The predicate device specifies Pump Battery Charge Time of < 9 hours to 95% capacity, whereas the proposed device specifies Pump Battery Charge Time of < 5 hours to 95% capacity. The Pump Battery Charge Time is provided in the labeling and does not raise any new questions of safety or effectiveness as the battery of the proposed device can charge to 95% capacity in 4 hours less than the predicate device. Therefore, the proposed device is substantially equivalent to the predicate device.
Remote Display Battery Type and Capacity	N/A- AC Power Only	N/A- AC Power Only	**Same**
1.1.10 Environmental Specifications			
Operating Temperature Range	+15° to +30° C (+59° to +86° F)	+5° to +40° C (+50° to +104° F)	**Different:** The Operating Temperature Range for the predicate device is +5°C to +40°C (+41°F to +104°F), but the proposed device Operating Temperature Range is +15°C to +30°C (+59°F to +86°F). This slight increase in the low limit of Operating Temperature Range and decrease in top limit of Operating Temperature Range does not affect its clinical use because a typical MRI suite is above 15°C and below 30°C. The difference in Operating Temperature Range of the proposed device does not raise questions of safety and effectiveness and is substantially equivalent to the predicate device.
Operating Relative Humidity Range	30% to 80% RH, non-condensing	0% to 80% RH, non-condensing	**Different:** The predicate device specifies an operating relative humidity (RH) range of 0% to 80% RH, whereas the proposed device specifies an operating relative humidity range of 30% to 80% RH. Both devices are used in the hospital or clinical environment which control their humidity to reduce growth of bacteria. The RH range of the proposed device does not raise questions of safety and effectiveness and is substantially equivalent to the predicate device.
Operating Altitude Range	Sea level to 3000 meters	N/A-Not Specified	**Different:** The predicate device's operating altitude range is not specified, whereas the proposed device specifies up to 3,000 m (9,750 ft). Providing the user with the operating altitude of the system is an improvement in labeling and does not raise questions of safety and effectiveness and is substantially equivalent to the predicate device.

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Short Term Storage and Transport Relative Humidity Range (during shipping)	10% to 90%, non-condensing	0% to 95% RH, non-condensing	**Different:** The predicate device specifies a storage and transport relative humidity range of 0% to 95% RH, whereas the proposed device specifies a range of 10% to 90% RH. Both devices recommend storage in a non-condensing humidity environment. The difference in RH range of the proposed device does not raise questions of safety and effectiveness and is substantially equivalent to the predicate device.
Long Term Storage and Transport Relative Humidity Range (up to 12 months)	45% to 75%, non-condensing	0% to 95% RH, non-condensing	**Different:** The predicate device specifies a storage and transport relative humidity range of 0% to 95% RH, whereas the proposed device specifies a range of 45% to 75% RH. Both devices recommend storage in a non-condensing humidity environment. The difference in RH range of the proposed device does not raise questions of safety and effectiveness and is substantially equivalent to the predicate device.
Short Term Storage and Transport Temperature Range (up to 7 days)	-20° to +60° C (-4° to +140° F)	-40° to +70° C (-40° to +158° F)	**Different:** The predicate device specifies a storage and transport temperature range of -40° to + 70° C (-40° to +158° F), whereas the proposed device specifies a short-term storage range of -20° to +60° C (-4° to +140° F). The difference in storage temperature range of the proposed device does not raise questions of safety and effectiveness and is substantially equivalent to the predicate device.
Long Term Storage and Transport Temperature Range (up to 12 months)	+18° to +28° C (+64.4° to +82.4° F)	-40° to +70° C (-40° to +158° F)	**Different:** The predicate device specifies a storage and transport temperature range of -40° to +70° C (-40° to +158° F), whereas the proposed device specifies a long-term storage range of +18° to +28° C (+64.4° to +82.4° F). It is not expected that the device will be stored for an extended period of time outside of some sort of environmental controls. Therefore, the difference in long term storage temperature range of the proposed device does not raise questions of safety and effectiveness and is substantially equivalent to the predicate device.
Storage and Transport Altitude Range	Sea level to 5000 meters	N/A-Not Specified	**Different:** The predicate device's storage and transport altitude range is not specified, whereas the proposed device specifies up to 5,000 m (16,250 ft.). Providing the user with the storage and transport altitude of the system is an improvement in labeling and does not raise questions of safety and effectiveness and is substantially equivalent to the predicate device.
Ingress Protection	IPX2	IPX1	**Different:** The predicate has an ingress protection rating of IPX1, whereas the proposed device has an ingress protection rating of IPX2. The higher rating is an improvement in ingress protection when compared to the predicate device. The increased rating does not raise questions of safety and effectiveness and is substantially equivalent to the predicate device.

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1.1.11 Wireless Communication Specifications			
Wireless Communication	Point to point, wireless Communication between IV Pump and Remote Display is achieved via wireless 2.4 GHz radio.	Point to point wireless Communication between IV Pump and Remote Display is achieved via wireless 2.4 GHz radio.	**Same**
Wireless Channels Available	8	6	**Different:** The predicate device offers up to 6 wireless channels, whereas the proposed device offers up to 8 wireless channels. The addition of the two channels increases the number of systems which can be used in the same area and reduces the likelihood that systems will be on the same channel. The increase in channels has been tested and verified to function without issue. Therefore, the difference in the Wireless Communication Specifications do not affect the safety or effectiveness of the device and are substantially equivalent to the predicate device.
Wireless Encryption	Encrypted for security	None	**Different:** The predicate device did not encrypt wireless communication, whereas the proposed device utilizes encryption for all pump and remote communication. Providing the user with encryption improves cybersecurity does not raise questions of safety and effectiveness and is substantially equivalent to the predicate device.
1.1.12 Performance Specifications and Features			
Flow Rate Range	0.4 to 1000 mL/hr in 0.1 mL/hr increments	0.1 to 1400 mL/hr	**Different:** The predicate device has a flow rate range of 0.1 mL/hr to 1,400 mL/hr, whereas the proposed device has a flow rate range of 0.4 mL/hr to 1,000 mL/hr. The change in flow rates does not affect the ability of the device to perform its intended use. Therefore, the proposed device is substantially equivalent to the predicate device for its intended use.
Flow Rate Accuracy	+/- 5% 1.0 mL/hr to 1000 mL/hr +/- 10% 0.4 ml/hr to <1.0 mL/hr (during the 6 hour Infusion Set life)	+/- 5% 1.0 mL/hr to 1400 mL/hr +/- 10% 0.1 ml/hr to <1.0 mL/hr (during the 6 hour Infusion Set life)	**Same**
Primary Volume to Be Infused (VTBI) Range	0.1 to 1000 mL	0.1 to 999 mL	**Different:** The predicate device has a VTBI range of 0.1 mL to 999 mL, whereas the proposed device has a VTBI rate range of 0.1 mL to 1,000 mL. The change in VTBI does not affect the ability of the device to perform its intended use. The difference of 999mL to 1000mL is inconsequential for the intended use of the device. Therefore, the proposed device is substantially equivalent to the predicate device.
Total Volume Infused (VI) Range	0.1 to 99999 mL	0.1 to 9999 mL	**Different:**

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			The predicate device has a Total Volume Infused Range of 0.1 mL to 9999 mL, whereas the proposed device has a flow rate range of 0.1 mL to 99999 mL. The change in Total Volume Infused does not affect the ability of the device to perform its intended use. Therefore, the proposed device is substantially equivalent to the predicate device.
Keep Vein Open (KVO) Rate Range	Programmed in Drug Library – OFF, Rate, Continue Primary	adjustable, 1 to 5 mL/hr, or OFF	**Different:** The predicate device has a KVO rate range that is adjustable from 1 mL/hr to 5 mL/hr, or OFF, whereas the proposed device has a KVO rate range that is programmed in the drug library at OFF, Continue Primary, or Rate. The rate can be set from 0.4 mL/hr to 20 mL/hr, The ability to set the KVO rate on the proposed device is intended to give the user more flexibility across its intended population based on each individual drug programmed in the drug library. Therefore, the proposed device is substantially equivalent to the predicate device.
Patient Line (downstream) Back-Pressure Range	+300 to -100 mmHg	+300 to -100 mmHg	**Same**
Downstream Occlusion Detection Range	1 to 10 PSI (6.9 to 68.8 kPa), user-adjustable	1 to 10 PSI (6.9 to 68.8 kPa), user-adjustable	**Same**
Occlusion Detection Mechanism	Two separate (upstream & downstream) semiconductor force sensors	Two separate (upstream & downstream) semiconductor force sensors	**Same**
Occlusion Detection (no flow) Time	Variable depending on IV Set, Flow Rate, and Occlusion Pressure Alarm Limit Setting. See "TIME TO DETECT PATIENT OCCLUSION" Table in section 25.9.1 of Operation Manual (REF 1234)	typically <30 sec, dependent on selected Flow Rate, 55 min max. @ 1 mL/hr	**Different:** The Occlusion Detection (no flow) Time labeling in the proposed device has been improved to provide users with more information of time-to-detect patient occlusions at varying flow rates, infusion sets (macrobore vs microbore), and pressure threshold alarm settings (the table is provided operation manual). Whereas the predicate provides labeling of "typically <30 sec, dependent on selected Flow Rate, 55 min max. @ 1 mL/hr." The specification clarification does not affect safety or effectiveness of the proposed device and provides useful information to the clinician.
Maximum Post-Occlusion Bolus Volume	0.7 mL max	0.7 mL max	**Same**
Air-in-Line Detection Method	Ultrasonic bubble detector	Ultrasonic bubble detector	**Same**
Air-in-Line Detector Threshold(s)	> 100 uL (+20%)	> 100 uL (+20%)	**Same**
Fluid Container Source Height Limits	+60 to -60 cm (+24 to -24 in) relative to pump center	+60 to -60 cm (+24 to -24 in) relative to pump center	**Same**
Audible Alarm Range Pump (at 1 Meter)	Minimum: 65 dBA Maximum: > 85 dBA @1 meter	Minimum: 65 dBA Maximum: > 85 dBA @ 1 Meter	**Same**

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User Event Log	Non-volatile memory retains each operating step and alarm - up to 5000 entries	Non-volatile memory retains each operating step and alarm - up to 5000 entries	**Same**
1.1.13 Alarms			
Alarms	Possible Free Flow Alarm Pump Failure Alarm Door Opened Alarm Bubble Detection Fault Alarm Bubble Detection Alarm Downstream (Patient) Occlusion Alarm Upstream (Inlet) Occlusion Alarm Low Battery Alarm Dead Battery Alarm Pump Key Stuck Alarm Depleted Battery Alarm AC Power Required Alarm Depleting Battery Alarm Defective Battery Alarm No Battery Detected Alarm Exceeded Battery Life Alarm Infusion Complete Alarm KVO Started Alarm End of Infusion Alarm Cannot Start - Service Required Alarm Cannot Start - IV Set Alarm Cannot Start - Cycle Door Alarm Cannot Start - Door Open Alarm Cannot Start - Dosing Parameters Alarm Cannot Start - Wrong Screen Alarm Patient Identifier Conflict Alarm No Action Alarm IV Set Expired Alarm Near End of Infusion Alarm IV Set Expiring Soon Alarm Battery Life Exceeded Alarm Software Mismatch Alarm Wrong Link Password Alarm Speaker Fault Alarm Battery Near End-of-Life Alarm VI Cleared Alarm Communication Lost (Remote Only)	Air-in-line Battery low Battery depleted Bolus complete Infusion complete Infusion not started Occlusion (upstream or downstream) Dose limits exceeded Service Error Code Communication Loss (Remote Only) KVO Alert	**Different**: Although some of the alarms have different names, all of the predicate Alarms are still represented in the proposed device. There are also additional new state-of-the-art alarms intended to increase awareness and reduce errors. The Alarms provided in the proposed device do not introduce new questions of safety or effectiveness and are substantially equivalent to the predicate device.

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SUMMARY OF PERFORMANCE TESTING (NON-CLINICAL):

To demonstrate substantial equivalence between the subject and predicate device the following non-clinical tests were performed:

1) Safety Assurance Case
2) Verification Testing of Product Requirements
3) Human Factors Validation Testing
4) MRI Environment Conditions of Use Testing

1) Safety Assurance Case: A safety assurance case for the MRidium 3870 Infusion Pump System was provided in accordance with the FDA Guidance document, *Infusion Pumps Total Product Life Cycle issued December 2, 2014*. The stated purpose of the safety assurance case is: "The MRidium 3870 Infusion Pump System is safe for its intended use".

The Safety Assurance Case is used to make a convincing argument, together with supporting evidence, that the 3870 System is adequately safe for its intended use. The top-level argument is supported by three lower-level claims that argue –

1) The residual risk of using the 3870 System is acceptable.
2) The 3870 System meets clinically valid essential performance specifications.
3) The 3870 System's design is reliable.

Evidence is referenced within the assurance case to demonstrate that the subject device is verified and validated for its intended use and to demonstrate substantial equivalence to the predicate device.

2) Verification Testing of Product Requirements: Verification testing of product requirements is provided for the following:

1) Verification of flow rate accuracy per AAMI TIR101
2) Essential Performance Testing
3) Reliability Testing
4) Air-in-line Performance Testing
5) Occlusion Performance Testing
6) Alarms Testing
7) Software Verification and Validation Testing
8) Cybersecurity Testing
9) Battery Testing
10) EMC/EMI Testing
11) Environmental Storage and Operating Conditions Testing
12) Shock and Vibration Testing
13) Electrical Safety Testing
14) Mechanical Testing
15) Biocompatibility Testing
16) Ingress Protection Testing

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17) Wireless Co-existence Testing
18) Standards Testing (IEC 60601 Series Certification (IEC 60601-1, IEC 60601-1-8, IEC 60601-1-6, IEC 62304, IEC 62366-1)

3) Human Factors Validation Testing: Iradimed Corporation's MRidium 3870 MRI Infusion Pump System complies with the applicable FDA Recognized Consensus Standards.

1) AAMI/ANSI HE75, Human factors engineering – Design of medical devices
2) ANSI/AAMI/IEC 62366, Medical devices – Application of usability engineering to medical devices
3) ANSI/AAMI/ISO 14971, Medical devices – Application of risk management to medical devices
4) IEC 60601-1-6, Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
5) IEC 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

4) MRI Environment Conditions of Use Testing: Iradimed Corporation's MRidium 3870 MRI Infusion Pump System was tested in its environment of use to ensure that it is safe and effective while operating in the MRI environment, including during MRI scanning sequences. Testing performed in the MRI environment included:

1) Magnetic Displacement Force, Static Spatial Gradients and Torque Verification
2) Spurious Emissions Verification (Image Artifact)
3) Verification of Essential Performance During MRI Scans
    - Flow Accuracy
    - Alarms
    - Unintended Bolus
    - Wireless Communication

Evidence of conformity with the MRI Environment Conditions of Use can be found in the bench testing section of this Submission and confirms that the 3870 System is as safe, as effective, and performs as well as or better than the predicate device.

CONCLUSION AND STATEMENT OF SUBSTANTIAL EQUIVALENCE:

The performance testing demonstrates that Iradimed Corporation's MRidium 3870 MRI Infusion Pump System described in this submission is substantially equivalent to the predicate device (K143369) MRidium 3860+ MRI Infusion Pump / Monitoring System.