K081087

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510(k) Summary of Safety and Effectiveness

Submitter Information:

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Contact: **Mr. Francis Casey**

APR - 7 2009

Date Prepared: January 5, 2009

Product Name:

Proprietary: MRidium 3860 MRI Infusion Pump/Monitoring System
Common: Infusion Pump and Infusion Sets, and Pulse Oximeter.
Classification: Class II (see 21 CFR - 870.5725 and 870.2700).

Predicate Devices:

The predicate device(s) are: MRidium 3850 Infusion Pump System (K050301); Nonin 7500FO Pulse Oximeter; the Medrad Continuum Infusion Pump System (510(k) numbers K032771, K021988, and K061128); Alaris PC-1 Infusion Pump System (510(k) number K012383); the CME Bodyguard 323 Infusion Pump with Pulse Oximeter (K060479); The MRidium 3860 Infusion Pump System is substantially equivalent to these predicate devices.

Device Description:

The MRidium 3860 MRI Infusion Pump/Monitoring System is an MRI compatible IV pump intended for use within the MR Scan room. The device shall operate to full specification in magnetic fields of up to 10,000 gauss and have RF emissions at the Larmor frequencies up to and including 3.0 Tesla MR scanners 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 minimal so as to avoid any 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, and 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 peristalitic pump channel which is controlled through the main pump assembly's display and controls. A remote display is also available for independent viewing and control from the adjacent MRI Control areas.

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

Additionally, the Dose Rate Calculator feature with the Drug Library option, allows the user to choose a patient's infusion protocol using user selected parameters, including volume to be infused, dose, concentration, weight, and/or time. The Drug Library includes common medications most frequently infused during MRI procedures. This Drug Library option feature can only be activated with a service-related, limited user access menu.

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. Testing was performed in MR conditional environments at 1.5T and 3T. 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 safely be placed on the patient's finger while inside an MR (magnetic resonance) environment.

Intended Uses:

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 intra-venous or intra-arterial fluids before, during, or after Magnetic Resonance Imaging (MRI) scans, functioning while either in a stationary or mobile position. 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.

Technological Comparison to Predicate Device(s):

The Iradimed Corporation MRidium 3860 MRI Infusion Pump/Monitoring System uses similar types of technology that are found in the predicate devices listed above, and are enumerated in Attachment 3 of this document.

A comparison of the technological characteristics of the MRidium 3860 MRI Infusion Pump/Monitoring System and the predicate device has been performed. The results of this comparison demonstrate that the MRidium 3860 MRI Infusion Pump/Monitoring System is equivalent in technological characteristics and the fundamental scientific technology of the predicate device.

Summary of Performance Testing:

The Iradimed Corporation's MRidium 3860 MRI Infusion Pump/Monitoring System conforms with national and available international product safety standards for medical device general safety, infusion therapy, pulse oximetry, electrical safety, and electromagnetic compatibility.

Functional and Safety Testing: The 3860 MRI Infusion Pump/Monitoring System has successfully undergone testing in order to demonstrate that it has appropriate functional features and is substantially equivalent to the predicate devices. Additionally, the pulse oximeter feature and fiberoptic sensor components of the 3860 System have successfully undergone both bench and clinical testing in order to demonstrate that it has appropriate functional features needed to demonstrate the safety and effectiveness of the system.

The conclusions drawn from these nonclinical tests demonstrate that the device is safe and effective, and performs as well or better that the predicate device.

Tests demonstrating consideration and mitigation of the identified potential hazards for this device have been completed, along with the design reviews, product verification and validation testing performed prior to product release.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Iradimed Corporation
C/o Mr. Robert Mosenkis
President
CITECH
5200 Butler Pike
Plymouth Meeting, Pennsylvania 19462

APR - 7 2009

Re: K090087
Trade/Device Name: Iradimed Corporation MRidium 3860 series MRI Infusion Pump/Monitoring System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: March 25, 2009
Received: March 26, 2009

Dear Mr. Mosenkis:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K090087

Indications for Use

510(k) Number (if known): K090087

Device Name: Iradimed Corporation MRidium 3860 series MRI Infusion Pump/Monitoring System

Indications For Use: The MRidium 3860 Series MRI Infusion Pump/Monitoring System indications for use are as follows:

Intended Uses:

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. 4.
- 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.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K090087