K050301

MAR 2 4 2005

(1 of 3)

510(k) Summary of Safety and Effectiveness

Submitter Information:

Iradimed Corporation
7457 Aloma Ave.
Suite 201
Winter Park, FL 32792

Phone: 407-677-8020
Fax: 407-677-5037
Contact: **Mr. Francis Casey**

Date Prepared: January 31, 2005

Product Name:

Trade Name:	MRidium™ 3850 Infusion Pump System
Common Name:	Infusion Pump and Infusion Sets.
Classification Name & Class:	Infusion Pump - Class II (see 21 CFR - 880.5725).

Predicate Devices:

The predicate device(s) are: the Medrad Continuum Infusion Pump System (510(k) numbers K032771 and K021988); Alaris PC-1 Infusion Pump System (510(k) number K012383); and their respective infusion sets. These predicate devices have similar performance specifications as the MRidium 3850 Infusion Pump System.

Device Description:

The MRidium 3850 MRI Infusion Pump 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 the 10,000 gauss-line of a 3.0 Tesla MR Scanner, 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 peristaltic pump channel which is controlled through the main pump assembly's display and controls.

The MRidium 1000 Series Infusion Sets utilize medical-grade PVC tubing with a medical-grade silicone rubber pumping segment that fits into a custom housing within the Pump. These Infusion Sets also contain the necessary flow stop/prevention devices,

needle-free access ports, and fluid bottle/bag insertion devices required for safe and effective fluid delivery.

Intended Uses:

The Iradimed Corporation's MRIDIUM 3850 Infusion Pump 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.

Technological Comparison to Predicate Device(s):

The MRidium™ 3850 MRI Infusion Pump System (including the MRidium 1000 Series Infusion Sets) is functionally identical and substantially equivalent to the Medrad Continuum MRI-Compatible System and Alaris PC-1 Infusion System (and their respective infusion sets) which are currently being marketed.

They are functionally equivalent in the following areas:

1. Patient Infusion Sets
2. AC/Battery Power Systems
3. Pump Drive and Control System
4. Air Bubble Detection System
5. Fluid Overpressure Limit System
6. Alarm Detection System
7. Keypad/ Information Display System
8. Communication System

The only notable difference in the technology is the use of a piezo-electric/ultrasonic motor, which is functionally identical to the commonly-used drive motors, but possesses inherent MRI-compatibility due to its immunity to the influence of magnetic fields.

The Iradimed Corporation MRIDIUM 3850 Infusion Pump System uses similar types of technology that are found in the predicate devices listed above. A detailed comparison of these similarities and differences has been performed, and demonstrates equivalence with the predicate devices.

Summary of Performance Testing:

The Iradimed Corporation's MRIDIUM 3850 Infusion Pump System (including the MRidium 1000 Series Infusion Sets) conforms with national and available international product safety standards for infusion therapy, electrical safety, and electromagnetic compatibility. Non-clinical testing has been performed using these standards to establish the device's performance. These include: IEC 60601-1-1; IEC60601-1-2; AAMI/ANSI ID26 (1998); IEC 60601-2-24; and UL2601.

The results of these non-clinical tests allow Iradimed Corporation to conclude that the MRidium™ 3850 MRI Infusion Pump System is substantially equivalent to the Medrad Continuum MRI-Compatible System and Alaris PC-1 Infusion System which are currently being marketed, and that they are as safe and effective as these devices in providing infusion therapy.

K045301 (P3 of P3)

Additionally, 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

MAR 2 4 2005

Iradimed Corporation
C/O Mr. Robert Mosenkis
Responsible Third Party Official
CITECH
5200 Butler Pike
Plymouth Meeting, Pennsylvania 19462-1298

Re: K050301
Trade/Device Name: MRidium 3850 Series MRI Infusion Pump
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: February 7, 2005
Received: February 8, 2005

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K954341

Indications for Use

510(k) Number (if known): Unknown

Device Name: ***Iradimed Corporation MRidium 3850 series MRI Infusion Pump***

Indications For Use:

The Iradimed Corporation's MRIDIUM 3850 Infusion Pump 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. The specific MRidium 3850 Series MRI Infusion Pump System (including the MRidium 1000 Series of Infusion Sets) indications for use are as follows:

1. Useful in the administration of fluids requiring precisely controlled infusion rates including blood or blood products, lipids, drugs, antibiotics, enteral solutions and other therapeutic fluids.
2. Useful in the following delivery routes: arterial, intravenous, spinal, subcutaneous, and enteral.
3. Useful in the following delivery modes: continuous, intermittent and bolus.
4. Although specifically intended for use in the MRI, this product can be useful in critical care, anesthesia, neonatal and pediatric applications or other healthcare settings where the use of the volumetric infusion pump can be monitored or supervised by a clinician.
5. Used inside the MRI room mounted outside the 10,000 Gauss line and with shielded magnets of field strength of 3.0 Tesla or less.

The MRidium 1000 Series Infusion Sets are intended as accessories to the MRidium 3850 MRI Infusion Pump, and are used in the administration of fluids for precisely controlled infusion rates.

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____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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) K954341