K073051

510(k) Summary of Safety and Effectiveness

DATE PREPARED: October 26, 2007

MAY 30 2008

NAME OF SUBMITTER:
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PROPRIETARY NAME: MEDRAD Continuum MR Infusion System with Wireless Remote Accessory

CLASSIFICATION NAME: Infusion Pump – Class II (see 21 CFR 880.5725)

COMMON NAME: Peristaltic Pump

PRODUCT CODE: FRN

PREDICATE DEVICES: K061128, MEDRAD Continuum MR Compatible Infusion System (3T Proximity)

K050301, Iradimed MRidium 3850 MRI Infusion Pump System

INDICATIONS FOR USE: The MEDRAD Continuum MR Infusion System with Wireless Remote Accessory is designed for patients who require medications and other fluids during an MR procedure. It is intended to provide infusion therapy directly prior to, during and immediately after the MR procedure functioning while either stationary or mobile. It is not intended to provide long-term patient care outside the MR environment. The system is to be used by trained medical staff, primarily critical care, emergency room and radiology nursing staff.

DEVICE DESCRIPTION AND COMPARISON TO PREDICATE DEVICES

The MEDRAD Continuum MR Infusion System with Wireless Remote Accessory is a modification of the MEDRAD Continuum MR Compatible Infusion System (3T Proximity) predicate device described in 510(k) submission K061128. Similar to the MEDRAD predicate device, the system is designed for patients requiring medications and other fluids during an MR imaging procedure. Both are designed for use in MR environments up to the 2000 Gauss line in magnet strengths up to and including 3T and are not intended to provide long-term patient care. Both systems connect to the existing patient administration line by the addition of a proprietary disposable and replace the bedside pump during the MR procedure. The proposed device and the predicate device are intended to be used by trained healthcare professionals, medical physicians, and critical care, emergency room, and radiology nursing staff. Neither is intended for the delivery of blood, blood products or nitroglycerine.

The Continuum MR Infusion System with Wireless Remote Accessory maintains the same intended use, similar operational parameters, and similar labeling (with the addition of a remote display specific operation manual) as the predicate device. The proposed device is used in a similar manner as both of the predicate devices described in the submission.

The MEDRAD Continuum MR Infusion System included in the proposed device has a similar design, similar materials of construction, similar components and similar infusion pump technology as the MEDRAD Continuum MR Compatible Infusion System (3T Proximity) predicate device. The primary difference between the two MEDRAD devices is the addition of the remote accessory and wireless radio technology. However, the proposed device and the Iradimed MRidium 3850 MRI Infusion Pump System with 3855 Optional Wireless Remote Control described in 510(k) submission K050301 have a similar intended use, similar wireless radio technology, and similar remote control functionality.

A tabular comparison of features and principles of operation for the MEDRAD Continuum MR Compatible Infusion System (3T Proximity) (Predicate) and MEDRAD Continuum MR Infusion System with Wireless Remote Accessory (Proposed) is contained in Table 2.

Table 2 Comparison of the MEDRAD Continuum MR Compatible Infusion System (3T Proximity) (Predicate) and MEDRAD Continuum MR Infusion System with Wireless Remote Accessory (Proposed)

PARAMETER	**PREDICATE DEVICE** Continuum MR Compatible Infusion System – (3.0T Proximity) - K061128	**PROPOSED DEVICE** MEDRAD Continuum MR Infusion System with Wireless Remote Accessory
Classification	CF	Same
Administration sets	Sterile, proprietary, single-use, standard PVC, free-flow protection	Same
Intended Use	The MEDRAD Continuum MR Compatible Infusion System (3T Proximity) is designed for patients who require maintenance medications and fluids during an MR procedure. It is intended to provide infusion therapy directly prior to, during and immediately after the MR procedure functioning while either stationary or mobile. It is not intended to provide long-term patient care outside the MR environment. The system is to be used by trained medical staff, primarily critical care, emergency room and radiology nursing staff.	The MEDRAD Continuum MR Infusion System with Wireless Remote Accessory is designed for patients who require medications and other fluids during an MR procedure. It is intended to provide infusion therapy directly prior to, during and immediately after the MR procedure functioning while either stationary or mobile. It is not intended to provide long-term patient care outside the MR environment. The system is to be used by trained medical staff, primarily critical care, emergency room and radiology nursing staff.
Flow Rate	Continuous: 0.1 to 99.9 ml/h in 0.1 ml/h increments, 100 to 1200 ml/h in 1 ml/h increments	Same
Housing	ABS	Same
Operating principle	Peristaltic Infusion Pump, Microprocessor controlled	Same
KVO Infusion rate	1 to 5 ml/h	0 to 5 ml/h *KVO input limit was lowered from 1 to 0 ml/h since last 510(k) clearance*
System accuracy	+/- 10%	Same
Occlusion pressure	User selectable: Low – 0.3 bar (5 psi), Medium – 0.5 bar (7.5 psi), High – 0.7 bar (10 psi)	Same

PARAMETER	PREDICATE DEVICE Continuum MR Compatible Infusion System – (3.0T Proximity) - K061128	PROPOSED DEVICE MEDRAD Continuum MR Infusion System with Wireless Remote Accessory
Pump Battery	Li-based rechargeable	Same
Pump Battery operation	4 hrs at 1200 ml/h	> 8 hrs at 125 ml/h (> 5 hrs at 1200 ml/h) *Slightly higher battery life since last 510(k) clearance*
Pump Battery charging	~6 hrs to 95% maximum battery capacity	Same
Air-in-line detector	User selectable	Same
Total time setting	100 hours	Same
Air sensor	Ultrasonic	Same
Prime rate	1600 to 1800 ml/h	Same
Bolus flow rate	0.1 to 1200 ml/h	Same
Bolus volume	0.1 to 100 ml	Same
Alarm Conditions	➢ Air in line ➢ Down occlusion ➢ Pump unattended ➢ Low battery ➢ End battery ➢ Fatal error ➢ End program ➢ Missing key ➢ Lock mode	➢ Air in line ➢ Down occlusion ➢ Pump unattended ➢ Low battery ➢ End battery ➢ Fatal error ➢ End program ➢ Missing key ➢ Lock mode ➢ Program Nearing End *Addition of the Program Nearing End alarm since last 510(k) clearance*
User Selectable Alarm Volume	Yes	Same
Program modes	➢ Continuous ➢ Dose ➢ Non-weight dose	Same
Integrated mounting clamp for IV pole	Yes	Same
Built In Free Flow Protection	Yes	Same
Automatic Bolus Function (Safety Feature)	Yes	Same
MR compatible	Yes (up to 2000 Gauss)	Same
Usability software features	Yes	➢ Bolus Review Screen ➢ Screen dimming ➢ Reset behavior for the "Total Volume Infused" ➢ Dose Rate Units setting *Addition of new usability software features since last 510(k) clearance*

A tabular comparison of features and principles of operation for the Iradimed MRidium 3850 MRI Infusion Pump System with MRidium 3855 Wireless Remote Control (Predicate) and MEDRAD Continuum MR Infusion System with Wireless Remote Accessory (Proposed) is contained in Table 3.

Table 3 Comparison of the Iradimed MRidium 3850 MRI Infusion Pump System with MRidium 3855 Wireless Remote Control (Predicate) and MEDRAD Continuum MR Infusion System with Wireless Remote Accessory (Proposed)

PARAMETER	**PREDICATE DEVICE** Iradimed MRidium 3850 MRI Infusion Pump System with MRidium 3855 Wireless Remote Control	**PROPOSED DEVICE** MEDRAD Continuum MR Infusion System with Wireless Remote Accessory
Optional Wireless Remote Accessory	Yes	Same
Infusion Management Features	Status of the pump operation, battery level, flow rate parameters and alarms	Same
Control Features	Start, stop, titrate, bolus	Same
RF Wireless Technology	Operates at 2.4 GHz	Same IEEE 802.11b/g

SUMMARY OF PERFORMANCE TESTING

Testing of the MEDRAD Continuum MR Infusion System with Wireless Remote Accessory is being conducted against applicable standards including IEC 60601-2-24, IEC 60601-1, UL 60601- 1 and IEC 60601-1-2. These standards represent standardized testing for safety and performance. These are the same standards used in the determination of substantial equivalence for the MEDRAD predicate device. Testing to the standards will be completed by third party certified test labs for the MEDRAD Continuum MR Infusion System with Wireless Remote Accessory with satisfactory test results required prior to release of the product.

STATEMENT OF SUBSTANTIAL EQUIVALENCE

The substantial equivalence comparisons demonstrate that the MEDRAD Continuum MR Infusion System with Wireless Remote Accessory contain technological features that do not differ significantly from currently marketed devices.

Verification and validation will be completed according to the Verification and Validation Test Plan to confirm that the design specifications for the MEDRAD Continuum MR Infusion System with Wireless Remote Accessory have been met and that the device meets the applicable requirements of the safety and performance standards cited.

Therefore, it has been determined that the Continuum MR Infusion System with Wireless Remote Accessory is substantially equivalent to the predicate devices described in the submission for its intended use when used as prescribed in the User Operation Manual.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 30 2008

Ms. Leslie S. O'Nan
Regulatory Affairs Specialist
MEDRAD, Incorporated
One Medrad Drive
Indianola, Pennsylvania 15051

Re: K073051
Trade/Device Name: MEDRAD Continuum MR Infusion System with Wireless Remote Accessory
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: May 9, 2008
Received: May 12, 2008

Dear Ms. O'Nan:

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

Indications for Use Statement

510(k) Number (if known): _____

Device Name: MEDRAD Continuum MR Infusion System with Wireless Remote Accessory

Indications for Use:

The MEDRAD Continuum MR Infusion System with Wireless Remote Accessory is designed for patients who require medications and other fluids during an MR procedure. It is intended to provide infusion therapy directly prior to, during and immediately after the MR procedure functioning while either stationary or mobile. It is not intended to provide long-term patient care outside the MR environment. The system is to be used by trained medical staff, primarily critical care, emergency room and radiology nursing staff.

Prescription Use ___X___ (Per 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use_____ (Part 21 CFR 807 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

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