SEP 2 3 2003

K032771

Special 510(k) Summary – Medrad Continuum MR Infusion System

OFFICIAL CONTACT:	Andrew P. Zeltwanger Regulatory Affairs Analyst Medrad, Inc. One Medrad Drive Indianola, PA 15051 (412) 767-2400 ext. 3005
CLASSIFICATION NAME:	Infusion Pump & Accessories [21 CFR 880.5725]
COMMON NAME(s):	Peristaltic Pump System
PROPRIETARY NAME(s):	Medrad Continuum MR Infusion System
PREDICATE DEVICE(s):	Medrad Continuum MR Infusion System (K021988)
INTENDED USE:	The Medrad Continuum MR Compatible Infusion System 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 of 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 UNMODIFIED PREDICATE:

The Medrad Continuum MR Compatible Infusion System has been modified to include two new programming options, and to remove two previous programming options. None of the modifications required changes to the system hardware, labeling, or disposable administration sets. The following two programs have been added as features to the Continuum MR Infusion System:

1. Dose Program – The Dose Program enables the administration of a weight-based dose in either micrograms/kg/min or milligrams/kg/min. This program is designed for use in procedures that require special dosing and infusion based on the patient's weight. The program calculates a flow rate in ml/hr based on the input parameters programmed by the user. The require parameters are:
    - Patient Weight (kg)
    - Drug Concentration (mg/ml)

- Dose (µg/kg/min or mg/kg/min)
- Volume (ml)

2. Bolus Program – The Bolus Program enables the Continuum MR Infusion System to administer a bolus to the patient. This program removes the need for an external syringe connection to the Continuum Administration Set for a bolus administration. The Bolus Program feature is available in both the Dose program and the *Rate Over Volume* mode of the Continuous Program. The Bolus Program prompts the user for the bolus volume and then administers the bolus at the user's command. The following parameters are available for the Bolus Program:
    - Bolus Flow Rate (programmable in the *Adjust Settings* Menu)
        a. 10 – 99.9 ml/hr in 0.1 ml increments
        b. 100 – 500 ml/hr in 1.0 ml increments
    - Bolus Volume (0.1 – 100 ml in 0.1 ml increments)

In addition to the inclusion of the two programs above, two of the existing programs, the Intermittent Program and the 25-steps Protocol, have been removed from the modified Continuum MR Infusion System.

The following table shows a comparison between the device components of the modified and unmodified Continuum MR Infusion System.

Parameters	Predicate Device	Modified Device
	Medrad Continuum MR Infusion Pump (K021988)	Medrad Continuum MR Infusion Pump
Classification	Peristaltic Infusion System	Same
Compatible IV Administration Set	Standard PVC Single Use Y Site Set Free Flow Protection	Same Administration Set
Flow Rate	0.1 – 100 ml/hr in 0.1 ml increments 100 – 500 ml/hr in 1.0 ml increments	Same
Housing	ABS	Same
Microprocessor Controlled	Yes	Same Hardware
KVO Infusion Rate	Configurable 1-5 ml/hr	Same
System Accuracy	± 10%	Same
Occlusion Pressure	User Selectable	Same
Battery	Li-Ion, Rechargeable	Same Battery
Battery Life	4 hr (at 500 ml/hr)	Same
Battery Charging	~ 6 hr to 95% max. battery capacity	Same
Air in Line Detector	User Adjustable	Same
Total Time Setting	100 hours	Same

Air Sensor	Ultrasonic	Same Sensor
Bolus Rate	N/A	10 – 99.9 ml/hr in .1 ml increments 100 – 500 ml/hr in 1 ml increments
Alarm Conditions 1. Air-in-line 2. Down Occlusion 3. Pump Unattended 4. Low Battery 5. End Battery 6. Fatal Error 7. End Program 8. Missing Key 9. Lock Mode	 1. Yes 2. Yes 3. Yes 4. Yes 5. Yes 6. Yes 7. Yes 8. Yes 9. Yes	 1. Same 2. Same 3. Same 4. Same 5. Same 6. Same 7. Same 8. Same 9. Same
Multi-Programs 1. Continuous Program 2. Intermittent Program 3. 25-Steps Protocol 4. Dose Program 5. Bolus Program	 1. Yes 2. Yes 3. Yes 4. No 5. No	 1. Same 2. Removed 3. Removed 4. Yes 5. Yes
Integrated Mounting for IV Pole	Yes	Same
Built-in Free Flow Protection	Yes	Same
User-selectable Occlusion Pressures	Yes	Same
Rate/Volume and Volume/Time Programming	Yes	Same
Bolus Capability	Manual, Syringe-induced bolus capability for administration set.	Programmable Bolus Function
User Selectable Alarm/Volume	Yes	Same
MRI Compatible	Yes	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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SEP 2 3 2003

Mr. Andrew P. Zeltwanger
Regulatory Affairs Analyst
Medrad, Incorporated
One Medrad Drive
Indianola, Pennsylvania 15051-0780

Re: K032771
Trade/Device Name: Medrad Continuum MR Infusion System
Regulation Number: 880.5725
Regulation Name: Infusion Pump & Accessories
Regulatory Class: II
Product Code: FRN
Dated: September 4, 2003
Received: September 8, 2003

Dear Mr. Zeltwanger:

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 (301) 594-4618. 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/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Intended Use

There has been no change to the indications for use as a result of the proposed modifications described in this submission.

Indications for Use Statement

510(k) Number: K032771

Device Name: Medrad Continuum MR Infusion System

Indications for Use:

The Medrad Continuum MR Compatible Infusion System 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 of the MR environment. The system is to be used by trained medical staff, primarily critical care, emergency room and radiology nursing staff.

Patricia Cucuzzella

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-the-Counter Use ____