K061128 MAY 22 2006

510(k) Summary

OFFICIAL CONTACT:	John M Kiste Regulatory Affairs Analyst MEDRAD, Inc. One Medrad Drive Indianola, PA 15051 (412) 767-2400 ext. 3444
CLASSIFICATION NAME:	Infusion Pump & Accessories [21 CFR 880.5725]
COMMON NAME(S):	Peristaltic Pump System
PROPRIETARY NAME:	MEDRAD Continuum MR Infusion System
PREDICATE DEVICE:	MEDRAD MR Continuum Infusion System (K032771)
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 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 Infusion System maintains the same intended use, similar operational parameters, similar labeling and is essentially used in a manner similar to the predicate device.

A label will be affixed to the system stating that when using the Continuum Infusion System in the MR environment it's casters brakes should be on and the system should not be placed in a static magnetic field exceeding 2000 gauss. The user's manual has also been updated to include this warning.

The Continuum MR Compatible Infusion System (3.0T) is comprised of the same components as the predicate device. Differences between the predicate device and the new Continuum MR Compatible Infusion System (3.0T) are detailed in the table below. The following Comparison Matrix identifies the similarities and differences between the new device and the predicate device.

Parameter	MEDRAD Continuum MR Compatible Infusion System – 1.5T	MEDRAD Continuum MR Compatible Infusion System – 3.0T
Classification	Type CF	Same
Compatible IV Administration Set	Standard PVC Single Use Y-Site Set Free Flow Protection	Same
Flow Rate	Continuous: 1 to 99.9 ml/h in 0.1 ml/h increments, 100 to 1200 ml/h in 1 ml/h increments	Same
Total Infused Volume	Continuous: 1 to 9,999 ml	Same
Housing	ABS	Same
Microprocessor Controlled	Yes	Same
KVO Infusion Rate	1 to 5 ml/h	Same
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
Battery	Li-Ion Rechargeable	Same
Battery Operation	4 hr @ 1200 ml/h	Same
Battery Charging	~6 hr 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 Rate	0.1 to 1200 ml/h	Same
Bolus Volume	0.1 to 100 ml	Same
Alarm Conditions		
➢ **Air-In-Line**	Yes	Yes
➢ **Down Occlusion**	Yes	Yes
➢ **Pump Unattended**	Yes	Yes
➢ **Low Battery**	Yes	Yes
➢ **End Battery**	Yes	Yes
➢ **Fatal Error**	Yes	Yes
➢ **End Program**	Yes	Yes
➢ **Missing Key**	Yes	Yes
➢ **Lock Mode**	Yes	Yes
Program Modes		

➢ **Continuous** ➢ **Dose** ➢ **Non-Weight Dose**	Yes Yes Yes	Yes Yes Yes
Integrated Mounting Clamp for IV Pole	Yes	Yes
Built in Free Flow Protection	Yes	Yes
Automatic Bolus Function (Safety Feature)	Yes	Yes
User Selectable Alarm Volume	Yes	Yes
Comprehensive Safety Features	Yes	Yes
Low Battery	Yes	Yes
MRI Compatible	Yes	Yes (up to 2000 gauss)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 2006

Mr. John M. Kiste
Regulatory Affairs Analyst
MEDRAD, Incorporated
One Medrad Drive
Indianola, Pennsylvania 15051

Re: K061128
Trade/Device Name: MEDRAD Continuum MR Compatible Infusion System (3T Proximity)
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: April 20, 2006
Received: April 25, 2006

Dear Mr. Kiste:

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

510(k) Number (if known): K061128

Device Name: MEDRAD Continuum MR Compatible Infusion System (3T Proximity)

Indications For Use:

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

[signature]

...ology, General Hospital,
... Control, Dental Devices

510(k) K061128