K022431

SEP 5 2002

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter's Name:	Medrad Inc.
Submitter's Address:	One Medrad Drive, Indianola, PA 15051 USA
Telephone Number:	(412) 767-2400, ext. 3536
Fax Number:	(412) 767-2499
Contact Person:	Frank Pelc
Date:	July 24, 2002
Proprietary Name:	Medrad Transfer Set
Common Name:	Intravascular Administration Set
Classification Name:	Intravascular Administration Set
Classification:	80 FPK, Class II
Predicate Device:	Merit Contrast Management System (K961794)

Device Description - The Medrad Transfer Set is medical disposable device used to transfer intravascular contrast media and saline from a spikeable container to a power injector syringe. The device components consist of a vented spike, connector tube, a means of manually stopping flow, female luer, and individually packaged sterile caps.

Substantial Equivalence - The information provided in this premarket notification demonstrates that the proposed device is substantially equivalent to legally marketed devices. The proposed Medrad Transfer Set is substantially equivalent to the Merit Contrast Management System (K961794). Both devices have the same intended use to deliver contrast media (and saline solutions) for diagnostic imaging procedures, and both allow multiple filling from one reservoir up to a 6 hour time limit.

A comparison of features and principles of operation between the proposed device and predicate device is provided in the table below.

COMPARISON DATA

Feature	Predicate Device (Merit Contrast Management System) K961794	Proposed Device: Medrad Transfer Set
Intended Use	Contrast media delivery system	Same
System Configuration	2 Part System - multi-fill spike system - per patient administration set	1 Part System - multi-fill spike system
Multi-fill	Yes, until reservoir is empty or time limit exceeded.	Same
Time limit	6 hours maximum	Same
Materials	Clear flexible plastic tubing, rigid plastic spike and stopcock	Polyvinyl chloride tubing, Acylontrile-butadiene-styrene
Packaging	Pouch, sealed	Same
Sterility	Ethylene Oxide (EtO) Sterilized	Same
Shelf Life	5 Years	1 Year (The shelf life will be extended to 5 years when satisfactory test results are completed.)
Connetion method	ISO 594 Luer	ISO 594 Luer
Sterile caps provided to cap connection port between fillings	Yes	Yes

Summary of differences between predicate and proposed devices –
The predicate device includes a separate disposable single-patient use tubing component. This component is attached to the open port on the administration set and leads to the patient, allowing fluid to be delivered to the patient without removing the filling component.

Medrad's transfer set will not include a separate tubing section. Medrad's transfer set must be removed from the syringe before the syringe can be connected to the patient; therefore it cannot come in contact with patient fluid through the syringe or administration set tubing. Additionally, the product labeling will state that the product is for single patient use only.

Intended Use – The Medrad Transfer Set is intended to be used in the delivery of contrast media and saline into a syringe.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 5 2002

Mr. Frank W. Pelc III
Regulatory Affairs Coordinator
Medrad, Incorporated
One Medrad Drive
Indianola, Pennsylvania 15051

Re: K022431
Trade/Device Name: Medrad Transfer Set
Regulation Number: 880.5440
Regulation Name: Intravascular Administrative Set
Regulatory Class: II
Product Code: LHI and FPK
Dated: July 24, 2002
Received: July 25, 2002

Dear Mr. Pelc:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K022431

INDICATION FOR USE

510(k) Number: K022431

Device Name: Medrad Transfer Set

Indications for Use/Intended Use:

The Medrad Transfer Set is intended to be used in the delivery of contrast media and saline into a syringe.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Vicki Hubbard for Pat Cucuzzella

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

510(k) Number: K022431

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)