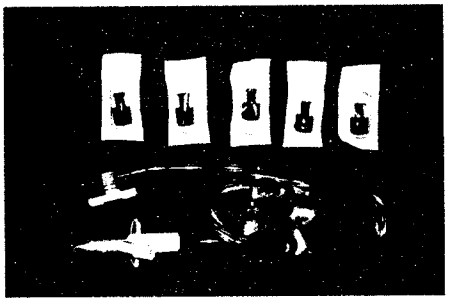
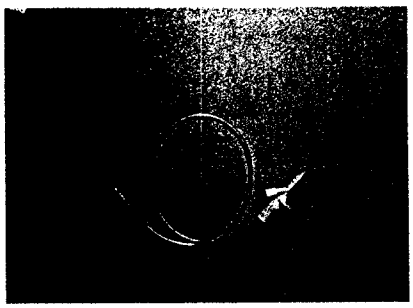
JUL 1 1 2003

K031808

Special 510(k) Summary – Medrad Swabbable Valve Transfer Set

OFFICIAL CONTACT:	Andrew P. Zeltwanger Regulatory Affairs Analyst Medrad, Inc. One Medrad Drive Indianola, PA 15051 (412) 767-2400 ext. 3005
CLASSIFICATION NAME:	Tubing, Fluid Delivery [21 CFR 880.5440]
COMMON NAME(s):	SVTS Transfer Set
PROPRIETARY NAME(s):	Medrad Swabbable Valve Transfer Set
PREDICATE DEVICE(s):	Medrad Transfer Set (K022431)
DEVICE DESCRIPTION:	The Medrad Swabbable Valve Transfer Set (SVTS) is a modified Medrad Transfer Set (K022431). The SVTS is a medical disposable device used to transfer contrast media and saline from a spikeable container to a power injector syringe. The SVTS is works in conjunction with the MR-CT Fill Station, and facilitates the delivery of contrast agent and/or saline into a syringe.
INTENDED USE:	The Medrad Swabbable Valve Transfer Set (SVTS) is intended to be used in the delivery of contrast media and saline into a syringe.
COMPARISON TO PREDICATE:	The following table shows a comparison between the device components of the SVTS and the predicate device, the Medrad Transfer Set (K022431).

		Predicate Device	Modified Device
		Medrad Stellant Transfer Set [equivalent to the Medrad Transfer Set (K022431)]	Swabbable Valve Transfer Set
Device Components	Illustration		
	Spike	Hyperal Vented Spike	Same
	Tubing	20.0 in. Length .160 in. Outer Diameter .110 in. Inner Diameter PVC – Medical Grade	23.0 in. Length .160 in. Outer Diameter (Same) .120 in. Inner Diameter PVC – Medical Grade (Same)
	Female Luer	None	Polycarbonate, Clear, Merit Medical Female Luer
	Dust Cap	Polypropylene Dust Cap	No Dust Cap
	Valve	One-way Stopcock, Pinch Clamp	Swabbable Threaded Valve (Halkey-Roberts)
	Adhesive	3321 Light Cure Adhesive Cyclohexanone Solvent	Same Same
Safety Requirements	Biocompatibility	Tested to ISO/AAMI 10993-7	Same
	Sterility	Ethylene Oxide (EtO) Sterilized	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2003

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

Re: K031808
Trade/Device Name: Medrad Swabbable Valve Transfer Set
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPK, FPA
Dated: June 6, 2003
Received: June 18, 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, 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

K031808

Intended Use

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

Indications for Use Statement

510(k) Number: _____

Device Name: Medrad Swabbable Valve Transfer Set

Indications for Use:

The Medrad Swabbable Valve Transfer Set (SVTS) is intended to be used in the delivery of contrast media and saline into a syringe. The SVTS is a needle-free system. Use of a needle-free system may aid in the prevention of needle-stick injuries.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Fabiola Cecente

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

510(k) Number: K031808

Prescription Use ✓ or Over-the-Counter Use ____