

MAY

4 1998

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

K980417

Submitters Name: Medrad, Inc.  
 Submitters Address: One Medrad Drive Indianola, PA 15051  
 Phone Number: (412) 767-2400, ext. 3212  
 Fax Number: (412) 767-8899  
 Contact Person: Sandra A. Pavlovic  
 Date: January 30, 1998

Classification Name: Unknown  
 Common Name: Sterile Disposables Kit  
 Proprietary Name: Medrad Disposable MRI Kit with  
 Check Valve

**Substantial Equivalence:** The Medrad Disposable MRI Kit with Check valve is substantially equivalent to the current Medrad Qwik-Fit MRI Disposables Kit (K943189). The Medrad Disposable MRI Kit with Check valve has the same intended use as the predicate device - to assist in filling and delivering intravascular contrast media and common flushing agents at various volumes and flow rates in an MR application. The kit may consist of one or all of the following:

- 2- 65 ml syringes (K935668)
- 96" Low Pressure Connector Tube/T-connector assembly (K943189)
- Fluid Delivery Device (Spike) - (K810624)
- Normally closed check-valve - B. Braun/Burron (K790062)
- Female/Female Luer Adapter - B.Braun/Burron (K942391)

The only difference between this kit and the predicate device is that this kit contains a normally closed check valve and a female/female luer Adapter. Device Verification and Validation Testing has been performed.

The normally closed check-valve is attached to the 96" LLPCT at the T-connector (K943189) and is used to restrict flow in one of two directions. The device is normally closed requiring a minimum amount of force to open. The check-valve attaches to the 'A' syringe and remains closed during saline flush from the 'B' syringe to prevent contrast trickle during this process.

The Female/Female Luer Adapter is a disposable device used to provide a fluid path between two vessels with male luer terminations. This device can be compared to the Medrad Quick Fill Tube (K800823) which is also a filling device.

All other components of the kit are identical to those in K943189.

The devices are sterilized using Ethylene Oxide gas. Validation is performed according to AAMI guidelines.

Medrad believes that the Medrad Disposable MRI Kit with Check valve and individual components introduces no new safety or efficacy concerns. It is my hope that the information provided here is sufficient to determine substantial equivalence for these devices.

### **STERILIZATION DATA**

The Medrad Disposable MRI Kit with Check-valve and its components are sterilized by Medrad, Inc. using Oxyfume 2000 (8.4 % Ethylene Oxide and 91.6 % HCFC-124). The sterilization process is the same one used to sterilize the complete line of Medrad sterile disposable devices.

#### **Sterility Validation:**

The sterilization validation is done using a Microbial Challenge-Overkill Method as described in the "Guideline for Industrial Ethylene Oxide Sterilization of Medical Devices," by the Association for the Advancement of Medical Instrumentation (AAMI) and the American National Standards Institute (ANSI). Reference ANSI/AAMI ST27-1988.

Annual re-validations are performed for established cycles of master product/load configurations as well as periodic product sterility determinations for fluid pathways, following routine sterilization's.

#### **Sterility Assurance Level (SAL):**

The Microbial Challenge System is represented by packaged product containing commercially prepared biological indicators of Bacillus Subtilis var. niger with spores numbering  $1 \times 10^6$ . Fifty test products are sterilized in each of three half cycle verification runs in the full load configuration. A Sterility Assurance Level (SAL) of  $10^{-6}$  is established.

### **Sterility Product Safety:**

**Residual levels:** Residual Ethylene Oxide measurements are made to ensure patient safety and the safety of attending medical personnel. Measurements for Ethylene Oxide, Ethylene Chlorohydrin, and Ethylene Glycol by:

- 1). Simulated-use aqueous extractions for product safety considerations.
- 2). Headspace for process characterization.

Reference: ANSI/AAMI ST29-1988 and ST30-1989. Limits are as practiced in industry and as presented in the Federal Register, Vol. 43, No. 122 - June 23, 1978.

Pre-release testing for EtO residuals have shown the following levels after 8 days of outgassing:

- Ethylene Oxide (via simulated-use aqueous extractions) = < 4ppm
- Ethylene Chlorohydrin (via aqueous extraction) =< 4ppm
- Ethylene Glycol (via aqueous extraction) = < 18 ppm

**Pyrogenicity:** Pyrogen (Endotoxin) testing is conducted per USP Rabbit Testing and/or USP Limulus Amebocyte Lysate (LAL) test methods. Reference US Pharmacopeia XXII, <151> Pyrogen Test, and <85> Bacterial Endotoxin Test.

**Biocompatibility:** ANSI-AMMI(ISO) testing as well as USP testing is conducted to assure Biocompatibility of sterile product with living biological systems. Reference: ANSI/AMMI/ISO 10993-1 through 11 and US Pharmacopoeia XXII, <87 & 88> Biological Reactivity Test Invitro and Invivo.

- Cytotoxicity - MEM
- Sensitization
- Systemic Tox
- Intracutaneous Tox
- Pyrogen Mat'l Mediated
- Hemolysis
- Particulate analysis
- Bacterio-/Fungistasis
- Physiochemical analysis
  - aqueous
  - non-aqueous
- Infrared analysis - ID "fingerprint"

**Packaging:**

The packaging used for the Medrad Disposable MRI Kit with Check-valve consists of a polystyrene tray and a coated Tyvek lid that is heat sealed to the styrene tray. The entire package is compatible with an EtO Sterilization Cycle.

**Shelf Life:**

At this point the ongoing Shelf Life testing process has confirmed that the kit has at least a two year Shelf Life from the date of sterilization. The testing will continue until it can be concluded that the product has a five year Shelf Life, which is standard for all Medrad sterile products.

The Shelf Life test method is based on the "Ethox Protocol for Accelerated aging" tests and uses the following sequence to simulate ambient storage:

**1 week at 130° and 70-80% RH**

**1 day at -4°F**

**1 week at 130°F and <15% RH**

This accelerated sequence is equivalent to 6 months of normal aging. The following tests will be conducted to ensure product efficacy:

**Flow tests**

**Pressure tests**

**ARO tests**

**COMPARISON DATA**  
**FEMALE/FEMALE LUER ADAPTER**

FEATURE	FEMALE/FEMALE LUER ADAPTER	QUICK FILL TUBE
Intended use	Fluid transfer from one vessel having a male termination to a syringe with a male termination.	Transfer of fluid from a bottle or vial to a syringe.
Material	Transparent ABS	Polyethylene
Disposable	Yes	Yes
Standard Luer Fitting	Yes - ANSI 70.1	No
Where used	MRI	MRI, CT, Angiography, Cardiology
Sterilized	Yes	Yes
Single Use	Yes	Yes

**COMPARISON DATA**  
**LOW PRESSURE CONNECTOR TUBE WITH CHECK VALVE**

FEATURE	Medrad 96" LLPCT	Medrad 96" LLPCT with Check Valve
Intended Use	Disposable device connected to a syringe and IV catheter for the administration of contrast media and flushing solutions.	Disposable device connected to a syringe and IV catheter for the administration of contrast media and flushing solutions.
Luer fitting	ANSI 70.1	ANSI 70.1
T- connector	Yes	Yes
Tubing Material	Clear Polyvinyl Chloride	Clear Polyvinyl Chloride
Luer Fitting Material	Clear Polycarbonate	Clear Polycarbonate
Check-valve	No	Yes
Where used	MRI	MRI
Sterilized	Yes	Yes
Single Use	Yes	Yes
Disposable	Yes	Yes



MAY 4 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Sandra A. Pavlovic  
Senior Regulatory Affairs Associate  
MEDRAD, Inc.  
One Medrad Drive  
Indianola, Pennsylvania 15051

Re: K980417  
Disposable MRI Kit with Check Valve  
Dated: February 3, 1998  
Received: February 3, 1998  
Regulatory Class: II  
21 CFR 892.1000/Procode: 90 LNH

Dear Ms. Pavlovic:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent 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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

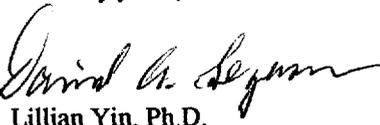
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639.

Page -2 - Ms. Sandra Pavlovic

Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

*for*   
Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

510(k) NUMBER (IF KNOWN): K980417

DEVICE NAME: Medrad Disposable MRI Kit with Check Valve

INDICATIONS FOR USE:

The Medrad Disposable MRI Kit with Check Valve is indicated for use in an MRI environment. The components of the kit are used to assist in filling and delivering intravascular contrast media and common flushing agents at various volumes and flow rates.

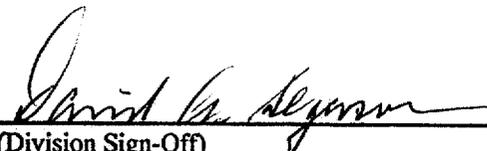
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use \_\_\_\_\_  
(Optional Format 1-2-96)

  
\_\_\_\_\_  
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K980417