

NOV - 5 2003

K033247

510(k) Summary

OFFICIAL CONTACT: Troy A. Jack
Regulatory Affairs Analyst
Medrad, Inc.
One Medrad Drive
Indianola, PA 15051
(412) 767-2400 ext. 3305

CLASSIFICATION NAME: Injector with Syringe, Angiographic

COMMON NAME(S): Powered Injector with Syringe

PROPRIETARY NAME: Medrad Spectris Solaris MR Injector System

PREDICATE DEVICE: Medrad Spectris Solaris MR Injector System
(K012950)

INTENDED USE: The Spectris Solaris MR Injection System is a syringe-based fluid delivery system indicated for delivery of contrast media during MR applications. It is intended to be used for the specific purpose of injecting intravenous MR contrast media and common flushing solutions into the human vascular system for diagnostic studies in magnetic resonance imaging (MRI) procedures. Only trained healthcare professionals are intended to operate this device.

DEVICE DESCRIPTION AND COMPARISON TO UNMODIFIED PREDICATE:

The Medrad Spectris Solaris MR Injection 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 3.0 Tesla-compatible injector system stating that the injector should be placed at a minimum of 4 ft. from the magnet bore when used with magnetic resonance imaging scanners having a field strength greater than 2.0 Tesla. The user's manual has also been updated to include this warning.

The Spectris Solaris MR Injector (3T Compatible) is comprised of the same two main components as the predicate device - Injector Head/Stand (HSU) and Display Control Unit (DCU). Differences between the predicate device and the new Spectris Solaris MR Injector are detailed in the table below. The following Comparison Matrix identifies the similarities and differences between the new device and the predicate device.

Feature: Injector System	Medrad Spectris Solaris MR Injector (K012950) Predicate	Medrad Spectris Solaris MR Injector
Flow Rate Injector	0.01 – 10 ml/s in 0.01 increments between .01 and 3.1 ml/s, 0.1 ml/s increments between 3.1 and 10 mls.	Same
Fractional volumes	Yes	Same
Remote Information Display	Color Touch screen	Same
Multi-Phase	6	Same
Protocol Storage Capability	Yes; 3 step procedure 32 protocols	Same
Hold Capability	Yes	Same
Safety Stop Mechanism	Yes	Same
Syringe System	2 total, 1– 115 ml syringe and 1- 65 ml syringe	Same
Air Detection Device	User observable	Same
Syringe Sensing	Yes	Same
Volume Remaining Readout	Graduation on syringe; LCD on Program Panel	Same
Programmed Volume	Yes, 1 to 63 ml and 1-115 ml	Same
Fill Rate	Configurable up to a maximum of 10 ml/sec	Same
Flow Rate	Variable	Same
KVO	Yes; 0.25 ml, time adjustable. Defaults at every 30 sec.	Same
Pressure Limit	325 PSI	Same
Start/Stop switch	Yes, Located at injector head or at display unit.	Same
Communication	Fiber Optic	Same
System Compatibility	0.2 – 2 T	0.2 – 3 T

Feature: Disposable System		
Syringe System	2 total, 1– 115 ml syringe and 1- 65 ml syringe, 2 - 65 ml syringes	
Intended Use	Saline/Contrast delivery	Same
Barrel Material Composition	PET	Same
Barrel length	4.5"	Same
Barrel OD	1.565"	Same
Barrel ID	1.415	Same
Plunger Material Composition	Polycarbonate	Same
Barrel Flange	Quik-Fit Design	Same
Packaging	Polystyrene tray with Tyvek Lid	Same
Sterilization	Ethylene Oxide	Same
Medrad –T connector		
T-connector	Polycarbonate	Same
Tubing	PVC	Same
Luer Fitting	Polycarbonate	Same
Length	96"	Same
Tubing ID	0.075"	Same
Maximum Pressure	350 PSI	Same



NOV - 5 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medrad, Inc.
c/o Mr. Troy A. Jack
Regulatory Affairs Analyst
One Medrad Drive
Indianola, PA 15051

Re: K033247
Medrad Spectris Solaris MR Injector
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic injector and syringe
Regulatory Class: Class II
Product Code: DXT
Dated: October 10, 2003
Received: October 14, 2003

Dear Mr. Jack:

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.

Page 2 – Mr. Troy Jack

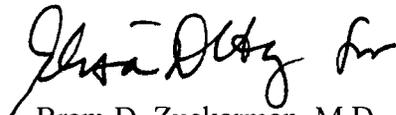
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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) 594-4648. 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,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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: K033241

Device Name: Medrad Spectris Solaris MR Injector

Indications for Use:

The Spectris Solaris MR Injection System is a syringe-based fluid delivery system indicated for delivery of contrast media during MR applications. It is intended to be used for the specific purpose of injecting intravenous MR contrast media and common flushing solutions into the human vascular system for diagnostic studies in magnetic resonance imaging (MRI) procedures. Only trained healthcare professionals are intended to operate this device.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices

510(k) Number

[Handwritten signature]
[Handwritten signature] 11/4/23

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

Prescription Use 90A for B02 11/4/23
(Per 21 CFR 801.109)