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K023183

Special 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
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Contact Person:	Frank Pelc
Date:	September 23, 2002
Proprietary Name:	Medrad Stellant CT Injector System
Common Name:	Powered Injector with Syringe
Classification:	DXT
Classification Name:	Injector and Syringe, Angiographic
Predicate Device:	Medrad EnVision CT Injector System K934086 and K993728

Medrad, Inc.
Medrad Drive
15051-0780
(412) 767-2400

Substantial Equivalence: The information provided in this premarket notification demonstrates that the proposed device is substantially equivalent to a legally marketed device. The proposed Stellant CT Injector System is substantially equivalent to the EnVision CT Injector System (K934086 and K993728).

The Medrad Stellant CT Injector System maintains the same intended use, similar operational parameters, similar labeling and is used in a manner similar to the predicate device.

Like the EnVision, the Stellant is a syringe-based fluid delivery system indicated for delivery of contrast media during computed tomography procedures. It is intended to be used for the specific purpose of injecting intravenous contrast medium into the human vascular system for computed tomography studies.

The Stellant CT Injector System is comprised of the same main components as the predicate device: an Injector Head, a Display Control Unit, and sterile disposables.

Medrad has established, as part of its Quality System, design controls in compliance with FDA's Quality System Regulations (QSRs). These design controls are applied to all Medrad product development processes and product design changes. These design controls were applied to the development of the Stellant CT Injector and meet the requirements of the FDA's QSRs.

As part of the design control a risk analysis was performed, and design verification and validation testing was conducted to support the conclusion drawn by the risk analysis.

Test results demonstrate that the design specifications for the Stellant CT Injector System were met and that the Stellant CT Injector System meets the applicable requirements of the international standards cited. Therefore, it has been determined that the Stellant CT Injection System is substantially equivalent to the predicate device, its predecessor, for its intended use when used as prescribed in the User Operation Manual.

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

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COMPARISON DATA

Feature	Proposed Device: Stellant CT Injector System	Predicate Device: EnVision CT Injector System (K934086 and K993728)
Intended Use	Intended to be used for the specific purpose of injecting intravenous contrast media into humans for diagnostic studies in computed tomography (CT) applications.	Same
Single or Dual Syringe System	Single and dual syringe models	Single syringe system
Information Display	Color LCD	Monochrome LCD
Programming Keys	Non-dedicated keys – software determined	Non-dedicaed Keys – Software Determined
Touch screen	Yes	Yes
Multi-Phase	1 – 6 phases per injection	1-10 Phases Per Injection
Arming Modes	Single	Single/Multi-Arm
Protocol Storage Capability	32 protocols	50 Protocols
Hold Capability	20 minutes max.	0 – 600 seconds
Scan Delay	1 – 300 seconds	0 – 99 seconds
Safety Stop Mechanism	Multi-layered software stops with backup monitoring	Electrical stop with a software backup system
Syringe System	Single syringe model: 200 ml syringe Dual syringe model: two 200 ml syringes	One 200 ml or 125 ml syringe
Programmed Volume	1 to 200 ml	1 to 200 ml or 1 to 125 ml depending on syringe size
Volume Remaining Readout	LED on injector head; graphical and numeric on LCD	LED
Fill Rate	Variable up to 10 ml/sec	2 ml/sec to 9.9 ml/sec
Flow Rate	0.1ml/s to 10.0 ml/s	0.1 ml/sec to 9.9 ml/sec
Programmable Pressure Limit	325 PSI default, user settable 50 to 300 PSI	Settable from 25 to 300 PSI
Pause	Programmable – 1 sec to 900 sec in 1 sec increments	Programmable – 1 sec to 10 min
Autofill	Fill rate 4 ml/sec	Fill rate 2 ml/sec to 9 ml/sec in 1 ml/sec increments
Retract Control	Yes (Automatic)	Yes
Remote Start Switch	Yes	Yes
Pressure Graph	Yes	No
Syringe Sensing	Yes	Yes
Autoload	Yes	Yes
Auto Dock/Retract/Advance	Yes; user-selectable autodock and advance; user-selectable auto-retract	No
Protocol Lock / Remote Arming	Yes	No
Remote Check for Air (from Head)	Yes	No
Scan Delay	1sec to 300 sec in 1sec increments	0 – 99 sec in 1 sec increments
Store/Recall	32 protocols	50 protocols
Test Inject	Yes	Yes
Syringe Heat Maintainer	Yes	Yes

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Sterile Disposables

Feature	Proposed Device: Stellant CT Injector System	Predicate Device: EnVision CT Injector System (K934086 and K993728)
Packaging	Tyvek lid covering polystyrene tray	Same
Sterilization	EtO sterilization	Same
Luer Fittings	ISO 594-1 & ISO 594-2 compliant design	Same
Syringe:		
Barrel Material Composition	PET	Same
Barrel Length	7.504"	7.273"
Barrel OD	2.002"	Same
Barrel ID	1.844"	Same
Plunger Material Composition	Polycarbonate	Same
Plunger Cover	Polyisoprene with silicone coating	Same
Connector Tubing Components:		
Maximum Pressure	400	355
Tube Material	PVC	Same
Tube Length	60"	Same
Bonding Agent	Cyclohexanone	Same
T-connector	Polycarbonate	Same
Spike	ABS	None
Priming Tube	Polyethylene	None

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 0 2003

Medrad, Inc.
Mr. Frank W. Pelc III
Regulatory Affairs Coordinator
One Medrad Drive
Indianola, PA 15051-0780

Re: K023183
Trade/Device Name: Medrad Stellant CT Injector System
Regulation Number: CFR 870.1650
Regulation Name: Angiographic injector and syringe.
Regulatory Class: Class II
Product Code: DXT
Dated: December 10, 2002
Received: December 11, 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), please contact the Office of Compliance at (301) 594-4635. 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 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Intended Use

Indications for Use Statement

510(k) Number: K023183

Device Name: Medrad Stellant CT Injector System

Indications for Use:

The Medrad Stellant CT Injector System is intended for the specific purpose of injecting intravenous contrast media into humans for diagnostic studies in computed tomography (CT) applications.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K023183

Prescription Use ✓ OR Over-The-Counter Use _____(Per 21 CFR 801.109)