K063090

510(K) SUMMARY

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MAR 2 7 2007

CLASSIFICATION NAME: Injector with Syringe, Angiographic

COMMON NAME(S): Powered Injector with Syringe

PROPRIETARY NAME: MEDRAD Stellant CT Injector System with XDS Accessory

PREDICATE DEVICE: MEDRAD Stellant CT Injector System with Imaging System Interface Module (K033881)

INTENDED 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. The MEDRAD Extravasation Detection System (XDS) accessory is designed to aid in the detection of intravenous contrast media from the injection site into the surrounding tissue during diagnostic studies in computed tomography (CT) applications.

CONTRAINDICATIONS: The XDS System is not intended for portable use or for use in an MR environment. The XDS System is designed for use on adults in antecubital injections only. The system is not validated for use on the back of the hand or in pediatrics.

The Control Room Module/Stellant Interface signal output is not intended to be used with any equipment other than with Medrad Stellant CT Injector models Sx and Dx.

DEVICE DESCRIPTION AND COMPARISON TO PREDICATE: The XDS Accessory may be added to the MEDRAD Stellant CT Injector System as an optional accessory. The injector system, when used with the XDS accessory, maintains the same intended use, same operational parameters, same labeling (with the addition of an XDS-specific operations manual). This device is also used in the same manner as the predicate device.

The Stellant CT Injector System with XDS accessory is a syringe-based fluid delivery system indicated for delivery of contrast media during computed tomography procedures. 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. The MEDRAD Extravasation Detection System (XDS) accessory is designed to aid in the detection of intravenous contrast media from the injection site into the surrounding tissue during diagnostic studies in computed tomography (CT) applications. The XDS accessory is designed to detect and notify the user before 20ml of fluid is extravasated within the sensors' field of view.

The XDS accessory does not replace or change the existing duties of the healthcare professionals performing a CT scan. This accessory provides a supplemental monitoring function to normal extravasation diligence and therefore does not impose additional risk to the patient. The device will exclusively interface with the Stellant CT Injector System, halting it in the event of an extravasation. This accessory does not otherwise alter the injector system's primary functions or performance during a CT procedure. Differences between the predicate device and the Stellant CT Injector System with XDS functionality are detailed in the Tables 1 and 2:

Table 1 - COMPARISON OF STELLANT CT INJECTOR SYSTEM w/ XDS ACCESSORY and STELLANT CT INJECTOR SYSTEM w/ ISI

Feature	Predicate Device: Stellant CT Injector System with ISI Accessory (K033881)	Proposed Device: Stellant CT Injector System with XDS Accessory
Intended Use	The MEDRAD Stellant CT Injector System with ISI Module is intended for the specific purpose of injecting intravenous contrast media into humans for diagnostic studies in computed tomography (CT) applications.	The MEDRAD Stellant CT Injector System with ISI Module is intended for the specific purpose of injecting intravenous contrast media into humans for diagnostic studies in computed tomography (CT) applications. The XDS accessory is designed specifically to aid in the detection of leakage of intravenous contrast media from the injection site into the surrounding tissue during diagnostic studies in computed tomography (CT) applications.
Single or Dual Syringe System	Single and dual syringe models	Same
Information Display	Color LCD	Same
Programming Keys	Non-dedicated keys – software determined	Same
Touch screen	Yes	Same
Multi-Phase	1 – 6 phases per injection	Same
Arming Modes	Single	Same
Protocol Storage Capability	32 protocols	Same
Hold Capability	20 minutes max.	Same
Scan Delay	1 – 300 seconds	Same
Safety Stop Mechanism	Multi-layered software stops with backup monitoring	Same
Syringe System	Single syringe model: one 200 ml syringe Dual syringe model: two 200 ml syringes	Same
Programmed Volume	1 to 200 ml	Same
Volume Remaining Readout	LED on injector head; graphical and numeric on LCD	Same
Fill Rate	Variable up to 10 mL/sec	Same
Flow Rate	0.1mL/sec to 10.0 mL/sec	Same
Programmable Pressure Limit	325 PSI default; user settable 50 to 325 PSI	Same
Pause	Programmable – 1 sec to 900 sec in 1 sec increments	Same
Autofill	Fill rate 4 mL/sec	Same
Retract Control	Yes (Automatic)	Same
Remote Start Switch	Yes	Same

Feature	Predicate Device: Stellant CT Injector System with ISI Accessory (K033881)	Proposed Device: Stellant CT Injector System with XDS Accessory
Pressure Graph	Yes	Same
Syringe Sensing	Yes	Same
Autoload	Yes	Same
Auto Dock/Retract/Advance	Yes; user-selectable autodock and advance; user-selectable auto-retract	Same
Protocol Lock / Remote Arming	Yes	Same
Remote Check for Air (from Head)	Yes	Same
Scan Delay	1 sec to 300 sec in 1 sec increments	Same
Store/Recall	32 protocols	Same
Test Inject	Yes	Same
Syringe Heat Maintainer	Yes	Same
Flow Profile Display	Yes	Same
Imaging System Interface Functionality	Yes	Same
Patient Sensor	N/A	Gold-plated antenna shrouded in ferro-plastic absorber covered by a silicone overmold
Extravasation Detector Performance	N/A	Audible and visual alert if an extravasation of up to 20ml is detected under sensor region. Will halt the Stellant injector system in the event of an extravasation event.

Table 2 - COMPARISON OF STELLANT CT INJECTOR SYSTEM AND XDS ACCESSORY DISPOSABLES

Feature	Predicate Device: Stellant CT Injector System (K033881)	Proposed Device: Stellant CT Injector System with XDS Accessory
Administration Set Packaging	Tyvek lid covering polystyrene tray	Same
Sterilization	EtO sterilization	Same
Method of determining Pyrogen-Freeness	Limulus Amebocyte Lysate test to USP requirements	Same
Luer Fittings	ISO 594-1 & ISO 594-2 compliant design	Same
Syringe:		
Barrel Material Composition	Polyethylene Terephthalate	Same
Barrel Length	7.504″	Same
Barrel OD	2.002″	Same
Barrel ID	1.844″	Same
Plunger Material Composition	Polycarbonate	Same
Plunger Cover	Polyisoprene	Same
Plunger Silicone Coating	Polydimethylsiloxane (Silicone)	Same
Barrel Flange	Easy-engage design for non-rotational orientation (no alignment necessary)	Same
Syringe sensing feature	Grooves at bottom of barrel to be optically identified	Same
Connector Tubing Components:		
Maximum Pressure	400 psi	Same
Tube Material	Medical grade PVC	Same
Tube Length	60″	Same
Bonding Agent	Cyclohexanone	Same
T-connector	Medical grade polycarbonate	Same
Contrast Media/Saline Container Spike	ABS	Same
Priming Tube	Low density polyethylene	Same
XDS Disposable Components:		
Sensor Interface Disposable (SID)	N/A	Medical Grade Tape (Polyester) with Acrylate Adhesive
SID Packaging	N/A	Polyester + Polyethylene with Paper Backing
SID Sterilization	N/A	EtO sterilization
Cable Management Tape (Quick Strips)	N/A	Medical Grade Tape (Polyethylene) with Acrylate Adhesive
Cable Management Tape (Quick Strips) Packaging	N/A	Polyester + Polyethylene with Paper Backing
Cable Management Tape (Quick Strips) Sterilization	N/A	EtO sterilization

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 27 2007

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

Re: K063090
Trade/Device Name: Stellant CT Injector System with Extravasation Detector Accessory
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector and Syringe
Regulatory Class: Class II
Product Code: IZQ
Dated: March 21, 2007
Received: March 23, 2007

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.

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 (240) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

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

Enclosure

Indications for Use

510(k) Number (if known): K063090

Device Name: MEDRAD Stellant CT Injector System with Extravasation Detection Accessory

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K063090