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K072886

510(K) SUMMARY

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DEC 2 1 2007

CLASSIFICATION NAME: Injector with Syringe, Angiographic

COMMON NAME(S): Powered Injector with Syringe

PROPRIETARY NAME: MEDRAD Stellant CT Injector System with P3T CardiacFlow

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

OptiVantage DH Injection System (K042744)
Mallinckrodt, Inc., Liebel-Flarsheim Business

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 Stellant P3T CardiacFlow software accessory is intended for use in CT angiography of cardiac structures, including coronary arteries, chambers of the heart, and thoracic and abdominal aorta during gated ECG acquisition.

The Stellant P3T CardiacFlow software accessory computes individual contrast injection protocols and scan timing, based on patient characteristics, scanner parameters and contrast concentration. The user will be required to confirm/change the suggested protocol before beginning an injection.

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CONTRAINDICATIONS: Stellant P3T CardiacFlow is not intended for use in Ungated CT angiography of the Right heart, Pulmonary trunk and Pulmonary Arteries for assessment of thrombo-emboli (dedicated Pulmonary Embolism (PE) studies), for angiography of the head/neck vessels, or for peripheral angiography.

The P3T CardiacFlow feature on the Stellant CT Injector is not intended for use on patients with compromised renal or some other contrast adverse related health issue.

DEVICE DESCRIPTION AND COMPARISON TO PREDICATE: MEDRAD Stellant CT Injector System operating software has been modified to include the P3T CardiacFlow accessory. P3T CardiacFlow is an optional, password-enabled accessory. The injector system, when used with P3T CardiacFlow, maintains the same intended use, same operational parameters, and same labeling (with the addition of a P3T CardiacFlow operations manual). This device is also used in the same manner as the predicate devices.

The MEDRAD Stellant CT Injector System with P3T CardiacFlow 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.

MEDRAD Stellant CT Injector System operating software has been modified to include the P3T CardiacFlow accessory. MEDRAD Stellant CT Injector System with P3T CardiacFlow maintains the same intended use, operational parameters, and labeling as the MEDRAD Stellant CT Injector System, with the addition of P3T CardiacFlow Instructions For Use. The P3T CardiacFlow accessory provides the convenience of generating patient-specific contrast injection protocols, and increases the consistency of individualized injection protocols among technologists. Stellant CT Injector System with P3T CardiacFlow is used in the same manner as the predicate device (Stellant CT Injector System without P3T CardiacFlow).

The Stellant safety architecture has not been modified nor impacted; additionally every injection protocol must be approved and locked by the practitioner. The practitioner

always has the option of modifying or deleting the P3T CardiacFlow suggested protocol.

A comparison of features and principles of operation between the proposed device and predicate devices is provided in Table 1 on the following page.

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Table 1: Comparison of Stellant CT Injector System with P3T CardiacFlow Accessory to Stellant CT Injector System with ISI Accessory and to the Mallinckrodt OptiVantage DH Power Injector with OptiBolus bolus shaping software (K042744)

Feature	Proposed Device: Stellant CT Injector System with P3T CardiacFlow Accessory	Predicate Device: Stellant CT Injector System with ISI Accessory (K033881)	Predicate Device: Mallinckrodt OptiVantage DH Power Injector with OptiBolus (K042744)
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 P3T CardiacFlow software accessory computes individual contrast injection protocols and scan timing, based on patient characteristics, scanner parameters and contrast concentration. The P3T CardiacFlow software accessory is	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 OptiVantage with OptiBolus software feature is designed to inject a radiopaque contrast media into a patient's vascular system, which enhances diagnostic images obtained with computed tomography (CT). The OptiBolus software feature is used to enable an exponential decaying flow rate injection that will optimize the contrast usage and provide an extended period of uniform enhancement.

Feature	Proposed Device: Stellant CT Injector System with P3T CardiacFlow Accessory	Predicate Device: Stellant CT Injector System with ISI Accessory (K033881)	Predicate Device: Mallinckrodt OptiVantage DH Power Injector with OptiBolus (K042744)
	intended for use in CT angiography of cardiac structures, including coronary arteries, chambers of the heart, and thoracic and abdominal aorta during gated ECG acquisition. The P3T CardiacFlow software accessory can be turned on or off by the user for any given injection The user will be required to confirm/change the suggested protocol before beginning an injection.		The OptiBolus software feature can be turned on or off by the user for any given injection protocol.
Single or Dual Syringe System	Dual syringe model	Single and dual syringe models	Dual syringe model
Information Display	Color LCD	Color LCD	Color LCD
Programming Keys	Non-dedicated keys – software determined	Non-dedicated keys – software determined	Control panel buttons: 8 soft-keys on touchscreen interface
Touch screen	Yes	Yes	Yes
Multi-Phase	Up to 6 phases per P3T CardiacFlow injection	1 – 6 phases per injection	6 phases per injection or a single OptiBolus injection

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Feature	Proposed Device: Stellant CT Injector System with P3T CardiacFlow Accessory	Predicate Device: Stellant CT Injector System with ISI Accessory (K033881)	Predicate Device: Mallinckrodt OptiVantage DH Power Injector with OptiBolus (K042744)
	protocol		protocol
Arming Modes	Single	Single	Single
Protocol Storage/Recall Capability	32 protocols	32 protocols	40 Protocols
Hold Capability	20 minutes max.	20 minutes max.	unknown
Safety Stop Mechanism	Multi-layered software stops with backup monitoring	Multi-layered software stops with backup monitoring	Electrical stop when injection parameters are out of spec.
Syringe System	Single syringe model: 200 ml syringe Dual syringe model: two 200 ml syringes	Single syringe model: 200 ml syringe Dual syringe model: two 200 ml syringes	All pre-filled volumes of Mallinckrodt 125 ml and Liebel-Flarsheim 200 ml
Programmed Volume	1 to 200 ml	1 to 200 ml	1 to 200 ml
Volume Remaining Readout	LED on injector head; graphical and numeric on LCD	LED on injector head; graphical and numeric on LCD	Display on Powerhead and Console
Fill Rate	Variable up to 10 mL/sec	Variable up to 10 mL/sec	2 to 15 mL/sec
Flow Rate	0.1mL/sec to 10.0 mL/sec	0.1mL/sec to 10.0 mL/sec	0.1 to 8 mL/sec
Programmable Pressure Limit	325 psi default, user settable 50 to 325 psi	325 psi default, user settable 50 to 325 psi	User settable up to 300 psi
Pause	Programmable – 1 sec to 900 sec in 1 sec increments	Programmable – 1 sec to 900 sec in 1 sec increments	unknown
Autofill	Fill rate 4 mL/sec	Fill rate 4 mL/sec	Fill rate unknown

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Feature	Proposed Device: Stellant CT Injector System with P3T CardiacFlow Accessory	Predicate Device: Stellant CT Injector System with ISI Accessory (K033881)	Predicate Device: Mallinckrodt OptiVantage DH Power Injector with OptiBolus (K042744)
Retract Control	Yes (Automatic)	Yes (Automatic)	Yes, manual
Remote Start Switch	Yes	Yes	Yes
Pressure Graph	Yes	Yes	No
Syringe Sensing	Yes	Yes	Yes
Autoload	Yes	Yes	No
Auto Dock/Retract/Advance	Yes; user-selectable autodock and advance; user-selectable auto-retract	Yes; user-selectable autodock and advance; user-selectable auto-retract	No
Protocol Lock / Remote Arming	Yes	Yes	No lock however, user may arm at head. (May have had related recall)
Check for Air	Yes	Yes	Yes
Scan Delay	1 sec to 300 sec in 1 sec increments	1 sec to 300 sec in 1 sec increments	1 sec increments starting at 1 sec. Max unknown
Test Inject	Yes	Yes	Yes
Syringe Heat Maintainer	Yes	Yes	Yes
Flow Profile Display	Yes	Yes	Yes
Imaging System Interface (ISI) Functionality	Yes	Yes	Yes
Protocol specialization	The P3T CardiacFlow software accessory computes individual	N/A	The OptiBolus software feature is used to enable an exponential

Feature	Proposed Device: Stellant CT Injector System with P3T CardiacFlow Accessory	Predicate Device: Stellant CT Injector System with ISI Accessory (K033881)	Predicate Device: Mallinckrodt OptiVantage DH Power Injector with OptiBolus (K042744)
	contrast injection protocols and scan timing, based on patient characteristics, scanner parameters and contrast concentration.		decaying flow rate injection that will optimize the contrast usage and provide an extended period of uniform enhancement.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 1 2007

MEDRAD, Inc.
c/o Ms. Lisa M. Casavant
Sr. Regulatory Affairs Specialist
One Medrad Drive
Indianola, PA 15051

Re: K072886
Stellant CT Injector System with Personalized Patient Protocol Technology (P3T)
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector and Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: October 4, 2007
Received: October 9, 2007

Dear Ms. Casavant:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

M. J. Hillebrenner

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): K072886

Device Name: MEDRAD Stellant CT Injector System with Personalized Patient Protocol Technology (P3T)

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.

The Stellant P3T software accessory is intended for use in CT angiography of cardiac structures, including coronary arteries, chambers of the heart, and thoracic and abdominal aorta during gated ECG acquisition.

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Contraindications:

Stellant P3T is not intended for use in Ungated CT angiography of the Right heart, Pulmonary trunk and Pulmonary Arteries for assessment of thrombo-emboli (dedicated Pulmonary Embolism (PE) studies), for angiography of the head/neck vessels, or for peripheral angiography.

The P3T feature on the Stellant CT Injector is not intended for use on patients with compromised renal or some other contrast adverse related health issue.

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)

M. Y. Hillebrenner
Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K072886