K082905

JAN 12 2009

510(K) SUMMARY

OFFICIAL CONTACT: Fortunato (Tito) Aldape
Director of Regulatory Affairs, CT SBU
MEDRAD, Inc.
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CLASSIFICATION NAME: Injector with Syringe, Angiographic

COMMON NAME(S): Powered Injector with Syringe

PROPRIETARY NAME: MEDRAD Stellant CT Injector System with P3T™ Cardiac

PREDICATE DEVICES: MEDRAD Stellant CT Injector System with P3T™ CardiacFlow (K072886)

Stellant Injector System
INTENDED USE: P3T™ Cardiac is intended for use with CT Angiography. P3T™ Cardiac 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.

P3T™ Cardiac Software Accessory
INTENDED USE: P3T™ Cardiac is intended for use with CT Angiography. P3T™ Cardiac 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.

INDICATIONS FOR USE: P3T™ Cardiac is indicated for use with CT Angiography of the cardiac structures, coronary arteries, chambers of the heart, pulmonary vasculature, and thoracic and abdominal aorta.

DEVICE DESCRIPTION AND COMPARISON TO PREDICATE: The MEDRAD Stellant CT Injector System with P3T™ Cardiac 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 includes P3T™ Cardiac, an optional, password-enabled software accessory. The injector system, when used with P3T™ Cardiac, maintains the same intended use, same operational parameters, and same labeling (with the addition of the P3T™ Cardiac operation manual), and is used in the same manner as the injector system without the software accessory.

The P3T™ Cardiac software accessory provides the convenience of generating patient-specific contrast injection protocols, and increases the consistency of individualized injection protocols among technologists.

The purpose of this submission is to obtain FDA clearance of the expansion of the indications of MEDRAD's previously cleared device, Stellant CT Injector System with P3T™ CardiacFlow.

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

Table 1: Comparison of Stellant Injector System with P3T™ CardiacFlow (K072886) to Stellant Injector System with P3T™ Cardiac.

Feature	Proposed Device: Stellant CT Injector System with P3T™ Cardiac	Predicate Device: Stellant CT Injector System with P3T™ CardiacFlow (K072886)
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™ Cardiac software accessory computes individual contrast injection protocols and scan timing, based on patient characteristics, scanner parameters and contrast concentration.	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.
Indications	P3T™ Cardiac is indicated for use with CT Angiography of the cardiac structures, coronary arteries, chambers of the heart, pulmonary vasculature, thoracic and abdominal aorta.	The 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.
User Interface	The P3T™ 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 P3T™ 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.
Single or Dual Syringe System	Dual syringe model	Dual syringe model
Information Display	Color LCD	Color LCD
Programming Keys	Non-dedicated keys – software determined	Non-dedicated keys – software determined
Touch screen	Yes	Yes

Feature	Proposed Device: Stellant CT Injector System with P3T™ Cardiac	Predicate Device: Stellant CT Injector System with P3T™ CardiacFlow (K072886)
Multi-Phase	Up to 6 phases per P3T™ injection protocol	Up to 6 phases per P3T™ injection protocol
Arming Modes	Single	Single
Protocol Storage/Recall Capability	32 protocols	32 protocols
Hold Capability	20 minutes max.	20 minutes max.
Safety Stop Mechanism	Multi-layered software stops with backup monitoring	Multi-layered software stops with backup monitoring
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
Programmed Volume	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
Fill Rate	Variable up to 10 mL/sec	Variable up to 10 mL/sec
Flow Rate	0.1mL/sec to 10.0 mL/sec	0.1mL/sec to 10.0 mL/sec
Programmable Pressure Limit	325 psi default, user settable 50 to 325 psi	325 psi default, user settable 50 to 325 psi
Pause	Programmable – 1 sec to 900 sec in 1 sec increments	Programmable – 1 sec to 900 sec in 1 sec increments
Autofill	Fill rate 4 mL/sec	Fill rate 4 mL/sec
Retract Control	Yes (Automatic)	Yes (Automatic)
Remote Start Switch	Yes	Yes
Pressure Graph	Yes	Yes
Syringe Sensing	Yes	Yes
Autoload	Yes	Yes
Auto Dock/Retract/Advance	Yes; user-selectable autodock and advance; user-selectable auto-retract	Yes; user-selectable autodock and advance; user-selectable auto-retract
Protocol Lock / Remote Arming	Yes	Yes
Check for Air	Yes	Yes
Scan Delay	1 sec to 300 sec in 1 sec increments	1 sec to 300 sec in 1 sec increments
Test Inject	Yes	Yes
Syringe Heat	Yes	Yes

Feature	Proposed Device: Stellant CT Injector System with P3T™ Cardiac	Predicate Device: Stellant CT Injector System with P3T™ CardiacFlow (K072886)
Maintainer		
Flow Profile Display	Yes	Yes
Imaging System Interface (ISI) Functionality	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MEDRAD, Inc.
c/o Mr. Fortunato (Tito) Aldape
Director of Regulatory Affairs, CT SBU
One MEDRAD Drive
Indianola, PA 15051

JAN 12 2009

Re: K082905
Trade/Device Name: P3T™ Cardiac
Common Name: Angiographic injector and syringe
Regulation Number: 21 CFR 870.1650
Regulatory Class: II
Product Code: DXT
Dated: December 21, 2008
Received: December 30, 2008

Dear Mr. Fortunato:

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) 276-0210. 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 Biometrics' (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,

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): K082905

Device Name: P3T™ Cardiac

Indications for Use:

INTENDED USE: P3T™ Cardiac is intended for use with CT Angiography. P3T™ Cardiac 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 (if applicable): None

Prescription Use ✓ (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)

Donna R. Vichinsky

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K082905