Bayer HealthCare

K132928

JAN 23 2014

510(k) Summary

Submitter:
MEDRAD, Inc. / Bayer Medical Care, Inc.
One Medrad Drive
Indianola, PA 15051

Contact Person:
Lisa A. Ewing
Principal Regulatory Affairs Specialist
Phone: (412) 406-3780
Fax: (412) 406-4052
Email: lisa.ewing@bayer.com

MEDRAD, INC.

One Medrad Drive
Indianola, PA 15051
U.S.A.

(412) 767-2400

www.ri.bayer.com

Date Prepared:
September 16, 2013

Device Trade Name:
MEDRAD Mark 7 Arterion Injection System
MEDRAD Mark 7 Arterion Syringe
MEDRAD Twist & Go Syringe

Common Name:
Angiographic Injector and Syringe

Classification Name:
Injector and Syringe, Angiographic [21 CFR 870.1650]

Product Code:
DXT

Classification:
Class II

Predicate Device(s):
The subject devices are equivalent to the following devices:
MEDRAD Mark 7 Arterion Injection System
- K113133, December 15, 2011
- K112086, October 14, 2011

Device Description:

MEDRAD Mark 7 Arterion Injector
The MEDRAD Mark 7 Arterion Injector is a software-controlled medical device used to inject contrast agents from a 150 ml disposable syringe. Commonly referred to as an automated injection system, it is designed to allow a user to fill a disposable syringe and perform an injection with a user-programmed volume and flow rate.

MEDRAD VFlow Hand Controller
For the Mark 7 Arterion Injector System, the MEDRAD VFlow Hand Controller is provided sterile for single patient use only. The hand controller provides the operator the ability to precisely control and instantaneously adjust variable flow rates of contrast during contrast injection and puffing operations.

When the injector is in the variable rate injection mode, the flow rate increases incrementally as the hand controller plunger is depressed, and decreases as the hand controller is released. In the fixed rate injection mode, the hand controller acts as a start switch, and release of the device ceases all flow. The VFlow Hand Controller requires the same amount of force to depress the plunger regardless of the set flow rate, volume, and pressure limit or the viscosity of the delivered contrast media. Additionally, the VFlow Hand Controller allows the clinician to step away from the radiation source during an injection.

Mark 7 Arterion Syringe and Twist & Go Syringe

The Twist & Go Syringe function is the same as the Mark 7 Arterion Syringe. The syringes are both supplied sterile and are designed to be loaded into the automated injector head from the front of the injector (front loading). The clear polycarbonate material used in both syringes improves visualization of residual air compared to opaque polypropylene. The Twist & Go Syringe enables single-handed attachment of the Twist & Go High Pressure Connector Tubing to the syringe.

Intended Use:

The MEDRAD Mark 7 Arterion Injection System is intended to be used specifically for the purposes of injecting contrast medium and common flushing solutions into humans for angiographic studies.

The MEDRAD Mark 7 Arterion Syringe, Quick Fill Tube and other MEDRAD supplied disposables are specifically intended for single use only with the MEDRAD Mark 7 Arterion Injection System for angiographic studies.

The MEDRAD Twist & Go Syringe, Quick Fill Tube and other MEDRAD supplied disposables are specifically intended for single use only with the MEDRAD Mark 7 Arterion Injection System for angiographic studies.

Comparison to Predicate: Design changes were made to the predicate device which included: updating injector software to include a new variable flow rate option, adding a variable flow rate ("VFlow") hand controller and adding a new configuration of the Arterion Syringe, which is called the Twist and Go Syringe.

Performance Data: Bench and laboratory testing were performed to support a determination of substantial equivalence to the predicate devices. Results from the testing provide assurance that the proposed devices conform to the requirements for their intended use. This included the following testing:

- Pérformance
- Safety
- EMC
- Package Integrity
- Environmental
- Pressure, burst, wet friction testing (syringe)
- System level testing with a MEDRAD automated injector (syringe)

Comparison Tables

Table 1. Comparison of Features in MEDRAD Mark 7 Arterion Injection System (predicate) and the modified MEDRAD Mark 7 Arterion Injection System (proposed).

Specification / Feature	Predicate Device: MEDRAD Mark 7 Arterion Injection System (K113133)	Proposed Device: MEDRAD Mark 7 Arterion Injection System	Rationale for Change
Indications for Use / Intended Use	The MEDRAD Mark 7 Arterion Injection System is intended to be used specifically for the purposes of injecting contrast medium and common flushing solutions into humans for angiographic studies.	The MEDRAD Mark 7 Arterion Injection System is intended to be used specifically for the purposes of injecting contrast medium and common flushing solutions into humans for angiographic studies.	No change.
Fill Volume	1 – 150 ml in 1 ml increments	1 – 150 ml in 1 ml increments	No change.
Fill Speed (user configurable for AutoFill)	1 – 10 ml/sec	1 – 10 ml/sec	No change.
Fill Speed (manual control by user)	1 – 20 ml/sec	1 – 20 ml/sec	No change.
Fixed Flow Rate	0.1 to 45.0 ml/sec in 0.1 ml increments (single and phased protocols) 0.1 to 59.9 ml/min in 0.1 ml/min increments (single ml/min protocol)	0.1 to 45.0 ml/sec in 0.1 ml increments (Single and Phased protocols) 0.1 to 59.9 ml/min in 0.1 ml/min increments (ml/m protocol)	No change.
Variable Flow Rate	N/A – not available	Variable: 1.0 – 10.0 ml/sec in 0.1 ml/sec increments	Variable Flow Rate is being added as an additional, optional feature to inject a set volume of contrast at a flow rate determined by the hand controller.
Flow Rate Rise Time	0.0 to 9.9 seconds in 0.1sec increments	0.0 to 9.9 seconds in 0.1 sec increments	No change.
Delay Time	0.0-99.9 seconds in 0.1 sec increments	0.0-99.9 seconds in 0.1 sec increments	No change.
Pressure Limit (150 ml syringe)	100-1200 psi or 689-8273 kPa in increments of 1 psi (kPa)	100-1200 psi or 689-8273 kPa in increments of 1 psi (kPa)	No change.

Syringe Heat Maintainer	35°C ± 5°C	35°C ± 5°C	No change.
Protocol Memory	40 Protocols	40 Protocols	No change.
Injection History Memory	50 Injections	50 Injections	No change.
Information Display	Color LCD	Color LCD	No change.
Programming Keys	Software generated via an LCD touch screen	Software generated via an LCD touch screen	No change.
Touch Screen	Yes	Yes	No change.
Multi-Phase	4 phases per protocol	4 phases per protocol	No change.
Arming Modes	Single and Multi arming modes	Single and Multi arming modes	No change.
Syringe System	Single (150 ml) syringe	Single (150 ml) syringe	No change.
Manual Retract Control	Yes	Yes	No change.
Check for Air Control	Yes	Yes	No change.
Variable Flow Option	No	Yes	Variable Flow Rate is being offered as an additional, optional feature to inject a set volume of contrast at a flow rate determined by the hand controller.
Hand Switch (start switch)	Yes	Yes	No change.
Foot Switch (start switch)	Yes	Yes	No change.
Variable Flow Hand Controller	No	Yes	Hand controller is being offered as an additional, optional accessory for use with the new variable flow rate software feature.
Splash Guard	Yes	Yes	No change.
Wiper Seal	Yes	Optional	Wiper seal is a redundant feature and is not a required component.

Table 2. Comparison of Features in MEDRAD Mark 7 Arterion Syringe (predicate), MEDRAD Mark 7 Arterion Syringe (proposed) and the MEDRAD Twist & Go Syringe (proposed).

	Component / Feature	Predicate Device: MEDRAD Mark 7 Arterion Syringe (K112086, K113133)	Proposed Device: MEDRAD Mark 7 Arterion Syringe	Proposed Device: MEDRAD Twist & Go Syringe	Rationale for Change
Labeling	Intended Use	The MEDRAD Mark 7 Arterion Syringe, Quick Fill Tube and other MEDRAD supplied disposables are specifically intended for single use only with the MEDRAD Mark 7 Arterion Injection System in the x-ray angiography environment.	The MEDRAD Mark 7 Arterion Syringe, Quick Fill Tube and other MEDRAD supplied disposables are specifically intended for single use only with the MEDRAD Mark 7 Arterion Injection System for angiographic studies.	The MEDRAD Twist & Go Syringe, Quick Fill Tube and other MEDRAD supplied disposables are specifically intended for single use only with the MEDRAD Mark 7 Arterion Injection System for angiographic studies.	No change in intended use, only updated syringe product name.
Construction	Syringe Volume	150 mL	150 mL	150 mL	No change.
	Syringe Length	8.61 inches	8.61 inches	8.61 inches	No change.
	Barrel OD	1.81 inches	1.81 inches	1.81 inches	No change.
	Barrel ID	1.60 inches	1.60 inches	1.60 inches	No change.
	FasTurn Nut at Syringe Tip	Yes	Yes	No	FasTurn Nut is not required for Twist & Go connection
	Dust Cover	Yes (sized to fit syringe tip with FasTurn nut)	Yes (sized to fit syringe tip with FasTurn nut)	Yes (sized to fit syringe tip without FasTurn nut)	Dust cover still present; dimensions of dust cover have changed to accommodate syringe tip without FasTurn Nut on Twist & Go Syringe
	Tubing Set Compatibility	Connects to female luer on high pressure connector tubing	Connects to female luer on high pressure connector tubing	Connects to Twist & Go luer connector on the MEDRAD Twist & Go High Pressure Connector Tubing	The Twist & Go Syringe is compatible with the Twist & Go High Pressure Connector Tubing
	Detents	Yes, molded in to syringe tip	Yes, molded in to syringe tip	No	Detents are not required without FasTurn Nut

Materials	Syringe Barrel	Polycarbonate	Polycarbonate	Polycarbonate	No change.
	Syringe Barrel ID Coating	Silicone	Silicone	Silicone	No change.
	Plunger	Polycarbonate	Polycarbonate	Polycarbonate	No change.
	Plunger Rubber Cover	Polyisoprene	Polyisoprene	Polyisoprene	No change.
	Plunger Coating	Silicone	Silicone	Silicone	No change.
	FasTurn Nut	Polycarbonate	Polycarbonate	N/A	FasTurn Nut is not required for Twist & Go connection
	Dust Cover	Polypropylene	Polypropylene	Polypropylene	No change.
Packaging	Type	Tyvek lid covering polystyrene tray	Tyvek lid covering polystyrene tray	Tyvek lid covering polystyrene tray	No change.
Biological	Sterilization	E-beam radiation	Gamma radiation	Gamma radiation	Updated mode of sterilization; SAL is unchanged.
	Sterility Assurance Level (SAL)	10^{-6}	10^{-6}	10^{-6}	No change.
	Shelf Life	2 years	2 years	2 years	No change.
	Pyrogenicity	Non-Pyrogenic Fluid Path	Non-Pyrogenic Fluid Path	Non-Pyrogenic Fluid Path	No change.
	Latex content	Not made with natural rubber latex	Not made with natural rubber latex	Not made with natural rubber latex	No change.
Performance	Pressure rating	1200 psi	1200 psi	1200 psi	No change.

Conclusion:

MEDRAD considers the MEDRAD Mark 7 Arterion Injection System, Mark 7 Arterion Syringe and Twist & Go Syringe to be substantially equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in functional design, materials, indications for use, fundamental scientific technology, and principles of operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 23, 2014

MEDRAD, Inc.
C/O Ms. Lisa A. Ewing
Principal Regulatory Affairs Specialist
One Medrad Drive
Indianola, PA 15051

Re: K132928
Trade/Device Name: MEDRAD Mark 7 Arterion Injection System
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector and Syringe
Regulatory Class: II
Product Code: DXT
Dated: December 23, 2013
Received: December 24, 2013

Dear Ms. Ewing:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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 Statement

510(k) Number: K132928

Device Name: MEDRAD Mark 7 Arterion Injection System
MEDRAD Mark 7 Arterion Syringe
MEDRAD Twist & Go Syringe

Indications for Use:

The MEDRAD Mark 7 Arterion Injection System is intended to be used specifically for the purposes of injecting contrast medium and common flushing solutions into humans for angiographic studies.

The MEDRAD Mark 7 Arterion Syringe, Quick Fill Tube and other MEDRAD supplied disposables are specifically intended for single use only with the MEDRAD Mark 7 Arterion Injection System for angiographic studies.

The MEDRAD Twist & Go Syringe, Quick Fill Tube and other MEDRAD supplied disposables are specifically intended for single use only with the MEDRAD Mark 7 Arterion Injection System for angiographic studies.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)