DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

August 14, 2015

Bayer Medical Care, Inc.
Lisa Ewing
Sr. Principal Regulatory Affairs Specialist
1 Bayer Drive
Indianola, PA 15051

Re: K143538
Trade/Device Name: MEDRAD MRXperion MR Injection System and MR Injection System Syringe Kit
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector And Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: December 12, 2014
Received: December 15, 2014

Dear Lisa 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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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: K143538

Device Name: MRXperion MR Injection System and MR Injection System Syringe Kit

Indications for Use:

The MEDRAD® MRXperion MR Injection System is a syringe-based fluid delivery system indicated for delivery of contrast media and saline during MR applications. It is intended to be used for the specific purpose of injecting intravenous MR contrast media and saline into the human vascular system for diagnostic studies in magnetic resonance imaging (MRI) applications with MRI scanners that have a magnetic field strength between 0.7 and 3.0 Tesla. Only trained healthcare professionals are intended to operate this device.

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)

Bayer HealthCare

510(k) Summary

K143538

Submitter:

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Date Prepared:

July 2, 2015

Device Trade Name:

MEDRAD MRXperion MR Injection System
MEDRAD MRXperion Sterile Disposable MRI Kit

Common Name:

Angiographic Injector and Syringe

Classification Name:

Injector and Syringe, Angiographic [21 CFR 870.1650]

Product Code:

DXT

Classification:

Class II

Predicate Device:

The subject device is equivalent to the following device:
Spectris Solaris EP MR Injection System
K042784, December 10, 2004

Reference devices:

- Weight Based Dosing Calculator - Nemoto Sonic Shot GX, K091734, May 21, 2010
- eGFR Calculator - E-Z-EM Empower MR Injection System, K062449, April 13, 2007

Device Description:

The MEDRAD MRXperion MR Injection System is a software-controlled medical device used for the administration of intravenous MR contrast media and saline into the human vascular system for diagnostic studies in magnetic resonance imaging (MRI) procedures. Commonly referred to as an automated injection system, it is designed to allow a user to fill disposable syringes and then to perform an injection with a user-programmed volume and flow rate.

The MEDRAD MRXperion MR Injector consists of two basic modules: a Scan Room Unit (SRU) and a Control Room Unit (CRU).

The SRU is comprised of an integral injector head, base assembly, pedestal, and a power supply.

- The injector head of the SRU physically performs the injection.
- The base assembly functions as the interface between the CRU, the injector head, and the SRU power supply.
- The injector head and base are located on a pedestal. The pedestal is designed with locking casters to allow the SRU to be moved when not connected to a patient.
- To power the base assembly, power is received from the AC mains and is converted to DC voltage by the SRU power supply.

The CRU consists of an All-in-One Computer (AIOC), pod, their dedicated power supplies, mechanical stand, and an optional hand switch.

- The AIOC provides a platform for the graphical user interface for the injector as well as the optional informatics applications. From the AIOC, an operator can use the touch-screen display to manage protocols, arm and disarm the injector, review injection real-time progress/feedback and history, access eGFR and patient Weight-Based Dosing calculators, and set system configuration options. The operator can also use the features of the optional informatics device from the AIOC.
- The pod provides injection start and stop functionality and contains the safety controls for the CRU.
- To power the AIOC and pod, each component receives AC mains power from its own dedicated off-the-shelf power supply.
- The AIOC and pod are mounted on a desk top mechanical stand.
- An optional hand switch gives the operator an additional means to start, hold, and stop an injection from the Control Room. The hand switch contains a light that identifies the state of the injector.

Indications for Use:

The MEDRAD® MRXperion MR Injection System is a syringe-based fluid delivery system indicated for delivery of contrast media and saline during MR applications. It is intended to be used for the specific purpose of injecting intravenous MR contrast media and saline into the human vascular system for diagnostic studies in magnetic resonance imaging (MRI) applications with MRI scanners that have a magnetic field strength between 0.7 and 3.0 Tesla. Only trained healthcare professionals are intended to operate this device.

Comparison to the Predicate Device:

The fundamental scientific technology, materials, sterilization process, manufacturing processes and risk assessment are unchanged from the predicate. The intended use and indications for use statement are unchanged from the predicate device with the exception that the MEDRAD MRXperion MR Injection System is indicated for use with MRI scanners that have a magnetic field strength between 0.7 and 3.0 Tesla. No new or different questions of safety or effectiveness are raised with the proposed modification.

Tables 1, 2 and 3 provide a detailed comparison of the MEDRAD MRXperion MR Injection System to the predicate Spectris Solaris EP MR Injection Device:

Table 1. Comparison of Fluid Delivery Features

Feature	MEDRAD MRXperion MR Injection System (Proposed)	Spectris Solaris EP (K042784)	Rationale for Change
Indications for Use / Intended Use	The MEDRAD® MRXperion MR Injection System is a syringe-based fluid delivery system indicated for delivery of contrast media and saline during MR applications. It is intended to be used for the specific purpose of injecting intravenous MR contrast media and saline into the human vascular system for diagnostic studies in magnetic resonance imaging (MRI) applications with MRI scanners that have a magnetic field strength between 0.7 and 3.0 Tesla. Only trained healthcare professionals are intended to operate this device.	The Spectris Solaris EP MR Injection System is a syringe-based fluid delivery system indicated for delivery of contrast media during MR applications. It is intended to be used for the specific purpose of injecting intravenous MR contrast media and common flushing solutions into the human vascular system for diagnostic studies in magnetic resonance imaging (MRI) procedures. Only trained healthcare professionals are intended to operate this device.	Updates for clarification of MR field strength only.
Fill Volume (Syringe A)	0.5 ml to max. syringe volume in: * 0.1 ml increments between 0.5 and 31 ml * 1 ml increments for 31 ml and above	0.5 ml to max. syringe volume in: * 0.1 ml increments between 0.5 and 31 ml * 1 ml increments for 31 ml and above	N/A. No change.
Fill Volume (Syringe B)	1 ml to max. syringe volume in 1 ml increments	1 ml to max. syringe volume in 1 ml increments	N/A. No change.
Fill Speed (low speed)	1.0 to 10.0 ml/s in 0.5 ml/s increments	1.0 to 10.0 ml/s in 0.5 ml/s increments	N/A. No change.

Feature	MEDRAD MRXperion MR Injection System (Proposed)	Spectris Solaris EP (K042784)	Rationale for Change
Fill Speed (high speed)	1.0 to 10.0 ml/s	1.0 to 10.0 ml/s	N/A. No change.
Flow Rate	0.01 to 10 ml/s	0.01 to 10 ml/s	N/A. No change.
Delay	N/A. Addressed by Pause Phase.	1 to 300 s in 1 s increments	MRXP allows Pause phase to be the first phase of the injection.
Pause Phase	1 to 1200 s	1 to 900 s	Longer Pause Phase added for customer convenience.
Programmable Pressure Limit (PSI/kPa)	Yes	Yes	N/A. No change.
Keep Vein Open (KVO)	Yes	Yes	N/A. No change.
Protocol Memory	60 protocols of up to 6 phases each	32 protocols of up to 6 phases each	Additional protocol memory storage added for customer convenience.
Injection History Memory	Previous 20 successful injections	Previous 20 successful injections	N/A. No change.
Information Display (Control Room)	Color LCD	Color LCD	N/A. No change.
Programming Keys (Control Room)	Software-generated via an LCD touch screen	Software-generated via an LCD touch screen	N/A. No change.
Programming Keys (Scan Room)	Dedicated keys on injector head	Dedicated keys on injector head	No change to technology. Additional keys added to MRXperion Injector Head for increased functionality in the scan room.
Multi-Phase	6 phases per injection	6 phases per injection	N/A. No change.

Feature	MEDRAD MRXperion MR Injection System (Proposed)	Spectris Solaris EP (K042784)	Rationale for Change
Safety Stop Mechanism	Software stops and electromechanical switch	Software stops	Additional safety stops included.
Syringe System	Dual Syringes	Dual Syringes	N/A. No change.
Syringe Docking	Non-rotational orientation	Keyed, rotational orientation	Customer convenience.
Docking	Manual and Automatic	Manual only	Customer convenience.
Fill Control	Manual and Automatic	Manual only	Automatic fill feature added for customer convenience.
Prime Control	Manual and Automatic	Manual only	Automatic prime feature added for customer convenience.
Retract Control	Manual and Automatic	Manual only	Automatic retract feature added for customer convenience.
Check for Air Confirmation	Operator visual inspection; user confirmed	Operator visual inspection; user confirmed	N/A. No change.
Start/Stop Switch	Control Room and Scan Room	Control Room	Customer convenience.
Hand Switch	Control Room (optional)	Control Room	Spectris Solaris EP did not have Start/Stop capability without the Hand Switch. The Hand Switch is not needed for MRXperion, as a Start/Stop switch was added to the MRXperion Injector Head and the Control Room Unit.
Communication	Fiber Optic	Fiber Optic	N/A. No change.

Feature	MEDRAD MRXperion MR Injection System (Proposed)	Spectris Solaris EP (K042784)	Rationale for Change
MR Compatibility	0.7T to 3.0T	0.2T to 3.0T	MRXperion is commercially targeted for scanners used in the majority of the US and worldwide market.
eGFR Calculator	Yes	No Reference Device - E-Z-EM Empower MR Injection System K062449	eGFR Calculator feature added for customer convenience.
Weight-Based Dosing Calculator	Yes	No Reference Device - Nemoto Sonic Shot GX K091734	Weight-Based Dosing Calculator feature added for customer convenience.
Informatics Compatibility	Yes	No	Informatics compatibility added for customer convenience.
Power management	The Base supplies power to the Injector Head and the main processor via an AC/DC power supply-module. A rechargeable lithium ion battery is used to power the motors in the base during an injection.	Rechargeable lead-acid battery power for the Scan Room Unit.	Improved power management scheme for longer battery life.

Table 2. Comparison of Syringe Kit Features

	Component / Feature	MEDRAD MRXperion MR Injection System Syringes (Proposed)	Spectris Solaris EP Syringes (Predicate)	Rationale for Change
Construction	Syringe Volume	65 ml (contrast), 115 ml (saline)	65 ml (contrast), 115 ml (saline)	N/A. No change.
	Dust Caps	Yes	Yes	N/A. No change.
	Tubing Set Compatibility	Connects to female luer on low pressure connector tubing	Connects to female luer on low pressure connector tubing	N/A. No change.
Materials	Syringe Barrel	PET	PET	N/A. No change.
	Syringe Barrel ID Coating	Silicone oil	Silicone oil	N/A. No change.
	Plunger	Polycarbonate	Polycarbonate	N/A. No change.
	Plunger Rubber Cover	Polyisoprene/ polybutadiene blend	Polyisoprene/ polybutadiene blend	N/A. No change.
	Plunger Coating	Silicone oil	Silicone oil	N/A. No change.
	Dust Covers	Polypropylene	Polypropylene	N/A. No change.
	Spikes	ABS	ABS	N/A. No change.
Pack-aging	Type, Material	Tyvek lid covering polystyrene tray	Tyvek lid covering polystyrene tray	N/A. No change.
	Shelf Life	3 years	5 years	MRXperion Syringe Kit currently qualified for 3 year shelf life.
Biological	Biocompatibility	Compliant to applicable sections of ISO/AAMI 10993-1:2009	Compliant to applicable sections of ISO/AAMI 10993-1:2009	N/A. No change.
	Sterilization	E-beam radiation	E-Beam and Gamma	N/A. No change.
	Sterility Assurance Level (SAL)	10^{-6}	10^{-6}	N/A. No change.
	Pyrogenicity	Non-Pyrogenic Fluid Path	Non-Pyrogenic Fluid Path	N/A. No change.
	Latex content	Not made with natural rubber latex	Not made with natural rubber latex	N/A. No change.
	DEHP	No	No	N/A. No change.
Perfor-mance	Pressure rating	350 psi (2410 kPa)	350 psi (2410 kPa)	N/A. No change.

Table 3. Comparison of tubing features

Item		MEDRAD MRXperion MRXperion MR Injection System Tubing (Proposed)	Spectris Solaris EP Tubing (Predicate)	Rationale for Change
Construction	Description	Low pressure connector tube with T-connector and check valve	Low pressure connector tube with T-connector and check valve	N/A. Same tubing, T-connector and check valve, no change.
	Syringe connection	Polycarbonate female luer and T-connector	Polycarbonate female luer and T-connector	N/A. Same tubing and T-connector, no change.
	Administration Set Connection	Polycarbonate male luer	Polycarbonate male luer	N/A. Same tubing, no change.
	Tubing Material	PVC	PVC	N/A. Same tubing, no change.
	Tubing Length	96”	96”	N/A. Same tubing, no change.
Packaging	Type, Material	Tyvek lid covering polystyrene tray	Tyvek lid covering polystyrene tray	N/A. Same tubing, no change.
	Shelf Life	3 years	5 years	MRXperion Syringe Kit currently qualified for 3 year shelf life.
Biological	Biocompatibility	Compliant to applicable sections of ISO/AAMI 10993-1:2009	Compliant to applicable sections of ISO/AAMI 10993-1:2009	N/A. Same tubing, no change.
	Pyrogenicity	Non-pyrogenic fluid path	Non-pyrogenic fluid path	N/A. Same tubing, no change.
	Latex content	Not made with natural rubber latex	Not made with natural rubber latex	N/A. Same tubing, no change.
	DEHP	No	No	N/A. Same tubing, no change.
	Sterilization Type	E-beam	E-Beam and Gamma	N/A. Same tubing, no change.
	Sterility Assurance Level (SAL)	10^{-6}	10^{-6}	N/A. Same tubing, no change.
Performance	Pressure Rating	350 psi (2410 kPa)	350 psi (2410 kPa)	N/A. Same tubing, no change.

Summary of Non-Clinical Testing:

Bench testing was performed or leveraged from the predicate to support the MEDRAD MRXperion MR Injection System and results demonstrate the MEDRAD MRXperion MR Injection System meets product specification and performance requirements. The following testing was successfully completed:

- Device performance testing included verification of the system disposable filling and preparation, protocol management, flow rates, pressures, timers, and calculator accuracy. Testing also verified that the device was not affected by environmental conditions such as atmospheric conditions and handling. All testing passed and the demonstrated product performance met all prior established acceptance criteria.
- Disposables performance testing included verification of the syringe and connector tubing mechanical functions and pressure capabilities (ISO-594), compatibility with MR contrast agents and other chemical agents (ISO-8536-4), and packaging (ISO-11607). Testing was performed using aged samples that had been sterilized and with samples that had been subjected to shipping conditions (ASTM 4169). All testing passed and the demonstrated product performance met all prior established acceptance criteria.
- Biocompatibility testing was conducted on the syringe and connector tubing kit to verify that it meets the requirements of ISO 10993 for an external communicating, indirect contact, less than 24 hour duration device.
- The syringe and connector tubing kit were shown to meet the requirements of ISO 10993 for an external communicating, indirect contact, less than 24 hour duration device. The syringe and connector tubing are supported by the following tests, all of which had acceptable results.
    - Cytotoxicity
    - Sensitization
    - Intracutaneous Reactivity
    - Acute Systemic Injection
    - Materials Mediated Pyrogen
    - Hemolysis
    - Partial Thromboplastin Time
    - Platelet & Leukocyte Counts
    - USP physiochemical testing

- Sterilization conditions have been validated on the syringe and connector tubing kit in accordance with ISO 11137-1, ISO 11137-2 and ISO 11137-3 to provide a Sterility Assurance Level of 10^{-6}. All testing passed and the demonstrated product performance met all prior established acceptance criteria.
- Safety and Compatibility testing included verification of configurations and specifications, circuitry, compliance with IEC 60601-1 and EMC requirements, electrical safety controls, ability to detect failures in communication and controls, programming keys, and sensors, and safe operation. Testing was conducted to ensure MRI compatibility with scanners ranging between 0.7T to 3.0T, including homogeneity, signal-to-noise, MR artifacts, susceptibility to gradients and high RF. All testing passed and the demonstrated product performance demonstrated met all prior established acceptance criteria.
- Shelf-life and shipping testing included verification that the system performance was not affected by three year aging and shelf-life packaged transit and storage (ISTA 1E). All testing passed and the demonstrated performance met all prior established acceptance criteria.
- Reliability testing was performed using statistical methods to demonstrate the capability to sequentially and repeatedly meet system performance requirements. Testing verified there was no degradation to performance when the MEDRAD MRXperion Injection System and Informatics processes were run simultaneously. All testing passed and the demonstrated performance met all prior established acceptance criteria.
- Simulated Use and Human Factors testing was performed by using the device and disposables in a simulated clinical environment to validate the clinical user needs were met by the design per ANSI/AAMI HE75:2009 and EN 62366:2008. Testing demonstrated that no new or different questions of safety or effectiveness were raised.

All test results demonstrate that the design, materials, and manufacturing processes of the MEDRAD MRXperion Injection System meet the established performance criteria and will perform as intended.

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for angiographic injectors and syringes.

Clinical Testing:

No clinical testing was required or performed to support this Traditional 510(k) Premarket Notification.

Statement of Equivalence:

Bayer Medical Care Inc. considers the MEDRAD MRXperion MR Injection System to be substantially equivalent to the predicate device listed above. This conclusion is based upon the device intended use and indications for use, similarities in functional design, materials, fundamental scientific technology, and principle of operation.