November 1, 2018

Bayer Medical Care Inc.
Katie Dillon
Regulatory Affairs Manager
1 Bayer Drive
Indianola, Pennsylvania 15051

Re: K182276
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: September 28, 2018
Received: October 1, 2018

Dear Katie Dillon:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael John -S
2018.11.01 14:44:18 -04'00'

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K182276

Device Name
MEDRAD® MRXperion MR Injection System and MR Injection System Syringe Kit

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(k) Summary

**Submitter:** Bayer Medical Care, Inc.
1 Bayer Drive
Indianola, PA 15051

**Contact Person:** Katie Dillon
Regulatory Affairs Manager
Phone: (412) 406-3212
Email: katie.dillon@bayer.com

**Date Prepared:** October 30, 2018

**Device Trade Name:** MEDRAD MRXperion MR Injection System
MEDRAD MRXperion MR Injection System Syringe 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 substantially equivalent to the following device:
MEDRAD MRXperion MR Injection System and MR Injection System Syringe Kit, K143538

**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.

**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:**

A new control room unit (CRU) has been developed as an alternative to the existing CRU used with the MEDRAD MRXperion MR Injection System. This design change does not involve any changes to the MEDRAD MRXperion MR Injection System Syringe Kit. Table 1 provides a comparison of the proposed MEDRAD MRXperion MR Injection System with the predicate device, the MEDRAD MRXperion MR Injection System cleared per K143538.

The fundamental scientific technology, principle of operation, and indications for use are unchanged from the predicate device, the MEDRAD MRXperion MR Injection System cleared per K143538. The differences between the proposed device and the predicate device do not introduce new issues of safety and effectiveness and do not change the indications for use or result in a different fundamental scientific technology.

**Table 1.** Comparison of MEDRAD MRXperion MR Injection System (proposed device) with predicate device.

| PARAMETER | PREDICATE DEVICE MRXperion MR Injection System (K143538) | PROPOSED DEVICE MRXperion MR Injection System (K182276) | RATIONALE FOR CHANGE |
|---|---|---|---|
| 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.<br><br>Only trained healthcare professionals are intended to operate this device. | Same | No change |
| Fill Volume (Syringe A) | 0.5 ml to max. syringe volume in:<br>*0.1 ml increments between 0.5 and 31 ml<br>* 1 ml increments for 31 ml and above | Same | No change |
| Fill Volume (Syringe B) | 1 ml to max. syringe volume in 1 ml | Same | No change |

| PARAMETER | PREDICATE DEVICE MRXperion MR Injection System (K143538) | PROPOSED DEVICE MRXperion MR Injection System (K182276) | RATIONALE FOR CHANGE |
|---|---|---|---|
| | increments | | |
| Fill Speed (low speed) | 1.0 to 10.0 ml/s in 0.5 ml/s increments | Same | No change |
| Fill Speed (high speed) | 1.0 to 10.0 ml/s in 0.5 ml/s increments | Same | No change |
| Flow Rate | 0.01 to 10 ml/s in increments of:<br>* 0.01 ml/s between 0.01 and 3.1 ml/s<br>* 0.1 ml/s between 3.1 and 10 ml/s | Same | No change |
| Delay | N/A. Addressed by Pause Phase. | Same | No change |
| Pause Phase | 1 to 1200 s in 1 s increments | Same | No change |
| Programmable Pressure Limit (PSI/kPa) | 100/690<br>150/1035<br>200/1380<br>250/1725<br>300/2070<br>325/2240 | Same | No change |
| Keep Vein Open (KVO) | Yes; 0.25 ml, time adjustable. Defaults at every 30 sec. | Same | No change |
| Protocol Memory | 60 protocols of up to 6 phases each | Same | No change |
| Injection History Memory | Previous 20 successful injections | Same | No change |
| Control Room Unit | Windows-based Control Room Unit (CRU) with separate hardware components. | Windows-based Control Room Unit with integrated hardware components | Integration of hardware components for aesthetic improvement, |

| PARAMETER | PREDICATE DEVICE MRXperion MR Injection System (K143538) | PROPOSED DEVICE MRXperion MR Injection System (K182276) | RATIONALE FOR CHANGE |
|---|---|---|---|
| | | | modular design and serviceability. No impact on safety and effectiveness. |
| Information Display (Control Room) | Color LCD | Same | No change |
| Programming Keys (Control Room) | Software-generated via an LCD resistive touch screen | Software-generated via LCD capacitive touch screen | Touch screen calibration not required for capacitive touch screen. No impact on safety and effectiveness. |
| Programming Keys (Scan Room) | Dedicated keys on injector head | Same | No change |
| Multi-Phase | 6 phases per injection | Same | No change |
| Safety Stop Mechanism | Software stops and electromechanical switch | Same | No change |
| Syringe System | Dual Syringes | Same | No change |
| Syringe Docking | Non-rotational orientation | Same | No change |
| Docking | Manual and Automatic | Same | No change |
| Fill Control | Manual and Automatic | Same | No change |
| Prime Control | Manual and Automatic | Same | No change |
| Retract Control | Manual and Automatic | Same | No change |
| Check for Air Confirmation | Operator visual inspection; user confirmed | Same | No change |
| Start/Stop Switch | Control Room and Scan | Same | No change |

| PARAMETER | PREDICATE DEVICE MRXperion MR Injection System (K143538) | PROPOSED DEVICE MRXperion MR Injection System (K182276) | RATIONALE FOR CHANGE |
|---|---|---|---|
| | Room | | |
| Hand Switch | Control Room (optional) | Same | No change |
| Communication | Fiber Optic | Same | No change |
| MR Compatibility | 0.7T to 3.0T | Same | No change |
| eGFR Calculator | Yes | Same | No change |
| Weight-Based Dosing Calculator | Yes | Same | No change |
| Informatics Compatibility | Yes | Same | No change |
| 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. | Same | No change |
| MRXperion MR Injection System Syringe Kit | There are no changes to the MRXperion MR Injection System Syringe Kit. | | No change |

**Performance Data:**

Verification and validation testing was conducted to assess the impact of the modification on the MEDRAD MRXperion MR Injection System. The following testing was successfully completed:

- Device performance testing included verification of fluid delivery, flow rates, volumes, and pressures. 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.

- 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. All testing passed and the demonstrated product performance demonstrated 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 MR 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 EN 62366-1: 2015 and FDA Guidance "Applying Human Factors and Usability Engineering to Medical Devices." Testing demonstrated that no new or different questions of safety or effectiveness were raised.
- Cleaning and disinfection validation was performed per FDA Guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," and confirmed that the injection system meets its cleaning and disinfection requirements.

All test results demonstrate that the design and materials of the MEDRAD MRXperion MR Injection System meet the established performance criteria and will perform as intended. The results of the design verification and validation, including human factors engineering evaluation, demonstrate that the subject device is substantially equivalent to its predicate device.

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 Special 510(k) Premarket Notification.

**Conclusion:**

Bayer Medical Care Inc. considers the MEDRAD MRXperion MR Injection System to be substantially equivalent to the predicate device listed above. The fundamental scientific technology, principle of operation, and indications for use are unchanged from the predicate device. The differences between the proposed device and the predicate device do not introduce new issues of safety and effectiveness.