February 13, 2026

Bayer Medical Care, Inc.
Colleen Witt
Director, Global Regulatory Strategy Devices
1 Bayer Drive
Indianola, Pennsylvania 15051-0780

Re: K252891
Trade/Device Name: MEDRAD MRXperion MR Injection System and MR Injection System Syringe Kit; MEDRAD ISI2 Module (ISI2)
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector And Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: January 16, 2026
Received: January 16, 2026

Dear Colleen Witt:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shruti N. Mistry -S

Shruti Mistry
Assistant Director
DHT3C: Division of Drug Delivery and General Hospital Devices, and Human Factors
OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252891

Device Name
MEDRAD MRXperion MR Injection System and MR Injection System Syringe Kit
MEDRAD ISI2 Module (ISI2)

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 procedures. 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. Only trained healthcare professionals are intended to operate this device.

For a complete list of compatible contrast agents for use with the MEDRAD® MRXperion MR Injection System, refer to the MRXperion MR Injection System operation manual.

The ISI2 Module is indicated for the specific purpose of allowing an injector to interface with an imaging scanner.

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.

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510(k) Summary K252891
Bayer Medical Care, Inc. MEDRAD® MRXperion MR Injection System

I. SUBMITTER

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Indianola, Pa 15051-0780

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Date Prepared: January 16, 2026

II. DEVICE

Name of Device: MEDRAD® MRXperion MR Injection System and MR Injection System Syringe Kit
MEDRAD® ISI2 Module (ISI2)
Common Name: Angiographic Injector and Syringe
Classification Name: Injector and Syringe, Angiographic
Classification Regulation: 21 CFR 870.1650
Regulatory Class: Class II
Product Code: DXT

III. PREDICATE DEVICE

Name of Device: MEDRAD® MRXperion MR Injection System and MR Injection System Syringe Kit
510(k) Number: K182276
Common Name: Angiographic Injector and Syringe
Classification Name: Injector and Syringe, Angiographic
Classification Regulation: 21 CFR 870.1650
Regulatory Class: Class II
Product Code: DXT

The MEDRAD® MRXperion MR Injection System was subject to a design-related recall in June 2016 which was closed in December 2016 (Recall Number Z-2244-2016).

IV. REFERENCE DEVICE

Name of Device:	MEDRAD® Centargo CT Injection System MEDRAD® ISI2 Module
510(k) Number:	K241849
Common Name:	Automatic injector for contrast media
Classification Name:	Injector, Contrast Medium, Automatic
Classification Regulation:	21 CFR 870.1650
Regulatory Class:	Class II
Product Code:	IZQ

This reference device has not been subject to a design-related recall.

V. DEVICE DESCRIPTION

The MRXperion Injection System is a software-controlled, electromechanical 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 MRXperion Injection System is comprised of a Scan Room Unit (SRU), Control Room Unit (CRU) and Single Use, Disposable Syringe Kit.

The SRU is located within the scan room whereas the control room unit is not. The SRU, via a wired connection, interfaces with the control room unit. The CRU, also known as the workstation, includes a graphical user interface for the injector. The operator can use the touchscreen display to manage protocols and initiate and execute injections. However, the SRU can be used to also initiate and execute injections.

The fluids are delivered from a single use only, sterile disposable set that includes one 65 mL syringe for contrast media and one 115 mL syringe for saline.

The injection system is intended to be used in an MR suite. The MR suite may be located in a mobile medical imaging trailer. The injection system is intended to be operated by personnel with training and experience in MR procedures and use of MR injection systems. Operators will consist of radiological technologists trained in the use of the equipment. This system is intended for use with the general patient population, including adults and pediatrics.

The MRXperion Injection System subject to this submission includes modified hardware and software as compared to the most recent clearance (K182276). The submission also includes an additional connectivity accessory, Imaging System Interface (ISI2) Module. The design changes do not involve any changes to the MRXperion MR Injection System Syringe Kit.

Below is a high-level summary of the modifications subject to this submission.

The significant changes to the MRXperion Injection System include:

1. Addition of the ISI2 Module Accessory
   The ISI2 module is an optional hardware accessory with embedded software which enables the MRXperion Injection System to interface with an MR scanner system. The ISI2 module synchronizes scan timing and simplifies operator workflow.

   The MRXperion Injection System CRU (User Interface and Certegra Platform) and Injector Head software was modified to enable communication with the ISI2 module.

   The MRXperion Injection System Indications for Use statement has been updated to include the ISI2 module indications.

2. Expanded Magnetic Field Strength Range
   The MRXperion Injection System magnetic field strength range has been expanded from '0.7T to 3.0T' to 'Up to and including 7.0T'. There were no hardware or software device modifications needed to support this expanded magnetic field strength range. The magnetic field strength range was removed from the indications for use and included as a warning within the MRXperion Injection System Operation Manual.

Other minor modifications include hardware and software changes to enhance overall system security, reliability, and operational efficiency:

- a. Hardware Modifications
  - i. A Trusted Platform Module (TPM) 2.0 hardware has been added to the existing MRXperion Workstation 3.0 which enables hardware-based cryptographic protection.
  - ii. A Head Interface Card (HIC) Bootloader update to improve system stability and enable authentication on the HIC.
- b. Software Modifications
  - i. Software self-upgrade implementation which allows authenticated users to perform critical software updates related to cybersecurity.
  - ii. Implementation of the Hash-Based Message Authentication Code (HMAC) between the MRXperion Scan Room Unit (SRU) and Control Room Unit (CRU). This implementation secures the communication between the SRU and CRU by ensuring message integrity and authenticity.

VI. 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. Only trained healthcare professionals are intended to operate this device.

For a complete list of compatible contrast agents for use with the MEDRAD® MRXperion MR Injection System, refer to the MRXperion MR Injection System Operation Manual.

The ISI2 Module is indicated for the specific purpose of allowing an injector to interface with an imaging scanner.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

A table comparing key features of the subject and predicate devices is provided below.

Table 1 – Key Feature Comparison

	Predicate Device: MEDRAD® MRXperion MR Injection System (K182276)	Subject Device: MEDRAD® MRXperion MR Injection System (K252891)	Comparison
Class	II	II	Same
FDA Regulation Number	21 CFR 870.1650	21 CFR 870.1650	Same
Classification Product Code	DXT	DXT	Same
Intended Use / 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.	The MEDRAD® MRXperion MR Injection System is a syringe-based fluid delivery system indicated for delivery of contrast media and saline during MR procedures. 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. Only trained healthcare professionals are intended to operate this device. For a complete list of compatible contrast agents for use with the MEDRAD MRXperion MR Injection System, refer to the MRXperion MR Injection System Operation Manual. The ISI2 Module is indicated for the specific purpose of allowing an injector to interface with an imaging scanner.	Same Intended Use Different Indications for Use – this difference does not change the intended use of the device. The safety and effectiveness of the MRXperion Injection System has been confirmed through verification and validation testing.

System Components			
System	MRXperion Scan Room Unit MRXperion Control Room Unit	MRXperion Scan Room Unit MRXperion Control Room Unit	Same
Accessories	Handswitch	Handswitch ISI2 Module	Different. The safety and effectiveness of the MRXperion Injection System accessory (ISI2) has been confirmed via non-clinical bench performance testing, software verification and validation testing, and ISI2 – MR Scanner Validation testing.
Disposables	MRXperion MR Injection System Syringe Kit Syringe A: Disposable 65 mL Syringe B: Disposable 115 mL	MRXperion MR Injection System Syringe Kit Syringe A: Disposable 65 mL Syringe B: Disposable 115 mL	Same
Physical Design			
Weight	Control Room Unit: 15.8 lbs Scan Room Unit: 94.0 lbs	Control Room Unit: 15.8 lbs Scan Room Unit: 94.0 lbs	Same
CRU (Workstation) Power Requirement Rated Voltage: Rated Current: Rated Frequency:	100-240 VAC 1.3A 50-60 Hz	100-240 VAC 1.3A 50-60 Hz	Same
SRU Power Requirement Rated Voltage: Rated Current: Rated Frequency:	100-240 VAC 120VA – 210VA 50-60 Hz	100-240 VAC 120VA – 210VA 50-60 Hz	Same

Display Type	Color LCD	Color LCD	Same
Characteristics			
Single Patient Use Disposable	Yes	Yes	Same
Used to administer contrast media and saline	Yes	Yes	Same
Operational Characteristics			
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	Same
Fill Volume (Syringe B)	1 mL to max syringe volume in 1 mL increments	1 mL to max syringe volume in 1 mL increments	Same
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	Same
Fill Speed (high 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	Same
Flow Rate	0.01 to 10 mL/s in increments of: - 0.01 mL/s between 0.01 and 3.1 mL/s - 0.1 mL/s between 3.1 and 10 mL/s	0.01 to 10 mL/s in increments of: - 0.01 mL/s between 0.01 and 3.1 mL/s - 0.1 mL/s between 3.1 and 10 mL/s	Same
Delay	N/A (addressed by Pause Phase)	N/A (addressed by Pause Phase)	Same
Pause Phase	1 to 1200s in 1s increments	1 to 1200s in 1s increments	Same
Programmable Pressure Limit (PSI/kPa)	100/690 150/1035 200/1380 250/1725	100/690 150/1035 200/1380 250/1725	Same

	300/2070 325/2240	300/2070 325/2240	
Keep Vein Open (KVO)	Yes; 0.25 mL, time adjustable. Defaults at every 30 seconds	Yes; 0.25 mL, time adjustable. Defaults at every 30 seconds	Same
Protocol Memory	60 protocols of up to 6 phases each	60 protocols of up to 6 phases each	Same
Injection History Memory	Previous 20 successful injections	Previous 20 successful injections	Same
Multi-Phase	6 phases per injection	6 phases per injection	Same
Volume Accuracy	Single Syringe A Injection: +/- (1% + 0.2 mL) of the programmed contrast volume for volumes ≤ 15.0 mL +/- (1% + 0.3 mL) of the programmed contrast volume for volumes > 15.0 mL Single Syringe B Injection: +/- (5% + 0.1 mL)	Single Syringe A Injection: +/- (1% + 0.2 mL) of the programmed contrast volume for volumes ≤ 15.0 mL +/- (1% + 0.3 mL) of the programmed contrast volume for volumes > 15.0 mL Single Syringe B Injection: +/- (5% + 0.1 mL)	Same
Flow Rate Accuracy	Single Syringe Injection: +/- (10% + 0.005 mL/s) when rate is 0.01 to 0.99 mL/s +/- (10% + 0.02 mL/s) when rate is 1 to 10 mL/s	Single Syringe Injection: +/- (10% + 0.005 mL/s) when rate is 0.01 to 0.99 mL/s +/- (10% + 0.02 mL/s) when rate is 1 to 10 mL/s	Same
Pause Accuracy	+/- (5% + 0.2 seconds)	+/- (5% + 0.2 seconds)	Same
KVO Volume Accuracy	+/- 0.05 mL, averaged over 10 consecutive boluses	+/- 0.05 mL, averaged over 10 consecutive boluses	Same
KVO Flow Rate Accuracy	1 mL/s +/- 0.2 mL/s	1 mL/s +/- 0.2 mL/s	Same
Safety Stop Mechanism	Software stops and electromechanical switch	Software stops and electromechanical switch	Same

Syringe System	Dual Syringes	Dual Syringes	Same
Syringe Docking	Non-rotational orientation	Non-rotational orientation	Same
Docking	Manual and automatic	Manual and automatic	Same
Fill Control	Manual and automatic	Manual and automatic	Same
Prime Control	Manual and automatic	Manual and automatic	Same
Retract Control	Manual and automatic	Manual and automatic	Same
Check for Air Confirmation	Operator visual inspection; user confirmed	Operator visual inspection; user confirmed	Same
Start/Stop Switch	Control Room and Scan Room	Control Room and Scan Room	Same
Communication	Fiber Optic	Fiber Optic	Same
MR Compatibility	0.7T to 3.0T	up to and including 7.0T	Different. The safety and effectiveness of the MRXperion Injection System in the expanded magnetic field strength has been confirmed through validation performance testing with OEM scanners and MR compatibility testing.
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.	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
Injector Software Features			
eGFR Calculator	Yes	Yes	Same
Weight-Based Dosing Calculator	Yes	Yes	Same
Informatics	Yes	Yes	Same

Disposables		
MRXperion MR Injection System Syringe Kit	There are no changes to the MRXperion MR Injection System Syringe Kit.	Same

VIII. INTENDED USE / INDICATIONS FOR USE COMPARISON

The Intended Use of the MRXperion Injection System 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 is not changing as a result of the proposed modifications. There are minor indication differences, which do not raise different questions of safety and effectiveness and do not result in a new intended use.

IX. TECHNOLOGICAL COMPARISON

The MRXperion Injection System with ISI2 Module has the same intended use, main technological characteristics, and operating principle as the predicate device (K182276). The design modifications characterizing the subject device are the addition of the ISI2 Module accessory and expanding the magnetic field strength range. These differences do not raise different questions of safety and effectiveness. Non-clinical and software verification and validation testing has demonstrated that the MRXperion Injection System meets its specified parameters and operates as intended. As a result, the device is deemed as safe and effective as the predicate device.

X. Non-Clinical Testing

Non-clinical testing according to the MRXperion Injection System Verification and Validation Plan has been completed for the modifications subject to this submission.

The following data has been provided in support of the substantial equivalence determination.

A. Performance Testing - Bench

Device non-clinical verification testing included the ISI2 testing for chemical resistance, environmental conditions, reliability, mobile environment impact testing, and shipping and handling testing. Additionally, validation testing has been completed with the MRXperion Injection System, ISI2 Module and Siemens MAGNETOM Vida Scanner (K203443) to demonstrate that when used together, they operate as intended.

MR validation performance testing has been completed with the Siemens MAGNETOM Free.Max 0.55T MR Scanner (K210611) and Siemens MAGNETOM Terra.X 7T MR Scanner (K232322) to demonstrate that both the MRXperion Injection System and MR Scanner met key performance requirements while operating together in the expanded magnetic field strength. Testing of the expanded magnetic field strength range was completed in accordance with FDA Guidance, Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment, October 2023.

All performance bench testing passed and the demonstrated product performance met all prior established acceptance criteria.

B. Software Verification and Validation Testing

Software verification and validation testing was performed in accordance with the following standards and guidance:

a. IEC 62304 Edition 1.1 2015-06, Medical Device Software, Software lifecycle processes
b. Off-The-Shelf Software Use in Medical Devices - Guidance for Industry and FDA Staff, August 2023
c. Guidance for the Content of Premarket Submissions for Device Software Functions - Guidance for Industry and FDA Staff, June 2023

Test results were evaluated against established acceptance criteria; all test results were acceptable.

C. Cybersecurity Testing

Cybersecurity Testing was conducted in accordance with FDA Guidance, Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, June 2025. Testing provided a reasonable assurance that the device and related systems are secure.

D. Human Factors Usability Validation Testing

Human Factors Usability assessment was completed in accordance with the following standards and guidance:

a. IEC 62366-1 Edition 1.1 2020-06, Medical Devices – Part 1: Application of Usability engineering to medical devices.
b. IEC 60601-1-6 Edition 3.2 2020-07, Medical Electrical Equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability
c. Applying Human Factors and Usability Engineering to Medical Devices - Guidance for Industry and FDA Staff, February 2016.
d. Content of Human Factors Information in Medical Device Marketing – Guidance for Industry and FDA Staff, Draft, December 9, 2022

Based on the assessment, the proposed modifications to the MRXperion Injection System are found acceptable regarding safe and effective use for the intended users, uses and use environments.

E. Interoperability Testing

Interoperability assessment was completed in accordance with the following standards and guidance:

a. Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices, September 2017
b. AAMI/UL 2800-1, 2022 Standard for Medical Device Interoperability
c. AAMI/UL 2800-1-1, 2022 Standard for Risk Concerns for Interoperable Medical Products
d. AAMI/UL 2800-1-2, 2022 Standard for Interoperable Item Development Life Cycle
e. AAMI/UL 2800-1-3, 2022 Standard for Interoperable Item Integration Life Cycle

Based on the assessment, the proposed modifications to the MRXperion Injection System are found acceptable. Testing has demonstrated that the ISI2 interaction with the MR Scanner did

not impact the MRXperion Injection System or Scanner performance as both systems performed as intended and comply with the intended specifications.

F. Electromagnetic Compatibility (EMC) and Electrical Safety Testing

Electrical Safety and Electromagnetic Compatibility (EMC) testing was performed in accordance with the following standards and the FDA guidance:

a. IEC 60601-1 Edition 3.2 2020-08, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
b. IEC 60601-1-2 Edition 4.1 2020-09, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
c. IEC TS 60601-4-2 Edition 1.0 2024-03, Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
d. FDA Guidance, Electromagnetic Compatibility (EMC) of Medical Devices, June 2022

Testing included verification of the MRXperion Injection System, including the ISI2 Module accessory. All testing passed and the demonstrated performance met all prior established acceptance criteria.

G. Clinical Testing

Clinical testing was not needed to support the determination of substantial equivalence based on the proposed modifications to the MRXperion Injection System.

Summary

In summary, the conclusions drawn from the nonclinical and verification and validation testing demonstrate that the modifications to the MRXperion Injection System are as safe and as effective as the currently cleared MRXperion Injection System (K182276).

XI. CONCLUSION

Bayer considers the modifications to the subject device, MRXperion Injection System, to be substantially equivalent to the predicate device, MRXperion Injection System, K182276. This conclusion is based upon the devices having the same intended use and similar technological characteristics. While there are differences in design and technology, these differences do not raise new questions of safety or effectiveness. The MRXperion Injection System has demonstrated the ability to perform within the specified parameters and operate as intended by the users of the device. As a result, its performance is deemed acceptable and substantially equivalent to the predicate device (K182276).