June 12, 2026

Bayer Medical Care, Inc.
Nishanth Reddy Deva
Associate Director, Global Regulatory Strategy Devices
1 Bayer Dr.
Indianola, Pennsylvania 15051

Re: K253688
Trade/Device Name: MEDRAD® Imaging Bulk Package Transfer Spike
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: PQH
Dated: May 26, 2026
Received: May 26, 2026

Dear Nishanth Reddy Deva:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

DAVID WOLLOSCHECK
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David Wolloscheck, Ph.D.
Assistant Director
DHT3C: Division of Drug Delivery and
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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)*
K253688

Device Name
MEDRAD® Imaging Bulk Package Transfer Spike

Indications for Use *(Describe)*
The MEDRAD® Imaging Bulk Package (IBP) Transfer Spike is indicated for the transfer of the following contrast media:
• Ambelvist® (gadoquatrane) injection in IBP
• Gadavist® (gadobutrol) injection in IBP

The Transfer Spike is used to transfer contrast media to empty, sterile hand syringes for MR procedures.

Discard the Transfer Spike after one of the following conditions has occurred first: (1) the Transfer Spike has been disconnected from the contrast media container; (2) the contrast media container has been depleted; or (3) after contrast media use time has elapsed since the container was penetrated.

For a specific contrast media use time, refer to the contrast media prescribing information or the contrast media IBP container label.

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.

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K253688 – 510(k) Summary
Bayer Medical Care, Inc. MEDRAD® Imaging Bulk Package Transfer Spike
The Summary is prepared in conformance with 21 CFR 807.92

I. SUBMITTER

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Date Prepared: June 11, 2026

II. DEVICE

Name of Device:	MEDRAD® Imaging Bulk Package Transfer Spike
Common Name:	Contrast Media Transfer Set
Classification Name:	Intravascular Administration Set
Classification Regulation:	21 CFR 880.5440
Regulatory Class:	Class II
Product Code:	PQH

III. PREDICATE DEVICE

Name of Device:	MEDRAD® Imaging Bulk Package Transfer Spike, K200280
Common Name:	Contrast Media Transfer Set
Classification Name:	Intravascular Administration Set
Classification Regulation:	21 CFR 880.5440
Regulatory Class:	Class II
Product Code:	PQH

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

IV. DEVICE DESCRIPTION

The MEDRAD® Imaging Bulk Package Transfer Spike ("Transfer Spike") is a sterile, single-use, pre-administration filling device designed for the aseptic transfer of contrast media from an Imaging Bulk Package (IBP) to sterile, empty hand syringes for use in magnetic resonance (MR) imaging procedures. The device is intended to be used by individuals with training and experience in diagnostic studies. It is intended to spike one bulk package of Gadavist® (gadobutrol) injection contrast media or Ambelvist® (gadoquatrane) injection contrast media. Each imaging bulk transfer spike consists of a spike and a swabable valve.

Transfer Spike is designed for single use with one IBP container; the Transfer Spike must not be reused or applied across multiple containers. It does not come in direct contact with patients, and each unit is provided sterile, individually packaged, and is not intended for reprocessing or resterilization.

V. INDICATIONS FOR USE

The MEDRAD® Imaging Bulk Package (IBP) Transfer Spike is indicated for the transfer of the following contrast media:

- Ambelvist® (gadoquatrane) injection in IBP
- Gadavist® (gadobutrol) injection in IBP

The Transfer Spike is used to transfer contrast media to empty, sterile hand syringes for MR procedures.

Discard the Transfer Spike after one of the following conditions has occurred first: (1) the Transfer Spike has been disconnected from the contrast media container; (2) the contrast media container has been depleted; or (3) after contrast media use time has elapsed since the container was penetrated.

For a specific contrast media use time, refer to the contrast media prescribing information or the contrast media IBP container label.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

A table comparing key features of the subject device (Transfer Spike) and predicate device (Transfer Spike) is provided below.

Table 1 – Key Feature Comparison

Item	Predicate Device (K200280): MEDRAD® Imaging Bulk Package (IBP) Transfer Spike	Subject Device (K253688): MEDRAD® Imaging Bulk Package (IBP) Transfer Spike	Comparison
Regulatory Classification			
Class	II	II	Same
FDA Regulation Number	880.5440	880.5440	Same
Classification Product Code	PQH (Intravascular administration set)	PQH (Intravascular administration set)	Same
Labeling			
Indications for Use	The MEDRAD® Imaging Bulk Package Transfer Spike (Transfer Spike) is indicated for the transfer of Gadavist® (gadobutrol) Injection contrast media as supplied in an approved Imaging Bulk Package presentation (30 mL or 65 mL) to empty, sterile hand syringes and/or empty, sterile syringes on single-use only syringe-based contrast power injection systems indicated for the controlled, automatic venous administration of contrast agents for MR procedures. The Transfer Spike is to be discarded after one of the following conditions has occurred first: the contrast media container has been depleted, the Transfer Spike has been disconnected from the contrast vial, or after 24 hours has elapsed since the container was penetrated.	The MEDRAD® Imaging Bulk Package (IBP) Transfer Spike is indicated for the transfer of the following contrast media: - Ambelvist® (gadoquatrane) injection in IBP - Gadavist® (gadobutrol) injection in IBP The Transfer Spike is used to transfer contrast media to empty, sterile hand syringes for MR procedures. Discard the Transfer Spike after one of the following conditions has occurred first: (1) the Transfer Spike has been disconnected from the contrast media container; (2) the contrast media container has been depleted; or (3) after contrast media use time has elapsed since the container was penetrated. For a specific contrast media use time, refer to the contrast media prescribing information	Same intended use, as the device continues to serve for aseptic transfer of contrast media from an IBP to sterile, empty syringes for use in Magnetic resonance (MR) imaging procedures. The expansion of the transfer spike to include Ambelvist® (gadoquatrane) and the removal of contrast use time from the indications for use statement do not introduce new intended use.

		or the contrast media IBP container label.	The subject device has been modified to remove reference to use with syringe-based contrast power injection systems, limiting use to hand syringes only from the indications for use do not introduce a new intended use.
Intended User	Trained healthcare professionals	Trained healthcare professionals	Same
Construction			
Spike	Vented Spike	Vented Spike	Same
Valve	Swabable	Swabable	Same
Materials			
Vented Spike	ABS	ABS	Same
Check Valve Air Filter	Spike Filter Housing: Polystyrene Spike Filter: Glass Fiber	Spike Filter Housing: Polystyrene Spike Filter: Glass Fiber	Same
Swabbable Valve	Medical Grade Polycarbonate, Silicone	Medical Grade Polycarbonate, Silicone	Same
Spike Guard	Low Density Polyethylene	Low Density Polyethylene	Same
Adhesive	Cyclohexane or 50/50 Cyclohexane/ MEK solvent and Loctite 3341 UV Core	Cyclohexane or 50/50 Cyclohexane/ MEK solvent and Loctite 3341 UV Core	Same
Packaging			
Type	Individually packaged in a Tyvek pouch	Individually packaged in a Tyvek pouch	Same
Shelf Life	3 years at release	3 years at release	Same
Biological			
Biocompatibility	Compliant to applicable sections of ISO/AAMI 10993-1:2018	Compliant to applicable sections of ISO/AAMI 10993-1:2018	Same
Pyrogenicity	Non-pyrogenic	Non-pyrogenic	Same
Sterilization	Radiation (Gamma)	Radiation (Gamma)	Same
Sterilization Assurance Level	10^{-6}	10^{-6}	Same
Performance			
Spike Valve Separation Torque	6 in/lbs	6 in/lbs	Same
Fill (Load) Rate	10mL/sec for manual fill 4mL/sec for autoload	10mL/sec for manual fill 4mL/sec for autoload	Same
Use Environment	Ambient (MR Suite)	Ambient (MR Suite)	Same

Transfer Spike Use Life	24 hours	24 hours	Same
Transfer Spike Assembly Use Time	24 hours for Gadavist® (Gadobutrol) injection in IBP	6 hours for Ambelvist® (gadoquatrane) injection in IBP 24 hours for Gadavist® (Gadobutrol) injection in IBP	Different and substantially equivalent. This difference does not change the intended use of the device. The safety and effectiveness of the MEDRAD® Imaging Bulk Package Transfer Spike has been confirmed through labeling verification, Human Factors Knowledge assessment, and chemical integrity testing to show the transfer spike can be used with Ambelvist® (gadoquatrane) injection in IBP with no additional risk.

VII. NON-CLINICAL TESTNG

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

A. Performance Testing – Bench

Performance bench testing was conducted, where applicable, to support the use of the Imaging Bulk Package Transfer Spike with Ambelvist® (gadoquatrane) injection in Imaging Bulk Package (IBP) presentations. Chemical Integrity was performed to demonstrate there are no increased concerns of safety when using the Transfer Spike with Ambelvist contrast media in an IBP presentation. Particulate testing was completed according to methodology prescribed in USP <788> Particulate Matter in Injections. The Transfer Spike disposables met all acceptance criteria and demonstrated that the device performs adequately with Ambelvist® IBP Injection.

All other performance bench testing, including functional performance, was leveraged from the predicate device (K200280), as no changes were made to the device design, materials, or mechanism of action.

B. Biocompatibility and Sterilization.

Biocompatibility testing and sterilization validation were leveraged from the predicate device (K200280). The subject device utilizes the same materials, patient-contacting components, and sterilization methods as the predicate. As no design, material, or processing changes were introduced, previously completed biocompatibility evaluations and sterilization validations remain applicable and sufficient to support the changes in this submission.

- ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.
- ISO 11737-1:2018+AMD1:2021 Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on product
- ISO 11737-2:2019 Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition validation and maintenance of a sterilization process
- ISO 11137-1: 2006+AMD2:2018 Sterilization of health care products - Radiation - Part 1: Requirements for development validation and routine control of a sterilization process for a medical device
- ISO 11137-2:2013+AMD1:2022 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose

C. MR Compatibility

MR compatibility information was leveraged from the predicate device (K200280). Transfer Spike is composed of materials that are non-magnetic, non-metallic, and non-conductive. Based on its material composition and design, the device does not introduce MR-related hazards such as magnetic field interactions, torque, or RF-induced heating, and does not alter the interaction of the system with the MR environment. Hence, there is no impact of Transfer Spike MR safety in MR environment.

The subject device does not include any changes in materials, design, or configuration that would impact MR safety compared to the previously cleared device. Therefore, no additional MR-specific testing was conducted, and the previously established MR compatibility conclusions remain applicable.

D. Human Factors

A Human Factors knowledge-based assessment was conducted to evaluate the proposed labeling modifications associated with this submission. Human Factors usability validation previously completed for the predicate device (K200280) was leveraged, as the device user interface, use environment, and primary operating tasks remain unchanged. The assessment was performed in accordance with the following standards and guidance:

- IEC 62366-1 Edition 1.1 2020-06 Consolidated version. Medical Devices – Part 1: Application of Usability engineering to medical devices.
- Applying Human Factors and Usability Engineering to Medical Devices (Guidance for Industry and FDA Staff), February 2016.

Based on this assessment, the proposed labeling modifications for the Imaging Bulk Package Transfer Spike do not introduce new use-related risks for the intended users, uses, or use environment.

Summary

In summary, the non-clinical testing and verification and validation activities demonstrate that the changes proposed in this submission do not affect the safety or effectiveness of the Imaging Bulk Package Transfer Spike. Testing leveraged from the predicate device (K200280), in combination with targeted performance testing and Human Factors knowledge-based assessment, supports the conclusion that the subject device is as safe and effective as the currently cleared Imaging Bulk Package Transfer Spike (K200280). No new non-clinical testing was conducted, as the changes in this submission are limited to labeling updates and the expansion of the indications to include new contrast media.

VIII. CONCLUSION

Bayer considers the subject device, Imaging Bulk Package Transfer Spike to be substantially equivalent to the predicate device, Imaging Bulk Package Transfer Spike, K200280. This conclusion is based upon the devices having the same intended use and same technological characteristics. While there are changes to the Transfer Spike labeling for the expanded indications to allow use of Ambelvist, these differences do not raise new questions of safety or effectiveness. Imaging Bulk Package Transfer Spike 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.