July 30. 2020

Bayer Medical Care Inc.
Leslie O'Nan
Director, Regulatory Affairs
1 Bayer Drive
Indianola, Pennsylvania 15051

Re: K200280
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: July 1, 2020
Received: July 2, 2020

Dear Leslie O'Nan:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 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,

for Payal Patel
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200280

Device Name
MEDRAD® Imaging Bulk Package Transfer Spike

Indications for Use *(Describe)*
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 65mL) 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.

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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K200280

510(k) Summary

Date Prepared: July 24, 2020

Submitter:
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Device Trade Name: MEDRAD® Imaging Bulk Package Transfer Spike

Common Name: Contrast Media Transfer Set

Classification Name: Intravascular Administration Set
Regulation Number: 21 CFR 880.5440
Product Code: PQH
Classification: Class II

Predicate Device: MEDRAD® Imaging Bulk Package Transfer Set (IBP Transfer Set)
Bayer U.S. LLC
K173913, May 04, 2018

Device Description: The MEDRAD® Imaging Bulk Package Transfer Spike (Transfer Spike) is a pre-administration filling device that is designed to transfer fluid from an imaging bulk package into multiple sterile syringes via a powered

injector system prior to an MR procedure. There is no direct patient contact with the use of this device. It is intended to spike one bulk package of Gadavist® (gadobutrol) injection contrast media only. Each imaging bulk transfer set consists of a spike and a swabbable valve. The transfer spike is provided sterile, individually packaged, and is not intended to be resterilized.

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.

Performance Testing:

Sterilization: Sterilization conditions have been validated on the Transfer Spike 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 indicates that the Transfer Spike complies with the standards.

Shelf-Life: Shelf-life testing included verification that the performance was not affected by accelerated aging up to three-years. All testing passed and the demonstrated product performance met all prior established acceptance criteria.

Packaging: The Transfer Spike is sterilized, and its packaging was validated in accordance with ISO 11607-1 and ISO 11607-2. All testing passed and indicates that the Transfer Spike complies with the standards.

Biocompatibility: The Transfer Spike indirect patient contact materials were verified in accordance with the following standard:

- ISO 10993-1: 2018 Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process
  The following test program was selected for an externally communicating, indirect blood path, limited contact (≤ 24 h) device:
  - Cytotoxicity
  - Sensitization
  - Irritation / Intracutaneous Reactivity
  - Acute Systemic Toxicity
    - Acute Systemic Injection
    - Materials Mediated Pyrogen
  - Hemocompatibility

Verification results indicated that the materials comply with the standard.

Performance – Bench: The Transfer Spike was tested for performance and verified in accordance with the following standards:

- ISO 80369-7 - Conical Fittings with 6% (Luer) taper for syringes, needles, and other medical equipment
- ISO 8536-4:2010, Infusion equipment for medical use – Part 4: Infusion sets for single use, gravity feed

Verification results indicate that the Transfer Spike complies with the standards.

Additional testing included:

- Microbial ingress testing conducted at time points, T = 0 hr, 7 hr, 11 hr, 15 hr, 20 hr, 24 hr, and bottle depletion for the following components:
    - Swabbable Valve
    - Bottle Septum
    - Spike
    - Syringe
- Injectable particulate Per USP <788>
- Chemical compatibility
    - Through evaluation of conformance to the approved release specifications of Gadavist® (gadobutrol).

Verification results indicate that the Transfer Spike complies with its predetermined specifications.

Predicate Device Comparison:

Item		Predicate Device: K173913 MEDRAD® Imaging Bulk Package Transfer Set	Proposed Device: K200280 MEDRAD® Imaging Bulk Package Transfer Spike	Comparison
Regulatory Classification	Class	II	II	Same
	FDA Regulation Number	880.5440	880.5440	Same
	Classification Product Code	PQH	PQH	Same
Labeling	Intended Use	The MEDRAD® Imaging Bulk Package Transfer Set is intended for the transfer of fluids from bulk containers to empty sterile syringes on syringe-based contrast delivery systems (injectors).	The MEDRAD® Imaging Bulk Package Transfer Spike (Transfer Spike) is intended for the transfer of fluid from bulk containers to sterile, empty hand syringes and/or sterile, empty syringes on syringe-based contrast delivery systems (injectors).	Adds use with sterile hand syringes. Testing demonstrated that the differences do not raise new questions of safety and effectiveness.

Item		Predicate Device: K173913 MEDRAD® Imaging Bulk Package Transfer Set	Proposed Device: K200280 MEDRAD® Imaging Bulk Package Transfer Spike	Comparison
	Indications for Use	The MEDRAD® Imaging Bulk Package Transfer Set (IBP Transfer Set) is indicated for the transfer of ULTRAVIST® (Iopromide), ISOVUE® (Iopamidol), and OMNIPAQUE™ (Iohexol) contrast media as supplied in an approved Imaging Bulk Package (IBP) presentation to empty sterile syringes on single-use only syringe-based contrast power injection systems indicated for the controlled, automatic venous administration of contrast agents for CT procedures. The Transfer Set is to be discarded after one of the following conditions has occurred first: the contrast media container has been depleted, the contrast media use time has expired, or 10 hours has elapsed since the container was penetrated.	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 proposed device has been tested with the listed contrast agent. Chemical compatibility testing including particulate testing as per USP <788> has demonstrated that the differences do not raise new questions of safety and effectiveness.

Item		Predicate Device: K173913 MEDRAD® Imaging Bulk Package Transfer Set	Proposed Device: K200280 MEDRAD® Imaging Bulk Package Transfer Spike	Comparison
Construction	Spike	Vented Spike	Vented Spike	Same
	Tubing Length	20"	N/A	No tubing in the Transfer Spike
	Valve	Swabable	Swabable	Same
Packaging	Type	Individually packaged in a Tyvek pouch	Individually packaged in a Tyvek pouch	Same
	Shelf Life	5 years at release	3 years at release	Shelf life testing has been completed and demonstrated that the differences do not raise new questions of safety and effectiveness.
Biological	Biocompatibility	Compliant to applicable sections of ISO/AAMI 10993-1:2009	Compliant to applicable sections of ISO/AAMI 10993-1:2018	Same (tested to newest version of the standard)
	Pyrogenicity	Non-pyrogenic	Non-pyrogenic	Same
	Latex content	This device is not made with natural rubber latex	This device is not made with natural rubber latex	Same
	Sterilization Type	Ethylene Oxide (EtO)	Radiation (Gamma)	Change to sterilization method. SAL remains 10^{-6}
	Sterilization Assurance Level (SAL)	10^{-6}	10^{-6}	Same

Item		Predicate Device: K173913 MEDRAD® Imaging Bulk Package Transfer Set	Proposed Device: K200280 MEDRAD® Imaging Bulk Package Transfer Spike	Comparison
Performance	Fill (Load) Rate	10 mL/sec for manual fill 4 mL/sec for autoload	10 mL/sec for manual fill 4 mL/sec for autoload	Same
	Use Environment	Ambient (CT Suite)	Ambient (MR Suite)	Same – Ambient environment of radiology suite
	Use Time	10 hours	24 hours	Use time aligns with the use time of Gadavist contrast media. Testing has been completed and demonstrated that the differences do not raise new questions of safety and effectiveness.

Conclusion:

All test results demonstrate that the design and materials of the MEDRAD® Imaging Bulk Package Transfer Spike (Transfer Spike) meet the established performance criteria and will perform as intended. Bayer considers the Transfer Spike to be substantially equivalent to the predicate device listed above. This conclusion is based upon device similarities in Indications for Use, functional design, the technological characteristics comparison and testing that demonstrates that the Transfer Spike is substantially equivalent to the predicate device.