May 4, 2018

Bayer U.S. LLC
Leslie O'Nan
Regulatory Affairs Manager
1 Bayer Drive
Indianola, Pennsylvania 15051

Re: K173913
Trade/Device Name: MEDRAD® Imaging Bulk Package Transfer Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: PQH
Dated: April 13, 2018
Received: April 16, 2018

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. 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.

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.

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,

Tina Kiang
-S

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K173913

Device Name
MEDRAD® Imaging Bulk Package Transfer Set

Indications for Use *(Describe)*
The MEDRAD® Imaging Bulk Package Transfer Set (IBP Transfer Set) is indicated for the transfer of ULTRAVIST® (Iopromide), ISOVUE® (Iopamidol), and OMNIPAQUE™ (Iohexal) 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.

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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K173913
510(k) Summary

Date Prepared: April 13, 2018

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Device Trade Name: MEDRAD® Imaging Bulk Package Transfer Set

Common Name: Iodinated Contrast Media Transfer Tubing Set

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

Predicate Device: Bracco Injeneering Transfer Set
Bracco Injeneering S.A.
K133147, June 20, 2014

Device Description: The MEDRAD® Imaging Bulk Package Transfer Set 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 a CT procedure. There is no direct patient contact with

the use of this device. It is intended to spike one bulk package of iodinated contrast media only. Each imaging bulk transfer set consists of a spike, flexible tubing, and a swabbable valve. The transfer set is provided sterile, individually packaged, and is not intended to be resterilized.

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™ (Iohexal) 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.

Performance Testing:

Sterilization: The Imaging Bulk Package Transfer Set is ethylene oxide (EtO) sterilized and was validated to a sterility assurance level of 10^{-6} in accordance with the following standard:

- ISO 11135-1: 2014, Sterilization of health care products Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.

Verification results indicate that the MEDRAD® Imaging Bulk Package Transfer Set complies with the standard.

Shelf-Life: The Imaging Bulk Package Transfer Set is sterilized and its packaging was validated in accordance with the following standard:

- ISO 11607-1: 2006 Packaging for terminally sterilized medical devices - Part 1: requirements for materials, sterile barrier systems and packaging systems; and

Verification results indicate that the MEDRAD® Imaging Bulk Package Transfer Set complies with the standard.

Biocompatibility: The MEDRAD® Imaging Bulk Package Transfer Set indirect patient contact materials were verified in accordance with the following standard:

- ISO 10993-1: 2009 (R2013) 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
    - Hemolysis
    - Partial Thromboplastin Time
    - Platelet and Leukocyte

Verification results indicated that the materials comply with the standard.

Performance – Bench: The MEDRAD® Imaging Bulk Package Transfer Set was tested for performance and verified in accordance with the following standards:

- ISO 594-2:1998, Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment -- Part 2: Lock fittings
- ISO 8536-4:2007, Infusion equipment for medical use – Part 4: Infusion sets for single use, gravity feed

Verification results indicate that the MEDRAD® Imaging Bulk Package Transfer Set complies with the standards.

Additional testing included:

- Microbial ingress testing conducted at time points, T = 0 hr, 4 hr, 10 hr, 14 hr, and bottle depletion for the following components:
    - Swabbable Valve
    - Bottle Septum
    - Spike
    - Syringe
- Chemical compatibility and injectable particulate – Through evaluation of conformance to the approved release specifications of ULTRAVIST® and USP monographs for ISOVUE® and OMNIPAQUE™
- Material compatibility – Through evaluation of the transfer set under worst-case conditions and simulated use with ULTRAVIST® 370 as solvent for leachable compounds.

Verification results indicate that the MEDRAD® Imaging Bulk Package Transfer Set complies with its predetermined specifications

Predicate Device Comparison:

Item	Predicate Device: Bracco Injeneering Transfer Set	Subject Device: MEDRAD® Imaging Bulk Package Transfer Set	Comparison
Intended Use	The 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 Set is intended for the transfer of fluids from bulk containers to empty sterile syringes on syringe based contrast delivery systems (injectors).	Same
Indications for Use	The Bracco Injeneering Transfer Set is a component of a contrast management system and is indicated for the transfer of Isovue® (Iopamidol Injection) contrast media as supplied in an Imaging Bulk Package to empty sterile syringes on single-use only syringe-based contrast injection systems indicated for the controlled, automatic administration on the venous side, of contrast agents for CT procedures. The Transfer Set is to be discarded after the contrast media container has been depleted or 10 hours has elapsed since the container was penetrated, whichever occurs first.	The MEDRAD® Imaging Bulk Package Transfer Set (IBP Transfer Set) is indicated for the transfer of ULTRAVIST® (Iopromide), ISOVUE® (Iopamidol), and OMNIPAQUE™ (Iohexal) 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 predicate device is indicated for use with ISOVUE® (Iopamidol) contrast media as supplied in an Imaging Bulk Package; whereas, the subject device is indicated for use with ULTRAVIST® (Iopromide), ISOVUE® (Iopamidol), and OMNIPAQUE™ (Iohexal) contrast media as supplied in an Imaging Bulk Package. The MEDRAD® Imaging Bulk Package Transfer Set has been tested with each of the listed contrast agents and testing has demonstrated that the differences do not raise new questions of safety and efficacy.

Item	Predicate Device: Bracco Injeneering Transfer Set	Subject Device: MEDRAD® Imaging Bulk Package Transfer Set	Comparison
Tubing Length	20"	20"	Same
Single Use	Yes	Yes	Same
Biocompatible	Yes	Yes	Same
Sterile	Yes	Yes	Same
Sterility Assurance Level	10^{-6}	10^{-6}	Same
Sterilization Method	Ethylene Oxide (EtO)	Ethylene Oxide (EtO)	Same
Disposable	Yes	Yes	Same
Shelf Life	one (1) year shelf life	five (5) year shelf life	Shelf life testing has demonstrated that the difference does not raise new questions of safety and efficacy.
Packaging	Individually packaged in a Tyvek pouch	Individually packaged in a Tyvek pouch	Same
Microbial Ingress Testing	Yes	Yes	Same
Chemical Compatibility Testing	Yes	Yes	Same
Material Compatibility Testing	Yes	Yes	Same

Conclusion:

Bayer considers the MEDRAD® Imaging Bulk Package Transfer Set 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 MEDRAD® Imaging Bulk Package Transfer Set is substantially equivalent to the predicate device.