December 5, 2019
Bayer Medical Care Inc.
Kelly Frank
Project Manager
1 Bayer Drive
Indianola, Pennsylvania 15051

Re: K193028
Trade/Device Name: MEDRAD Mark 7 Arterion Injection System
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector And Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: November 4, 2019
Received: November 5, 2019

Dear Kelly Frank:

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 CAPT Alan Stevens
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)*
K193028

Device Name
MEDRAD Mark 7 Arterion Injection System

Indications for Use *(Describe)*

MEDRAD® Mark 7 Arterion Injection System

The MEDRAD® Mark 7 Arterion Injection System is indicated to be used specifically for the purposes of injecting contrast medium and common flushing solutions into humans for angiographic studies.

Imaging System Interface (ISI)

The ISI option is indicated for the specific purpose of allowing a MEDRAD® Mark 7 Arterion Injection System to interface with an angiography imaging system.

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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510(k) Summary

Submitter:	Bayer Medical Care, Inc. 1 Bayer Drive Indianola, PA 15051
Contact Person:	Kelly Frank Project Manager Phone: (412) 576-7583 Email: kelly.frank@bayer.com
Date Prepared:	October 24, 2019
Device Trade Name:	MEDRAD® Mark 7 Arterion Injection System
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® Mark 7 Arterion Injection System, K132928.

Device Description:

The MEDRAD Mark 7 Arterion Injector is a software-controlled medical device used to inject contrast agents from a 150 ml disposable syringe. Commonly referred to as an automated injection system, it is designed to allow a user to fill a disposable syringe and perform an injection with a user programmed volume and flow rate.

Indications for Use:

MEDRAD Mark 7 Arterion Injection System

The MEDRAD Mark 7 Arterion Injection System is indicated to be used specifically for the purposes of injecting contrast medium and common flushing solutions into humans for angiographic studies.

Imaging System Interface (ISI)

The ISI option is indicated for the specific purpose of allowing a MEDRAD Mark 7 Arterion Injection System to interface with an angiography imaging system.

Comparison to the Predicate Device:

The modification is an administrative update to include mention of the ISI (Imaging System Interface) module in the Indications for Use for the MEDRAD Mark 7 Arterion Injection System. This update does not involve any changes to the MEDRAD Mark 7 Arterion Injection System Syringe Kit. Table 1 provides a comparison of the proposed MEDRAD Mark 7 Arterion Injection System with the predicate device, the MEDRAD Mark 7 Arterion Injection System cleared per K132928.

The fundamental scientific technology, principle of operation, and intended use are unchanged from the predicate device, the MEDRAD Mark 7 Arterion Injection System cleared per K132928. The differences between the proposed device and the predicate device do not introduce new issues of safety and effectiveness.

Table 1. Comparison of MEDRAD Mark 7 Arterion Injection System (proposed device) with predicate device.

PARAMETER	**PREDICATE DEVICE** Mark 7 Arterion Injection System (K132928)	**PROPOSED DEVICE** Mark 7 Arterion Injection System	**RATIONALE FOR CHANGE**
Indications for Use	The MEDRAD Mark 7 Arterion Injection System is intended to be used specifically for the purposes of injecting contrast medium and common flushing solutions into humans for angiographic studies.	The MEDRAD Mark 7 Arterion Injection System is indicated to be used specifically for the purposes of injecting contrast medium and common flushing solutions into humans for angiographic studies. The ISI option is indicated for the specific purpose of allowing a MEDRAD Mark 7 Arterion Injection System to interface with an angiography imaging system.	Administrative update to add ISI module specific indications for use statement
Fill Volume	1 – 150 ml in 1 ml increments	Same	No change
Fill Speed (user	1 – 10 ml/sec	Same	No change

PARAMETER	PREDICATE DEVICE Mark 7 Arterion Injection System (K132928)	PROPOSED DEVICE Mark 7 Arterion Injection System	RATIONALE FOR CHANGE
configurable for AutoFill)			
Fill Speed (manual control by user)	1 – 20 ml/sec	Same	No change
Fixed Flow Rate	0.1 to 45.0 ml/sec in 0.1 ml increments (Single and Phased protocols) 0.1 to 59.9 ml/min in 0.1 ml/min increments (ml/m protocol)	Same	No change
Variable Flow Rate	1.0 – 10.0 ml/sec in 0.1 ml/sec increments	Same	No change
Flow Rate Rise Time	0.0 to 9.9 seconds in 0.1sec increments	Same	No change
Delay	0.0 to 9.9 seconds in 0.1sec increments	Same	No change
Pressure Limit (150 ml syringe)	100-1200 psi or 689-8273 kPa in increments of 1 psi (kPa)	Same	No change
Syringe Heat Maintainer	35°C + 5°C	Same	No change
Protocol Memory	40 protocols	Same	No change
Injection History	50 injections	Same	No change

PARAMETER	PREDICATE DEVICE Mark 7 Arterion Injection System (K132928)	PROPOSED DEVICE Mark 7 Arterion Injection System	RATIONALE FOR CHANGE
Memory			
Information Display	Color LCD	Same	No change
Programming Keys	Software-generated via an LCD touch screen	Same	No change
Touch Screen	Yes	Same	No change
Multi-Phase	4 phases per protocol	Same	No change
Arming Modes	Single and Multi-arming modes	Same	No change
Syringe System	Single (150 ml) syringe	Same	No change
Manual Retract Control	Yes	Same	No change
Check for Air Control	Yes	Same	No change
Variable Flow Option	Yes	Same	No change
Hand Switch (start switch)	Yes	Same	No change
Foot Switch (start switch)	Yes	Same	No change
Variable Flow Hand Controller	Yes	Same	No change
Splash Guard	Yes	Same	No change
Wiper Seal	Optional	Same	No change

Performance Data:
Verification testing was not necessary to demonstrate that the modified indication for use remains safe and effective. Performance testing performed with MEDRAD Mark 7 Arterion Injection System which was provided in previous 510(k)s remains applicable.

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 Mark 7 Arterion Injection System to be substantially equivalent to the predicate device listed above. The fundamental scientific technology, principle of operation, and intended 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.