December 13, 2019

Bayer Medical Care, Inc.
Alison Maloney
Head Regulatory Affairs Radiology
100 Bayer Blvd
Whippany, New Jersey 07981

Re: K192370
Trade/Device Name: MEDRAD Stellant FLEX CT Injection System with Certegra Workstation
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector And Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: October 16, 2019
Received: October 17, 2019

Dear Alison Maloney:

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 M. 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)*
K192370

Device Name
MEDRAD® Stellant FLEX CT Injection System with Certegra® Workstation

Indications for Use *(Describe)*
The MEDRAD® Stellant FLEX CT Injection System with Certegra® Workstation, including Stellant FLEX CT Syringe Kits and Connector Tubing, is indicated for the specific purpose of injecting intravenous imaging agents, including saline, into humans for diagnostic studies in computed tomography (CT) and mammography. For complete prescribing information, refer both to the current drug labeling and to the device labeling for information relating to "imaging agent".

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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K191060

510(k) SUMMARY

Bayer Medical Care, Inc. MEDRAD® Stellant FLEX CT Injection System with Certegra® Workstation

Submitter: Bayer Medical Care, Inc.
1 Bayer Drive
Indianola, PA 15051
Phone: (862) 404-8106

Contact Person: Alison Maloney
Head Regulatory Affairs Radiology
Phone: (862) 404-8106
Email: alison.maloney@bayer.com

Date Prepared: December 12, 2019

Device Tradename: MEDRAD® Stellant FLEX CT Injection System with Certegra® Workstation

Common or Usual Name: Injector and Syringe, Angiographic

Product Code: DXT

Classification: Class II, 21 CFR Part 870.1650, Angiographic injector and syringe

Predicate Device: MEDRAD® Stellant FLEX CT Injection System with Certegra® Workstation, K182273

Device Description:

The MEDRAD® Stellant FLEX CT Injection System with Certegra® Workstation is a software-controlled power injection system used for the administration of intravenous imaging agents, including saline, into humans for diagnostic studies in computed tomography (CT) and mammography. The system is comprised of an injector head and mount, a base, and a workstation. Commonly referred to as an automated injection system, it is designed to allow a user to fill disposable syringes to perform an injection with a user-programmed volume, flow rate and/or duration.

Refer to the Comparison to Predicate Device section for additional information regarding device functions, specifications, etc.

Intended Use / Indications for Use:

The MEDRAD® Stellant FLEX CT Injection System with Certegra® Workstation, including Stellant FLEX CT Syringe Kits and Connector Tubing, is indicated for the specific purpose of injecting intravenous imaging agents, including saline, into humans for diagnostic studies in computed tomography (CT) and mammography. For complete prescribing information, refer both to the current drug labeling and to the device labeling for information relating to "imaging agent".

Substantial Equivalence / Comparison of Technological Characteristics:

The purpose of this submission is to modify the Indications for Use for the MEDRAD® Stellant FLEX CT Injection System with Certegra® Workstation cleared per K182273. This is an administrative update to add mammography.

The only modifications that were made to the MEDRAD® Stellant FLEX CT Injection System with Certegra® Workstation cleared per K182273 are to the labeling. The fundamental scientific technology, software graphical user interface, and principle of operation are the same as those of the predicate device.

A comparison between the modified device and the device cleared per K182273 is provided in Table 1 and Table 2. As illustrated in Table 1, the fluid delivery features and performance specifications are the same for the predicate and subject device Injection System and WorkStation. Table 2 illustrates that the features of the Injection System Syringe Kits also remain the same as those of the predicate device.

Table 1: **Device Comparison Table of Subject and Predicate Device Fluid Delivery Features and Performance Specifications**

Feature	Subject Device MEDRAD® Stellant FLEX CT Injection System with Certegra® Workstation	Predicate Device MEDRAD® Stellant FLEX CT Injection System with Certegra® Workstation	Comments
Intended Use	The MEDRAD® Stellant FLEX CT Injection System with Certegra® Workstation is intended for injecting intravenous contrast media and saline into the human vascular system for diagnostic studies.	The MEDRAD® Stellant FLEX CT Injection System with Certegra® Workstation is intended for injecting intravenous contrast media and saline into the human vascular system for diagnostic studies.	Same

Feature	Subject Device MEDRAD® Stellant FLEX CT Injection System with Certegra® Workstation	Predicate Device MEDRAD® Stellant FLEX CT Injection System with Certegra® Workstation	Comments
Indications for Use	The MEDRAD® Stellant FLEX CT Injection System with Certegra® Workstation, including Stellant FLEX CT Syringe Kits and Connector Tubing, is indicated for the specific purpose of injecting intravenous imaging agents, including saline, into humans for diagnostic studies in computed tomography (CT) and mammography. For complete prescribing information, refer both to the current drug labeling and to the device labeling for information relating to "imaging agent".	The MEDRAD® Stellant FLEX CT Injection System with Certegra® Workstation, including Stellant FLEX CT Syringe Kits and Connector Tubing, is indicated for the specific purpose of injecting intravenous contrast media or saline into humans for diagnostic studies in computed tomography (CT).	Mammography has been added. Use of saline wording slightly changed
Single or Dual Syringe System	Dual syringe	Dual syringe	Same
Volume Range	1 to 200 ml or 1 to 150 ml (depending on 200 ml or 150 ml syringe size)	1 to 200 ml or 1 to 150 ml (depending on 200 ml or 150 ml syringe size)	Same
Fill Speed	1.0 to 10.0 ml/s	1.0 to 10.0 ml/s	Same
Flow Rate Range	0.1 to 10 ml/s	0.1 to 10 ml/s	Same
Pause Phase	1 to 900 s	1 to 900 s	Same
Hold Capability	20 minutes max.	20 minutes max.	Same
Autofill	Yes	Yes	Same
Programmable Pressure Limit (PSI/kPa)	Choice of 50/345, 100/689, 150/1034, 200/1379,	Choice of 50/345, 100/689, 150/1034, 200/1379,	Same

Feature	Subject Device MEDRAD® Stellant FLEX CT Injection System with Certegra® Workstation	Predicate Device MEDRAD® Stellant FLEX CT Injection System with Certegra® Workstation	Comments
	225/1551, 250/1724, 300/2068, 325/2241	225/1551, 250/1724, 300/2068, 325/2241	
Protocol Memory	250 protocols of up to 6 phases each	250 protocols of up to 6 phases each	Same
Protocol Programming Parameters	Flow rate, volume and/or duration	Flow rate, volume and/or duration	Same
Parametric Data Output / Informatics Compatibility	Yes	Yes	Same
Injection History Memory	Unlimited	Unlimited	Same
Control Room Unit	Windows-based Workstation with integrated hardware components	Windows-based Workstation with integrated hardware components	Same
Information Display (Control Room)	Color LCD	Color LCD	Same
Programming Keys (Workstation)	Software-generated via an LCD touch screen	Software-generated via an LCD touch screen	Same
Programming Keys (Head Module)	Dedicated keys on injector Head	Dedicated keys on injector Head	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 (Hand Switch)	Start, Stop and Pause functionality	Start, Stop and Pause Functionality	Same

Feature	Subject Device MEDRAD® Stellant FLEX CT Injection System with Certegra® Workstation	Predicate Device MEDRAD® Stellant FLEX CT Injection System with Certegra® Workstation	Comments
Pressure Graph	Yes	Yes	Same
Syringe Sensing	Optical (Barcode)	Optical (Barcode)	Same
Autoload	Yes	Yes	Same
Auto Dock/Retract/Advance	Yes; user-selectable auto- dock and advance; user-selectable auto-retract	Yes; user-selectable auto- dock and advance; user-selectable auto-retract	Same
Protocol Lock / Remote Arming	Yes	Yes	Same
Simultaneous Injection	Yes (DualFlow)	Yes (DualFlow)	Same
Test Inject	Yes	Yes	Same
Reminders	1 to 300 s in 1 s increments	1 to 300 s in 1 s increments	Same
Syringe Heat Maintainer	Yes	Yes	Same
Syringe Heat Maintainer Range	95 degrees F +/- 9 degrees (35 degrees C +/- 5 degrees)	95 degrees F +/- 9 degrees (35 degrees C +/- 5 degrees)	Same
P3T Functionality	Includes P3T Cardiac, P3T PA, and P3T Abdomen functionality	Includes P3T Cardiac, P3T PA, and P3T Abdomen Functionality	Same
P3T Cardiac Indications	P3T Cardiac is indicated for use with CT Angiography of the cardiac structures, coronary arteries, chambers of the heart, pulmonary vasculature, thoracic,	P3T Cardiac is indicated for use with CT Angiography of the cardiac structures, coronary arteries, chambers of the heart, pulmonary	Same

Feature	Subject Device MEDRAD® Stellant FLEX CT Injection System with Certegra® Workstation	Predicate Device MEDRAD® Stellant FLEX CT Injection System with Certegra® Workstation	Comments
	and abdominal aorta.	vasculature, thoracic, and abdominal aorta.	
P3T PA Indications	P3T PA is indicated for use with CT Angiography of the cardiac structures, coronary arteries, chambers of the heart, pulmonary vasculature, thoracic, and abdominal aorta.	P3T PA is indicated for use with CT Angiography of the cardiac structures, coronary arteries, chambers of the heart, pulmonary vasculature, thoracic, and abdominal aorta.	Same
P3T Abdomen Indications	P3T Abdomen is indicated for use with CT imaging of abdominal organs (i.e., liver, pancreas, kidneys).	P3T Abdomen is indicated for use with CT imaging of abdominal organs (i.e., liver, pancreas, kidneys).	Same
P3T User Interface	When licensed, the user can opt to use the P3T software accessories for any given injection. The user is required to confirm or change the suggested protocol before beginning an injection.	When licensed, the user can opt to use the P3T software accessories for any given injection. The user is required to confirm or change the suggested protocol before beginning an injection.	Same
Imaging System Interface (ISI) - Functionality	Yes. The ISI module option is indicated for the specific purpose of allowing an injector to interface with a CT scanner.	Yes. The ISI module option is indicated for the specific purpose of allowing an injector to interface with a CT scanner.	Same
Connect.CT	Yes. The Connect.CT	Yes. The Connect.CT application is	Same

Feature	Subject Device MEDRAD® Stellant FLEX CT Injection System with Certegra® Workstation	Predicate Device MEDRAD® Stellant FLEX CT Injection System with Certegra® Workstation	Comments
Functionality	application is indicated for the specific purpose of allowing the injector to interface with a CT scanner	indicated for the specific purpose of allowing the injector to interface with a CT scanner	

Table 2: **Device Comparison Table of Subject and Predicate Device Injection System Syringe Kits**

	Feature	Subject Device MEDRAD® Stellant FLEX Syringe Kits	Predicate Device MEDRAD® Stellant FLEX Syringe Kits	Comments
Construction	Injector compatibility	MEDRAD® Stellant FLEX CT Injection System with Certegra® Workstation	MEDRAD® Stellant FLEX CT Injection System with Certegra® Workstation	Same
	Syringe Volume (contrast)	Choice of 150 ml or 200 ml	Choice of 150 ml or 200 ml	Same
	Syringe Volume (saline)	Choice of 150 ml or 200 ml	Choice of 150 ml or 200 ml	Same
Materials	Syringe Barrel	PET	PET	Same
	Syringe Barrel Lubrication	Silicone	Silicone	Same
	Plunger Support Ring	Polycarbonate	Polycarbonate	Same
	Plunger Cover	Polypropylene and TPV with colorant	Polypropylene and TPV with colorant	Same
	Dust Caps	Polypropylene	Polypropylene	Same
	Spikes	ABS	ABS	Same
	Packaging Type, Material	Tyvek lid covering polystyrene tray	Tyvek lid covering polystyrene tray	Same
Biological	Sterilization	E-Beam	E-Beam	Same
	Sterility Assurance Level (SAL)	10-6	10-6	Same
	Pyrogenicity	Non-Pyrogenic Fluid Path	Non-Pyrogenic Fluid Path	Same
	Latex Content	Not made with natural rubber latex	Not made with natural rubber latex	Same
	DEHP	No	No	Same
Performance	Pressure Rating	400 psi (2410 kPa)	400 psi (2410 kPa)	Same
	Syringe Sensing and Identification	Labeling, 2D barcode	Labeling, 2D barcode	Same
	Fluid Detection	Clear Syringe, FluiDots and Beacon indicators	Clear Syringe, FluiDots and Beacon indicators	Same

Discussion of similarities/differences:

The fundamental scientific technology, software graphical user interface, and principle of operation are the same as those of the predicate device.

The only modifications that were made to the MEDRAD® Stellant FLEX CT Injection System with Certegra® Workstation cleared per K182273 are to the labeling. The labeling change consists of updating the disposable instruction for use to include the new indications for use. The operation manual was also updated to include a warning of safe distance between the patient and non-

patient devices, general training requirements, references to studies on use of contrast imaging agent in mammography and updating of IFU.

The difference in IFU was supported by clinical literature references. The labeling was modified to add a diagram of the mammography suite and a caution about not installing the Workstation in the patient area. The required training section was also updated. However, this labeling is the same approach used in the existing contrast enhanced mammography machines to mitigate the same risk.

The addition of mammography to the indication for use does not raise different questions of safety and effectiveness as confirmed by the literature references.

Non-Clinical Performance Data:

Based on the risk analysis, it was determined that there are no new hazards as a result of the modification to the IFU. Therefore, verification testing was not necessary to demonstrate that the modified indication for use remains safe and effective.

Performance testing performed with the subject device which was provided in previous 510(k)s remains applicable.

Clinical Performance Data:

Zanardo, et. al[1] reviewed technical parameters, acquisition protocols and adverse reactions (ARs) for contrast-enhanced spectral mammography (CESM). A systematic search in databases, including MEDLINE/EMBASE, was performed to extract publication year, country of origin, study design; patients; mammography unit/vendor, radiation dose, low-/high energy tube voltage; contrast molecule, concentration and dose; injection modality, ARs and acquisition delay; order of views; examination time. Of 120 retrieved articles, 84 were included from 22 countries (September 2003–January 2019), totaling 14,012 patients. The aim of this work was to review CESM studies focusing on adopted technique, contrast agent issues and acquisition workflow.

Example protocols described in Zanardo, et. al[1] have utilized different available non-ionic LOCM concentrations in dose ranges between 1-2 ml/kg. Injector flow rates between 1.5 -5 ml/s and iodine concentrations of 300 mg I/ml or higher were used. Of the studies that included a specification of the contrast injection modality, automated power injectors were used in 85% of the studies (90% of the patients). Of the total patient population from the study, 62% of the patients received a saline flush. The scan delay between completed injection and start of the imaging sequence ranged from 0.5 to 5 minutes, most commonly 2 minutes.

Zanardo, et. al[1] notes that the common use of a power contrast injector (87% of all studies, with the remaining 13% coming from a single research group) is assumed from CT and MRI protocols in which it has been demonstrated to be effective in obtaining a stable contrast inflow and bolus shape. Moreover, the use of a power injector allows for the administration of a bolus chaser reported only in 42% of all articles, a technical refinement that has shown good results in CT.

The Zanardo, et. al[1] data confirm that the flow rates, dosage and volume of contrast media as well as the scan delays used in CEM are consistent with those of CT imaging and use of Stellant FLEX. Therefore, the Zanardo, et. al[1] article supports a substantial equivalence finding for use of Stellant FLEX in CEM.

MEDRAD® Stellant FLEX CT Injection System with Certegra® Workstation may be used to deliver an iodinated X-ray contrast agent within its approved dose range and route of administration. In addition to the example protocols from Zanardo 20191 and other literature or guidelines, the injector can deliver protocols prescribed by the licensed healthcare professional if those are within the injector specifications.

The MEDRAD® Stellant FLEX CT Injection System with Certegra® Workstation, is intended only for use with approved contrast agents. For complete prescribing information, refer to current drug labeling.

[1]Zanardo, M, et al. (2019) Technique, protocols and adverse reactions for contrast-enhanced spectral mammography (CESM): a systematic review. Insights into Imaging 10:76.

Substantial Equivalence:

The MEDRAD® Stellant FLEX CT Injection System with Certegra® Workstation is substantially equivalent in design, performance, and technological characteristics to the predicate devices for its intended purpose. The minor differences in indication for use between the MEDRAD® Stellant FLEX CT Injection System with Certegra® Workstation and its predicate device raise no new issues of safety or effectiveness. Thus, the MEDRAD® Stellant FLEX CT Injection System with Certegra® Workstation is substantially equivalent.