August 17, 2018

Bayer Medical Care Inc.
Lisa Ewing
Deputy Director, Global Regulatory Strategy
1 Bayer Drive
Indianola, Pennsylvania 15051

Re: K173773
Trade/Device Name: MEDRAD Stellant FLEX CT Injection System with Certegra Workstation, MEDRAD Stellant FLEX Syringe Kits, MEDRAD Stellant CT Injection System with Certegra Workstation, MEDRAD Stellant Syringe Kits, MEDRAD Stellant Connector Tubing, P3T Cardiac, P3T PA, P3T Abdomen, ISI, Connect.CT
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector And Syringe
Regulatory Class: Class II
Product Code: DXT, IZQ
Dated: July 19, 2018
Received: July 20, 2018

Dear Lisa Ewing:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Michael John -S
2018.08.17 12:34:14 -04'00'

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173773

Device Name
MEDRAD® Stellant FLEX CT Injection System with Certegra Workstation, MEDRAD® Stellant FLEX Syringe Kits, MEDRAD® Stellant CT Injection System with Certegra Workstation, MEDRAD® Stellant Syringe Kits, MEDRAD® Stellant Connector Tubing

Indications for Use *(Describe)*

MEDRAD® Stellant FLEX CT Injection System with Certegra Workstation
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) applications.

MEDRAD® Stellant FLEX Syringe Kits
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) applications.

MEDRAD® Stellant CT Injection System with Certegra Workstation
The MEDRAD® Stellant CT Injection System with Certegra Workstation is indicated for the specific purpose of injecting intravenous contrast media or saline into humans for diagnostic studies in computed tomography (CT) applications.

MEDRAD® Stellant Syringe Kits
The contents of this package are intended to be used in the delivery of contrast media or saline. They are indicated for single-use on one patient only with MEDRAD® Stellant Injectors.

MEDRAD® Stellant Connector Tubing
The contents of this package are intended to be used in the delivery of contrast media or saline. They are indicated for single-use on one patient only with MEDRAD® Stellant Injectors.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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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)*
K173773

Device Name
P3T Cardiac, P3T PA, P3T Abdomen, ISI, Connect.CT

Indications for Use *(Describe)*

P3T Cardiac
P3T Cardiac 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
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 Abdomen
P3T Abdomen is indicated for use with CT imaging of abdominal organs (i.e., liver, pancreas, kidneys).

ISI
The ISI module option is indicated for the specific purpose of allowing an injector to interface with a CT scanner.

Connect.CT
The Connect.CT application is indicated for the specific purpose of allowing the injector to interface with a CT scanner.

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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510(k) Summary

Submitter: Bayer Medical Care Inc.
1 Bayer Drive
Indianola, PA 15051

Contact Person: Lisa A. Ewing
Deputy Director, Global Regulatory Strategy, Device New Product Development
Phone: (412) 406-3780
Email: lisa.ewing@bayer.com

Date Prepared: August 15, 2018

Device Trade Name: MEDRAD® Stellant FLEX CT Injection System with Certegra Workstation
MEDRAD® Stellant FLEX Syringe Kits
MEDRAD® Stellant CT Injection System with Certegra Workstation
MEDRAD® Stellant Syringe Kits
MEDRAD® Stellant Connector Tubing
P3T Cardiac
P3T PA
P3T Abdomen
ISI
Connect.CT

Common Name: Angiographic Injector and Syringe

Classification Name: Injector and Syringe, Angiographic [21 CFR 870.1650]

Product Code: DXT, IZQ

Classification: Class II

Primary Predicate Device: The subject device is substantially equivalent to the following devices:
Injector System – MEDRAD Stellant CT Injector System with P3T Cardiac, K082905

Secondary Predicate Device: Syringe Kit – MEDRAD Stellant CT Injector System with Extravasation Detection System Accessory, K063090

Device Description:

MEDRAD Stellant FLEX CT Injection System with Certegra Workstation

The MEDRAD Stellant FLEX CT Injection System with Certegra Workstation is a software-controlled medical device used for the administration of intravenous CT contrast media and saline into the human vascular system for diagnostic studies in Computed Tomography (CT) procedures. 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.

MEDRAD Stellant CT Injection System with Certegra Workstation

The MEDRAD Stellant CT Injection System with Certegra Workstation is a software-controlled medical device used for the administration of intravenous CT contrast media and saline into the human vascular system for diagnostic studies in Computed Tomography (CT) procedures. 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.

Personalized Patient Protocol Technology (P3T)

The Stellant P3T software accessories compute individual contrast injection protocols and scan timing, based on patient characteristics, scanner parameters and contrast concentration for individualized dosing, and for increasing the consistency of individualized injection protocols among clinicians.

Imaging System Interface (ISI)

The ISI module options allow an injector to interface with a CT scanner.

Connect.CT

The Connect.CT application allows an injector to interface with a CT scanner.

Indications for Use:

MEDRAD® Stellant FLEX CT Injection System with Certegra Workstation

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) applications.

MEDRAD® Stellant FLEX Syringe Kits

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) applications.

MEDRAD® Stellant CT Injection System with Certegra Workstation

The MEDRAD® Stellant CT Injection System with Certegra Workstation is indicated for the specific purpose of injecting intravenous contrast media or saline into humans for diagnostic studies in computed tomography (CT) applications.

MEDRAD® Stellant Syringe Kits

The contents of this package are intended to be used in the delivery of contrast media or saline. They are indicated for single-use on one patient only with MEDRAD Stellant Injectors.

MEDRAD® Stellant Connector Tubing

The contents of this package are intended to be used in the delivery of contrast media or saline. They are indicated for single-use on one patient only with MEDRAD® Stellant Injectors.

P3T Cardiac

P3T Cardiac 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

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 Abdomen
P3T Abdomen is indicated for use with CT imaging of abdominal organs (i.e., liver, pancreas, kidneys).

ISI
The ISI module option is indicated for the specific purpose of allowing an injector to interface with a CT scanner.

Connect.CT
The Connect.CT application is indicated for the specific purpose of allowing the injector to interface with a CT scanner.

Comparison to the Predicate Device:

The fundamental scientific technology, principle of operation and intended use/indications for use of the proposed devices are unchanged from the predicate devices, the MEDRAD Stellant CT Injection System cleared in K082905 and the MEDRAD Stellant Syringe Kits cleared in K063090. Additionally, the proposed injection systems (MEDRAD Stellant FLEX CT Injection System with Certegra Workstation and MEDRAD Stellant CT Injection System with Certegra Workstation) and the predicate Stellant CT Injection System share similarities in functional design, performance specifications and materials.

The tables below provide a detailed comparison of the MEDRAD Stellant FLEX CT Injection System with Certegra Workstation to the predicate MEDRAD Stellant CT Injection System, the MEDRAD Stellant CT Injection System with Certegra Workstation to the predicate MEDRAD Stellant CT Injection System, the MEDRAD Stellant FLEX Syringe Kits to the predicate MEDRAD Stellant Syringe Kits, the MEDRAD Stellant Syringe Kits to the predicate MEDRAD Stellant Syringe Kits, and the MEDRAD Stellant Connector Tubing to the predicate MEDRAD Stellant Connector Tubing.

Table 1. Comparison of Fluid Delivery Features and Performance Specifications in MEDRAD Stellant CT Injection System as cleared in K082905 (Predicate) and MEDRAD Stellant FLEX CT Injection System with Certegra Workstation K173773 (Proposed).

Feature	*MEDRAD Stellant CT Injection System as cleared in K082905 (Predicate)*	*MEDRAD Stellant FLEX CT Injection System with Certegra Workstation K173773 (Proposed)*	*Rationale for Change*
Indications for Use	The MEDRAD Stellant CT Injection System is intended for the specific purpose of injecting intravenous contrast media into humans for diagnostic studies in computed tomography (CT) applications.	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) applications.	Product name updated; references to Stellant FLEX syringe kits and connector tubing, as well as saline, added for clarity.
Single or Dual Syringe System	Available in both single or dual syringe injector head model.	Dual syringe model only	Only dual syringe head model available on Stellant FLEX.
Volume Range	1 to 200 ml (for 200 ml syringe size)	1 to 200 ml or 1 to 150 ml (depending on 200 ml or 150 ml syringe size)	Consistency with offered syringe volumes.
Fill Speed	1.0 to 10.0 ml/s	Same	N/A
Flow Rate Range	0.1 to 10 ml/s	Same	N/A
Pause Phase	1 to 900 s	Same	N/A
Hold Capability	20 minutes max.	Same	N/A
Autofill	Yes	Same	N/A
Programmable Pressure Limit (PSI/kPa)	Choice of 50/345, 100/689, 150/1034, 200/1379, 250/1724, 300/2068, 325/2241	Choice of 50/345, 100/689, 150/1034, 200/1379, 225/1551, 250/1724, 300/2068, 325/2241	Option of 225 PSI/1551 kPa added to dropdown menu for user convenience.
Protocol Memory	32 protocols of up to 6 phases each	250 protocols of up to 6 phases each	Customer convenience of ability to store additional protocols.
Protocol Programming Parameters	Flow rate and volume (system calculates duration)	Flow rate, volume and/or duration	Added functionality for user to program by any two of three parameters. System calculates the third.
Parametric Data Output / Informatics Compatibility	None	Yes	Data output and informatics compatibility added for customer convenience.
Injection History Memory	None	Unlimited	Customer convenience of ability to access injection history.
Control Room Unit	VxWorks-based display control unit	Windows-based Workstation	Current technology; informatics accessory compatibility.

Feature	*MEDRAD Stellant CT Injection System as cleared in K082905 (Predicate)*	*MEDRAD Stellant FLEX CT Injection System with Certegra Workstation K173773 (Proposed)*	*Rationale for Change*
Information Display (Control Room)	Color LCD	Same	N/A
Programming Keys (Control Room)	Software-generated via an LCD touch screen	Same	N/A
Retract Control	Manual and Automatic	Same	N/A
Check for Air Confirmation	Operator visual inspection; user confirmed	Same	N/A
Start/Stop Switch (Hand Switch)	Start, Stop and Pause functionality	Same	N/A
Pressure Graph	Yes	Same	N/A
Syringe Sensing	Optical	Optical (Barcode)	Different technology required for encoding additional syringe information.
Autoload	Yes	Same	N/A
Auto Dock/Retract/Advance	Yes; user-selectable auto-dock and advance; user-selectable auto-retract	Same	N/A
Protocol Lock / Remote Arming	Yes	Same	N/A
Simultaneous Injection	Yes (DualFlow)	Same	N/A
Test Inject	Yes	Same	N/A
Scan Delay	1 to 300 s in 1 s increments	None	Scan Delay with Reminders on Stellant FLEX to allow for more than one user-defined timed notification.
Reminders	None	1 to 300 s in 1 s increments	Reminders are user-defined timing notifications generated during the injection sequence. Expanded capability from single purpose Scan Delay to allow for more than one user-defined timed notification from the start of the injection.
Syringe Heat Maintainer	Yes	Same	N/A
Syringe Heat Maintainer Range	95 degrees F +/- 9 degrees (35 degrees C +/- 5 degrees)	Same	N/A
P3T Functionality	Includes P3T Cardiac, P3T PA and P3T Abdomen functionality	Same	N/A
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, and abdominal aorta.	Same	N/A

Feature	*MEDRAD Stellant CT Injection System as cleared in K082905 (Predicate)*	*MEDRAD Stellant FLEX CT Injection System with Certegra Workstation K173773 (Proposed)*	*Rationale for Change*
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.	Same	N/A
P3T Abdomen Indications	P3T Abdomen is indicated for use with CT imaging of abdominal organs (i.e., liver, pancreas, kidneys).	Same	N/A
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.	Same	N/A
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.	Same	N/A
Connect.CT Functionality	Yes. The Connect.CT application is indicated for the specific purpose of allowing the injector to interface with a CT scanner	Same	N/A

Table 2. Comparison of Fluid Delivery Features and Performance Specifications in MEDRAD Stellant CT Injection System as cleared in K082905 (Predicate) and MEDRAD Stellant CT Injection System with Certegra Workstation K173773 (Proposed).

Feature	*MEDRAD Stellant CT Injection System as cleared in K082905 (Predicate)*	*MEDRAD Stellant CT Injection System with Certegra Workstation K173773 (Proposed)*	*Rationale for Change*
Indications for Use	The MEDRAD Stellant CT Injection System is intended for the specific purpose of injecting intravenous contrast media into humans for diagnostic studies in computed tomography (CT) applications.	The MEDRAD Stellant CT Injection System with Certegra Workstation is indicated for the specific purpose of injecting intravenous contrast media or saline into humans for diagnostic studies in computed tomography (CT) applications.	Product name updated; reference to saline added for clarity.
Single or Dual Syringe System	Available in both single or dual syringe injector head model.	Dual syringe model only	Only dual syringe head model available on Stellant with Certegra Workstation.
Volume Range	1 to 200 ml (for 200 ml syringe size)	Same	N/A
Fill Speed	1.0 to 10.0 ml/s	Same	N/A
Flow Rate Range	0.1 to 10 ml/s	Same	N/A
Pause Phase	1 to 900 s	Same	N/A
Hold Capability	20 minutes max.	Same	N/A
Autofill	Yes	Same	N/A
Programmable Pressure Limit (PSI/kPa)	Choice of 50/345, 100/689, 150/1034, 200/1379, 250/1724, 300/2068, 325/2241	Choice of 50/345, 100/689, 150/1034, 200/1379, 225/1551, 250/1724, 300/2068, 325/2241	Option of 225 PSI/1551 kPa added to dropdown menu for user convenience.
Protocol Memory	32 protocols of up to 6 phases each	250 protocols of up to 6 phases each	Customer convenience of ability to store additional protocols.
Protocol Programming Parameters	Flow rate and volume (system calculates duration)	Flow rate, volume and/or duration	Added functionality for user to program by any two of three parameters. System calculates the third.
Parametric Data Output / Informatics Compatibility	None	Yes	Data output and informatics compatibility added for customer convenience.
Injection History Memory	None	Unlimited	Customer convenience of ability to access injection history.
Control Room Unit	VxWorks-based display control unit	Windows-based Workstation	Current technology; informatics accessory compatibility.
Information Display (Control Room)	Color LCD	Same	N/A
Programming Keys (Control Room)	Software-generated via an LCD touch screen	Same	N/A
Retract Control	Manual and Automatic	Same	N/A

Feature	*MEDRAD Stellant CT Injection System as cleared in K082905 (Predicate)*	*MEDRAD Stellant CT Injection System with Certegra Workstation K173773 (Proposed)*	*Rationale for Change*
Check for Air Confirmation	Operator visual inspection; user confirmed	Same	N/A
Start/Stop Switch (Hand Switch)	Start, Stop and Pause functionality	Same	N/A
Pressure Graph	Yes	Same	N/A
Syringe Sensing	Optical	Same	N/A
Autoload	Yes	Same	N/A
Auto Dock/Retract/Advance	Yes; user-selectable auto-dock and advance; user-selectable auto-retract	Same	N/A
Protocol Lock / Remote Arming	Yes	Same	N/A
Simultaneous Injection	Yes (DualFlow)	Same	N/A
Test Inject	Yes	Same	N/A
Scan Delay	1 to 300 s in 1 s increments	None	Scan Delay with Reminders on Stellant FLEX and Stellant with Certegra Workstation to allow for more than one user-defined timed notification.
Reminders	None	1 to 300 s in 1 s increments	Reminders are user-defined timing notifications generated during the injection sequence. Expanded capability from single purpose Scan Delay to allow for more than one user-defined timed notification from the start of the injection.
Syringe Heat Maintainer	Yes	Same	N/A
Syringe Heat Maintainer Range	95 degrees F +/- 9 degrees (35 degrees C +/- 5 degrees)	Same	N/A
P3T Functionality	Includes P3T Cardiac, P3T PA and P3T Abdomen functionality	Same	N/A
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, and abdominal aorta.	Same	N/A

Feature	*MEDRAD Stellant CT Injection System as cleared in K082905 (Predicate)*	*MEDRAD Stellant CT Injection System with Certegra Workstation K173773 (Proposed)*	*Rationale for Change*
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.	Same	N/A
P3T Abdomen Indications	P3T Abdomen is indicated for use with CT imaging of abdominal organs (i.e., liver, pancreas, kidneys).	Same	N/A
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.	Same	N/A
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.	Same	N/A
Connect.CT Functionality	Yes. The Connect.CT application is indicated for the specific purpose of allowing the injector to interface with a CT scanner.	Same	N/A

Table 3 Comparison of MEDRAD Stellant CT Injection System Syringe Kits and Connector Tubing as cleared in K063090 (Predicate) and Stellant FLEX CT Injection System Syringe Kits K173773 (Proposed).

Feature		*MEDRAD Stellant Syringe Kits & Connector Tubing as cleared in K063090 (Predicate)*	*MEDRAD Stellant FLEX Syringe Kits & Connector Tubing K173773 (Proposed)*	*Rationale for Change*
Indications for Use		The contents of this package are intended to be used in the delivery of contrast media or saline. They are indicated for single-use on one patient only with MEDRAD Stellant Injectors.	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) applications.	Consistency of Stellant FLEX syringe kit indications for use statement with Stellant FLEX CT Injection System. No change to intent of indications for use.
Construction	Injector compatibility	MEDRAD Stellant CT Injection System, MEDRAD Stellant CT Injection System with Certegra Workstation	MEDRAD Stellant FLEX CT Injection System with Certegra Workstation	Stellant FLEX syringe interface modified to accommodate 2D barcode and reader.
	Syringe Volume (contrast)	200 ml	Choice of 150 ml or 200 ml	Smaller Stellant FLEX syringe offered for customer value.
	Syringe Volume (saline)	200 ml	Choice of 150 ml or 200 ml	Smaller Stellant FLEX syringe offered for customer value.
Materials	Syringe Barrel	PET	Same	N/A
	Syringe Barrel Lubrication	Silicone	Same	N/A
	Plunger Support Ring	Polycarbonate	Same	N/A
	Plunger Cover	Polyisoprene with carbon black colorant	Polypropylene and TPV with new colorant	(Current) Design updated for cost optimization. (FLEX) Stellant FLEX colorant added for beacon fluid detection technology.
	Dust Caps	Polypropylene	Same	N/A
	Spikes	ABS	Same	N/A
	Packaging Type, Material	Tyvek lid covering polystyrene tray	Same	N/A
Biological	Sterilization	Ethylene Oxide	E-Beam	Updated mode of sterilization; SAL is unchanged.
	Sterility Assurance Level (SAL)	10^{-6}	Same	N/A
	Pyrogenicity	Non-Pyrogenic Fluid Path	Same	N/A
	Latex Content	Not made with natural rubber latex	Same	N/A
	DEHP	No	Same	N/A

Feature		*MEDRAD Stellant Syringe Kits & Connector Tubing as cleared in K063090 (Predicate)*	*MEDRAD Stellant FLEX Syringe Kits & Connector Tubing K173773 (Proposed)*	*Rationale for Change*
Performance	Pressure Rating	400 psi (2410 kPa)	Same	N/A
	Syringe Sensing and Identification	Labeling, grooves at bottom of barrel to be optically identified	Labeling, 2D barcode	Barcode added to syringe barrel include additional syringe identification
	Fluid Detection	Clear syringe, FluiDots indicators	Clear Syringe, FluiDots and Beacon indicators	Beacon indicator added to Stellant FLEX syringe as an additional fluid detection method.

Table 4 Comparison of MEDRAD Stellant CT Injection System Syringe Kits as cleared in K063090 (Predicate) and the MEDRAD Stellant CT Injection System Syringe Kits K173773 (Proposed)

Feature		*MEDRAD Stellant Syringe Kits as cleared in K063090 (Predicate)*	*MEDRAD Stellant Syringe Kits K173773 (Proposed)*	*Rationale for Change*
Indications for Use		The contents of this package are intended to be used in the delivery of contrast media or saline. They are indicated for single-use on one patient only with MEDRAD Stellant Injectors.	Same	N/A
Construction	Injector compatibility	MEDRAD Stellant CT Injection System, MEDRAD Stellant CT Injection System with Certegra Workstation	Same	N/A
	Syringe Volume (contrast)	200 ml	Same	N/A
	Syringe Volume (saline)	200 ml	Same	N/A
Materials	Syringe Barrel	PET	Same	N/A
	Syringe Barrel Lubrication	Silicone	Same	N/A
	Plunger Support Ring	Polycarbonate	Same	N/A
	Plunger Cover	Polyisoprene with carbon black colorant	Polypropylene and TPV (same black colorant as predicate)	Design updated for cost optimization.
	Dust Caps	Polypropylene	Same	N/A
	Spikes	ABS	Same	N/A
	Packaging Type, Material	Tyvek lid covering polystyrene tray	Same	N/A
Biol	Sterilization	Ethylene Oxide	E-Beam	Updated mode of sterilization; SAL is

Feature		*MEDRAD Stellant Syringe Kits as cleared in K063090 (Predicate)*	*MEDRAD Stellant Syringe Kits K173773 (Proposed)*	*Rationale for Change*
				unchanged.
	Sterility Assurance Level (SAL)	10^{-6}	Same	N/A
	Pyrogenicity	Non-Pyrogenic Fluid Path	Same	N/A
	Latex Content	Not made with natural rubber latex	Same	N/A
	DEHP	No	Same	N/A
Performance	Pressure Rating	400 psi (2410 kPa)	Same	N/A
	Syringe Sensing and Identification	Labeling, grooves at bottom of barrel to be optically identified	Same	N/A
	Fluid Detection	Clear syringe, FluiDots indicators	Same	N/A

Table 5 Comparison of MEDRAD Stellant Connector Tubing as cleared in K063090 (Predicate) and MEDRAD Stellant Connector Tubing K173773 (Proposed)

Feature	*MEDRAD Stellant Syringe Kits & Connector Tubing as cleared in K063090 (Predicate)*	*MEDRAD Stellant Connector Tubing K173773 (Proposed)*	*Rationale for Change*
Description	Low pressure connector tube assembly offered in two configurations – one for dual syringe injection (with T-connector), one for single syringe injection (without T-connector)	Same	N/A
Pressure Rating	400 psi (2410 kPa)	Same	N/A
Tubing Length	60”	Same	N/A
Tubing material	PVC	Same	N/A
T-connector material	Polycarbonate	Same	N/A
Packaging Materials, Type	Tyvek membrane, polyethylene pouch	Same	N/A
Sterilization	Ethylene Oxide	Ethylene Oxide when packaged standalone; E-beam when packaged in Stellant Syringe Kits; E-beam when packaged in Stellant FLEX Syringe Kits	Alternative modes of sterilization used when packaged in syringe kits; SAL is unchanged.
Sterility Assurance Level (SAL)	10^{-6}	Same	N/A
Pyrogenicity	Non-Pyrogenic Fluid Path	Same	N/A
Latex Content	Not made with natural rubber latex	Same	N/A
DEHP	Yes	No	Removal of DEHP.

Performance Data:

The MEDRAD Stellant FLEX CT Injection System with Certegra Workstation, the MEDRAD Stellant FLEX Syringe Kits, the MEDRAD Stellant CT Injection System with Certegra Workstation, the MEDRAD Stellant Syringe Kits, and the MEDRAD Stellant Connector Tubing share common design elements with the predicate MEDRAD Stellant CT Injection System, the predicate MEDRAD Stellant Syringe Kits, and the predicate MEDRAD Stellant Connector Tubing. Complete bench testing was performed on all design changes unique to the MEDRAD Stellant FLEX CT Injection System with Certegra Workstation and MEDRAD Stellant FLEX Syringe Kits. Likewise, complete bench testing was performed on all design changes unique to the MEDRAD Stellant CT Injection System with Certegra Workstation and MEDRAD Stellant Syringe Kits. Where bench testing on shared elements of the design existed from the predicate MEDRAD Stellant CT Injection System, the MEDRAD Stellant Syringe Kits, and from similar devices, performance requirements and test data were analyzed and leveraged. The combined bench test results and analysis results confirm that the MEDRAD Stellant FLEX CT Injection System with Certegra Workstation, the MEDRAD Stellant FLEX Syringe Kits, the MEDRAD Stellant CT Injection System with Certegra Workstation, the MEDRAD Stellant Syringe Kits, and the MEDRAD Stellant Connector Tubing meet product specification and performance requirements.

The following testing was successfully completed:

- Device performance testing included verification of the system disposable filling and preparation, protocol management, fluid delivery—both sequential and simultaneous, flow rates, volumes, and pressures. Testing also verified that the device was not affected by environmental conditions such as atmospheric conditions and handling. All testing passed and the demonstrated product performance met all prior established acceptance criteria.
- Disposables performance testing included verification of the syringe and connector tubing mechanical functions and pressure capabilities (ISO 594), and packaging (ISO 11607-1). Testing was performed using aged samples that had been sterilized and with samples that had been subjected to shipping conditions (ASTM D4169). All testing passed and the demonstrated product performance met all prior established acceptance criteria.
- Biocompatibility testing was conducted on the MEDRAD Stellant FLEX Syringe Kits, the MEDRAD Stellant Syringe Kits, and the MEDRAD Stellant Connector Tubing to verify that these devices meet the requirements of ISO 10993-1:2009. Based on guidance of ISO 10993-1:2009, Table A.1, the following test program was selected for an externally communicating, indirect blood path, limited contact ($\leq$ 24 h) device:
    - Cytotoxicity
    - Hemocompatibility
        - Hemolysis
    - Sensitization
    - Irritation / Intracutaneous Reactivity
    - Acute Systemic Toxicity
        - Acute Systemic Injection
        - Materials Mediated Pyrogen

- Sterilization conditions have been validated on the syringe and connector tubing kits 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 the demonstrated product performance met all prior established acceptance criteria.
- Safety and Compatibility testing included verification of configurations and specifications, circuitry, compliance with IEC 60601-1 and EMC requirements, electrical safety controls, ability to detect failures in communication and controls, programming keys, and sensors, and safe operation. All testing passed and the demonstrated product performance demonstrated met all prior established acceptance criteria.
- Shelf-life and shipping testing included verification that the system performance was not affected by four-year aging and shelf-life (for disposable syringes and connector tubing) and packaged transit and storage (ISTA 2A, for the injector system). All testing passed and the demonstrated performance met all prior established acceptance criteria.
- Reliability testing was performed using statistical methods to demonstrate the capability to sequentially and repeatedly meet system performance requirements. Testing verified there was no degradation to performance when the Stellant FLEX CT Injection System with Certegra Workstation and Informatics processes were run simultaneously. Similarly, testing verified there was no degradation to performance when the Stellant CT Injection System with Certegra Workstation and Informatics processes were run simultaneously. All testing passed and the demonstrated performance met all prior established acceptance criteria.
- Simulated Use and Human Factors testing was performed by using the injector systems and disposables in a simulated clinical environment to validate the clinical user needs were met by the design per EN 62366-1: 2015 and FDA Guidance "Applying Human Factors and Usability Engineering to Medical Devices." Testing demonstrated that no new or different questions of safety or effectiveness were raised.
- Cleaning and disinfection validation was performed per FDA Guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," and confirmed that the injection systems meets their cleaning and disinfection requirements.

All test results demonstrate that the design and materials of the MEDRAD Stellant FLEX CT Injection System with Certegra Workstation, the MEDRAD Stellant FLEX Syringe Kits, the MEDRAD Stellant CT Injection System with Certegra Workstation, the MEDRAD Stellant Syringe Kits, and the MEDRAD Stellant Connector Tubing meet the established performance criteria and will perform as intended. The results of the design verification and validation, including human factors engineering evaluation, demonstrate that the subject devices are substantially equivalent to their predicate devices.

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 Traditional 510(k) Premarket Notification.

Conclusion:

Bayer considers the MEDRAD Stellant FLEX CT Injection System with Certegra Workstation, the MEDRAD Stellant FLEX Syringe Kits, the MEDRAD Stellant CT Injection System with Certegra Workstation, the MEDRAD Stellant Syringe Kits, and the MEDRAD Stellant Connector Tubing to be substantially equivalent to the predicate devices, the MEDRAD Stellant CT Injection System cleared in K082905 and the Stellant Syringe Kits cleared in K063090. This conclusion is based upon the devices having the same intended use, energy type and principle of operation, and having similar technological characteristics, particularly with regard to similarities in functional design, software features, usability and workflow, materials and fundamental scientific technology.