November 5, 2024

Imaxeon Pty Ltd
% Dr. Gopal Abbineni
Director, Regulatory Affairs, Radiology Medical Devices
Bayer Medical Care, Inc.
1 Bayer Drive
Indianola, Pennsylvania 15051

Re: K241849
Trade/Device Name: MEDRAD Centargo CT Injection System; MEDRAD Centargo Day Set; MEDRAD Centargo Patient Line; MEDRAD Centargo Replacement Spike; MEDRAD ISI2 Module (ISI2)
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector And Syringe
Regulatory Class: Class II
Product Code: IZQ
Dated: October 2, 2024
Received: October 3, 2024

Dear Dr. Gopal Abbineni:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Shruti N. Mistry -S

Shruti Mistry
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241849

Device Name

MEDRAD Centargo CT Injection System;
MEDRAD Centargo Day Set;
MEDRAD Centargo Patient Line;
MEDRAD Centargo Replacement Spike;
MEDRAD ISI2 Module (ISI2)

Indications for Use *(Describe)*

MEDRAD® Centargo CT Injection System is an automated contrast injection system that is indicated for the controlled, automatic administration, on the venous side, of ULTRAVIST® (Iopromide), ISOVUE® (Iopamidol), OPTIRAY® (Ioversol) or OMNIPAQUE™ (Iohexol) contrast media as supplied in an approved Imaging Bulk Package (IBP) presentation and 0.9% Sodium Chloride Injection USP (saline) to human subjects undergoing examinations in computed tomography (CT). The system is to be used by and under quasi-continuous supervision of trained healthcare professionals in an appropriate licensed healthcare facility, in a room designated for radiological procedures that involve intravascular administration of contrast agent.

The Day Set is used for a maximum time of twenty four (24) hours, or for a maximum of 25 bottles of contrast media, whichever comes first. The Patient Line must be discarded after each patient procedure. The Replacement Spike is for single-container use only and must be discarded with the fluid container. Contrast media containers are to be discarded after their respective use times have expired or the Day Set use life has expired, whichever occurs first.

Saline should only be used to deliver multiple single doses to multiple patients when used with the MEDRAD® Centargo CT Injection System and the provided Saline Tag. Once the port of the saline container is punctured, it should not be removed from the work area during the entire period of use. Saline containers are to be discarded with the Day Set.

The ISI2 module is indicated for the specific purpose of allowing an injector to interface with an imaging 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.

510(k) Summary
Imaxeon Pty Ltd. MEDRAD® Centargo CT Injection System
The Summary is prepared in conformance with 21CFR 807.92

I. SUBMITTER

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Date Prepared: October 4, 2024

II. DEVICE

Trade Name:	MEDRAD® Centargo CT Injection System MEDRAD® Centargo Day Set MEDRAD® Centargo Patient Line MEDRAD® Centargo Replacement Spike MEDRAD® ISI2 Module
Common Name:	Automatic injector for contrast media
Classification Name:	Injector, Contrast Medium, Automatic
Classification Regulation:	21 CFR 870.1650
Regulatory Class:	Class II
Product Code:	IZQ

III. PREDICATE DEVICE

Trade Name: CT Exprès™ 3D Contrast Media Delivery System

510(k) Number: K151048
Common Name: Automatic injector for contrast media
Classification Name: Injector, Contrast Medium, Automatic
Classification Regulation: 21 CFR 870.1650
Regulatory Class: Class II
Product Code: IZQ
This predicate has not been subject to a design-related recall.

IV. REFERENCE DEVICE

Trade Name: MEDRAD® Stellant FLEX CT Injection System with Certegra® Workstation
Number: K192370
Common Name: Injector and Syringe, Angiographic
Classification Name: Injector and Syringe, Angiographic
Classification Regulation: 21 CFR 870.1650
Regulatory Class: Class II
Product Code: DXT

V. DEVICE DESCRIPTION

The MEDRAD® Centargo CT Injection System (Centargo) is an automated contrast injection system intended to be used to inject intravenous contrast media and saline into humans for diagnostic studies in CT applications. Centargo is intended for use with the following approved contrast media in an Imaging Bulk Package (IBP):

- ULTRAVIST® (Iopromide) NDA 021425/S-034
- ISOVUE® (Iopamidol) NDA 020327/S-023
- OPTIRAY® (Ioversol) IBP NDA 020923/S-026
- OMNIPAQUE™ (Iohexol) NDA 020608/S-045

Centargo is based on well-established technologies for injection, using a piston-based electromechanical device. The system is designed to protect the patient against air injection by incorporating multiple sensors to detect air within the fluid pathway. The system is comprised of two main modules:

- Scan Room Unit – responsible for handling the contrast/saline and delivering injections
- Control Room Unit - controls, monitors, and communicates with the Scan Room Unit through wired or wireless connection

The Scan Room Unit is located within the scan room whereas the Control Room Unit is not. When communicating via wired or wireless connection, the Control Room Unit can remotely control the Scan Room Unit and initiate and execute injections. However, the Scan Room Unit can operate independently without the use of the Control Room Unit via the Scan Room Unit's graphical user interface (GUI).

The Scan Room Unit is available in two different configurations:

- Pedestal with battery and AC power

- Overhead mount with AC power only

The fluids are delivered from a multi-patient disposable set (Day Set) through a single use patient line (Patient Line). The Day Set is labeled for 24 hours or for a maximum of 25 bottles of contrast media, whichever comes first. Fluid source spikes (Replacement Spike) are for single container use.

The system is intended to be used in a CT suite. It is intended to be operated by personnel with training and experience in CT procedures and use of CT injection systems. Operators will consist of radiological technologists trained in the use of the equipment. This system is intended for use on the general patient population, including adults and pediatrics.

Options and Accessories

All optional set-ups and accessories for Centargo are related to software-based features. They are either software license enabled or require a hardware accessory to be connected (the ISI2 Module).
The following types of options are available for Centargo:

- Scanner connectivity related options – enables injectors and scanners to communicate
- Smart Protocols related options -- computes individualized contrast injection protocols
- Automated documentation related options – transfers data with external systems

Scanner connectivity related options

These options enable injectors and scanners to communicate, enhancing clinical capability by synchronizing scan timing and simplifying operator workflow. There are three different options for connecting a Centargo to a scanner:

- ISI-700 (accessory ISI2 Module required) – Proprietary interface
- ISI-900 (accessory ISI2 Module required) – CiA-425 standard based, Class IV
- Connect.CT (software only) – Proprietary interface

Smart Protocols related options

Injection protocols may be either fixed standard protocols with fixed volumes and rates for all patients (i.e., one size fits all), or they can be personalized for each patient (e.g., be weight based). Protocols can also be adapted for the iodine concentration in use as well as the scanner tube voltage. Finally, protocols can also be adapted for the particulars of some study types and the specific CT scanner capabilities being used. The three kinds of Smart Protocols available on Centargo are:

- Personalized Patient Protocol Technology (P3T)
- Iodine Load/Dose Based Protocols, Iodine Delivery Rate Based Protocols
- Tube Voltage Based Protocols

Automated documentation related options

Centargo by default is a standalone injection system that operates in accordance with its intended use without any network connections being required. If a customer prefers to have injection information transmitted to their hospital system (e.g., Radiology Information System (RIS)), they may purchase one or

more automated documentation options. These options are for customer convenience and are not themselves considered medical devices as their sole function is to transfer data.

VI. INDICATIONS FOR USE

MEDRAD® Centargo CT Injection System is an automated contrast injection system that is indicated for the controlled, automatic administration, on the venous side, of ULTRAVIST® (Iopromide), ISOVUE® (Iopamidol), OPTIRAY® (Ioversol), or OMNIPAQUE™ (Iohexol) contrast media as supplied in an approved Imaging Bulk Package (IBP) presentation and 0.9% Sodium Chloride Injection USP (saline) to human subjects undergoing examinations in computed tomography (CT). The system is to be used by and under quasi-continuous supervision of trained healthcare professionals in an appropriate licensed healthcare facility, in a room designated for radiological procedures that involve intravascular administration of contrast agent.

The Day Set is used for a maximum time of twenty-four (24) hours, or for a maximum of 25 bottles of contrast media, whichever comes first. The Patient Line must be discarded after each patient procedure. The Replacement Spike is for single-container use only and must be discarded with the fluid container. Contrast media containers are to be discarded after their respective use times have expired or the Day Set use life has expired, whichever occurs first.

Saline should only be used to deliver multiple single doses to multiple patients when used with the MEDRAD® Centargo CT Injection System and the provided Saline Tag. Once the port of the saline container is punctured, it should not be removed from the work area during the entire period of use. Saline containers are to be discarded with the Day Set.

The ISI2 Module is indicated for the specific purpose of allowing an injector to interface with an imaging scanner.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

A table comparing key features of the subject device (Centargo) and predicate device (CT Exprès) is provided below.

Table 1 – Key Feature Comparison

Item	Predicate Device (K151048): CT Exprès™ 3D Contrast Media Delivery System	Subject Device (K241849): MEDRAD® Centargo CT Injection System	Comparison
Class	II	II	Same
FDA Regulation Number	21 CFR 870.1650	21 CFR 870.1650	Same
Classification Product Code	IZQ	IZQ	Same
Intended Use/ Indications for Use	The CT Exprès™ 3D Contrast Media Delivery System is indicated for controlled automatic administration, on the venous side, of contrast media and saline, to human subjects while undergoing examination by means of a computed tomography (CT) scanner. The CT Exprès™ 3D Contrast Media Delivery System is specifically indicated for use in CT procedures for the delivery of Isovue (Iopamidol Injection) contrast media as supplied in Imaging Bulk Package (IBP), for a maximum of 20 bottles of contrast media or a maximum of ten (10) hours, whichever comes first, per Day Set III HP disposable. The Bottle Spike disposable is for single-bottle use only and must be discarded with the contrast media bottle. The Patient Set disposable must be discarded after each patient procedure. The CT Exprès™ 3D is to be used only by and under quasi-continuous supervision of trained health care professionals in an appropriate licensed health care facility, in a room designated for radiological procedures that	MEDRAD® Centargo CT Injection System is an automated contrast injection system that is indicated for the controlled, automatic administration, on the venous side, of ULTRAVIST® (Iopromide), ISOVUE® (Iopamidol), OPTIRAY® (Ioversol), or OMNIPAQUE™ (Iohexol) contrast media as supplied in an approved Imaging Bulk Package (IBP) presentation and 0.9% Sodium Chloride Injection USP (saline) to human subjects undergoing examinations in computed tomography (CT). The system is to be used by and under quasi-continuous supervision of trained healthcare professionals in an appropriate licensed healthcare facility, in a room designated for radiological procedures that involve intravascular administration of contrast agent. The Day Set is used for a maximum time of twenty-four (24) hours, or for a maximum of 25 bottles of contrast media, whichever comes first. The Patient Line must be discarded after each patient procedure. The Replacement Spike is for single-container use only and must be discarded with the fluid container. Contrast media	Same Intended Use

Item	Predicate Device (K151048): CT Exprès™ 3D Contrast Media Delivery System	Subject Device (K241849): MEDRAD® Centargo CT Injection System	Comparison
	involve intravascular administration of a contrast agent.	containers are to be discarded after their respective use times have expired or the Day Set use life has expired, whichever occurs first. Saline should only be used to deliver multiple single doses to multiple patients when used with the MEDRAD® Centargo CT Injection System and the provided Saline Tag. Once the port of the saline container is punctured, it should not be removed from the work area during the entire period of use. Saline containers are to be discarded with the Day Set. The ISI2 Module is indicated for the specific purpose of allowing an injector to interface with an imaging scanner.	
System Components			
System	CT Exprès Injector Unit CT Exprès Control Panel	Centargo Scan Room Unit Centargo Control Room Unit	Same
Accessories	CT Exprès Hand Switch CT Exprès Stand	ISI2 Module	Different and Substantially Equivalent
Heat Maintainer	CT Exprès Bottle Insulator	Heat maintainer is integral to the device	Different and Substantially Equivalent
Disposables	CT Exprès Day Set III HP CT Exprès Patient Set CT Exprès Bottle Spike Type B (25mm)	Centargo Day Set Centargo Patient Line Centargo Replacement Spike	Same
Physical Design			

Item	Predicate Device (K151048): CT Exprès™ 3D Contrast Media Delivery System	Subject Device (K241849): MEDRAD® Centargo CT Injection System	Comparison
Weight	Injector: Approx. 10 kg Console: Approx. 2.1 kg	Injector (Scan Room Unit): Approx. 75 kg Control Room Unit: Approx. 7 kg	Different and Substantially Equivalent
Dimensions	Injector: 44 x 32 x 16 cm Console: 30 x 20 x 22 cm	Injector (Scan Room Unit): 168 x 76 x 69 cm Control Room Unit (W3CZ): 27 x 38 x 20 cm Control Room Unit (Workflow Hub): 27 x 36 x 19 cm	Different and Substantially Equivalent
Power Requirement **Rated Voltage:** **Rated Current:** **Rated Frequency:**	 110 to 240 V AC 1.6 A 50/60Hz	 100 to 240 V AC 336-377 VA 50/60Hz	Different and Substantially Equivalent
Display Type	Color LCD with touch screen	Color LCD with touch screen	Same
Characteristics			
Remote Operation	Yes	Yes	Same
Single Patient Use Disposable	Patient Set	Patient Line	Same
Operating Principle	Rotary peristaltic pump	Servo driven piston	Different and Substantially Equivalent
Used to administer contrast media and saline	Yes	Yes	Same
Operational Characteristics			
Programmable Pressure Limit	Yes, 8 bar (ca. 120 psi)	Yes, 20.68 bar (300 psi). User programmable	Different and Substantially Equivalent
Injection Capabilities	Up to 24 phases per patient (8 phases per injection; up to 3 injections per patient)	Up to 60 phases per patient (6 phases per injection: up to 10 injections per patient)	Different and Substantially Equivalent
Injection Rates for Contrast Media	0.5-9.0 mL/s	0.1 to 10 mL/s	Different and Substantially Equivalent

Item	Predicate Device (K151048): CT Exprès™ 3D Contrast Media Delivery System	Subject Device (K241849): MEDRAD® Centargo CT Injection System	Comparison
Injection Rates for Saline	0.1-9.0 mL/s	0.1 to 10 mL/s	Different and Substantially Equivalent
Injection Volume per Injection	10-200 mL per injection	1-400 mL per injection 1 mL to 200 mL for contrast and flush phases, 1 mL to 400 mL for Dual Flow phases, in 1 mL increments. A total of 400 mL of contrast can be delivered in the same injection if both contrast reservoirs contain the same type and concentration.	Different and Substantially Equivalent –
Flow Rate Accuracy	± 10% for a programmed injection volume between 10 mL and 59 mL ± 6% for a programmed injection volume between 60 mL and 200 mL	±(5% + 0.1) mL/s when averaged over 2 seconds for flow rates >5 mL/s or averaged over 10 mL for flow rates ≤5 mL/s	Different and Substantially Equivalent –
Volume Accuracy	± 10% for a programmed injection volume between 10 mL and 59 mL ± 6% for a programmed injection volume between 60 mL and 200 mL	**Contrast or saline phase:** • ±(2% + 1) mL **Simultaneous (DualFlow) phase:** For ratio <80%, or that occurs following a contrast phase of ≥20 mL: • Combined fluid volume: ±(4% +2) mL • Contrast: ±(4% +2) mL • Saline: ±(4% +2) mL For ratio ≥80% without preceding contrast phase of 20 mL or greater:	Different and Substantially Equivalent –

Item	Predicate Device (K151048): CT Exprès™ 3D Contrast Media Delivery System	Subject Device (K241849): MEDRAD® Centargo CT Injection System	Comparison
		• Combined fluid volume: +(4% + 7) mL /- (4% +2) mL • Contrast: ±(4% +2) mL • Saline: +(4% + 7) mL /- (4% +2) mL	
Contrast Media Container Volume	200 & 500 mL (IBPs)	200 & 500 mL (IBPs)	Same
Saline Flush	Yes	Yes	Same
Needle Size	16-24 G	18-24 G	Different and Substantially Equivalent –
Injection Pause	0-400 seconds	0-900 seconds	Different and Substantially Equivalent –
Injection Protocol Storage	Yes	Yes	Same
Priming/Filling Rate	1.5 mL/s (manual) 6.0 mL/s (automatic)	2.0 mL/s (manual) 6.0 mL/s (automatic)	Different and Substantially Equivalent
Air Detection Principle	Outlet: Ultrasound	Inlet: Optical Outlet: Ultrasonic In reservoir: Software	Different and Substantially Equivalent
Technical Detection Limit of air in tubing	0.04 mL	0.001 mL	Different and Substantially Equivalent

Item	Predicate Device (K151048): CT Exprès™ 3D Contrast Media Delivery System	Subject Device (K241849): MEDRAD® Centargo CT Injection System	Comparison
Air Detector Alert Limit	For programmed injection volume ≤ 35 mL CM, 1.25 mL For programmed injection volume ≥ 35 mL CM, 1.25 mL if fragment air bubble, otherwise an additional air volume of 0.75 mL is tolerated. Note: The volume of the Patient Set (after the air detector) is 8 mL	In reservoir: 1 mL Outlet: 1 mL or greater Note: The volume of the Patient Line after the air detector is approximately 11 mL	Different and Substantially Equivalent
Occlusion Detection Principle	Fail safe piezo-resistive pressure sensor	Software control via motor current monitoring	Different and Substantially Equivalent
Occlusion Detection Alert Limit	132 PSI ± 17.4 PSI (9.1 bar ± 1.2 bar)	Settable to 300 psi. Maximum over pressure is programmed value +50 psi	Different and Substantially Equivalent
Injector Software Features (Optional features)			
Smart Protocols: Personalized Patient Protocol Technology (P3T) Cardiac	No	Yes. 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.	Different and Substantially Equivalent
Smart Protocols: Personalized Patient Protocol Technology (P3T) PA	No	Yes. 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.	Different and Substantially Equivalent
Smart Protocols: Personalized Patient Protocol	No	Yes. P3T Abdomen is indicated for use with CT imaging of abdominal organs (i.e., liver, pancreas, kidneys).	Different and Substantially Equivalent

Item	Predicate Device (K151048): CT Exprès™ 3D Contrast Media Delivery System	Subject Device (K241849): MEDRAD® Centargo CT Injection System	Comparison
Technology (P3T) Abdomen			
Smart Protocols: Iodine Load/Dose Based, Iodine Delivery Rate Based, and Tube Voltage Based Protocols	No	Yes. Iodine Load/Dose Based, Iodine Delivery Rate Based, and Tube Voltage Based Protocols	Different and Substantially Equivalent
Informatics	No	Yes - This feature offers the user the ability to associate patient/exam information with injection details and send the output to one or more hospital systems (e.g. Radiology Information System)	Different and Substantially Equivalent
Connectivity Accessory			
Imaging System Interface (ISI2) Accessory	No	Yes. The ISI2 Module is indicated for the specific purpose of allowing an injector to interface with a scanner.	Different and Substantially Equivalent
Connect.CT	No	Yes. The Connect.CT application is indicated for the specific purpose of allowing the injector to interface with a CT scanner.	Different and Substantially Equivalent
Disposables			
Patient Tubing			
Components	Patient Set Cassette Patient Set Tubing Pinch Clamp Patient Connector with Safety Cap	Patient Line Tube 2X check valves Patient Line Connector	Different and Substantially Equivalent
Safety Feature Against Re-use	Break away pin designed to break on insertion	Via software controls	Different and Substantially Equivalent

Item	Predicate Device (K151048): CT Exprès™ 3D Contrast Media Delivery System	Subject Device (K241849): MEDRAD® Centargo CT Injection System	Comparison
Day Set			
Components	T-connector Contrast media line x2 Spike for saline line Saline line Filter x2 Reservoir x2 Tubing guide x2	Reservoir x3 Manifold Plunger x3 Inlet tubing x3 Air detector tubing Spike adapter x3 Replaceable spike with dust cap x3 Stopcock x3	Different and Substantially Equivalent
Contrast Media Line Tubing Material	PVC tubing	PVC Tubing	Same
Saline Line Tubing Material	PVC tubing	PVC Tubing	Same
Spike			
Spike Size	25 mm	28 mm	Different and Substantially Equivalent
Safety Feature Against Re-Use	Spike tip designed to break off into bottle on removal	Spike is removable with the bottle, labeling instructions on workflow	Different and Substantially Equivalent
Biocompatibility			
Biocompatibility Testing	Yes	Yes	Same

VIII. INTENDED USE/INDICATIONS FOR USE COMPARISON

Intended Use/Indications for Use comparison discussion:

The Intended Use of Centargo is the same as the CT Exprès 3D Contrast Media Delivery System as both devices are intended for the controlled, automatic administration of contrast media and saline on the venous side to human subjects while undergoing examination by means of a computed tomography (CT) scanner. The differences in allowing the use of different contrast agents do not change the intended use of the device. All of the contrast agents are iodinated agents, Centargo has been tested to demonstrate the compatibility with the listed contrast agents, and the differences in contrast agents do not raise different questions of safety and effectiveness when compared to the predicate device. The substantial equivalence of the MEDRAD® Centargo CT Injection System has been confirmed through chemical compatibility testing, biocompatibility and EMC testing.
The ISI2 is included in the indications for use statement to specify the scanner connectivity via cables. While there are differences between the subject device and predicate in terms of scanner connectivity, our successful software testing confirmed there are no new or different questions of safety or effectiveness.
The additional of the saline tag in the indications for use statement adds clarity for users and based on our usability studies, mention of it does not raise new or different questions of safety and effectiveness when compared to the predicate device.

IX. TECHNOLOGICAL COMPARISON

Technological comparison discussion:

Both systems aim to deliver fluids consistently and reliably according to user programmed protocols. Although there are differences in the technology used to deliver fluids (Plunger/barrel-based vs peristaltic pump), the Centargo system fluid delivery performance has been demonstrated to be as safe and effective as the predicate device. Likewise, while there are differences in physical design and operational characteristics, Centargo has demonstrated device performance against established acceptance criteria and testing did not raise new questions of safety and effectiveness.

Software features and connectivity accessories are available on Centargo and were verified and validated using the same test methods as the reference device (MEDRAD® Stellant FLEX CT Injection System, (K192370). Testing with Centargo did not raise new questions of safety and effectiveness when compared to the predicate device.

Both the predicate (CT Exprès) and subject (Centargo) devices are used in conjunction with disposables that create a fluid pathway from the bottles of contrast media and the saline

container to the patient. While there are differences in design, the disposables have demonstrated device performance against established acceptance criteria and testing did not raise new questions of safety and effectiveness when compared to the predicate device.

While there are differences in design and technology, these differences do not raise new questions of safety and effectiveness when compared to the predicate device. Centargo has demonstrated its ability to perform within its specified parameters and operate as intended by users of the device. As a result, the device is deemed as safe and effective as the predicate device.

X. PERFORMANCE DATA

A. Performance Testing

- Device performance testing included verification of the system injection volume and flow rate accuracy, pressure accuracy, air detection, heat maintenance, battery performance, occlusion detection, and protocol management. 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.
- The Centargo device is a Class II device and is classified by the FDA per 21 CFR 870.1650 (Angiographic Injector and Syringe). There are no special controls for the injector itself. However, as the system also includes disposables, the device testing included verification and validation in accordance with the Guidance for Industry and FDA Staff, Intravascular Administration Sets Premarket Notification Submissions [510(k)]: July 11, 2008. Testing addressed the risks and recommended mitigation measures identified in the guidance.
- The MEDRAD® Centargo CT Injection System disposables were tested for performance and verified in accordance with the following standard:
    - ISO 8536-4:2010, Infusion equipment for medical use-Part 4: Infusion sets for single use. Only applicable requirements from ISO 8536-4 were tested. The results indicate the disposable conforms to its pre-determined specifications.

B. Software Verification and Validation Testing

Software verification and validation was performed in accordance with the following standards:

- IEC 62304 Edition 1.1 2015-06 Consolidated Version: Medical device Software-Software life cycle processes FDA Guidance for the Content of Premarket Submissions for Device Software Functions Contained in Medical Devices: Guidance for Industry and FDA Staff, June 14, 2023, and Guidance for Industry and Food and Drug Administration Staff - Off-The-Shelf Software Use in Medical Devices, August 11, 2023. Test results were evaluated against established acceptance criteria; all test results were acceptable.
- Cybersecurity testing was conducted according to Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions Final Guidance for Industry and Food and Drug Administration Staff, September 27, 2023. Testing provides a reasonable assurance that the device and related systems are cybersecure.

C. Biocompatibility Testing

The MEDRAD® Centargo CT Injection System disposables have both direct and indirect patient contacting materials which were verified in accordance with the following standard:

- ISO 10993-1 Fifth Edition:2018, Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process.

The following endpoints were evaluated to characterize the biocompatibility profile based on the classification of the devices (externally communicating, indirect blood path, limited contact (<= 24 h)):

- Cytotoxicity
- Hemocompatibility (Hemolysis only)
- Sensitization
- Irritation / Intracutaneous Reactivity
- Acute Systemic Toxicity
- Materials Mediated Pyrogenicity

Particulate testing was completed according to methodology described in USP <788> Particulate Matter in Injections. The Centargo sterile disposables met all acceptance criteria and have been determined to be compatible for their intended use.

D. Chemical Compatibility Testing

Chemical Integrity testing was performed to support the material compatibility of the MEDRAD® Centargo CT Injection System Disposable sets with the following contrast media:

- ULTRAVIST® (Iopromide) Image Bulk Presentation
- ISOVUE® (Iopamidol) Image Bulk Presentation
- OPTIRAY® (Ioversol) Image Bulk Presentation
- OMNIPAQUE™ (Iohexol) Image Bulk Presentation

E. Cleaning and Disinfection Validation Testing

Cleaning/disinfection validation was performed, and testing results demonstrated the efficacy of the cleaning and disinfection procedures.

F. Sterility, Packaging, and Shelf-Life Testing

The MEDRAD® Centargo CT Injection System disposable sets are Radiation sterilized and are validated to a SAL of 10^{-6}. The testing was performed as per the following standards.

- ISO 11737-1 Third edition 2018-01 [Including AMD1:2021] Sterilization of health care products-Microbiological methods-Part 1: Determination of a population of microorganisms on products.
- ISO 11737-2 Third edition 2019-12 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition validation and maintenance of a sterilization process.

- ISO 11137-1 First edition 2006-04-15- Sterilization of health care products-Radiation-Part1: requirements for development validation and routine control of a sterilization process for medical devices.
- ISO 11137-2 Third edition 2013-06-01 [Including AMD1:2022]: Sterilization of health care products- Radiation Part 2: Establishing the sterilization dose.
- IS0 11607-1 Second edition 2019-02: Packaging for terminally sterilized medical devices-part 1: Requirements for materials sterile barrier systems and packaging systems.
- The sterilization testing passed, and the product performance met all prior established acceptance criteria.
- Disposables functional testing was performed on accelerated aged samples and results confirmed the performance for the labeled shelf-life.
- Package stability testing was demonstrated via verification of aged product that had been pre-conditioned. Testing was acceptable to satisfy the package testing requirements. Additionally, product testing was successfully completed after exposure to shipping and handling conditions.

G. Contamination Control Testing

Bayer performed the following contamination control studies:

- Microbial ingress study and
- Cross contamination study

Based on the results obtained, it has been concluded that MEDRAD® Centargo CT Injection System has the ability to maintain sterile fluid path and resist the ingress of microorganisms when used as intended.

H. Human Factors/ Usability Testing

Human Factors/Usability testing were performed in a simulated use environment to optimize the device design and support the safe use of the MEDRAD® Centargo CT injection System. The summative evaluation is conducted as per the following standard and FDA Guidance.

- IEC 62366-1 Edition 1.1 2020-06 Consolidated version. Medical devices-Part 1: Application of Usability engineering to medical devices.
- Applying Human Factors and Usability Engineering to Medical Devices (Guidance for Industry and FDA Staff) February 3, 2016.

The results demonstrated that the overall residual risk is low, and users can operate the system as safely and effectively as the predicate device.

I. Reliability Testing

Reliability testing was performed using statistical methods to demonstrate the capability to meet system performance requirements sequentially and repeatedly. All testing passed and the demonstrated performance met all prior established acceptance criteria.

J. Electromagnetic Compatibility (EMC) and Electrical Safety Testing

Electromagnetic compatibility and electrical safety testing were performed in accordance with the following standards:

- ANSI/AAMI ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- ANSI AAMI IEC 60601-1-2:2014+AMD1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

Testing included verification of both configurations, including in conjunction with the ISI2 Module accessory. All testing passed and the demonstrated performance met all prior established acceptance criteria.

K. Animal Studies: Not Applicable

L. Clinical Testing: Not Applicable

Summary

In summary, the conclusions drawn from the nonclinical and other tests (discussed above) demonstrate that the device is as safe, as effective, and performs as well as or better than the predicate device (K151048).

XI. CONCLUSION

Bayer considers the MEDRAD® Centargo CT Injection System (Centargo) to be substantially equivalent to the predicate device, CT Exprès™ 3D Contrast Media Delivery System (K151048). This conclusion is based upon the devices having the same intended use and comparable technological characteristics. While there are differences in design and technology, these differences do not raise new questions of safety or effectiveness when compared to the predicate device. Centargo has demonstrated its ability to perform within its specified parameters and operate as intended by the users of the device. As a result, its performance is deemed acceptable and substantially equivalent to the predicate device.