September 24, 2025

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

Re: K252689
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: August 26, 2025
Received: August 26, 2025

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.*

510(k) Number *(if known)*
K252689

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, via the venous route, of a contrast agent and 0.9% Sodium Chloride Injection USP (saline) to patients undergoing examinations in computed tomography (CT).
The system is intended for use by and under direct quasi-continuous supervision of trained healthcare professionals to assure the integrity of the contrast agent and the injection system, in an appropriate licensed healthcare facility, in a room designated for radiological procedures that involve intravascular administration of a contrast agent.

For a complete list of compatible contrast agents for use with the MEDRAD® Centargo CT Injection System, refer to the Centargo CT Injection System Operation Manual.

The Day Set is used for a maximum time of twenty-four (24) hours, or for a maximum of 25 bottles of contrast agents, 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 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
Imaxeon Pty Ltd. MEDRAD® Centargo CT Injection System
The Summary is prepared in conformance with 21CFR 807.92
**K252689**

## I. SUBMITTER

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Date Prepared: September 16, 2025

## II. DEVICE

| | |
|---|---|
| Trade Name: | MEDRAD® Centargo CT Injection System<br>MEDRAD® Centargo Day Set<br>MEDRAD® Centargo Patient Line<br>MEDRAD® Centargo Replacement Spike<br>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: | MEDRAD® Centargo CT Injection System |
| 510(k) Number: | K241849 |
| 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. DEVICE DESCRIPTION

The MEDRAD® Centargo CT Injection System (Centargo) is an automated contrast injection system intended to be used to inject intravenous contrast agents and saline into humans for diagnostic studies in CT applications. Centargo is intended for use with the approved contrast agent in a single-dose container and Imaging Bulk Package (IBP)

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 agents, 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.

## V. INDICATIONS FOR USE

MEDRAD® Centargo CT Injection System is an automated contrast injection system that is indicated for the controlled, automatic administration, via the venous route, of a contrast agent and 0.9% Sodium Chloride Injection USP (saline) to patients undergoing examinations in computed tomography (CT). The system is intended for use by and under direct quasi-continuous supervision of trained healthcare professionals to assure the integrity of the

contrast agent and the injection system, in an appropriate licensed healthcare facility, in a room designated for radiological procedures that involve intravascular administration of a contrast agent.

For a complete list of compatible contrast agents for use with the MEDRAD® Centargo CT Injection System, refer to the Centargo CT Injection System Operation Manual.

The Day Set is used for a maximum time of twenty-four (24) hours, or for a maximum of 25 bottles of contrast agents, 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 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.

## VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

A table comparing key features of the subject device (Centargo) and predicate device (Centargo, K241849) is provided below.

Table 1 – Key Feature Comparison

| Item | Predicate Device (K241849): MEDRAD® Centargo CT Injection System | Subject Device (K252689): 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** | 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. | MEDRAD® Centargo CT Injection System is an automated contrast injection system that is indicated for the controlled, automatic administration, via the venous route, of a contrast agent and 0.9% Sodium Chloride Injection USP (saline) to patients undergoing examinations in computed tomography (CT). The system is intended for use by and under direct quasi-continuous supervision of trained healthcare professionals to assure the integrity of the contrast agent and the injection system, in an appropriate licensed healthcare facility, in a room designated for radiological procedures that involve intravascular administration of a contrast agent. | Same Intended Use as both are intended to deliver CT contrast agents.<br><br>Minor differences in not listing the specific contrast agents in the indications for use statement, do not raise different questions of safety and effectiveness as the information is presented in a separate section of the user manual. |

| Item | Predicate Device (K241849): MEDRAD® Centargo CT Injection System | Subject Device (K252689): MEDRAD® Centargo CT Injection System | Comparison |
|---|---|---|---|
| | 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.<br><br>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. | For a complete list of compatible contrast agents for use with the MEDRAD® Centargo CT Injection System, refer to the Centargo CT Injection System Operation Manual.<br><br>The Day Set is used for a maximum time of twenty-four (24) hours, or for a maximum of 25 bottles of contrast agents, 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 agent containers are to be discarded after their respective use times have expired or the Day Set use life has expired, whichever occurs first.<br><br>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 | |

| Item | Predicate Device (K241849): MEDRAD® Centargo CT Injection System | Subject Device (K252689): MEDRAD® Centargo CT Injection System | Comparison |
|---|---|---|---|
| | The ISI2 Module is indicated for the specific purpose of allowing an injector to interface with an imaging scanner. | removed from the work area during the entire period of use. Saline containers are to be discarded with the Day Set.<br><br>The ISI2 Module is indicated for the specific purpose of allowing an injector to interface with an imaging scanner. | |
| **System Components** | | | |
| **System** | Centargo Scan Room Unit<br>Centargo Control Room Unit | Centargo Scan Room Unit<br>Centargo Control Room Unit | Same |
| **Accessories** | ISI2 Module | ISI2 Module | Same |
| **Heat Maintainer** | Heat maintainer is integral to the device | Heat maintainer is integral to the device | Same |
| **Disposables** | Centargo Day Set<br>Centargo Patient Line<br>Centargo Replacement Spike | Centargo Day Set<br>Centargo Patient Line<br>Centargo Replacement Spike | Same |
| **Physical Design** | | | |
| **Weight** | Injector (Scan Room Unit): Approx. 75 kg<br>Control Room Unit: Approx. 7 kg | Injector (Scan Room Unit): Approx. 75 kg<br>Control Room Unit: Approx. 7 kg | Same |
| **Dimensions** | Injector (Scan Room Unit): 168 x 76 x 69 cm | Injector (Scan Room Unit): 168 x 76 x 69 cm | Same |

| Item | Predicate Device (K241849): MEDRAD® Centargo CT Injection System | Subject Device (K252689): MEDRAD® Centargo CT Injection System | Comparison |
|---|---|---|---|
| | Control Room Unit (W3CZ): 27 x 38 x 20 cm<br>Control Room Unit (Workflow Hub): 27 x 36 x 19 cm | Control Room Unit (W3CZ): 27 x 38 x 20 cm<br>Control Room Unit (Workflow Hub): 27 x 36 x 19 cm | |
| **Power Requirement**<br>**Rated Voltage:**<br>**Rated Current:**<br>**Rated Frequency:** | 100 to 240 V AC<br>336-377 VA<br>50/60Hz | 100 to 240 V AC<br>336-377 VA<br>50/60Hz | Same |
| **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** | Servo driven piston | Servo driven piston | Same |
| **Used to administer contrast agent and saline** | Yes | Yes | Same |
| **Operational Characteristics** | | | |
| **Programmable Pressure Limit** | Yes, 20.68 bar (300 psi). User programmable | Yes, 20.68 bar (300 psi). User programmable | Same |
| **Injection Capabilities** | Up to 60 phases per patient (6 phases per injection: up to 10 injections per patient) | Up to 60 phases per patient (6 phases per injection: up to 10 injections per patient) | Same |

| Item | Predicate Device (K241849): MEDRAD® Centargo CT Injection System | Subject Device (K252689): MEDRAD® Centargo CT Injection System | Comparison |
|---|---|---|---|
| **Injection Rates for Contrast Agent** | 0.1 to 10 mL/s | 0.1 to 10 mL/s | Same |
| **Injection Rates for Saline** | 0.1 to 10 mL/s | 0.1 to 10 mL/s | Same |
| **Injection Volume per Injection** | 1-400 mL per injection<br><br>1 mL to 200 mL for contrast and flush phases, 1 mL to 400 mL for Dual Flow phases, in 1 mL increments.<br><br>A total of 400 mL of contrast can be delivered in the same injection if both contrast reservoirs contain the same type and concentration. | 1-400 mL per injection<br><br>1 mL to 200 mL for contrast and flush phases, 1 mL to 400 mL for Dual Flow phases, in 1 mL increments.<br><br>A total of 400 mL of contrast can be delivered in the same injection if both contrast reservoirs contain the same type and concentration. | Same |
| **Flow Rate Accuracy** | ±(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 | ±(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 | Same |
| **Volume Accuracy** | **Contrast or saline phase:**<br>• ±(2% + 1) mL<br><br>**Simultaneous (DualFlow) phase:**<br>For ratio <80%, or that occurs following a contrast phase of ≥20 mL:<br>• Combined fluid volume: ±(4% +2) mL<br>• Contrast: ±(4% +2) mL<br>• Saline: ±(4% +2) mL | **Contrast or saline phase:**<br>• ±(2% + 1) mL<br><br>**Simultaneous (DualFlow) phase:**<br>For ratio <80%, or that occurs following a contrast phase of ≥20 mL:<br>• Combined fluid volume: ±(4% +2) mL<br>• Contrast: ±(4% +2) mL<br>• Saline: ±(4% +2) mL | Same |

| Item | Predicate Device (K241849): MEDRAD® Centargo CT Injection System | Subject Device (K252689): MEDRAD® Centargo CT Injection System | Comparison |
|---|---|---|---|
| | For ratio ≥80% without preceding contrast phase of 20 mL or greater:<br>• Combined fluid volume: +(4% + 7) mL /- (4% +2) mL<br>• Contrast: ±(4% +2) mL<br>Saline: +(4% + 7) mL /- (4% +2) mL | For ratio ≥80% without preceding contrast phase of 20 mL or greater:<br>• Combined fluid volume: +(4% + 7) mL /- (4% +2) mL<br>• Contrast: ±(4% +2) mL<br>• Saline: +(4% + 7) mL /- (4% +2) mL | |
| **Contrast Agent Container Volume** | 200-500 ml | 50-500 ml | Different and substantially equivalent. This difference does not change the intended use of the device. Safety and effectiveness of the MEDRAD® Centargo CT Injection System has been confirmed through labeling verification and integration analysis. |
| **Saline Flush** | Yes | Yes | Same |
| **Needle Size** | 18-24 G | 18-24 G | Same |
| **Injection Pause** | 0-900 seconds | 0-900 seconds | Same |

| Item | Predicate Device (K241849): MEDRAD® Centargo CT Injection System | Subject Device (K252689): MEDRAD® Centargo CT Injection System | Comparison |
|---|---|---|---|
| **Injection Protocol Storage** | Yes | Yes | Same |
| **Priming/Filling Rate** | 2.0 mL/s (manual)<br>6.0 mL/s (automatic) | 2.0 mL/s (manual)<br>6.0 mL/s (automatic) | Same |
| **Air Detection Principle** | Inlet: Optical<br>Outlet: Ultrasonic<br>In reservoir: Software | Inlet: Optical<br>Outlet: Ultrasonic<br>In reservoir: Software | Same |
| **Technical Detection Limit of air in tubing** | 0.001 mL | 0.001 mL | Same |
| **Air Detector Alert Limit** | In reservoir: 1 mL<br>Outlet: 1 mL or greater<br><br>Note: The volume of the Patient Line after the air detector is approximately 11 mL | In reservoir: 1 mL<br>Outlet: 1 mL or greater<br><br>Note: The volume of the Patient Line after the air detector is approximately 11 mL | Same |
| **Occlusion Detection Principle** | Software control via motor current monitoring | Software control via motor current monitoring | Same |
| **Occlusion Detection Alert Limit** | Settable to 300 psi. Maximum over pressure is programmed value +50 psi | Settable to 300 psi. Maximum over pressure is programmed value +50 psi | Same |
| **Injector Software Features (Optional features)** | | | |
| **Smart Protocols: Personalized Patient Protocol** | Yes. P3T Cardiac is indicated for use with CT Angiography of the cardiac structures, coronary arteries, chambers of the heart, | Yes. P3T Cardiac is indicated for use with CT Angiography of the cardiac structures, coronary arteries, chambers | Same |

| Item | Predicate Device (K241849): MEDRAD® Centargo CT Injection System | Subject Device (K252689): MEDRAD® Centargo CT Injection System | Comparison |
|---|---|---|---|
| **Technology (P3T) Cardiac** | pulmonary vasculature, thoracic, and abdominal aorta. | of the heart, pulmonary vasculature, thoracic, and abdominal aorta. | |
| **Smart Protocols: Personalized Patient Protocol Technology (P3T) PA** | 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. | 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. | Same |
| **Smart Protocols: Personalized Patient Protocol Technology (P3T) Abdomen** | Yes. P3T Abdomen is indicated for use with CT imaging of abdominal organs (i.e., liver, pancreas, kidneys). | Yes. P3T Abdomen is indicated for use with CT imaging of abdominal organs (i.e., liver, pancreas, kidneys). | Same |
| **Smart Protocols: Iodine Load/Dose Based, Iodine Delivery Rate Based, and Tube Voltage Based Protocols** | Yes. Iodine Load/Dose Based, Iodine Delivery Rate Based, and Tube Voltage Based Protocols | Yes. Iodine Load/Dose Based, Iodine Delivery Rate Based, and Tube Voltage Based Protocols | Same |
| **Informatics** | 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) | 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) | Same |
| **Connectivity Accessory** | | | |
| **Imaging System Interface (ISI2) Accessory** | Yes. The ISI2 Module is indicated for the specific purpose of allowing an injector to interface with a scanner. | Yes. The ISI2 Module is indicated for the specific purpose of allowing an injector to interface with a scanner. | Same |
| **Connect.CT** | Yes. The Connect.CT application is indicated for the specific purpose of | Yes. The Connect.CT application is indicated for the specific purpose of | Same |

| Item | Predicate Device (K241849): MEDRAD® Centargo CT Injection System | Subject Device (K252689): MEDRAD® Centargo CT Injection System | Comparison |
|---|---|---|---|
| | allowing the injector to interface with a CT scanner. | allowing the injector to interface with a CT scanner. | |
| **Disposables** | | | |
| **Patient Tubing** | | | |
| **Components** | Patient Line Tube<br>2X check valves<br>Patient Line Connector | Patient Line Tube<br>2X check valves<br>Patient Line Connector | Same |
| **Safety Feature Against Re-use** | Via software controls | Via software controls | Same |
| **Day Set** | | | |
| **Components** | Reservoir x3<br>Manifold<br>Plunger x3<br>Inlet tubing x3<br>Air detector tubing<br>Spike adapter x3<br>Replaceable spike with dust cap x3<br>Stopcock x3 | Reservoir x3<br>Manifold<br>Plunger x3<br>Inlet tubing x3<br>Air detector tubing<br>Spike adapter x3<br>Replaceable spike with dust cap x3<br>Stopcock x3 | Same |
| **Contrast Agent Line Tubing Material** | PVC tubing | PVC Tubing | Same |
| **Saline Line Tubing Material** | PVC tubing | PVC Tubing | Same |
| **Spike** | | | |
| **Spike Size** | 28 mm | 28 mm | Same |
| **Safety Feature Against Re-Use** | Spike is removable with the bottle, labeling instructions on workflow | Spike is removable with the bottle, labeling instructions on workflow | Same |
| **Biocompatibility** | | | |

| Item | Predicate Device (K241849): MEDRAD® Centargo CT Injection System | Subject Device (K252689): MEDRAD® Centargo CT Injection System | Comparison |
|---|---|---|---|
| **Biocompatibility Testing** | Yes | Yes | Same |

## VII. INTENDED USE/INDICATIONS FOR USE COMPARISON

Intended Use/Indications for Use comparison discussion:

The Intended Use of proposed modification to Centargo is the same as the cleared Centargo CT Injection devices as both devices are intended for the controlled, automatic administration of contrast agent and saline on the venous side to human subjects while undergoing examination by means of a computed tomography (CT) scanner. There are minor indication differences in not listing the specific contrast agents in the indications for use statement, which do not raise different questions of safety and effectiveness and do not result in a new intended use.

## VIII. TECHNOLOGICAL CHARACTERISTICS

The MEDRAD® Centargo CT Injection System possesses the same technological characteristics as the predicate. Both subject device and predicate aim to deliver fluids consistently and reliably according to user programmed protocols. The Centargo system fluid delivery performance has been demonstrated to be as safe and effective as the predicate device.

## IX. PERFORMANCE ASSESSMENT

### A. System Integration Analysis

Centargo CT Injection System integration testing was successfully performed to ensure the system is capable of operation with single-dose (50 ml) contrast presentations as per the design specifications.

### B. Human Factors Assessment

Human Factors assessment was completed in accordance with the following standards and guidance:

- IEC 62366-1 Edition 1.1 2020-06 Consolidated version. Medical devices-Part 1: Application of Usability engineering to medical devices.
- IEC 60601-1-6 Edition 3.2 2020-07, Medical Electrical Equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability
- Applying Human Factors and Usability Engineering to Medical Devices (Guidance for Industry and FDA Staff) February 3, 2016.
- Content of Human Factors Information in Medical Device Marketing Submissions (Draft Guidance for Industry and Food and Drug Administration Staff), December 2022 (Draft)

### C. Other Tests:

Electromagnetic Compatibility/Electrical Safety testing, Biocompatibility, Chemical Compatibility, Cleaning and Disinfection, Sterilization, Packaging and Shelf-life testing, Contamination Control Testing, Software Verification and Validation, Cybersecurity and Device performance testing has been previous conducted as part of K241849 and is being leveraged.

Based on the assessment, the proposed modifications to the MEDRAD® Centargo CT Injection System are found acceptable regarding safe and effective use for the intended users, uses and use environments.

**Summary**

In summary, the conclusions drawn from the previously submitted nonclinical and other tests (discussed above) demonstrate that the device is safe and effective as the predicate device (K241849).

## X. CONCLUSION

Bayer considers the MEDRAD® Centargo CT Injection System (Centargo) to be substantially equivalent to the predicate device, Centargo CT Injection System (K241849). This conclusion is based upon the devices having the same intended use and same technological characteristics. 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.