November 24, 2021

ControlRad, Inc.
% Ms. Patricia Jones
VP Regulatory Affairs
Secure BioMed Evaluations
7828 Hickory Flat Highway, Suite 120
WOODSTOCK GA 30188

Re: K213455
Trade/Device Name: ControlRad® Select Model Z
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, JAA, IZI
Dated: October 25, 2021
Received: October 26, 2021

Dear Ms. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

, for

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213455

Device Name
ControlRad® Select Model Z

Indications for Use *(Describe)*
The ControlRad® Select Model Z with the Artis zee is indicated to provide fluoroscopic imaging of the patient during diagnostic, surgical, and interventional procedures while reducing patients and clinicians' radiation exposure (Dose Area Product) outside of the ControlRad Select Model Z 's region of interest (ROI) as compared to Artis zee non-collimated image area. 1 The ControlRad Select Model Z semi-transparent filter should not be used in lieu of the Artis zee's collimators, as they block the most radiation, but can help physicians balance dose reduction with the need to visualize structures outside the ROI when it is considered clinically advantageous to do so. Clinical applications may include cardiac angiography, neuro-angiography, general angiography, rotational angiography, multipurpose angiography and whole body radiographic/fluoroscopic procedures as well as procedures next to the table for i.e. patient extremities.

Additional procedures that can be performed include angiography in the operating room, image guided surgery by X-ray, by image fusion, and by navigation systems. The examination table as an integrated part of the system can be used for X-ray imaging, surgery and interventions.

1 Relative to open Field of View (FOV), the ControlRad Select Model Z reduces at least 85% of the Dose Area Product at 65 kVp and ROI with width and length that are smaller than 1/5 the edge size of the full FOV.

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: ControlRad® Select Model Z - K213455

Company Name:
ControlRad, Inc.
275 Scientific Dr NW
Suite 1100
Norcross, Georgia 30092, USA
P: 1-800-522-5148

Date Prepared: October 25, 2021

This 510(k) Summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

1. **General Information:**
   Applicant Name:
   ControlRad, Inc.
   Chris Fair
   275 Scientific Dr NW
   Suite 1100
   Norcross, Georgia 30092, USA
   P: 1-800-522-5148
   Establishment Registration Number: 3015709927

2. **Contact Person:**
   Patricia D. Jones, VP of Regulatory
   Secure BioMed Evaluations
   7828 Hickory Flat Highway, Suite 120
   Woodstock, GA 30188
   770-837-2681 (direct)
   Regulatory@SecureBME.com (email)

   Secondary Contact:
   Linda Braddon, Ph.D.
   Secure BioMed Evaluations
   7828 Hickory Flat Hwy
   Suite 120
   Woodstock, GA 30188
   770-837-2681
   Regulatory@SecureBME.com

3. **Device Name and Classification:**

Trade Name:	ControlRad® Select Model Z
Classification Name:	Image-intensified fluoroscopic X-ray System
Common Name:	Interventional Fluoroscopic X-ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1650

Device Class:		II
Product Codes:	**Primary**:	OWB
	Secondary:	JAA, IZI

4. Primary Predicate Device:

Trade Name:		ControlRad® Select Model Z
510(k) Clearance:		K202431
Clearance Date:		December 23, 2020
Classification Name:		Image-intensified Fluoroscopic x-ray System
Common Name:		Interventional Fluoroscopic X-ray System
Classification Panel:		Radiology
Regulation Number:		21 CFR §892.1650
Device Class:		II
Product Codes:	**Primary**:	OWB
	Secondary:	JAA, IZI

Reference Device:

Trade Name:		Artis zee
510(k) Clearance:		K181407
Clearance Date:		August 15, 2018
Classification Name:		Image-intensified fluoroscopic x-ray System
Common Name:		Interventional Fluoroscopic X-ray System
Classification Panel:		Radiology
Regulation Number:		21 CFR §892.1650
Device Class:		II
Product Codes:	**Primary**:	OWB
	Secondary:	IZI, JAA, JAK

5. Indications for Use:

The ControlRad® Select Model Z with Siemens Artis zee is indicated to provide fluoroscopic imaging of the patient during diagnostic, surgical, and interventional procedures while reducing patients' and clinicians' radiation exposure (Dose Area Product) outside of the ControlRad® Select Model Z's region of interest (ROI) as compared to Artis zee non-collimated image area. [1]The ControlRad® Select Model Z semi-transparent filter should not be used in lieu of the Artis zee's collimators, as they block the most radiation, but can help physicians balance dose reduction with the need to visualize structures outside the ROI when it is considered clinically advantageous to do so. Clinical applications may include cardiac angiography, neuro-angiography, general angiography, rotational angiography, multipurpose angiography, and whole body radiographic/fluoroscopic procedures as well as procedures next to the table for i.e., patient extremities.

Additional procedures that can be performed include angiography in the operating room, image guided surgery by X-ray, by image fusion, and by navigation systems. The examination table as an integrated part of the system can be used for X-ray imaging, surgery, and interventions.

[1] Relative to open Field of View (FOV), the ControlRad Select Model Z reduces at least 85% of the Dose Area Product at 65 kVp and ROI with width and length that are smaller than 1/5 the edge size of the full FOV.

6. Device Description:

The ControlRad® Select Model Z is a set of components mounted on the Artis zee system and cannot be used independent of the Artis zee system.

The ControlRad® Select Model Z consists of a ControlRad® filter mounted onto the Siemens Medical Artis zee (K181407) C-arm. The ControlRad® filter is installed semi-permanently (i.e., the filter may be removed to return the C-arm to its original condition) to aid in reducing both patient and clinicians' radiation exposure while providing fluoroscopic imaging of the patient during diagnostic, surgical and interventional procedures.

The ControlRad® Filter is an optional component installed on the Siemens Artis zee's collimator to further reduce radiation emissions. The ControlRad® Select Model Z is only compatible with the 30 x 40 detector and associated collimator. Use of this system on other sizes is prohibited.

The additional radiation reduction provided by the ControlRad® Filter will be outside the clinician-selected ROI and within the un-collimated region/image FOV.

The main components of the ControlRad® Select Model Z which are used with the Artis zee are:

- ControlRad® Tablet
- ControlRad® Filter
- ControlRad® Hardware
- ControlRad® Software and Firmware Modules
- ControlRad® Communication Interface

The ControlRad® Select Model Z is a system used to assist trained clinicians which is used to provide X-ray images when the clinician performs a medical procedure while reducing the patients and clinicians' radiation exposure (Dose Area Product) outside of the ControlRad® Select Model Z's region of interest (ROI) as compared to the Artis zee non-collimated image area. The ControlRad® Select Model Z can help physicians balance dose reduction with the need to visualize structures outside the ROI when it is considered clinically advantageous to do so.

ControlRad® Select Model Z contains a titanium filter. Two filter sizes are available with nominal thicknesses of 2.5mm or 3.0 mm, both of which are partially transparent to X-ray radiation.

Based on the user selection of the Artis zee collimator the ControlRad® Filter region of interest (ROI), radiation will be reduced. The X-ray beam inside the ROI is not impacted by the ControlRad® Filters. All radiation outside the ROI and inside the Artis zee collimated area will be filtered. This can help physicians balance dose reduction with the need to visualize structures outside the ROI when it is considered clinically advantageous to do so.

The ControlRad® Select Model Z allows physicians to select a customizable region of interest (ROI) using a ControlRad® dedicated screen Tablet. The proprietary technology then adjusts the semi-transparent titanium filters to deliver a high-quality image. This allows the Artis zee to generate an image in the selected physician's ROI while providing a lower radiation dose to the periphery. The result is a reduction in the overall radiation dose and exposure to the patient and the healthcare team while providing the physician the contextual information needed outside the ROI.

The workflow is therefore supported with lower radiation than with conventional imaging settings.

The ControlRad® Filter is designed to always include the center of the FOV in the ROI. Therefore, when selecting an ROI by the user, the actual ROI might be expanded to include the center of the FOV.

The ControlRad® Select Model Z is a product that can be mounted only on the following configurations of the Artis zee: floor, ceiling, and bi-plane systems.

Reason for Submission:
This Special 510(K) submission is requesting clearance for the ControlRad® Select Model Z to be installed on the Artis zee large collimator.

Technological Characteristics:
The ControlRad® Select Model Z consists of the following main components: ControlRad® Tablet, ControlRad® Filter, ControlRad® Hardware, ControlRad® Software and Firmware Modules and ControlRad® Communication Interface all installed on the Siemens Artis zee. The ControlRad® Select Model Z components are installed semi-permanently on the cleared Siemens Artis zee (K181407) and operate in parallel to the Siemens Artis zee. The removal of the ControlRad® components will restore the device to OEM specifications.

The ControlRad® Select Model Z components provide the following functionalities:

- The CR Tablet provides the user operational control of the ControlRad® Select Model Z device via a Graphical User Interface ("GUI"). The CR Tablet enables the clinician to select a Region of Interest ("ROI") on the image displayed on the CR Tablet, which is the same image that is displayed on the Siemens Artis zee's live monitor.

- The CR Filter is installed on top of the Artis zee's collimator. The CR Filter does not affect or modify the functionality of the collimator. The CR Filter is a semi-transparent filter which reduces the X-ray radiation outside the clinician-selected ROI typically by 44% to 98%. The actual dose reduction achieved will depend upon specific imaging parameters such as Siemens collimator settings, the kVp and the percentage of the non-collimated image covered by the ControlRad Filter.

- The ControlRad® Hardware, Software and Firmware Modules control the ControlRad® Filter positioning, which is determined by the location of the clinician-selected ROI and perform image processing.

- The ControlRad® Communication Interface provides communication between the various components of the ControlRad® Select Model Z and the Artis zee.

Principles of Operation:
The Siemens Artis zee provides an image whose boundaries are defined by the Siemens' collimator, i.e., the image FOV is defined by the Siemens non-collimated region. The image FOV size is not affected or modified by the ControlRad® Select Model Z.

Within the Siemens Artis zee non-collimated image region, when using a clinician selected Region of Interest ("ROI") on the ControlRad® Tablet, the ControlRad® Filters reduce radiation exposure outside the ROI. The resulting image has two parts:

- The image inside the clinician-selected ROI (unfiltered radiation area in the FOV), which has at least the same image quality in the ROI as the Siemens Artis zee (K181407).

- The image outside the clinician-selected ROI (filtered radiation area in the FOV), a lower-dose processed image which provides peripheral image context to the ROI.

The Siemens Artis zee's collimator, when used, also reduces radiation emission. However, that collimator reduces radiation emission by blocking the delivery of radiation to the area covered by the collimator. As a result, the Siemens Artis zee's image FOV is limited to the non-collimated region. The ControlRad® Filter can be used along with the Siemens Artis zee's collimator to further reduce radiation emissions, and the additional radiation reduction provided by the ControlRad® Filter will be outside the clinician-selected ROI and within the un-collimated region/image FOV.

The ControlRad® Select Model Z is a product that can be mounted only on the following configurations of the Artis zee: floor, ceiling, bi-plane, and zeego systems.

The clinician has the option not to use the CR Filter. In this case, the Siemens Artis zee operates as if the CR Filter was not present.

Substantial Equivalence:

The ControlRad® Select Model Z is a substantial equivalent to the legally marketed predicate listed below:

Predicate Device Name and Manufacturer	510(k) Number	Clearance Date	Comparable Properties
Primary Predicate	K202431	12/23/2020	• Indications for use • CR Trace Tablet • ControlRad® Trace Filter • ControlRad® Hardware • ControlRad® Software and Firmware Modules • ControlRad® Communication Interface • Dose Reduction Claim
ControlRad® Select Model Z ControlRad®			

7. Comparison of Technological Characteristics with the Predicate device:

The ControlRad® Select Model Z for use with Siemens Artis zee has the same Indications for Use Statement as the cleared predicate ControlRad® Select Model Z (K202431). The ControlRad® Select Model Z is identical in construction to the predicate with exception to the size of the ControlRad hardware to attach to the collimator that partners with Siemens Artis zee 30x40cm detector. The performance data demonstrates that the ControlRad® Select Model Z is at least as safe and effective as the predicate device and is substantially equivalent to the predicate device. A comparison table of technological characteristics of the ControlRad® Select Model Z device for use with Siemens Artis zee compared to those of the predicate is provided below:

Device / Feature	Subject Device ControlRad, Inc's ControlRad® Select Model Z (Large)	Primary Predicate Device ControlRad, Inc's ControlRad® Select Model Z (Small) (K202431)	Comparison Results
Indications for Use Statement	The ControlRad® Select Model Z with Siemens Artis zee is indicated to provide fluoroscopic imaging of the patient during diagnostic, surgical, and interventional procedures while reducing patients and clinicians' radiation exposure (Dose Area Product) outside of the ControlRad Select Model Z's region of interest (ROI) as compared to Artis zee non-collimated image area.[1] The ControlRad Select Model Z semi-transparent filter should not be used in lieu of the Artis zee's collimators, as they block the most radiation, but can help physicians balance dose reduction with the need to visualize structures outside the ROI when it is considered clinically advantageous to do so. Clinical applications may include cardiac angiography, neuro-angiography, general angiography, rotational angiography, multipurpose angiography and whole body radiographic/fluoroscopic procedures as well as procedures next to the table for i.e., patient extremities. Additional procedures that can be performed include angiography in the operating room, image guided surgery by X-ray, by image fusion, and by navigation systems. The examination table as an integrated part of the system can be used for X-ray imaging, surgery and interventions. [1] Relative to open Field of View (FOV), the ControlRad Select Model Z reduces at least 85% of the Dose Area Product at 65 kVp and ROI with width and length that are smaller than 1/5 the edge size of the full FOV.	The ControlRad® Select Model Z with Siemens Artis zee is indicated to provide fluoroscopic imaging of the patient during diagnostic, surgical, and interventional procedures while reducing patients and clinicians' radiation exposure (Dose Area Product) outside of the ControlRad Select Model Z's region of interest (ROI) as compared to Artis zee non-collimated image area.[1] The ControlRad Select Model Z semi-transparent filter should not be used in lieu of the Artis zee's collimators, as they block the most radiation, but can help physicians balance dose reduction with the need to visualize structures outside the ROI when it is considered clinically advantageous to do so. Clinical applications may include cardiac angiography, neuro-angiography, general angiography, rotational angiography, multipurpose angiography and whole body radiographic/fluoroscopic procedures as well as procedures next to the table for i.e., patient extremities. Additional procedures that can be performed include angiography in the operating room, image guided surgery by X-ray, by image fusion, and by navigation systems. The examination table as an integrated part of the system can be used for X-ray imaging, surgery and interventions. [1] Relative to open Field of View (FOV), the ControlRad Select Model Z reduces at least 85% of the Dose Area Product at 65 kVp and ROI with width and length that are smaller than 1/5 the edge size of the full FOV.	**Same:**
Technical Specification			
X-ray Radiation Source	The X-ray Tube of Siemens Medical Solutions, Inc. Artis zee	The X-ray Tube of Siemens Medical Solutions, Inc. Artis zee	**Same:** This is the exact same component cleared in the Referenced Device: Siemens' Artis zee (K181407). Provided in this Submission is System Validation testing Summaries.

Device / Feature	Subject Device ControlRad, Inc's ControlRad® Select Model Z (Large)	Primary Predicate Device ControlRad, Inc's ControlRad® Select Model Z (Small) (K202431)	Comparison Results
System Configuration	ControlRad Filter and Image Processing SW/HW mounted on Artis zee	ControlRad Filter and Image Processing SW/HW mounted on Artis zee	**Comparable:** This is the exact same components cleared in the Primary Predicate Device with exception to the size of the ControlRad hardware to attach to the collimator that partners with Siemens Artis zee 30x40cm detector. Provided in this submission is Bench Testing and System Validation Testing Summaries.
X-ray Modulation			
X-ray Modulation Component	CR Filter 2.5mm thru 3.0mm	CR Filter 2.5mm thru 3.0mm	**Same:** This is the exact same components cleared in the Primary Predicate Device. Provided in this submission is Bench Testing and System Validation Summaries.
X-ray Radiation Modulation	Semi-transparent filter; Reduces radiation outside the aperture typically by 44% to 98%.	Semi-transparent filter; Reduces radiation outside the aperture typically by 44% to 98%.	**Same:** This is the exact same components cleared in the Primary Predicate Device. Provided in this submission is Bench Testing and System Validation Summaries that demonstrates that the device is as safe and effective as the Primary Predicate Device and does not raise different questions of safety and effectiveness than the Predicate Device.
Aperture shape	Blades: Rectangular	Blades: Rectangular	**Same:** This is the exact same component cleared in the Primary Predicate Device. Provided in this submission is Bench Testing and System Validation Testing Summaries.
Aperture Control	Set by the user using the CR Tablet	Set by the user using the CR Tablet	**Same:** This is the exact same functionality cleared in the Primary Predicate Device. Provided in this submission is Bench Testing and System Validation Testing Summaries.
Image Processing			
Image Area Processed	Area outside ROI	Area outside ROI	**Same:** This is the exact same feature cleared in the Primary Predicate Device. Provided in this submission is Bench Testing and System Validation Testing Summaries.

Device / Feature	Subject Device ControlRad, Inc's ControlRad® Select Model Z (Large)	Primary Predicate Device ControlRad, Inc's ControlRad® Select Model Z (Small) (K202431)	Comparison Results
Processing Bits	16 bits	16 bits	**Same:** This is the exact same feature cleared in the Primary Predicate Device. Provided in this submission is Bench Testing and System Validation Summaries.
Processing Rate	30 fps	30 fps	**Same:** This is the exact same feature cleared in the Primary Predicate Device. Provided in this submission is Bench Testing and System Validation Testing. Summaries.
Processing Occurrence	Area outside ROI: Only when the CR Filter is engaged	Area outside ROI: Only when the CR Filter is engaged	**Same:** This is the exact same feature cleared in the Primary Predicate Device. Provided in this submission is Bench Testing and System Validation Testing Summaries.
Image Layout Information	All image layout information originally available for Siemens Artis zee plus the following: • Percentage of Dose Area Product (DAP) reduction when using ControlRad Filter and/or Siemens Arits zee Collimator • ROI frame border	All image layout information originally available for Siemens Artis zee plus the following: • Percentage of Dose Area Product (DAP) reduction when using ControlRad Filter and/or Siemens Arits zee Collimator • ROI frame border	**Same:** This is the exact same feature cleared in the Primary Predicate Device. Provided in this submission is Bench Testing and System Validation Testing Summaries.
Parameters Accuracy Specifications			
Dose Area Product (DAP) Accuracy for total x-ray field of the ControlRad Filter and Artis zee systems combined*	±35%*	±35%*	**Same:** This is the exact same feature cleared in the Primary Predicate Device. Provided in this submission is Bench Testing and System Validation Testing Summaries.
Electrical Requirements			

Device / Feature	Subject Device ControlRad, Inc's ControlRad® Select Model Z (Large)	Primary Predicate Device ControlRad, Inc's ControlRad® Select Model Z (Small) (K202431)	Comparison Results
Electrical Requirements	Artis zee Components: Power requirements Generator POLYDOROS A100 Plus: AC 400 V ± 10 %, 50/60 Hz ± 1 Hz Power requirements System control cabinet: AC 400 V ± 10 %, 50/60 Hz ± 1 Hz ControlRad Components: SCIP BOX Input: 230 VAC, 0.6A TABLET POWER SUPPLY Input: 24 VDC, 0.5A SELECT FILTER Input: 28 VDC, 0.9A ROUTER Input : 12DC, 1A ROUTER POWER SUPPLY Input : 230VAC, 0.5A	Artis zee Components: Power requirements Generator POLYDOROS A100 Plus: AC 400 V ± 10 %, 50/60 Hz ± 1 Hz Power requirements System control cabinet: AC 400 V ± 10 %, 50/60 Hz ± 1 Hz ControlRad Components: SCIP BOX Input: 230 VAC, 0.6A TABLET POWER SUPPLY Input: 24 VDC, 0.5A SELECT FILTER Input: 28 VDC, 0.9A ROUTER Input : 12DC, 1A ROUTER POWER SUPPLY Input : 230VAC, 0.5A	**Same:** This is the exact same feature cleared in the Primary Predicate Device. Provided in this submission is Bench Testing and System Validation Testing Summaries.

8. Performance Data:

ControlRad® conducted the following performance tests to demonstrate that the ControlRad® Select Model Z for use with Siemens Artis zee complies with performance standards, functions as intended and is at least as safe and effective as the Primary Predicate Device:

- V3.0.5 Software Verification: Verification of the v3.0.5 software.
- Impact of Air Kerma: Verification that the ControlRad® components on the reference system do not significantly increase Air Kerma (ControlRad® components integrated with the Artis zee system) when compared to the Artis zee system alone.
- Impact of Cover on Air Kerma: Verification that the X-ray radiation for a Siemens Artis zee system with 30cm x 40cm detector and associated collimator (Artis zee Large) with installed CRS Z LD is not affected by the ControlRad® cover with and without addition of the Aluminum versus Siemens cover with and without the Aluminum added to the cover.
- Air Kerma and Air Kerma Rate Accuracy: Verification that the AK and AKR of the subject system (ControlRad® components integrated with the Artis zee system) is ±35% of the Artis zee system alone per 21 CFR 1020.32.
- Radiation Dose Structure Report (RDSR) AK Accuracy: Verification that the cumulative AKR as referenced in the RDSR of the subject system (ControlRad® components integrated with the Artis zee system) is ± 35% of the Artis zee system alone.
- Reference Air Kerma Warning Functionality: Verification that the Reference Air Kerma Warning Functionality is not impacted on the subject system (ControlRad® components integrated with the Artis zee system) when compared to the Artis zee system alone.
- Dose Area Product (DAP) Accuracy: Demonstrate the DAP measurements of the subject system (ControlRad® components integrated with the Artis zee system) is ±35% of the Artis zee system per IEC 60601-2-43.
- Dose Area Product (DAP) Reduction: To verify the subject system (ControlRad® components

integrated with the Artis zee system) is able to reduce DAP as noted in the indications for use (Relative to open Field of View (FOV), the ControlRad® Select Model Z reduces at least 85% of the Dose Area Product at 65 kVp and ROI with width and length that are smaller than 1/5 the size of the full FOV).

- Accuracy of Procedure Dose Indicators: Verification that the accuracy of procedure dose indicators reported at the end of a procedure by the ControlRad® Select Model Z Large Detector (CRS Z LD) when installed on a Siemens Artis zee system with 30cm x 40cm detector and associated collimator do not exceed ±35% for any of the dose indicators.
- ControlRad® Filter Attenuation: Verification of the claim that ControlRad® Select Model Z when installed in Artis zee C-arm contributes to reduction of Dose Area Product (DAP).
- Leakage Radiation Evaluation: To evaluate the impact of the ControlRad® components on the reference device leakage radiation measurements.
- Stray Radiation Evaluation: To evaluate the impact of the ControlRad® components on the reference device stray radiation measurements.
- Recovery Management: To verify recovery management of ControlRad Select Model Z as required by IEC 60601-2-43, section 201.4.101
- Mechanical Impact on Filter Cover: To verify that impact to the filter / collimator cover does not create unacceptable risk per IEC 60601-1 requirements.
- Anti-Collision Detection: Verification of the collision detection function of the Siemens Artis zee with ControlRad® Select Model Z filter / collimator cover installed.
- Focal Spot to Patient Distance: Verification that the focal spot to skin distance implementation per IEC 60601-2-54, section 203.9 requirements.
- Tensile Strength Evaluation: Verification that additional mass from the Select Model Z filter does not create unacceptable risk from tensile strength per IEC 60601-1 requirements.
- Filter Motion Assembly Reliability: Verification of filer motion reliability over the expected service life of the filter assembly.
- Comparative image quality inside the ROI: Verification that image quality inside the ROI is at least the same quality as the image that would be gathered with the Artis zee alone.
- Comparative image quality outside the ROI: Characterization testing to quantify the level of image quality degradation outside the region of interest as a result of the CR filter blades
- Image quality evaluation via clinical simulations: Validation that the image quality outside the ROI is clinically relevant following degradation due to use of the ControlRad filters.
- DAP Chamber Change Justification: Justification of the change in DAP chamber from the original chamber used in the Artis zee system as a result of the addition of the CR filter.
- Wireless Devices and Cybersecurity Evaluation: To evaluate the ControlRad® Select Model Z's compliance with the requirements of FDA Guidance documents: “Radio Frequency Wireless Technology in Medical Devices” and “Postmarket Management of Cyber Security in Medical Devices”.
- Cybersecurity Controls & Justification for Control of Risk. Verification of cybersecurity risk controls.

Verification and Validation:

Software Documentation for a Moderate Level of Concern software per FDA’s Guidance Document “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” issued on May 11, 2005 and “Off-The-Shelf Software Use in Medical Devices” is also included as part of this submission. The performance data demonstrates continued conformance with special controls for medical devices containing software. Non-clinical tests were conducted on ControlRad® Select Model Z during product development.

Risk analysis was completed, and risk control was implemented to mitigate identified hazards. The testing results support that all the software specifications have met the acceptance criteria. Testing for verification and validation for the device was found acceptable to support the claims of substantial equivalence.

ControlRad® Select Model Z was tested and found to be safe and effective for intended users, uses and use environments through the design control verification and validation process. Usability testing per IEC 60601-1-6 showed that usability related hazards are addressed in the system test according to the operator's manual and in simulated clinical use tests with customer report and feedback form. Customer employees are adequately trained in the use of this equipment.

ControlRad® conforms to the cybersecurity requirements by implementing a process for the prevention of unauthorized access, modifications, misuse or denial of use, or the unauthorized use of information that is stored, accessed or transferred from a medical device to an external recipient. Provided in the Software Section is the required cybersecurity information.

Summary:
Performance tests were conducted to test the functionality of ControlRad® Select Model Z System. These tests have been performed to assess the functionality of the Subject Device. Results of all conducted testing was found acceptable and does not raise any new issues of safety or effectiveness.

9. Performance Standards:

The ControlRad® Select Model Z complies with the following performance standards:

- ISO 14971 Medical devices - Application of risk management to medical devices
- IEC 60601-1 - Medical Electrical Equipment Part 1: General requirements for safety
- IEC 60601-1-2 Medical Electrical Equipment – Part 2. Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-1-3 Medical Electrical Equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
- IEC 60601-1-6 Medical Electrical Equipment - Part 1-6: General Requirementsfor Basic Safety and Essential Performance - Collateral Standard: Usability
- IEC 62304 Medical device software – Software life cycle processes
- IEC 60825-1 Safety of laser products – Part1: Equipment classification and requirements [Including: Technical Corrigendum 1 (2008), interpretation Sheet 1 (2007), Interpretation Sheet 2 (2007)]
- IEC 60601-2-28 Medical electrical equipment – Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
- IEC 60601-2-43 Medical electrical equipment – Part 2-43: Particular requirements for the safety and essential performance of X-ray equipment for interventional procedures.

- IEC 60601-2-54 Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipmentfor radiography and radioscopy
- FDA 21 CFR 1020.30-32 Federal Performance Standard for Diagnostic X-ray Systems

10. Conclusion as to Substantial Equivalence:

The ControlRad® Select Model Z is installed on the Siemens Artis zee (K181407). The ControlRad® Select Model Z is technologically identical to ControlRad® Select Model Z, cleared in K202431. The comparison of technological characteristics, non-clinical performance data and software validation data demonstrates that the Subject Device does not raise any new questions regarding safety or effectiveness when compared to the Predicate Device that is currently marketed for the same intended use.