ControlRad, Inc.
% Linda Braddon, Ph.D.
CEO
Secure BioMed Evaluations
7828 Hickory Flat Highway, Suite 120
WOODSTOCK GA 30188

July 1, 2021

Re: K211782
Trade/Device Name: ControlRad® Select Model Z, ControlRad® Trace Model 9, ControlRad® Trace Model 8
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, JAA, IZI
Dated: June 7, 2021
Received: June 9, 2021

Dear Dr. Braddon:

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)*
K211782

Device Name
ControlRad® Select Model Z

Indications for Use *(Describe)*
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.

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.

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)*
K211782

Device Name
ControlRad® Trace Model 9

Indications for Use *(Describe)*

The ControlRad® Trace Model 9, when used with OEC® 9900 Elite, is indicated to provide fluoroscopic and spot-film imaging of the patient during diagnostic, surgical, and interventional procedures while reducing patients and clinicians' radiation exposure (Dose Area Product) outside of the ControlRad® Trace's region of interest (ROI) as compared to OEC® 9900 Elite non-collimated image area.[1] The ControlRad® Trace semi-transparent filter should not be used in lieu of the OEC® 9900 Elite'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 cholangiography, endoscopic, urologic, orthopedic, neurologic, vascular, cardiac, critical care and emergency room procedures.

[1] Relative to open Field of View (FOV), the ControlRad® Trace Model 9 reduces at least 50% of the Dose Area Product at 50 kVp and ROI with width and length that are smaller than 1/3 the diameter 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.

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)*
K211782

Device Name
ControlRad® Trace Model 8

Indications for Use *(Describe)*

The ControlRad® Trace Model 8, when used with OEC® 9800/OEC® 9800 Plus, is indicated to provide fluoroscopic and spot-film imaging of the patient during diagnostic, surgical, and interventional procedures while reducing patients and clinicians' radiation exposure (Dose Area Product) outside of the ControlRad Trace's region of interest (ROI) as compared to the OEC® 9800/OEC® 9800 Plus non-collimated image area.[1] The ControlRad Trace semi-transparent filter should not be used in lieu of the OEC® 9800/OEC® 9800 Plus' 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 cholangiography, endoscopic, urologic, orthopedic, neurologic, vascular, cardiac, critical care and emergency room procedures.

[1] Relative to open Field of View (FOV), the ControlRad® Trace Model 8 reduces at least 50% of the Dose Area Product at50 kVp and ROI with width and length that are smaller than 1/3 the diameter 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.

510(k) SUMMARY: ControlRad® Select Model Z
ControlRad® Trace Model 9
ControlRad® Trace Model 8

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

Date Prepared: June 29, 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 Affairs
   Secure BioMed Evaluations
   7828 Hickory Flat Highway, Suite 120
   Woodstock, GA 30188
   770-837-2681 (direct)
   Regulatory@SecureBME.com

   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
   ControlRad® Trace Model 9
   ControlRad® Trace Model 8
   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 Devices for ControlRad® Select Model Z; ControlRad® Trace Model 9 and ControlRad® Trace Model 8:

Information	Primary Predicate	Primary Predicate	Primary Predicate
Trade Name	ControlRad® Select Model Z	ControlRad® Trace Model 9	ControlRad® Trace Model 8
510(k) Clearance	K202431	K200663	K183109
Clearance Date	December 23, 2020	June 24, 2020	May 13, 2019
Classification Name	Image-Intensified Fluoroscopic X-ray System	Image-Intensified Fluoroscopic X-ray System	Image-Intensified Fluoroscopic X-ray System
Common Name	Interventional Fluoroscopic X-ray System	Interventional Fluoroscopic X-ray System	Interventional Fluoroscopic X-ray System
Classification Panel	Radiology	Radiology	Radiology
Regulation Number	21 CFR §892.1650	21 CFR §892.1650	21 CFR §892.1650
Device Class	II	II	II
Product Codes	**Primary:** OWB **Secondary:** JAA, IZI	**Primary:** OWB **Secondary:** OXO, JAA	**Primary:** OWB **Secondary:** OXO, JAA
	The ControlRad® Select Model Z is installed on the system below:	**The ControlRad® Trace Model 9 is installed on the system below:**	**The ControlRad® Trace Model 8is installed on the system below:**
Trade Name	Artis zee	GE Healthcare Surgery, OEC ® 9900 Elite	GE Healthcare Surgery, OEC® 9800 Plus
510(k) Clearance	K181407	K122234	K132027
Clearance Date	August 15, 2018	August 16, 2012	December 5, 2012
Classification Name	Image-intensified fluoroscopic X-ray System	Image-intensified fluoroscopic X-ray System	Image-intensified fluoroscopic X-ray System
Common Name	Interventional Fluoroscopic X-Ray System	Interventional Fluoroscopic X-Ray	Interventional Fluoroscopic X-Ray System
Classification Panel	Radiology	Radiology	Radiology
Regulation Number	892.1650	892.1650	892.1650
Device Class	II	II	II
Product Codes	**Primary:** OWB **Secondary:** IZI, JAA, JAK	**Primary:** OWB **Secondary**: OXO, JAA	**Primary:** OWB **Secondary:** LLZ

5. Indications for Use Statements

Indications for Use Statement for ControlRad® Select Model Z
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.

Indications for Use Statement for ControlRad® Trace Model 9

The ControlRad® Trace Model 9, when used with OEC® 9900 Elite, is indicated to provide fluoroscopic and spot-film imaging of the patient during diagnostic, surgical, and interventional procedures while reducing patients and clinicians' radiation exposure (Dose Area Product) outside of the ControlRad® Trace's region of interest (ROI) as compared to OEC® 9900 Elite non-collimated image area.[1] The ControlRad® Trace semi-transparent filter should not be used in lieu of the OEC® 9900 Elite'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 cholangiography, endoscopic, urologic, orthopedic, neurologic, vascular, cardiac, critical care and emergency room procedures.

[1] Relative to open Field of View (FOV), the ControlRad® Trace Model 9 reduces at least 50% of the Dose Area Product at 50 kVp and ROI with width and length that are smaller than 1/3 the diameter of the full FOV.

Indications for Use Statement for ControlRad® Trace Model 8

The ControlRad® Trace Model 8, when used with OEC® 9800/OEC® 9800 Plus, is indicated to provide fluoroscopic and spot-film imaging of the patient during diagnostic, surgical, and interventional procedures while reducing patients andclinicians' radiation exposure (Dose Area Product) outside of the ControlRad Trace's region of interest (ROI) as comparedto the OEC® 9800/OEC® 9800 Plus non-collimated image area.[1] The ControlRad Trace semi-transparent filter should notbe used in lieu of the OEC® 9800/OEC® 9800 Plus' 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 cholangiography, endoscopic, urologic, orthopedic, neurologic, vascular, cardiac, critical care and emergency room procedures.

[1] Relative to open Field of View (FOV), the ControlRad Trace Model 8 reduces at least 50% of the Dose Area Product at50 kVp and ROI with width and length that are smaller than 1/3 the diameter of the full FOV.

6. Device Descriptions for ControlRad® Select Model Z; ControlRad® Trace Model 9, and ControlRad® Trace Model 8 are provided below:

ControlRad® Select Model Z 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. ControlRad® hereby submits this Bundled Special 510(k) "Catch-Up" to request clearance to market the ControlRad® Select Model Z with SW version v3.0.1 and a dose reduction claim: 85% of the Dose Area Product (DAP) at 65 kVp with width and length that are smaller than 1/5 the edge size of the full Field Of View (FOV).

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 20x20 detector and associated collimator. Use of this system on other sizes is prohibited.

ControlRad® Select Model Z Device Description

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 3mm, 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) the 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 semi-transparent titanium filters to deliver the designed 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.

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.

ControlRad® Select Model Z Device Description

- 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), alower-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 radiationto 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 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.

Reason for Submission:
This Bundled Special 510(K) submission provides FDA with "Catch Up" 510(k) information for minor changes made and implemented on the following cleared 510(k) product: ControlRad® Select Model Z (K202431). These changes were evaluated and documented via the process identified in FDA's guidance document "Deciding When to Submit a 510(k) for a Change to an Existing Device", October 25, 2017.

ControlRad® Trace Model 9 Device Description

The ControlRad® Trace Model 9 consists of the following main components: ControlRad Trace Tablet, ControlRad Trace Filter, ControlRad Hardware, ControlRad Software and Firmware Modules and ControlRad Communication Interface all installed on the OEC 9900 Elite. The ControlRad® Trace Model 9 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 Trace's region of interest (ROI) as compared to the OEC 9900 Elite non-collimated image area.

ControlRad® Trace Model 9 Device Description

The ControlRad® Trace Model 9 can help physicians balance dose reduction with the need to visualize structures outside the ROI when it is considered clinically advantageous to do so.

Technological Characteristics:
The ControlRad® Trace Model 9 consists of the following main components: ControlRad® Trace Tablet ControlRad® Trace Filter, ControlRad® Hardware, ControlRad® Software and Firmware Modules and ControlRad® Communication Interface all installed on the OEC 9900 Elite.
The ControlRad® Trace Model 9 components are installed semi-permanently in the cleared GE Healthcare Surgery's OEC® 9900 Elite (K122234) and operate in parallel to the GE Healthcare Surgery's OEC® 9900 Elite. The removal of the ControlRad® components will restore the device to OEM specifications.

The ControlRad® Trace Model 9 components provide the following functionalities:

- The CR Trace Tablet provides the user operational control of the ControlRad® Trace Model 9 device via a Graphical User Interface ("GUI"). The CR Trace Tablet enables the clinician to select a Region of Interest ("ROI") on the image displayed on the CR Trace Tablet, which is the same image that is displayed on the GE Healthcare Surgery's OEC® 9900 Elite's live monitor.

- The CR Trace Filter is installed on top of the GE Healthcare Surgery's OEC® 9900 Elite's collimator. The CR Trace Filter does not affect or modify the functionality of the collimator. The CR Trace Filter is a semi-transparent filter which reduces the X-ray radiation outside the clinician-selected ROI, typically by 61% to 97%. The actual dose reduction achieved will depend upon specific imaging parameters such as OEC collimator settings, the kVp and the percentage of the OEC non-collimated image covered by the ControlRad® Trace Filter.

- The ControlRad® Hardware, Software and Firmware Modules control the ControlRad® Trace Filter's 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® Trace Model 9 and between the ControlRad® Trace Model 9 and the GE Healthcare Surgery's OEC® 9900 Elite.

Principles of Operation:
The GE Healthcare Surgery's OEC® 9900 Elite provides an image whose boundaries are defined by the OEC® 9900 Elite's collimator, i.e., the image FOV is defined by the OEC non-collimated region. The image FOV size is not affected or modified by the ControlRad® Trace Model 9.

Within the OEC® 9900 Elite non-collimated image region, when using a clinician selected Region of Interest ("ROI") on the ControlRad® Trace Tablet, the ControlRad® Trace 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 GE Healthcare Surgery's OEC® 9900 Elite (K122234); and

- 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 GE Healthcare Surgery's OEC® 9900 Elite'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 GE Healthcare Surgery's OEC® 9900 Elite's image FOV is limited to the

ControlRad® Trace Model 9 Device Description

non-collimated region. The ControlRad® Trace Filter can be used along with the GE Healthcare Surgery's OEC® 9900 Elite's collimator to further reduce radiation emissions, and the additional radiation reduction provided by the ControlRad® Trace Filter will be outside the clinician-selected ROI and within the un-collimated region/image FOV.

The clinician has the option not to use the CR Trace Filter. In this case, the GE Healthcare Surgery's OEC® 9900 Elite operates as if the CR Trace Filter was not present.

Reason for Submission:
This Bundled Special 510(K) submission provides FDA with "Catch Up" 510(k) information for minor changes made and implemented on the following cleared 510(k) product: ControlRad® Trace Model 9 (K200663). These changes were evaluated and documented via the process identified in FDA's guidance document "Deciding When to Submit a 510(k) for a Change to an Existing Device", October 25, 2017.

ControlRad® Trace Model 8 Device Description

The ControlRad® Trace Model 8 is an accessory to the cleared OEC 9800/OEC 9800 Plus system. The ControlRad® Trace Model 8 accessory installed in the OEC 9800/OEC 9800 Plus is a system used to assist trained clinicians. The system 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® Trace's region of interest (ROI) as compared to the OEC 9800/OEC 9800 Plus non-collimated image area. The ControlRad® Trace Model 8 can help physicians balance dose reduction with the need to visualize structures outside the ROI when it is considered clinically advantageous to do so.

Technological Characteristics:
The ControlRad® Trace Model 8 consists of the following main components: ControlRad ("CR") Trace Tablet, CR Trace Filter, CR Hardware, CR Software and Firmware Modules and CR Communication Interface.

The ControlRad® Trace Model 8 components are installed semi-permanently on the cleared GE Healthcare Surgery's OEC® 9800 Plus (K132027) and operate in parallel to the GE Healthcare Surgery's OEC® 9800 Plus. The ControlRad® Trace Model 8 components provide the following functionalities:

- The CR Trace Tablet provides the user operational control of the ControlRad® Trace Model 8 device via a Graphical User Interface ("GUI"). The CR Trace Tablet enables the clinician to select a Region of Interest ("ROI") on the image displayed on the CR Trace Tablet, which is the same image that is displayed on the GE Healthcare Surgery's OEC® 9800 Plus's live monitor.

- The CR Trace Filter is installed on top of the GE Healthcare Surgery's OEC® 9800 Plus's collimator. The CR Trace Filter does not affect or modify the functionality of the collimator. The CR Trace Filter is a semi-transparent filter which reduces the X-ray radiation outside the clinician-selected ROI, typically by 60% to 90%.

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

- The CR Communication Interface provides communication between the various components of the ControlRad® Trace Model 8 and between the ControlRad® Trace Model 8 and the GE Healthcare Surgery's OEC® 9800 Plus.

ControlRad® Trace Model 8 Device Description

Principles of Operation:
The GE Healthcare Surgery's OEC® 9800 Plus (K132027) provides an image that its boundaries are defined by the GE Healthcare Surgery's OEC® 9800 Plus's collimator, i.e., the image FOV is defined by the un-collimated region of the GE Healthcare Surgery's OEC® 9800 Plus (K132027). The image FOV size is not affected or modified by the ControlRad® Trace Model 8.

Within the image field/un-collimated region of the GE Healthcare Surgery's OEC® 9800 Plus (K132027), the ControlRad® Trace Model 8 allows the clinician to select a Region of Interest ("ROI") and it reduces radiation exposure outside the clinician-selected ROI using the CR Trace Filter, resulting with an image that consists of the following 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 GE Healthcare Surgery's OEC® 9800 Plus (K132027); and
- The image outside the clinician-selected ROI (filtered radiation area in the FOV), a low-dose processed image which provides peripheral image context to the ROI.

The GE Healthcare Surgery's OEC® 9800 Plus'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 GE Healthcare Surgery's OEC® 9800 Plus's image FOV is limited to the un-collimated region. The CR Trace Filter can be used along with the GE Healthcare Surgery's OEC® 9800 Plus's collimator to further reduce radiation emissions, and the additional radiation reduction provided by the CR Trace Filter will be outside the clinician-selected ROI and within the un-collimated region/image FOV.

The clinician has the option not to use the CR Trace Filter. In this case, the GE Healthcare Surgery's OEC® 9800 Plus operates as if the CR Trace Filter was not present.

Reason for Submission:
This Bundled Special 510(K) submission provides FDA with "Catch Up" 510(k) information for minor changes made and implemented on the following cleared 510(k) product: ControlRad® Trace Model 8 (K183109). These changes were evaluated and documented via the process identified in FDA's guidance document "Deciding When to Submit a 510(k) for a Change to an Existing Device", October 25, 2017.

7. 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 ControlRad® Select Model Z ControlRad®	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 • Installed on Siemens Artis zee (K181407)

The **ControlRad® Trace Model 9** is substantial equivalent to the legally marketed predicate listed below:

Predicate Device Name and Manufacturer	510(k) Number	Clearance Date	Comparable Properties
Primary Predicate	K200663	06/24/2020	• Indications for use • CR Trace Tablet • ControlRad Trace Filter • ControlRad Hardware • ControlRad Software and Firmware Modules • ControlRad Communication Interface • Dose Reduction Claim • Installed on GE Healthcare Surgery, OEC ® 9900 Elite (K122234)
ControlRad® Trace Model 9 ControlRad®			

The **ControlRad® Trace Model 8** is substantial equivalent to the legally marketed predicate listed below:

Predicate Device Name and Manufacturer	510(k) Number	Clearance Date	Comparable Properties
Primary Predicate	K183109	05/13/2019	• Indications for use • CR Trace Tablet • ControlRad Trace Filter • ControlRad Hardware • ControlRad Software and Firmware Modules • ControlRad Communication Interface • Dose Reduction Claim • Installed on GE Healthcare Surgery, OEC® 9800 Plus (K132027)
ControlRad® Trace Model 8 ControlRad®			

8. 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 as the cleared predicate ControlRad® Select Model Z (K202431). The ControlRad® Select Model Z is identical in construction to the predicate. 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:

Comparison Table: ControlRad® SelectModel Z			
Device Feature	**Subject Device ControlRad® Select Model Z (K211782)**	**Primary Predicate Device ControlRad® SelectModel Z (K202431)**	**Comparison Results**
Regulation Number	21 CFR §892.1650	21 CFR §892.1650	**Same**
Indications for use Statement	The ControlRad® Select Model Z with Siemens Artis zee is indicated to provide fluoroscopic 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	The ControlRad® Select Model Z with Siemens Artis zee is indicated to provide fluoroscopic 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	**Same**

	width and length that are smaller than 1/5 the edge size of the full FOV.	and length that are smaller than 1/5 the edge size of the full FOV.	
X-ray Radiation Source	The X-ray Tube of SiemensMedical Solutions, Inc. Artis zee	The X-ray Tube of SiemensMedical Solutions, Inc. Artis zee	**Same**
System Configuration	ControlRad Filter and Image Processing SW/HW mountedon Artis zee	ControlRad Filter and Image Processing SW/HW mounted on Artis zee	**Same**
X-ray Modulation Component	CR Filter 2.5mm or 3.0mm	CR Filter 2.5mm or 3.0mm	**Same**
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**
Aperture shape	Blades: Rectangular	Blades: Rectangular	**Same**
Aperture Control	Set by the user using the CRTablet	Set by the user using the CRTablet	**Same**
Image Area Processed	Area outside ROI	Area outside ROI	**Same**
Processing Bits	16 bits	16 bits	**Same**
Processing Rate	30 fps	30 fps	**Same**
Processing Occurrence	Area outside ROI: Only when the CR Filter is engaged	Area outside ROI: Only when the CR Filter is engaged	**Same**
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 Artis zee Collimator • ROI frame border • ControlRad Logo andBranding	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 Artiszee Collimator • ROI frame border • ControlRad Logo andBranding	**Same**
Dose Area Product (DAP) Accuracy for total x-ray field of the ControlRad Filter & Artis zee systems combined*	±35%*	±35%*	**Same**
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**

The **ControlRad® Trace Model 9** for use with GE Healthcare Surgery's OEC® 9900 Elite has the same intended use and the same indications for use as the cleared predicate. The ControlRad® Trace Model 9 is identical in construction to the primary predicate which works with OEC® 9900 Elite. The performance data demonstrates that the ControlRad® Trace Model 9 is at least as safe and effective as the predicate device and is substantially equivalent to that predicate device. A comparison table of technological characteristics of the ControlRad® Trace Model 9 device for use with OEC® 9900 Elite comparison information is provided below:

Comparison Table: ControlRad® Trace Model 9			
Device Feature	**Subject Device ControlRad® TraceModel (K211782)**	**Primary Predicate Device ControlRad® Trace Model 9 (K200663)**	**Comparison Results**
Device Class	Class II	Class II	**Same**
Product Codes	Primary: OWB Secondary: OXO, JAA	Primary: OWB Secondary: OXO, JAA	**Same**
Regulation Number	21 CFR §892.1650	21 CFR §892.1650	**Same**
Indications for use	The ControlRad® Trace Model9, when used with OEC® 9900 Elite, is indicated to provide fluoroscopic and spot-film imaging of the patient during diagnostic, surgical, and interventional procedures whilereducing patients and clinicians'radiation exposure (Dose Area Product) outside of the ControlRad Trace's region of interest (ROI) as compared to OEC® 9900 Elite non- collimated image area.[1] The ControlRad Trace semi- transparent filter should not be used in lieu of the OEC® 9900 Elite'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 cholangiography, endoscopic, urologic, orthopedic, neurologic, vascular, cardiac, critical care and emergency room procedures. [1]Relative to open Field of View (FOV), the ControlRad Trace Model 9 reduces at least 50% of the Dose Area Product at 50 kVp and ROI with width and length that are smaller than 1/3 the diameter of the full FOV.	The ControlRad® Trace Model9, when used with OEC® 9900 Elite, is indicated to provide fluoroscopic and spot-film imaging of the patient during diagnostic, surgical, and interventional procedures while reducing patients and clinicians' radiation exposure (Dose Area Product) outside of the ControlRad Trace's region of interest (ROI) as compared to OEC® 9900 Elite non-collimated image area.[1] The ControlRad Trace semi-transparent filter should not be used in lieu of the OEC® 9900 Elite'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 cholangiography, endoscopic, urologic, orthopedic, neurologic, vascular, cardiac, critical care and emergency room procedures. [1]Relative to open Field of View (FOV), the ControlRad Trace Model 9 reduces at least 50% of the Dose Area Product at 50 kVp and ROI with width and length that are smaller than 1/3 the diameter of the full FOV.	**Same**
X-ray Modulation Component	CR Trace Filter	CR Trace Filter	**Same**
X-Ray Radiation Modulation	Reduces X-ray radiation outside the aperture/ROI typically by 61% to 97%	Reduces X-ray radiation outside the aperture/ROI typically by 61% to 97%	**Same**

Aperture Shape	Rectangular	Rectangular	**Same**
Aperture Control	Set by the user using the CR Trace Tablet	Set by the user using the CR Trace Tablet	**Same**
Image Area Processed	Image area outside the ROI	Image area outside the ROI	**Same**
Processing Bits	12 bits	12 bits	**Same**
Processing Rate	30 fps	30 fps	**Same**
Processing Occurrence	Only when the CR Trace Filter is engaged	Only when the CR Trace Filter is engaged	**Same**
Image Layout Information	Dose Area Product (DAP) value and/or percentage of DAP reduction when using ControlRad Trace Filterand/or OEC Collimators ROI frame border	Dose Area Product (DAP) value and/or percentage of DAP reduction when using ControlRad Trace Filterand/or OEC Collimators ROI frame border	**Same**
Dose Area Product (DAP) Accuracy for total x-ray field of the ControlRad Trace Filter and OEC systems combined*	*Overall: ±35% For DAP reported byControlRad® Trace Model 9	*Overall: ±35% For DAP reported byControlRad® Trace Model 9	**Same**
Electrical Requirements	60 / 50 Hz; 120 VAC (±10%), 15A 200/220/230/240VAC (±10%), 10A	60 / 50 Hz; 120 VAC (±10%), 15A 200/220/230/240VAC (±10%), 10A	**Same**

The **ControlRad® Trace Model 8** for use with GE Healthcare Surgery's OEC® 9800 Plus (K132027) has the same indications for use as the cleared predicate ControlRad® Trace Model 8 (K183109). The ControlRad® Trace Model 8 is identical in construction to the predicate. The performance data demonstrates that the ControlRad® Trace Model 8 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® Trace Model 8 device for use with GE Healthcare Surgery's OEC® 9800 Plus (K132027) comparison information is provided below:

Comparison Table: ControlRad® Trace Model 8			
Device Feature	**Subject Device ControlRad® Trace Model 8 (K211782)**	**Primary Predicate Device ControlRad® Trace Model 8 (K183109)**	**Comparison Results**
Device Class	Class II	Class II	**Same**
Product Codes	Primary: OWB Secondary: OXO, JAA	Primary: OWB Secondary: OXO, JAA	**Same**
Regulation Number	21 CFR §892.1650	21 CFR §892.1650	**Same**
Indications for use	The ControlRad® Trace Model 8, when used with OEC 9800/OEC 9800 Plus, is indicated to provide fluoroscopic and spot-film imaging of the patient during diagnostic, surgical, and interventional procedures while reducing patients and clinicians' radiation exposure (Dose Area Product) outside of the ControlRad Trace's region of interest (ROI) as compared to the OEC 9800/OEC 9800 Plus non-collimated image area. [1]The ControlRad Trace semi-transparent filter should not be used in lieu of the OEC 9800/OEC 9800 Plus' 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 cholangiography, endoscopic, urologic, orthopedic, neurologic, vascular, cardiac, critical care and emergency room procedures. [1]Relative to open Field of View (FOV), the ControlRad Trace Model 8 reduces at least 50% of the Dose Area Product at 50 kVp and ROI with width and length that are smaller than 1/3 the diameter of the full FOV.	The ControlRad® Trace Model 8, when used with OEC 9800/OEC 9800 Plus, is indicated to provide fluoroscopic and spot-film imaging of the patient during diagnostic, surgical, and interventional procedures while reducing patients and clinicians' radiation exposure (Dose Area Product) outside of the ControlRad Trace's region of interest (ROI) as compared to the OEC 9800/OEC 9800 Plus non-collimated image area. [1]The ControlRad Trace semi-transparent filter should not be used in lieu of the OEC 9800/OEC 9800 Plus' 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 cholangiography, endoscopic, urologic, orthopedic, neurologic, vascular, cardiac, critical care and emergency room procedures. [1]Relative to open Field of View (FOV), the ControlRad Trace Model 8 reduces at least 50% of the Dose Area Product at 50 kVp and ROI with width and length that are smaller than 1/3 the diameter of the full FOV.	**Same**

Comparison Table: ControlRad® Trace Model 8			
Device Feature	**Subject Device ControlRad® Trace Model 8 (K211782)**	**Primary Predicate Device ControlRad® Trace Model 8 (K183109)**	**Comparison Results**
X-ray Modulation Component	CR Trace Filter	CR Trace Filter	**Same**
X-ray Radiation Modulation	Reduces X-ray radiation outside the aperture/ROI typically by 60% to 90%	Reduces X-ray radiation outside the aperture/ROI typically by 60% to 90%	**Same**
Aperture shape	Rectangular	Rectangular	**Same**
Aperture Control	Set by the user using the CR Trace Tablet	Set by the user using the CR Trace Tablet	**Same**
Image Area Processed	Image area outside the ROI	Image area outside the ROI	**Same**
Processing Bits	Same	Same	**Same**
Processing Rate	Same	Same	**Same**
Processing Occurrence	Only when the CR Trace Filter is engaged	Only when the CR Trace Filter is engaged	**Same**
Image Layout Information	Estimated DAP, Estimated percentage of DAP reduction when using CR Trace Filter, ROI frame border;	Estimated DAP, Estimated percentage of DAP reduction when using CR Trace Filter, ROI frame border;	**Same**
Dose Area Product (DAP) Accuracy	Overall: ±35% For DAP reported by ControlRad® Trace Model 8	Overall: ±35% For DAP reported by ControlRad® Trace Model 8	**Same**
Electrical Requirements	Same	Same	**Same**

9. 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 predicate Siemens Artis zee.

ControlRad® Select Model Z Performance Data:

- 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.
- 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 systemalone.
- 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).
- Filter Attenuation Testing: Demonstrate the x-ray radiation attenuation by the addition of the ControlRad® components on the reference system show a 44 to 98%attenuation outside the ROI.
- 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.
- Collision Sensor Functionality Evaluation: To verify that the collision sensor functionality is maintained when using the ControlRad® filter / collimator covers.
- Focal spot to patient distance: To verify the focal spot to skin distance implementation per IEC 60601-2-54, section 203.9 requirements.
- Tensile Strength Evaluation: To verify that additional mass from the Select Model Z filter does not create unacceptable risk from tensile strength per IEC 60601-1 requirements.
- Filter Motion Reliability Testing: To verify the durability of the mechanical filter assembly in frame of a random motion stress test.
- Comparative image quality inside the ROI: Verifies 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: 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: To validate that the image quality outside the ROI in clinically relevant following degradation

due to use of the ControlRad filters.

- DAP Chamber Change Justification: To justify 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
- Touch-In-Glove Bench Test: To verify the sensitivity of the ControlRad® tablet when using sterile radiation reducing gloves.
- 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".

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.

The 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 of preventing 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 do not raise any new issues of safety or effectiveness.

ControlRad® Trace Model 9 Performance Data:

ControlRad® conducted the following performance tests to demonstrate that the ControlRad® Trace Model 9 for use with GE Healthcare Surgery's OEC® 9900 Elite complies with performance standards, functions as intended and is at least as safe and effective as the predicate GE Healthcare Surgery's OEC® 9900 Elite:

- Impact on Air Kerma Test was performed in order to evaluate the impact of the ControlRad® Trace Model 9 on Air Kerma (AKR) measurements of GE Healthcare Surgery's OEC 9900 Elite.
- Dose-Area-Product (DAP) calculation accuracy test was performed to demonstrate that DAP calculations of the ControlRad® Trace Model 9 when installed in GE Healthcare Surgery's OEC 9900 Elite system are within ±35% of measured DAP values.
- DAP Reduction Accuracy Test was performed to demonstrate the ControlRad® Trace Model 9 when installed on the OEC 9900 Elite reduces at least 50% of the DAP at 50kVp and ROI with width and length are smaller than 1/3 the diameter of the full FOV.
- Dose-Area-Product (DAP) Reduction Accuracy Test was performed to demonstrate that DAP Reduction calculations of the ControlRad® Trace Model 9 when installed in GE Healthcare Surgery's OEC 9900 Elite system are within ±35% of the DAP Reduction values.
- ControlRad® Trace Filter Attenuation Test was performed to evaluate the attenuation level of the filters of the ControlRad® Trace Model 9.
- Comparative Image Quality inside the ROI Test was performed to demonstrate that the image quality of the OEC 9900 Elite with installed ControlRad® Trace Model 8 within the ROI is of at least the same image quality compared to the image quality of the OEC 9900 Elite alone.
- Comparative Image Quality outside the ROI Test was performed in order to evaluate the filtered image quality outside the ROI of the OEC 9900 Elite with installed ControlRad® Trace Model 9 in the periphery image outside the ROI compared to the image quality of the OEC 9900 Elite alone.
- Image Quality Clinical Simulations was preformed to evaluate the image quality inside and outside the ROI and the ability of the filtered image outside the ROI to provide image context to the ROI, of a clinically simulated image obtained by the GE Healthcare Surgery's OEC® 9900 Elite with installed ControlRad® Trace Model 9.
- Touch-In-Gloves Bench Test was performed in order to demonstrate that the CR Trace Tablet's touchscreen operates as intended when using sterile radiation protective gloves and touchscreen drape.
- Wireless Technology and Cybersecurity Evaluation was performed in order to evaluate the ControlRad® Trace Model 9's compliance with the requirements set forth in FDA Guidance documents titled "Radio Frequency Wireless Technology in Medical Devices" and "Postmarket Management of Cyber Security in Medical Devices".

In all performance tests the ControlRad® Trace Model 9 system when installed in GE Healthcare Surgery's OEC® 9900 Elite system performed and functioned as intended and observations were as expected.

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® Trace Model 9 during product development.

The 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® Trace Model 9 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 of preventing 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® Trace Model 9 System. These tests have been performed to assess the functionality of the Subject Device. Results of all conducted testing was found acceptable and do not raise any new issues of safety or effectiveness.

ControlRad® Trace Model 8 Performance Data:
ControlRad® conducted the following performance tests to demonstrate that the ControlRad® Trace Model 8 for use with GE Healthcare Surgery's OEC® 9800 Plus complies with performance standards, functions as intended and is at least as safe and effective as the predicate GE Healthcare Surgery's OEC® 9800 Plus:

- Impact on Air Kerma Test was performed in order to evaluate the impact of the ControlRad® Trace Model 8 on Air Kerma (AKR) measurements of GE Healthcare Surgery's OEC 9800 Plus.
- DAP calculation accuracy test was performed to demonstrate that DAP calculations of the ControlRad® Trace Model 8 when installed in OEC 9800/OEC 9800 Plus system are within ±35% of measured DAP values.

- DAP Reduction Test was preformed to demonstrate that the ControlRad® Trace Model 8 when installed in the OEC 9800/OEC 9800 Plus system reduces at least 50% of the DAP at 50 kVp and ROI with width and length that are smaller than 1/3 the diameter of the full FOV.
- DAP Reduction Accuracy Test was performed to demonstrate that DAP Reduction calculations of the ControlRad™ Trace Model 8 when installed in OEC 9800/OEC 9800 Plus system are within ±35% of measured DAP Reduction values.
- ControlRad® Trace Filter Attenuation Test was performed to evaluate the attenuation level of the filters of the ControlRad® Trace Model 8.
- Comparative Image Quality Inside the ROI Test was performed to demonstrate that the image quality of the GE Healthcare Surgery’s OEC 9800 with installed ControlRad® Trace Model 8 within the ROI is at least with the same image quality compared to the image quality of the GE Healthcare Surgery’s OEC 9800 Plus alone.
- Comparative Image Quality Outside the ROI Test was performed in order to evaluate the filtered image quality outside the ROI of the GE Healthcare Surgery’s OEC 9800 with installed ControlRad® Trace Model 8 in the periphery image outside the ROI compared to the image quality of the GE Healthcare Surgery’s OEC 9800 Plus alone.
- Image Quality Clinical Simulations was performed to evaluate the image quality inside and outside the ROI and the ability of the filtered image outside the ROI to provide image context to the ROI, of a clinically simulated image obtained by the GE Healthcare Surgery’s OEC® 9800 Plus with installed ControlRad® Trace Model 8.
- Touch-In-Gloves Bench Test was performed in order to demonstrate that the CR Trace Tablet's touchscreen operates as intended when using sterile radiation protective gloves and touchscreen drape.
- Wireless Technology and Cybersecurity Evaluation was performed in order to evaluate the ControlRad® Trace Model 8's compliance with the requirements set forth in FDA Guidance documents titled "Radio Frequency Wireless Technology in Medical Devices" and "Postmarket Management of Cyber Security in Medical Devices".

In all performance tests the ControlRad® Trace Model 8 system when installed in OEC 9800/OEC 9800 Plus system performed and functioned as intended and observations were as expected.

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 8 during product development.

The 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 8 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 of preventing 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 8 System. These tests have been performed to assess the functionality of the Subject Device. Results of all conducted testing was found acceptable and do not raise any new issues of safety or effectiveness.

10. Performance Standards for ControlRad® Select Model Z, ControlRad® Trace Model 9, and ControlRad® Trace Model 8

ControlRad® Select Model Z complies with the following performance standards:	
1.	ISO 14971 Medical devices - Application of risk management to medical devices
2.	IEC 60601-1 - Medical Electrical Equipment Part 1: General requirements for safety
3.	IEC 60601-1-2 Medical Electrical Equipment – Part 2. Collateral standard: Electromagnetic compatibility - Requirements and tests
4.	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
5.	IEC 60601-1-6 Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability
6.	IEC 62304 Medical device software – Software life cycle processes
7.	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)]
8.	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
9.	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.
10.	IEC 60601-2-54 Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
11.	FDA 21 CFR 1020.30-32 Federal Performance Standard for Diagnostic X-ray Systems

ControlRad® Trace Model 9 complies with the following performance standards:	
1.	ISO 14971 Medical devices - Application of risk management to medical devices
2.	IEC 60601-1 - Medical Electrical Equipment Part 1: General requirements for safety
3.	IEC 60601-1-2 Medical Electrical Equipment – Part 2. Collateral standard: Electromagnetic compatibility - Requirements and tests
4.	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
5.	IEC 60601-1-6 Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability
6.	IEC 62304 Medical device software – Software life cycle processes
7.	FDA 21 CFR 1020.30-32 Federal Performance Standard for Diagnostic X-ray Systems

ControlRad® Trace Model 8 complies with the following performance standards:	
1.	ISO 14971 Medical devices - Application of risk management to medical devices
2.	IEC 60601-1 - Medical Electrical Equipment Part 1: General requirements for safety
3.	IEC 60601-1-2 Medical Electrical Equipment – Part 2. Collateral standard: Electromagnetic compatibility - Requirements and tests
4.	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
5.	IEC 60601-1-6 Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability
6.	IEC 62304 Medical device software – Software life cycle processes
7.	FDA 21 CFR 1020.30-32 Federal Performance Standard for Diagnostic X-ray Systems

11. Conclusion as to Substantial Equivalence:

ControlRad® Select Model Z Conclusión Statement:
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. Minor changes implemented via the "Letter to File" process do not raise any new questions regarding safety and effectiveness of the device as demonstrated through updated performance testing.

ControlRad® Trace Model 9 Conclusión Statement:
The ControlRad® Trace Model 9 is a line extension of the Trace Model family of products (K183109) and is installed on the GE Healthcare Surgery's OEC® 9900 Elite (K122234). The ControlRad® Trace Model 9 is technological identical to Trace Model 8 with the exception of software modifications necessary for Trace Model 9 to be compatible with the GE Healthcare Surgery's OEC® 9900 Elite (K122234); however, those technological differences do not raise different questions of safety and effectiveness. Performance data demonstrate that the ControlRad® Trace Model 9 is at least as safe and effective as the GE Healthcare Surgery's OEC® 9900 Elite (K122234). In conclusion, the ControlRad® Trace Model 9 when used with GE Healthcare Surgery's OEC® 9900 Elite is substantially equivalent to that predicate devices.

ControlRad® Trace Model 8 Conclusión Statement:
The ControlRad® Trace Model 8 for use with OEC 9800/OEC 9800 Plus has the same intended use and the same indications for use of the cleared in the primary predicate device (K183109). Minor changes implemented via the "Letter to File" process do not raise any new questions regarding safety and effectiveness of the device as demonstrated through updated applicable bench test summaries of performance testing and the conducted risk analysis. Performance data demonstrate that the ControlRad® Trace Model 8 for use with OEC 9800/OEC 9800 Plus is at least as safe and effective as the cleared predicate device.