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

June 24, 2020

Re: K200663
Trade/Device Name: ControlRad™ Trace Model 9
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, OXO, JAA
Dated: April 9, 2020
Received: April 10, 2020

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200663

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.

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510(k) SUMMARY

ControlRad, Inc's
ControlRad™ Trace Model 9

K200663

Applicant's name: ControlRad, Inc.
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Date Prepared: June 15, 2020

Subject Device:

Device Name	ControlRad™ Trace Model 9
Common Name	Interventional Fluoroscopic X-ray System
Regulation	21 CFR §892.1650
Classification Name	Image-intensified fluoroscopic x-ray system
Class	II
Panel	Radiology
Product Code(s)	Primary: OWB Secondary: OXO, JAA

Predicate Device:

Device Name	ControlRad™ Trace Model 8 (K183109)
Common Name	Interventional Fluoroscopic X-ray System
Regulation	21 CFR §892.1650
Classification Name	Image-intensified fluoroscopic x-ray system
Class	II
Panel	Radiology
Product Code(s)	Primary: OWB Secondary: OXO, JAA

Reference Device:

Device Name	GE Healthcare Surgery, OEC® 9900 Elite (K122234)
Common Name	Interventional Fluoroscopic X-ray System
Regulation	21 CFR §892.1650
Classification Name	Image-intensified fluoroscopic x-ray system
Class	II
Panel	Radiology
Product Code(s)	Primary: OWB Secondary: OXO, JAA

Indications for Use

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.

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. 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 that its 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 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.

Comparison of Technological Characteristics with the Predicate devices

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 predicate with the only modifications being the design differences to work with OEC® 9900 Elite. The performance data demonstrates that the ControlRad™ Trace Model 9 is at least as safe and effective as the predicate and reference devices and is substantially equivalent to the predicate and reference devices. A comparison table of technological characteristics of the ControlRad™ Trace Model 9 device for use with OEC® 9900 Elite compared to those of the predicates is provided below:

Feature \ Device	ControlRad, Inc's ControlRad™ Trace Model 9 (Subject Device)	ControlRad, Inc's ControlRad™ Trace Model 8 (K183109) (Predicate Device)	GE Healthcare Surgery's OEC 9900 Elite (K122234) (Reference)
510(k) Number	K200663	K183109	K122234
Device Class	Class II	Class II	Class II
Product Codes	Primary: OWB Secondary: OXO, JAA	Primary: OWB Secondary: OXO, JAA	Primary: OWB Secondary: OXO, JAA
Regulation Number	21 CFR §892.1650	21 CFR §892.1650	21 CFR §892.1650
Indications for use	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.	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 OEC® 9900 Elite is designed to provide fluoroscopic and spot-film images of the patient during diagnostic, surgical and interventional procedures. Examples of clinical application may include cholangiography, endoscopy, urologic, orthopedic, neurologic, vascular, cardiac, critical care and emergency room procedures.
X-ray Modulation			
X-ray Modulation Component	CR Trace Filter	CR Trace Filter	Iris Collimator and Semitransparent Leaf/Leaves Collimator

Device / Feature	ControlRad, Inc's ControlRad™ Trace Model 9 (Subject Device)	ControlRad, Inc's ControlRad™ Trace Model 8 (K183109) (Predicate Device)	GE Healthcare Surgery's OEC 9900 Elite (K122234) (Reference)
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%	Completely blocks X-ray radiation outside the aperture
Aperture shape	Rectangular	Rectangular	Leaf/Leaves: Rectangular-Like (2 straight edges and 2 round edges) Iris: Octagonal.
Aperture Control	Set by the user using the CR Trace Tablet	Set by the user using the CR Trace Tablet	Set by the user using the Collimator Control buttons on GE Healthcare Surgery's OEC® 9900 Elite's c-arm unit control panel
Image Processing			
Image Area Processed	Image area outside the ROI	Image area outside the ROI	Entire Image
Processing Bits	12 bits	12 bits	12 bits
Processing Rate	30 fps	30 fps	30 fps
Processing Occurrence	Only when the CR Trace Filter is engaged	Only when the CR Trace Filter is engaged	At all times
Image Layout Information	Dose Area Product (DAP) value and/or percentage of DAP reduction when using ControlRad Trace Filter and/or OEC Collimators ROI frame border	Dose Area Product (DAP) value and/or percentage of DAP reduction when using ControlRad Trace Filter and/or OEC Collimators ROI frame border	Hospital, Physician and Patient's name, date and time , X-ray Generator's voltage and current settings, Brightness and Contrast settings, Magnification level, Accumulated Exposure Time per Examination, Accumulated Air Kerma;
Parameters Accuracy Specifications			
Dose Area Product (DAP) Accuracy for total x-ray field of the ControlRad Trace Filter and OEC systems combined*	*Overall: ±35% For DAP reported by ControlRad™ Trace Model 9	*Overall: ±35% For DAP reported by ControlRad™ Trace Model 8	Overall accuracy: ±40% (with Iris Field and Sutter Field > 5cm).
Electrical Requirements			
Electrical Requirements	60 / 50 Hz; 120 VAC (±10%), 15A	60 / 50 Hz; 120 VAC (±10%), 15A	60 / 50 Hz; 120 VAC (±10%), 15A

Feature \ Device	ControlRad, Inc's ControlRad™ Trace Model 9 (Subject Device)	ControlRad, Inc's ControlRad™ Trace Model 8 (K183109) (Predicate Device)	GE Healthcare Surgery's OEC 9900 Elite (K122234) (Reference)
	200/220/230/240VAC (±10%), 10A.	200/220/230/240VAC (±10%), 10A.	200/220/230/240VAC (±10%), 10A.

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.
- Filter motion reliability testing was performed due to changes in assembly of the Trace 9 filter.
- 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".
- Due to weight changes with the workstation, an instability test was performed to ensure compliance with IEC 60601-1 Instability in transport position and Instability from horizontal and vertical forces clauses.

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.

Performance Standards

The ControlRad™ Trace Model 9 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 Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability
- IEC 62304 Medical device software – Software life cycle processes
- FDA 21 CFR 1020.30-32 Federal Performance Standard for Diagnostic X-ray Systems

Substantial Equivalence

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 including filter reliability testing and instability testing confirmed 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.