May 13, 2019

ControlRad, Inc.
% Sasha Gelfand
QA/RA Director
ControlRad, Ltd.
20 HaTaas St.
Kfar Saba, 4442520
ISRAEL

Re: K183109
Trade/Device Name: 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, OXO, JAA
Dated: March 28, 2019
Received: April 1, 2019

Dear Sasha Gelfand:

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 and Part 809); 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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)*
K183109

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 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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K183109

510(k) SUMMARY

ControlRad, Inc's
ControlRad™ Trace Model 8

Applicant's name: ControlRad, Inc.
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Contact Person: Sasha Gelfand
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Date Prepared: March 21, 2019

Name of Device: ControlRad™ Trace Model 8

Common or Usual Name: Accessory to Image-Intensified Fluoroscopic X-ray System

Classification: **Classification Regulation No:** 21 CFR §892.1650
Classification Name: Image-intensified fluoroscopic x-ray system
Regulation Class: II
Classification Panel: Radiology

Product Code: **Primary:** OWB - Interventional fluoroscopic x-ray system
Secondary: OXO – Image-Intensified Fluoroscopic X-ray System, Mobile;
JAA – System, x-ray, fluoroscopic, image-intensified

Predicate Device: GE Healthcare Surgery, OEC® 9800 Plus (K132027)

Reference Device: NuVasive, LessRay™ (K123226)

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.

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 Trace Tablet, ControlRad Trace Filter, ControlRad Hardware, ControlRad Software and Firmware Modules and ControlRad Communication Interface.

The ControlRad™ Trace Model 8 components are installed semi-permanently in the cleared OEC 9800/OEC 9800 Plus, and operate in parallel to the OEC 9800/OEC 9800 Plus. The ControlRad™ Trace Model 8 components provide the following functionalities:

- The ControlRad Trace Tablet provides the user operational control of the ControlRad™ Trace Model 8 device via a Graphical User Interface ("GUI"). The ControlRad Trace Tablet

enables the clinician to select a Region of Interest ("ROI") on the image displayed on the ControlRad Trace Tablet, which is the image that is displayed on the OEC 9800/OEC 9800 Plus's live monitor.

- The ControlRad Trace Filter is installed on top of the OEC 9800/OEC 9800 Plus's collimator. The ControlRad Trace Filter does not affect or modify the functionality of the OEC collimator. The ControlRad 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 8 and between the ControlRad™ Trace Model 8 and the OEC 9800/OEC 9800 Plus.

Principles of Operation

The OEC 9800/OEC 9800 Plus provides an image that its boundaries are defined by the OEC 9800/OEC 9800 Plus'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 8.

Within the OEC 9800/OEC 9800 Plus 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 OEC 9800/OEC 9800 Plus; and
- The image outside the clinician-selected ROI (filtered radiation area in the FOV), which has a lower-dose processed image, providing peripheral image context to the ROI.

The OEC 9800/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 OEC 9800/OEC 9800 Plus's image FOV is limited to the non-collimated region. The ControlRad Trace Filter can be used along with the OEC 9800/OEC 9800 Plus'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 ControlRad Trace Filter. In this case, the OEC 9800/OEC 9800 Plus operates as if the ControlRad Trace Filter was not present. **Comparison of Technological Characteristics with the Predicate Device**

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 predicate/parent device, except for the inclusion of the subject accessory's specific function of radiation exposure reduction, which does not affect/modify the predicate parent device's cleared indications for use.

The ControlRad™ Trace Model 8 has different components and thus different technological characteristics than the OEC 9800/OEC 9800 Plus. However, those technological differences do not raise different questions of safety and effectiveness as this accessory raises the same questions as the cleared parent device's collimator component with respect to the system's image FOV, image quality, and radiation emissions. FDA's clearance of Nuvasive's 510(k)-cleared Lessray System (K173314) ("Lessray"), which is an accessory to fluoroscopic systems and a reference device, shows that acceptable methods exist for evaluating whether those technological differences impact the safety and/or effectiveness of the parent device. The performance data demonstrates that the ControlRad™ Trace Model 8 for use with OEC 9800/OEC 9800 Plus is at least as safe and effective as the OEC 9800 Plus. Thus, the ControlRad™ Trace Model 8 when used with OEC 9800/OEC 9800 Plus is substantially equivalent to that parent/predicate device.

A comparison table of technological characteristics of the ControlRad™ Trace Model 8 accessory device for use with GE Healthcare Surgery's OEC 9800 Plus (K132027) compared to those of the predicate/parent device is provided below:

Device / Feature	ControlRad, Inc's ControlRad™ Trace Model 8 (Subject Device)	GE Healthcare Surgery's OEC 9800 Plus (K132027) (Predicate Device)
510(k) Number	K183109	K132027
Device Class	Same	Class II
Product Codes	Same	Primary: OWB Secondary: OXO, JAA
Regulation Number	Same	21 CFR §892.1650
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 OEC 9800 Plus is designed to provide fluoroscopic and spot-film imaging of the patient during diagnostic, surgical and interventional procedures. Clinical application may include cholangiography, endoscopy, urologic, orthopedic, neurologic, vascular, cardiac, critical care and emergency room procedures.
X-ray Modulation		
X-ray Modulation Component	ControlRad Trace Filter	Iris Collimator and Leaves Collimator
X-ray Radiation Modulation	Reduces X-ray radiation outside the aperture/ROI typically by 61% to 97%	Completely blocks X-ray radiation outside the aperture
Aperture shape	Rectangular	Leaf/Leaves: Rectangular-Like (2 straight edges and 2 round edges) Iris: Octagonal.
Aperture Control	Set by the user using the ControlRad Trace Tablet	Set by the user using the Collimator Control buttons on OEC 9800 Plus's C-arm unit control panel

Device / Feature	ControlRad, Inc's ControlRad™ Trace Model 8 (Subject Device)	GE Healthcare Surgery's OEC 9800 Plus (K132027) (Predicate Device)
Image Processing		
Image Area Processed	Image area outside the ROI	Entire Image
Processing Bits	Same	12 bits
Processing Rate	Same	30 fps
Processing Occurrence	Only when the ControlRad 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;	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	Overall: ±35% For DAP reported by ControlRad™ Trace Model 8	Overall accuracy: ±40% (with Iris Field and Sutter Field > 5cm).
Electrical Requirements		
Electrical Requirements	Same	60/50 Hz; 120 VAC (±10%), 15A 200/220/230/240VAC (±10%), 10A.

Performance Data

ControlRad conducted the following performance tests to demonstrate that the ControlRad™ Trace Model 8 for use with OEC 9800/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 actual Air Kerma (AKR) of the OEC 9800/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 OEC 9800/OEC 9800 Plus with installed ControlRad Trace Model 8 within the ROI is of at least with the same image quality compared to the image quality of the OEC 9800/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 OEC 9800/OEC 9800 Plus with installed ControlRad Trace Model 8 in the periphery image outside the ROI compared to the image quality of the OEC 9800/OEC 9800 Plus 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 OEC 9800/OEC 9800 Plus with installed ControlRad™ Trace Model 8.
- Touch-In-Gloves Bench Test was performed in order to demonstrate that the ControlRad 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.

Performance Standards

The ControlRad™ Trace Model 8 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 1-2. 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 8 for use with OEC 9800/OEC 9800 Plus has the same intended use and the same indications for use of the cleared predicate/parent device (K132027), except for the inclusion of the subject accessory's specific function of radiation exposure reduction, which does not affect/modify the predicate parent device's cleared indications for use. The ControlRad™ Trace Model 8 has different technological characteristics than the GE Healthcare Surgery's OEC 9800 Plus (K132027), however those technological differences do not raise different questions of safety and effectiveness. 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 OEC 9800 Plus (K132027). Thus, the ControlRad™ Trace Model 8 when used with OEC 9800/OEC 9800 Plus is substantially equivalent to that parent/predicate device.