December 27, 2024

GE Hualun Medical Systems Co. Ltd.
% Michelle Huettner
Director, Regulatory Affairs - IGT and Oncology
No 1 Yong Chang North Road,
Beijing Economic Technological Development Zone, Beijing
CHINA 100176

Re: K240828
Trade/Device Name: OEC One ASD
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OXO, JAA, OWB
Dated: November 28, 2024
Received: November 29, 2024

Dear Michelle Huettner:

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

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

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Gabriela M. Rodal -S Digitally signed by Gabriela M. Rodal -S for

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240828

Device Name
OEC One ASD

Indications for Use *(Describe)*
The OEC One ASD mobile C-arm system is designed to provide fluoroscopic and digital spot images of adult and pediatric patient populations during diagnostic, interventional, and surgical procedures. Examples of a clinical application may include: orthopedic, gastrointestinal, endoscopic, urologic, neurologic, vascular, critical care, and emergency procedures.

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) Number: K240828

510(k) Summary of Safety and Effectiveness

OEC One ASD

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) Summary of Safety and Effectiveness information is submitted in accordance with the requirement of 21 CFR Part 807.87(h).

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: December 27, 2024

Submitter: GE HUALUN MEDICAL SYSTEMS CO., Ltd
No. 1 Yong Chang North Road,
Beijing Economic Technological Development Zone, Beijing 100176
China

Primary Contact: Lifeng Wang
Regulatory Affairs Manager- IGT
Tel: +8613381164329
e-mail: lifeng.wang@gehealthcare.com

Secondary Contacts: Michelle Huettner
Director, Regulatory Affairs - IGT and Oncology
GE HealthCare
Tel: 901-558-8035
e-mail: michelle.huettner@gehealthcare.com

PRODUCT IDENTIFICATION

Device Trade Name:	OEC One ASD
Regulation Name:	Image-intensified Fluoroscopic x-ray system
Classification Panel:	Radiology
Regulation:	21CFR 892.1650
Classification:	Class II
Product Code:	OXO
Subsequent Product Codes	JAA, OWB
Manufacturer:	GE HUALUN MEDICAL SYSTEMS CO., Ltd No. 1 Yong Chang North Road, Beijing Economic Technological Development Zone, Beijing 100176 China

Predicate Device:

Device Name:	OEC One
510(k) number:	K182626
Manufacturer:	GE HUALUN MEDICAL SYSTEMS CO., Ltd No. 1 Yong Chang North Road, Beijing Economic Technological Development Zone, Beijing 100176 China
Regulation Name:	Image-intensified Fluoroscopic x-ray system
Regulation:	21CFR 892.1650
Classification:	Class II
Product Code:	OWB
Subsequent Product Code:	OXO, JAA

Device Description:

The OEC One ASD is a mobile C-arm X-ray system to provide fluoroscopic images of the patient during diagnostic, interventional, and surgical procedures such as orthopedic, gastrointestinal, endoscopic, urologic, neurologic, vascular, critical care, and emergency procedures. These images help the physician visualize the patient's anatomy and localize clinical regions of interest. The system consists of a mobile stand with an articulating arm attached to it to support an image display monitor (widescreen monitor) and a TechView tablet, and a "C" shaped apparatus that has a flat panel detector on the top of the C-arm and the X-ray Source assembly at the opposite end.

The OEC One ASD is capable of performing linear motions (vertical, horizontal) and rotational motions (orbital, lateral, wig-wag) that allows the user to position the X-ray image chain at various angles and distances with respect to the patient anatomy to be imaged. The C- arm is mechanically balanced allowing for ease of movement and capable of being "locked" in place using a manually activated lock.

The subject device is labelled as OEC One ASD.

The purpose of this premarket notification is to demonstrate that the subject device, OEC One ASD, is a modification of and is substantially equivalent to the predicate device OEC One (K182626).

Proposed Device Modification:

The modified OEC One ASD employs the same fundamental scientific technology as that of the unmodified predicate device (K182626). The primary change for the subject device is to introduce an amorphous silicon (a-Si) flat panel detector as the image receptor. Roadmap functionality, which is optional in the predicate device (K182626), has been removed and a printer shelf has been integrated into the subject device to place the applicable printer on.

Indications for Use:

The OEC One ASD mobile C-arm system is designed to provide fluoroscopic and digital spot images of adult and pediatric patient populations during diagnostic, interventional, and surgical procedures. Examples of a clinical application may include: orthopedic, gastrointestinal, endoscopic, urologic, neurologic, vascular, critical care, and emergency procedures.

The intended use and indications for use are unchanged from the predicate device.

Technology:

The indications for use are identical and the technology is similar to the predicate device.

The primary change on the subject device is to introduce an Amorphous Silicon (a-Si) solid state flat panel X-ray detector. A printer shelf is integrated into the subject device for the user to place the applicable printer on. The electrical boards have been re-laid out or redesigned to be more compact to make space for the printer shelf. The image shape changed from a circle to a squircle by introducing the flat panel detector and squircle secondary collimator. The X-Ray source monoblock remains unchanged from that of the predicate device OEC One (K182626). The hardware changes also include using an up-to-date computer, tablet and monitor that offers more image storage, processing speed, and higher resolution display, driven by IT technology advancement.

Its software is based on the architecture, design and code base of the predicate device OEC One (K182626). The software architecture framework was updated to a platform-based architecture with no significant changes in order to support different OEC C-Arm products. The modifications were also being made to support the flat panel detector, the necessary imaging and post-processing applications related to the flat panel detector, and device specific features/functionality. The design followed the same design control process and software development lifecycle process that is compliant to IEC 62304 used in the predicate OEC One.

The table below compares the main performance data of the proposed device with the predicate device.

Comparison between the Subject Device and Predicate Device

	Predicate Device **OEC One (K182626)**	**Subject Device** **OEC One ASD**	**Discussion of differences**
Image Receptor	Image Intensifier Detective Quantum Efficiency (DQE): 65% Modulation Transfer Function (MTF): 45%	21cm Amorphous Silicon (a-Si) Flat Panel Detector DQE: 70% (0 lp/mm) MTF: 46% (1.0 lp/mm)	Substantially Equivalent. The change of the image receptor is to enhance the device performance.

	Predicate Device **OEC One (K182626)**	**Subject Device** **OEC One ASD**	**Discussion of differences**
	Field of View: • 9 inch • 6 inch • 4.5 inch	Field of View: • 21 cm • 15 cm • 11 cm	No new hazards or hazard situations were raised due to this change. The performance testing indicated that the subject device is still effective. This change did not raise any new safety and effectiveness concerns.
Image Matrix Size	1000×1000	1520×1520	Substantially Equivalent. This change is driven by the detector pixel matrix to get higher resolution. This change did not raise any new safety and effectiveness concerns.
Image Shape	Circle	Squircle	Substantially Equivalent. The squircle shape provides an enhanced viewing area without exposing the areas at the corners, which are not typically clinically needed. The squircle design can maintain the identical size and shape even when the image is rotated. This change did not raise any new safety and effectiveness concerns.
Anti-scatter Grid	Line Rate: 60 L/cm Ratio: 10:1 Focal Distance: 100 cm	Line Rate: 74 L/cm Ratio: 14:1 Focal Distance: 100 cm	Substantially Equivalent. The grid's specification is defined based on the image receptor's pixel size, which has been updated because of the introduction of flat panel detector. This change did not raise any new safety and effectiveness concerns.

	Predicate Device **OEC One (K182626)**	**Subject Device** **OEC One ASD**	**Discussion of differences**
Monoblock	Type: Stationary Anode Focal Spot: 0.6 x 1.4 & 1.4 (IEC60336) Anode Heat Capacity: 76,000 H.U. Anode Cooling Rate: 37,000 H.U/min Housing Heat Capacity: 900,000 H.U Housing Cooling Rate: 12,500 H.U./min	Type: Stationary Anode Focal Spot: 0.6 x 1.4 & 1.4 (IEC60336) Anode Heat Capacity: 76,000 H.U. Anode Cooling Rate: 37,000 H.U/min Housing Heat Capacity: 900,000 H.U Housing Cooling Rate: 12,500 H.U./min	Identical.
X-ray Generator	40 kHz High Frequency Max Power 2.5 kW Peak Tube Potential: 40-110 kVp Fluoroscopy: 0.1-4.0 mA High Level Fluoro: 0.2-25.0 mA Pulsed Fluoro: 1, 2, 4, 8, 12 pulses/sec Digital Spot: 0.2-10.0 mA (for 100-120V system)	40 kHz High Frequency Max Power 2.5 kW Peak Tube Potential: 40-110 kVp Fluoroscopy: 0.1-8.0 mA High Level Fluoro: 0.2-25.0 mA Pulsed Fluoro: 1, 2, 4, 8, 12 pulses/sec Digital Spot: 2-10.0 mA (for 100-120V system)	Substantially Equivalent. mA range changing in Fluoroscopy mode is caused by different image processing parameters of Auto Brightness Stable (ABS) to get optimized image quality. mA range changing in Digital Spot mode is to get optimized image quality by increasing tube current (mA) especially on thin anatomy such as hands. This change did not raise any new safety and effectiveness concerns.
Collimator	Iris, Tungsten Dual Leaf Shutter Collimator Iris Preview Collimator Shutter Preview Circle shape secondary collimator	Iris, Tungsten Dual Leaf Shutter Collimator Iris Preview Collimator Shutter Preview Squircle shape secondary collimator	Substantially Equivalent. Secondary collimator has been modified to achieve the squircle field of view. This change did not raise any new safety and effectiveness concerns.
X-ray Control Modes	Auto Mode Manual Mode (Normal Fluoro, Low Dose Fluoro, High Level Fluoro)	Auto Mode Manual Mode (Normal Fluoro, Low Dose Fluoro, High Level Fluoro)	Identical.

	Predicate Device **OEC One (K182626)**	**Subject Device** **OEC One ASD**	**Discussion of differences**
Imaging Modes	Continuous – Fluoroscopy • Normal Dose • High Level Dose • Low Dose Pulsed Fluoroscopy • Normal Dose • High Level Dose • Low Dose Digital Spot • Normal Dose • Low Dose Roadmap • Normal Dose • Low Dose Subtraction • Normal Dose • Low Dose	Continuous – Fluoroscopy • Normal Dose • High Level Dose • Low Dose Pulsed Fluoroscopy • Normal Dose • High Level Dose • Low Dose Digital Spot • Normal Dose Subtraction • Normal Dose • Low Dose	Substantially Equivalent. Digital Spot Low Dose mode will not be provided as Digital Spot mode creates a short-duration, high mA exposure to produce a single high quality image. Therefore, the low dose mode is not necessary for Digital Spot mode. The user can still get similar functionality by using Fluoroscopy. Roadmap mode will not be provided based on marketing positioning, however, user can still get the similar functionality by applying the peak opacify function on contrast-agent-flowed cine. This change did not raise any new safety and effectiveness concerns.
Imaging Features	Auto X-Ray technique control Noise and motion reduction (TNR) Auto/Manual Brightness and Contrast Control Negate Swap and auto-swap Save and auto-save Last image hold Edge enhancement Zoom & Roam Image rotation Image flip/ invert Manual/Auto Smart Metal AutoTrak Patient Annotation	Auto X-Ray technique control Noise and motion reduction (TNR) Auto/Manual Brightness and Contrast Control Negate Swap and auto-swap Save and auto-save Last image hold Edge enhancement Zoom (Live Zoom) & Roam Image rotation Image flip/ invert Manual/Auto Smart Metal AutoTrak	Substantially Equivalent. Digital Pen (previously cleared in OEC Elite K171565) has been added so that user can draw lines on image display for planning or educational purposes. Zoom feature has improved with Live Zoom so it could be performed during a fluoro shot or Cine run. These changes did not raise any new safety and effectiveness concerns.

	Predicate Device **OEC One (K182626)**	**Subject Device** **OEC One ASD**	**Discussion of differences**
	Markers Measurement Functions Peak Opacification Cine Recording/Playback • Cine Automatic Image Playback • Cine Frame-by-Frame Review • Fluorostore(up to 240 frames recording) Re-Registration Variable Landmarking Mask save/Recall Reference Image Hold	Patient Annotation Markers Measurement Functions Peak Opacification Cine Recording/Playback • Cine Automatic Image Playback • Cine Frame-by-Frame Review • Fluorostore(up to 240 frames recording) Re-Registration Variable Landmarking Mask save/Recall Reference Image Hold Digital Pen	
Monitor Display	Colored 27″ monitor Resolution: 1920x1080 Brightness: 600 cd/m2 Touch screen 8bit image display on monitor	Colored 27″ monitor Resolution: 3840 x 2160 Brightness: 600 cd/m2 Touch screen 10bit image display on monitor	Substantially Equivalent. The monitor was updated to a higher resolution one. This change was driven by IT technology advancement by using a more state of the art display technology which achieves the same or better functionality. This change did not raise any new safety and effectiveness concerns.
Display Articulation	180 degree swivel 5 degrees tilt up 25 degrees tilt down Monitor viewable from all 4 sides Horizontal and Vertical viewing angle 178 degrees 20cm up vertical travel	180 degree swivel 5 degrees tilt up 25 degrees tilt down Monitor viewable from all 4 sides Horizontal and Vertical viewing angle 178 degrees 20cm up vertical travel	Identical

	Predicate Device **OEC One (K182626)**	**Subject Device** **OEC One ASD**	**Discussion of differences**
	20cm down vertical travel Extension arm rotation 210 degrees Spring arm rotation 180 degrees Position monitor above C-arm by folding articulation arm within system footprint	20cm down vertical travel Extension arm rotation 210 degrees Spring arm rotation 180 degrees Position monitor above C-arm by folding articulation arm within system footprint	
Tech View Tablet	Size: 10.1 inch Resolution: 1280 × 800 OS: Android 5.1	Size: 10.1 inch Resolution: 1280 × 800 OS: Android 11.0	Substantially Equivalent Android OS has been upgraded to Android 11.0. This change was driven by IT technology advancement by using a more state of the art display technology which achieves the same functionality. This change did not raise any new safety and effectiveness concerns.
C-Arm Physical Dimensions	Depth of Arc: 26.0″ (66 cm) Source Image Distance: 39.4″ (100 cm) Lateral Rotation: 410° (+205° / -205°) Wig/Wag: 25° (+12.5°/-12.5°) Orbital Rotation: 120° (90° underscan /30° overscan) Horizontal Movement: 7.9″ (20cm) Vertical Travel: 17.5″ (44 cm)	Depth of Arc: 26.0″ (66 cm) Source Image Distance: 39.4″ (100 cm) Lateral Rotation: 410° (+205° / -205°) Wig/Wag: 25° (+12.5°/-12.5°) Orbital Rotation: 150° (95° underscan /55° overscan) Horizontal Movement: 7.9″ (20cm) Vertical Travel: 17.5″ (44 cm)	Substantially Equivalent. The orbital rotation was changed to a larger range to make the user easily use the system. This change did not raise any new safety and effectiveness concerns.

	Predicate Device **OEC One (K182626)**	**Subject Device** **OEC One ASD**	**Discussion of differences**
Image Storage	100,000 Images	150,000 Images	Substantially Equivalent. This change was driven by IT technology advancement by using a more state of the art computing technology which achieves the same or better functionality. This change did not raise any new safety and effectiveness concerns.
Wireless Printing Module and Printers	N/A	Wireless Printing Module Printers	Substantially Equivalent The printer is used to create reference image that is not for diagnostic purpose. The wireless printing module is not used to control the device operations nor X-ray activation. The changes from wired printer to wireless printer does not significantly affect the use of the device. No new risks raised or existing risks was changed due to this change. This change did not raise any new safety and effectiveness concerns.
Video Distributor	DVI, BNC	DP, BNC	Substantially Equivalent. This change was driven by IT technology advancement by using a more state of the art computing technology which achieves the same or better functionality. This change did not raise any new safety and effectiveness concerns.
Laser Aimer	Red Laser	Green Laser	Substantially Equivalent. Laser has been updated for introducing green laser as well as

	Predicate Device **OEC One (K182626)**	**Subject Device** **OEC One ASD**	**Discussion of differences**
	Image intensifier side laser Aimer: CLASS IIIa/3R laser product Wavelength: 650 nm Optical output power: ≤5.0 mW	Flat panel detector side laser aimer and Tube side laser aimer: CLASS 2 laser product Wavelength: 510nm-530nm Optical output power: 1mW	introducing tube side laser aimer for users' convenience. Both lasers meet the IEC 60825-1: 2014 and 21CFR 1040.10 laser products requirement. This change did not raise any new safety and effectiveness concerns.
Image Processing	Noise and motion artifact reduction, Autotrak, ABS, Smart window, smart metal, ADRO (Adaptive Dynamic Range Optimization) (based on CPU) Note: ADRO is to optimize the post processing algorithm to achieve optimized dynamic range and improved contrast for visualization of more anatomical details.	Noise and motion artifact reduction, Autotrak, ABS (based on CPU) Smart window, smart metal, ADRO (Adaptive Dynamic Range Optimization) (based on GPU)	Substantially Equivalent The noise and motion artifact reduction, AutoTrak and ABS, are same with OEC One (K182626) while Smart window, smart metal post processing modules are based on GPU calculation which is because GPU has a better calculation speed which can more suitable to detectors. ADRO is an available feature on OEC One (K182626) that is changed to base on GPU for better calculation speed. This change did not raise any new safety and effectiveness concerns.

The system continues to meet all applicable IEC 60601-1 series of standards, NEMA XR-27, and applicable parts of 21CFR Subchapter J.

The changes described above do not change the control mechanism, operating principle, energy type, or the scientific technology of the predicate devices.

Determination of Substantial Equivalence:

GE HealthCare believes the OEC One ASD is of comparable type and substantially equivalent to the cleared predicate OEC One.

Non-Clinical Performance Testing

The verification and validation testing has been successfully completed as required by design control procedures under GE HealthCare's quality system. The system has been tested and is compliant with the following FDA-recognized consensus standards and FDA guidance documents:

FDA-recognized consensus standards

- ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]. Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - FDA recognition number 19-46.

- IEC 60601-1-2 Edition 4.1 2020-09 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests. FDA recognition number 19-36.

- IEC 60601-1-3 Edition 2.2 2021-01 Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment. FDA recognition number 12-336.

- IEC 60601-1-6 Edition 3.2 2020-07 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability. FDA recognition number 5-132.

- IEC 60601-2-28 Edition 3.0 2017-06 Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis. FDA recognition number 12-309.

- IEC 60601-2-54 Edition 1.2 2018-06 Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy. FDA recognition number 12-317.

- IEC 60601-2-43 Edition 2.2 2019-10 Medical electrical equipment - Part 2-43: Particular requirements for the safety and essential performance of X-ray equipment for interventional procedures. FDA recognition number 12-329.

- IEC 62304 Edition 1.1 2015-06 Medical device software - Software life cycle processes. FDA recognition number 13-79.

- IEC 62366-1 Edition 1.1 2020-06 Medical devices - Part 1: Application of usability engineering to medical devices. FDA recognition number 5-129.

FDA guidance

- Pediatric information for X-ray imaging device premarket notifications, Nov 28, 2017
- Content of Premarket Submissions for Device Software Functions, June 14, 2023
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, September 27, 2023

- Radio frequency wireless technology in medical devices- Guidance for Industry and Food and Drug Administration Staff, Aug 14, 2013
- Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices: Guidance for Industry and Food and Drug Administration Staff, Sep 01, 2016

All applicable 21CFR Subchapter J performance standards are met. 1020.30 Diagnostic X-Ray Systems and their major components, 1020.32 Fluoroscopic equipment, 1040.10 Laser products.

The OEC One ASD system was developed under the GE HealthCare Quality Management System, including design controls, risk management and software development life cycle processes. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Required Reviews
- Design Reviews
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

The substantial equivalence was also based on a basic software documentation level.

Clinical Testing

OEC One ASD is substantially equivalent to the cleared predicate OEC One. The indication for use is identical and has equivalent/identical technological characteristics. This type of premarket notification supports using scientific, established, engineering-based performance testing. The system has been fully tested/evaluated by using engineering bench testing. In addition, comparative clinical images were evaluated to demonstrate substantial equivalence for the OEC One ASD compared to the cleared predicate.

Substantial Equivalence Conclusion

OEC One ASD follows the same design control process and software development lifecycle processes as the predicate OEC One (K182626).

The differences discussed in this section do not introduce any adverse effects nor raise new questions of safety and effectiveness. Based on the successful verification and validation testing, additional performance bench testing, conformance to standards, and development under the GE HealthCare Quality Management System, we believe that OEC One ASD is substantially equivalent to the cleared predicate device OEC One (K182626) and therefore, is safe and effective for its intended use.