



November 26, 2025

GE Hualun Medical Systems Co., Ltd
% Lifeng Wang
Regulatory Affairs Manager
No. 1 Yong Chang North Road, Economic Technological
Development Zone Beijing,
BEIJING 100176
CHINA

Re: K253269

Trade/Device Name: OEC One CFD
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OXO, JAA, OWB
Dated: September 29, 2025
Received: September 29, 2025

Dear Lifeng Wang:

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,

A large, light blue watermark of the letters 'FDA' is positioned behind the signature. The signature 'Lu Jiang' is written in a black, cursive script over the watermark.

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K253269

Device Name

OEC One CFD

Indications for Use (Describe)

The product 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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

Date: November 26, 2025

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: Bryan Behn
Sr. Director - Regulatory Affairs
GE HealthCare
Tel: (262) 2475502
e-mail: Bryan.Behn@gehealthcare.com

PRODUCT IDENTIFICATION

Device Trade Name: OEC One CFD

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

Primary Predicate Device:

<u>Device Trade Name:</u>	OEC One ASD
<u>510(k) number:</u>	K240828
<u>Regulation:</u>	21CFR 892.1650
<u>Classification:</u>	Class II
<u>Product Code:</u>	OXO
<u>Subsequent Product Codes</u>	JAA, OWB
<u>Manufacturer:</u>	GE HUALUN MEDICAL SYSTEMS CO., Ltd No. 1 Yong Chang North Road, Beijing Economic Technological Development Zone, Beijing 100176 China

Reference Device

<u>Device Trade Name:</u>	OEC Elite
<u>510(k) number:</u>	K172550
<u>Regulation:</u>	21CFR 892.1650
<u>Classification:</u>	Class II
<u>Product Code:</u>	OXO
<u>Subsequent Product Codes</u>	JAA, OWB
<u>Manufacturer:</u>	GE OEC Medical Systems Inc 384 Wright Brothers Drive Salt Lake City, Utah 84116

Device Description:

The OEC One CFD 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 CFD 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 CFD.

Proposed Device Modification:

The modified OEC One CFD employs the same fundamental scientific technology as that of the unmodified predicate device (K240828). The primary change for the subject device is to introduce the optional Image Stitching and Deep learning-based Trajectory Pointer software features.

Indications for Use:

The product 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 the optional Image Stitching and Deep learning-based Trajectory Pointer software features.

Table 1 below summarizes the main feature/technological differences and similarities between the predicate device and the proposed device.

Table 1 Comparison between the Subject Device and Predicate Device

	<u>Predicate Device</u> OEC One ASD (K240828)	<u>Subjected Device</u> OEC One CFD	<u>Discussion of Differences</u>
Image Receptor	21cm Amorphous Silicon (a-Si) Flat Panel Detector	21cm and 31cm CMOS Flat Panel Detector	<p>Substantially Equivalent.</p> <p>The change of the image receptor is to enhance the device performance.</p> <p>Both detector technology is widely used in mobile fluoroscopic C-arm imaging system.</p> <p>Also see comparison with the cleared reference device OEC Elite (K172550) that using the identical CMOS detectors in Table 2 in the following section</p> <p>This change did not raise any new safety and effectiveness concerns.</p>

	<u>Predicate Device</u> OEC One ASD (K240828)	<u>Subjected Device</u> OEC One CFD	<u>Discussion of Differences</u>
Image Matrix Size	21cm: 1520×1520	21cm: 1536x1496 31cm: 1548x1524	Substantially Equivalent. Slightly changed for 21cm Flat Panel Detector (FPD). The image matrix size is determined by the physical dimensions of the detector. 31cm FPD is larger than the 21 cm FPD, therefore it is different with OEC One ASD. This change did not raise any new safety and effectiveness concerns.
Monoblock	Type: Stationary Anode Focal Spot (IEC60336): -Small Focal: 0.6 x 1.4 -Large Focal: 1.4 Housing Heat Capacity: 900,000 HU Housing Cooling Rate: 12,500 HU/min	Type: Stationary Anode Focal Spot (IEC60336): -Small Focal: 0.6 -Large Focal: 1.2 Housing Heat Capacity: 1,200,000 HU Housing Cooling Rate: 20,000 HU/min	Substantial Equivalent. The focal spot size, heat capacity and cooling rate have been changed to enhance monoblock performance. The system verification and validation have been executed and passed. These changes did not raise any new safety and effectiveness concern.
X-ray Generation	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 Digital Spot:2- 10 mA (for 100-120V system)	20 kHz High Frequency Max Power 4.0 kW Peak Tube Potential: 40- 120 kVp Fluoroscopy: 0.1- 12.0 mA High Level Fluoro: 0.2- 40.0 mA Digital Spot:2- 15 mA (for 100-120V system)	Substantial Equivalent. The maximum power, kVp and mA updated to get the full capability of the tube-insert to enhance the system performance. The frequency of the X-ray generator is adjusted to fit the 4kW max power. These changes are performance enhancement, and the X-ray generation

	<u>Predicate Device</u> OEC One ASD (K240828)	<u>Subjected Device</u> OEC One CFD	<u>Discussion of Differences</u>
			control mechanism is not changed. The system verification and validation have been executed and passed. These changes did not raise any new safety and effectiveness concern.
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.
Imaging Modes	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	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 Roadmap -Normal Dose -Low Dose	Substantially Equivalent. Roadmap provides a modified subtracted image on the left area of the monitor showing the difference between the current fluoroscopic image and a roadmap mask image. It is useful for providing the anatomical location of pathology for proper placement of a catheter, balloon, or stent. Roadmap function is the same as the cleared device OEC One (K182626). 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	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	Identical.

	<u>Predicate Device</u> OEC One ASD (K240828)	<u>Subjected Device</u> OEC One CFD	<u>Discussion of Differences</u>
	Edge enhancement Zoom (Live Zoom) & Roam Image rotation Image flip/ invert Manual/Auto Smart Metal AutoTrak Patient Annotation Markers Measurement Functions Peak Opacification Cine Recording/Playback · Cine Automatic Image Playback · Cine Frame-by-Frame Review · Fluorostore Re-Registration Variable Landmarking Mask save/Recall Reference Image Hold Digital Pen	Edge enhancement Zoom (Live Zoom) & Roam Image rotation Image flip/ invert Manual/Auto Smart Metal AutoTrak Patient Annotation Markers Measurement Functions Peak Opacification Cine Recording/Playback · Cine Automatic Image Playback · Cine Frame-by-Frame Review · Fluorostore Re-Registration Variable Landmarking Mask save/Recall Reference Image Hold Digital Pen	
Collimator	Iris, Tungsten Dual Leaf Shutter Collimator Iris Preview Collimator Shutter Preview Squirele shape secondary collimator	Iris, Tungsten Dual Leaf Shutter Collimator Iris Preview Collimator Shutter Preview Squirele shape secondary collimator	Identical.
Anti-scatter Grid	For 21cm detector: - Line Rate: 74L/cm - Ratio: 14:1 - Focal Distance: 100 cm	For 21cm detector: - Line Rate: 74L/cm - Ratio: 14:1 - Focal Distance: 100 cm For 31cm detector: - Line Rate: 60L/cm - Ratio: 10:1 - Focal Distance: 100 cm	Substantially Equivalent. Identical for 21cm grid. Adding 31cm grid due to the introduction of 31cm flat panel detector. This change did not raise any new safety and effectiveness concerns.

	<u>Predicate Device</u> OEC One ASD (K240828)	<u>Subjected Device</u> OEC One CFD	<u>Discussion of Differences</u>
Image Shape	Squirecle	Squirecle	Identical.
Monitor Display	Colored 27” monitor Resolution: 3840 x 2160 Brightness: 600cd/m2 Touch screen 10 bit image display on monitor	Colored 27” monitor Resolution: 3840 x 2160 Brightness: 600cd/m2 Touch screen 10 bit image display on monitor	Identical.
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 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	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 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	Identical.
Tech View Tablet	Size: 10.1 inch Resolution: 1280 × 800	Size: 12.1 inch Resolution: 1280 × 800	Substantially Equivalent. This change was driven by IT technology advancement by using a more state-of-the-art technology which achieves the same or better functionality. This change did not raise any new safety and effectiveness concerns.
Image Storage	150,000 Images	150,000 Images	Identical.

	<u>Predicate Device</u> OEC One ASD (K240828)	<u>Subjected Device</u> OEC One CFD	<u>Discussion of Differences</u>
C-Arm Physical Dimensions	Free Space in Arc: 30.7” (78 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)	Free Space in Arc: 30.7” (78 cm) Depth of Arc: 27.2” (69 cm) Source Image Distance: 39.4” (100 cm) Lateral Rotation: 410° (+205° / -205°) Wig/Wag: 25° (+12.5°/-12.5°) Orbital Rotation: 180° (95° underscan / 90° overscan) Horizontal Movement: 7.9” (20cm) Vertical Travel: 17.5” (44 cm)	Substantial Equivalent. The depth of arc and the orbital rotation angle are changed to a larger range to make it easier for the user to use the system. These changes did not raise any new safety and effectiveness concern.
Printing	Wireless Printing Module Printers	Wireless Printing Module Printers	Identical.
Video Distributor	DP, BNC	DP, BNC	Identical.
Laser Aimer	Green Laser Flat panel detector side/Tube side Laser aimer: - CLASS 2 laser product - Wavelength: 510nm-530nm Optical output power: 1mW	Green Laser Flat panel detector side/Tube side Laser aimer: - CLASS 2 laser product - Wavelength: 510nm-530nm Optical output power: 1mW	Identical.
Image Processing	Noise and motion artifact reduction, Autotrak, ABS (based on CPU) Smart window, smart metal, ADRO (based on GPU)	Noise and motion artifact reduction, Autotrak, ABS (based on CPU) Smart window, smart metal, ADRO (based on GPU)	Identical
OEC One Touch Tableside	N/A	Tech View Tablet IPX3	Substantially Equivalent. The added optional OEC One Touch Tableside

	<u>Predicate Device</u> OEC One ASD (K240828)	<u>Subjected Device</u> OEC One CFD	<u>Discussion of Differences</u>
			<p>provided identical function/feature that had already existed on the tablet on the system except for the ability to adjust the collimator during live X-rays.</p> <p>This change did not raise any new safety and effectiveness concerns.</p>
Live Cast (wireless video)	N/A	Wireless video - Transmitter - Receiver -5.1-5.9 GHz	<p>Substantially Equivalent.</p> <p>This feature is to introduce an optional wireless video module which enables the user to cast the system displays wirelessly to the selected external displays simultaneously. It functions in the same way as the cleared device OEC Elite (K172550).</p> <p>This change did not raise any new safety and effectiveness concerns.</p>
OEC Display Cart	27" monitor Resolution: 1920X1080 Non-touch Screen	27" monitor Resolution: 1920X1080 Touch Screen	<p>Substantially Equivalent.</p> <p>The added touch screen feature provided identical function/feature that had already existed on the system monitor. It cannot alter or control X-ray radiation of the system.</p> <p>This change did not raise any new safety and effectiveness concerns.</p>
External Video Input (Picture in Picture)	N/A	Yes	<p>Substantially Equivalent.</p> <p>This feature is to display the external video input on the right side of the C-arm system monitor while the</p>

	<u>Predicate Device</u> OEC One ASD (K240828)	<u>Subjected Device</u> OEC One CFD	<u>Discussion of Differences</u>
			<p>left side of monitor is the live image from the X-ray mobile C-arm system. This feature makes user more convenient to view the images from other devices such as endoscope etc.</p> <p>It functions in the same way as the cleared device OEC Elite (K172550).</p> <p>This change did not raise any new safety and effectiveness concerns.</p>
Image Stitching	N/A	Yes	<p>Substantially Equivalent.</p> <p>Image Stitching is to create a composite view from multiple image acquisitions to aid in surgical procedures of the spine, long bone, or pelvis.</p> <p>The verification and validation test to meet design inputs and user needs for this feature have been tested and the result was passed.</p> <p>This change did not raise any new safety and effectiveness concerns.</p>
Trajectory Pointer	N/A	Yes	<p>Substantially Equivalent.</p> <p>Trajectory Pointer is a feature utilizing deep learning technology to segment the Kirschner-wire then utilize a traditional algorithm to present a visual guideline to aid in positioning Kirschner-wires or similar straight, solid metallic devices.</p>

	<u>Predicate Device</u> OEC One ASD (K240828)	<u>Subjected Device</u> OEC One CFD	<u>Discussion of Differences</u>
			<p>The verification and validation test to meet design inputs and user needs for this feature have been tested and the result was passed.</p> <p>This change did not raise any new safety and effectiveness concerns.</p>

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 and differences described above did not require clinical data in order to establish safety or efficacy.

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 CFD is of comparable type and substantially equivalent to the cleared predicate OEC One ASD.

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

- IEC 60601-1 Edition 3.2 2020-08 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance. FDA recognition number 19-49.
- ANSI AAMI IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests [Including Amendment 1 (2021)]. 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 2.0 2022-09 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 12-348.
- IEC 60601-2-43 Edition 3.0 2022-12 Medical electrical equipment - Part 2-43: Particular requirements for the safety and essential performance of X-ray equipment for interventional procedures. FDA recognition number 12-351.
- 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, June 27, 2025
- 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 CFD 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.

Summary of Testing for Trajectory Pointer

Summary test results including acceptance criteria or other information supporting the appropriateness of the characterized performance are provided below.

Information about clinical subgroups and confounders present in the dataset:

- Anatomy (Limbs, Joints, Hands and feet, Spine, Others)
- K-wire Presence (Y/N)
- Intersection / Block Existence(Y/N)
- kV range (40-120)
- Existence of Other Metal Instruments or Implants(Y/N)
- K-wire Contrast (Clear outline / Saturated edge)
- Ethnicity/Country (US, China, EU /Australia, Phantoms)
- K-wire Quantity (0-10)

Test dataset:

- Test data covers the entire range of values for all confounders, thereby ensuring that the dataset is fully representative of real-world application scenarios.
- Total dataset included 3078 images, 307 were used for test dataset and the rest for training/tuning.

Demographic distribution of test dataset:

- Ethnicity/Country: US (51.1%), China (35.8%), Phantom (9.8%), EU/Australia (3.3%)

Expected performances:

- The MAAP (Minimal Acceptable Algorithm Performance) of the success rate is defined with a high accuracy: At least 95% of test dataset should have a Dice score above 0.9.

Performance demonstrated on test dataset:

- For Last Image Hold(LIH) images, success rate: 98.8% with a 95% confidence level. For Fluoroscopy images, success rate: 97.1% with a 95% confidence level.
- The success rate of both models exceeded the predefined MAAP (95%), demonstrating the algorithm performs as expected.

Information about equipment and protocols used to collect images:

- All images were collected from GE OEC Mobile C-arm devices: OEC One CFD, OEC One ASD, OEC One, OEC Elite MiniView

Information about how the reference standard was derived from the dataset:

- On each image, the contours of K-wires were manually outlined by trained annotators.
- 3 U.S. board certified radiologists check annotations to make sure the ground truth is correct.

Description of how independence of test data from training data was ensured:

- To prevent data leakage and ensure statistical independence between the training and test data sets, two specific measures were implemented:
 - Similarity-based deduplication of K-wire images by comparing ground truth annotations.
 - Rigorous data splitting. This approach guarantees that all K-wire instances in the test data set are unique and strictly independent from those in the training data set.

Additional performance testing for trajectory pointer feature using commercially available anthropomorphic phantoms that contain human simulated bone was performed. All tests passed the pre-defined acceptance criteria demonstrating a satisfactory quality for visual extended guideline to indicate the direction of K-wires or similar straight, solid metallic devices provided by OEC One CFD with trajectory pointer option.

Summary of Testing for Image Stitching

Testing using commercially available anthropomorphic phantoms of applicable body parts (spine, long bone, and pelvis) that contain human simulated bone was performed. All tests passed the pre-defined acceptance criteria demonstrating a satisfactory quality for stitched images provided by OEC One CFD with image stitching option.

Overall Image Performance Testing

Overall image performance testing was performed using commercially available anthropomorphic phantoms of representative body parts that contain human simulated bone and vascular to demonstrate that fluoroscopic anatomical images are quality images. Additional engineering testing was performed to substantiate the performance claims related to dose and image quality. In addition, sample clinical images were evaluated to demonstrate substantial equivalence for the OEC One CFD with Image Stitching and Trajectory Pointer options to the cleared predicate device.

Substantial Equivalence Conclusion

OEC One CFD follows the same design control process and software development lifecycle processes as the predicate OEC One ASD (K240828). It is substantially equivalent to the cleared predicate OEC One ASD. 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. 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, reader study results, conformance to standards, and development under the GE HealthCare Quality Management System, we believe that OEC One CFD is substantially equivalent to the cleared predicate device OEC One ASD (K240828) and therefore, is safe and effective for its intended use.