February 25, 2025

GE Medical Systems SCS
℅ Ning WEN
Regulatory Affairs Program Manager
283 Rue De La Miniere
BUC, 78530
FRANCE

Re: K243446
Trade/Device Name: 3DXR
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, QIH
Dated: November 6, 2024
Received: January 24, 2025

Dear Ning WEN:

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,

Lu Jiang

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.

Submission Number *(if known)*

K243446

Device Name

3DXR

Indications for Use *(Describe)*

3DXR is the AW application which is intended to perform the three-dimensional (3D) reconstruction computation of any images acquired with a 3D Acquisition mode of the X-ray interventional system for visualization under Volume Viewer.
The 3D Acquisition modes are intended for imaging vessels, bones and soft tissues as well as other internal body structures.
The 3D reconstructed Volume assist the physician in diagnosis, surgical planning, Interventional procedures and treatment follow-up.

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 of Safety and Effectiveness

K243446

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

Date:	January 24, 2025
Submitter:	GE Medical Systems SCS Establishment Registration Number - 9611343 283, rue de la Minière 78530 Buc, France
Primary Contact:	Ning WEN Regulatory Affairs Program Manager GE HealthCare, (GE Medical Systems SCS) Tel: +33 6 2324 6023 Email: ning.wen@gehealthcare.com
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Device Trade Name: Common/Usual Name: Regulation Number: Primary Product Code: Secondary Product Code: Regulatory Class:	**3DXR** **3DXR**, with **CleaRecon DL** option 21CFR 892.1650, Image-intensified fluoroscopic x-ray system OWB QIH Class II
Predicate Device: Device Name: Manufacturer: 510(k) number: Regulation Number: Product Code: Regulatory Class:	 3DXR GE Medical Systems SCS K181403 21CFR 892.1650, Image-intensified fluoroscopic x-ray system OWB Class II

Device Description and Marketed Devices:

3DXR is a post-processing software-only application, runs on Advantage Workstation (AW) platform [K110834], and performs 3D reconstruction for the CBCT 3D acquisition images (input) acquired from the fixed interventional X-ray system [K181403, K232344]. The reconstructed 3D volume (output) is visualized under Volume Viewer application [K041521].

The proposed **3DXR** is a modification from the predicate 3DXR [included and cleared in K181403]. A new option, called **CleaRecon DL**, based on Deep-Learning (DL) technology, is added in the proposed subject 3DXR application. This new CleaRecon DL option triggered this subject 510(k) submission.

The proposed **3DXR** with **CleaRecon DL** option addresses the same user needs as predicate 3DXR. The goal of CleaRecon DL option is to remove streak artifacts caused by the pulsatile nature of blood flow around contrasted objects such as contrast medium injected vessels and stent structures.

The primary features/functions of the proposed software are:

- 3D Reconstruction for the CBCT images.
- CleaRecon DL: powered by a Deep-Learning algorithm, ability to remove streak artifacts caused by the pulsatile nature of blood flow and appearing around contrasted objects such as contrast medium injected vessels and devices.
- 3DStent: ability to reconstruct coronary stent with the compensation of the respiratory and cardiac motion.
- Ability to read Imaging Purposes information on CBCT images (containing the acquisition system 3D preset information).
- Motion Freeze: ability to reduce the artifacts caused by involuntary respiratory motion.
- Metal Artifact Reduction (MAR): ability to reduce the artifacts induced by the presence of metallic devices.
- Active Tracker Detection: allowing to localize and record Active Tracker position for future automatic registration of reconstructed volume with Ultrasound images.
- Iodine Streaks Reduction: ability to reduce the streak artifacts induced by the high density of iodine.
- Scatter Reduction: ability to reduce the scatter-induced non-uniformities.
- Extended Range: allowing to increase the dynamic range of the 3D Volume.
- CT Format: labeling the reconstructed 3D Volume with CT format.
- Image Filters.
- 3D Volume Size selection.
- 3D Sub Volume selection.

Intended Use:

3DXR is the AW application which is intended to perform the three-dimensional (3D) reconstruction computation of any images acquired with a 3D Acquisition mode of the X-ray interventional system for visualization under Volume Viewer.

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The 3D Acquisition modes are intended for imaging vessels, bones and soft tissues as well as other internal body structures.

The 3D reconstructed Volume assist the physician in diagnosis, surgical planning, Interventional procedures and treatment follow-up.

Technology:

The proposed device 3DXR employs the same fundamental scientific technology as its predicate device 3DXR [K181403].

In addition, the proposed device 3DXR includes an option CleaRecon DL powered by a Deep-Learning (DL) Convolutional Neural Network (CNN) for removing streak artifacts. The CleaRecon DL algorithm was trained and qualified using pairs of images with and without streak artifacts.

Device Modification Overview:

The table below summarizes the substantive feature/technological differences and similarities between the predicate device and the proposed device:

Specification	**Predicate Device: 3DXR [K181403]**	**Proposed Device: 3DXR**
Indications for Use	Identical	Identical
Patient Population	No limitations on the patient population	Same, except for CleaRecon DL option which is validated for adult population only
3D Reconstruction	Yes	Yes
CleaRecon DL	No, streak artifacts reduction by Iodine Streaks Reduction only	Yes, streak artifacts removal powered by DL-based algorithm
3DStent	No, 3D reconstruction of moving object with the compensation of the respiratory motion	Yes, 3D reconstruction of coronary stent with the compensation of the respiratory and cardiac motion
Imaging Purposes	No, read multiple acquisition system DICOM tags to identify the clinical protocol	Yes, read acquisition system 3D preset in Imaging Purposes DICOM tag
Motion Freeze	Identical	Identical
Metal Artifact Reduction	Identical	Identical
Active Tracker Detection	Identical	Identical
Iodine Streaks Reduction	Identical	Identical
Scatter Reduction	Yes	Yes
Extended Range	Identical	Identical
CT Format	Identical	Identical
Image Filters	Yes	Yes
3D Volume Size selection	Identical	Identical
3D Sub Volume selection	Yes	Yes

Determination of Substantial Equivalence:

Summary of Non-Clinical, Design Control Testing

The proposed device, 3DXR, has successfully completed the required design control testing per GE HealthCare Quality Management System. No additional hazards were identified, and no unexpected test results were observed. The proposed device complies with NEMA PS 3.1 - 3.20 Digital Imaging and Communications in Medicine (DICOM) Set (Radiology) standard. It was designed and manufactured under the Quality System Regulations of 21CFR 820 and ISO 13485.

The following quality assurance measures were applied to the development of the device:

- Requirements Definition
- Risk Analysis
- Technical Design Reviews
- Formal Design Reviews
- Software Development Lifecycle
- Performance testing (Verification, Validation)
- System Testing (Verification, Validation)

The proposed 3DXR has been successfully verified on the AW VolumeShare workstation [K110834] platform. All of the testing and results did not raise new or different questions of safety and effectiveness other than those already associated with the predicate device.

The substantial equivalence determination is also based on the software documentation for a BASIC level.

Additional Non-Clinical Testing

Engineering bench testing was used to demonstrate the performances of the new CleaRecon DL algorithm's capabilities to remove streak artifacts from CBCT reconstructions.

Performance was first tested on a segregated test dataset of image pairs (with and without applying CleaRecon DL for streak artifact correction), independent from the dataset for training and tuning of CleaRecon DL algorithm. Mean Absolute Error (MAE) and Structural Similarity Index Measure (SSIM) were computed for two samples. Acceptance criteria were reduction of MAE and increase of SSIM. A statistically significant reduction in MAE and increase in SSIM were observed between the two samples. It was thus concluded that the CleaRecon DL option reduces streak artifacts on tested images.

Performance was then tested on phantoms. CBCT images acquisitions made with the fixed interventional X-ray system [K181403, K232344] were performed with simulated streak artifacts conditions and without (reference). MAE with respect to the reference and standard deviation (SD) were computed to quantify streak artifact reduction. Acceptance criteria were reduction of MAE and SD. The reduction of both MAE and SD was observed leading to the conclusion that CleaRecon DL reduces streak artifacts on phantoms.

The engineering bench testing passed the predefined acceptance criteria, demonstrated the CleaRecon DL performance to remove streak artifacts, and no degradation of image quality, nor other concerns related to safety and performance were observed.

Summary of Clinical Testing

A retrospective clinical image quality evaluation was conducted to demonstrate the performances of the new CleaRecon DL algorithm's capabilities to remove streak artifacts from CBCT reconstructions and to ensure final validation of CleaRecon DL derived outputs.

110 independent exams (each from a unique patient) coming from 13 clinical sites were used in this evaluation, including:

Brain/Head: 20 patients
Liver/Abdomen: 30 patients
Prostate/Pelvic: 20 male patients
Aorta/Stent-graft: 20 patients
Other anatomies: 20 patients

These exams were retrospectively collected from the CBCT acquisitions performed with the fixed interventional X-ray system [K181403, K232344] on adult patients (pediatrics excluded) undergoing interventional procedures. 80 patients came from the US, 26 patients came from France, 4 patients came from Japan. These exams were anonymized. There were no inclusion/exclusion criteria of age (within adult range) and sex/gender (except for prostate). These exams were independent and never used for the training and tuning of CleaRecon DL algorithm.

13 clinicians were recruited for this evaluation. Each of the 110 exams (with and without applying CleaRecon DL) was prepared so that the conventional reconstruction images and the images reconstructed with CleaRecon DL option were presented side by side on AW, with the same display conditions, and were compared / evaluated at least 3 times independently, resulting in 490 pairs of clinicians' evaluations.

For each image comparison, the physicians were asked (through 8 questions):

- to evaluate the impact of CleaRecon DL on CBCT image quality,
- to confirm that CleaRecon DL removes streaks artifacts and assess whether it brings other artifacts when compared to the conventional CBCT reconstruction.
- to assess if CleaRecon DL provides a clearer image and how it impacts their confidence in image interpretation.
- to assess if it brings artificial structures and/or hides important anatomical structures.

The evaluation results met the predefined acceptance criteria and substantiated the performance claims. In 98% of the cases, the CBCT images reconstructed with CleaRecon DL option are evaluated as clearer than the conventional CBCT images.

Within 489 reviews, clinicians did not identify any structure or pattern that has been hidden or artificially created by CleaRecon DL when compared to the original reconstruction.

Substantial Equivalence Conclusion

The changes to the predicate device 3DXR do not create new Intended Use nor Indication for Use. The proposed device 3DXR has identical or substantially equivalent technological characteristics as its predicate device.

GE HealthCare's quality system's design, verification, and risk management processes did not identify any new questions of safety or effectiveness, hazards, unexpected results, or adverse effects stemming from the changes to the predicate.

Based on the development under GE HealthCare's quality system, successful design verification and validation, software documentation for a "Basic" level, along with the engineering bench testing and the clinical evaluation by physicians demonstrate that the proposed 3DXR is substantially equivalent to, and hence as safe and as effective for its Intended Use as the legally marketed predicate device.