August 28, 2025

GE Hualun Medical Systems Co., Ltd
℅ Ma Kenny
Manager, Regulatory Affairs - WHXR
No.1, Yong Chang North Road, Beijing Economic Technological Development Zone
BEIJING, BEIJING 100176
CHINA

Re: K250788
Trade/Device Name: Definium Tempo Select
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: KPR, MQB
Dated: July 30, 2025
Received: July 30, 2025

Dear Ma Kenny:

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.

510(k) Number *(if known)*
K250788

Device Name

Definium Tempo Select

Indications for Use *(Describe)*

The Definium Tempo Select is intended to generate digital radiographic images of the skull, spinal column, chest, abdomen, extremities, and other body parts in patients of all ages. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position and the system is intended for use in all routine radiography exams. Optional image pasting function enables the operator to stitch sequentially acquired radiographs into a single image. The device is not intended for mammographic applications.

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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510K Summary

Definium Tempo Select

510(k) Summary:

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

Date:	August 27, 2025
Owner/Submitter: 21 CFR 807.92(a)(1)	GE Hualun Medical Systems Co., Ltd. No.1, Yong Chang North Road, Beijing Economic Technological Development Zone, 100176 Beijing P.R. China
Primary Contact Person:	Kenny Ma Manager, Regulatory Affairs, WHXR GE Hualun Medical Systems Co., Ltd. Email: Kenny.Ma@gehealthcare.com Contact Phone Number: +86 (181) 01130591
Secondary Contact Person:	Christopher Paulik Senior Regulatory Affairs Manager GE HealthCare (GE Medical Systems, LLC) Email: Christopher.A.Paulik@gehealthcare.com Contact Phone Number: +1 (262) 8945415
Device Trade Name: 21 CFR 801.92(a)(2)	Definium Tempo Select
510(k) Reference number	K250788
Common/Usual Name:	Digital Radiographic System
Regulation Name:	Stationary X-Ray System
Regulation:	21 CFR 892.1680
Classification:	Class II
Product Code:	KPR
Subsequent Product Code(s):	MQB
Predicate Device: 21 CFR 807.92(a)(3)	Discovery XR656 HD with VolumeRad (K191699) 21CFR 892.1680 (KPR, MQB) Class II
Predicate Device Manufacturer	GE Hualun Medical Systems Co., Ltd. No.1, Yong Chang North Road, Beijing Economic Technological Development Zone, 100176 Beijing P.R. China
Reference Device:	Definium Pace Select (K231892) 21CFR 892.1680 (KPR, MQB) Class II
Reference Device Manufacturer:	GE Hualun Medical Systems Co., Ltd. No.1, Yong Chang North Road, Beijing Economic Technological Development Zone, 100176 Beijing P.R. China

Device Description: 21 CFR 807.92(a)(4)	The Definium Tempo Select Radiography X-ray System is designed as a modular system with components that include an Overhead Tube Suspension (OTS) with a tube, an auto collimator and a depth camera, an elevating table, a motorized wall stand, a cabinet with X-ray high voltage generator, a wireless access point and wireless detectors in exam room and PC, monitor and control box with hand-switch in control room. The system generates diagnostic radiographic images which can be reviewed or managed locally and sent through a DICOM network for applications including reviewing, storage and printing. By leveraging platform components/ design, Definium Tempo Select is similar to the predicate device Discovery XR656 HD (K191699) and the reference device Definium Pace Select (K231892) with regards to the user interface layout, patient worklist refresh and selection, protocol selection, image acquisition, and image processing based on the raw image. This product introduces a new high voltage generator which has the same key specifications as the predicate. A wireless detector used in referenced product Definium Pace Select is introduced. Image Pasting is improved with individual exposure parameter adjustable on images on both Table and Wall Stand Mode. Tube auto angulation is added for better auto positioning based on current auto-positioning. Camera Workflow is introduced based on existing depth camera. OTS is changed with 4 axis motorizations. An update was made to the previously cleared Tissue Equalization feature under K013481 to introduce a Deep Learning AI model that provides more consistent image presentations to the user which reduces additional workflow to adjust the image display parameters. The other minor changes including PC change, Wall Stand change and Table change.

Indications for Use: 21 CFR 807.92(a)(5)	The Definium Tempo Select is intended to generate digital radiographic images of the skull, spinal column, chest, abdomen, extremities, and other body parts in patients of all ages. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position and the system is intended for use in all routine radiography exams. Optional image pasting function enables the operator to stitch sequentially acquired radiographs into a single image. This device is not intended for mammographic applications.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE: 21CFR807.92(a)(6)

A comparison of the indications for use and technological features of the subject and predicate device is provided in Table 1 below.

Table 1: High-level Comparison of Subject Device to Predicate

Specification	Predicate Device Discovery XR656 HD K191699	Proposed Device Definium Tempo Select K250788	Discussion of differences between Definium Tempo Select and Predicate
Intended Use	General Purpose Digital Radiographic Imaging System	General Purpose Digital Radiographic Imaging System	Identical
Indications for Use	The Discovery XR656 HD is intended to generate digital radiographic images of the skull, spinal column, chest, abdomen, extremities, and	The Definium Tempo Select is intended to generate digital radiographic images of the skull, spinal column, chest, abdomen,	Equivalent The VolumeRAD is removed from the proposed device.

Specification	Predicate Device Discovery XR656 HD K191699	Proposed Device Definium Tempo Select K250788	Discussion of differences between Definium Tempo Select and Predicate
	other body parts in patients of all ages. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position and the system is intended for use in all routine radiography exams. Optional image pasting function enables the operator to stitch sequentially acquired radiographs into a single image. The Discovery XR656 HD incorporates AutoGrid, which is an optional image processing software installed as a part of the systems Helix image processing software. AutoGrid can be used in lieu of an anti-scatter grid to improve image contrast in general radiographic images by reducing the effects of scatter radiation. When the VolumeRAD option is included on the system, the system can generate tomographic images of human anatomy including the skull, spinal column, chest, abdomen, extremities, and other body parts in patients of all ages. When the VolumeRAD option is used for patients undergoing thoracic imaging, it is indicated for the detection of lung nodules. VolumeRAD generates diagnostic images of the chest that aid the radiologist in achieving superior detectability of lung nodules versus posterior-anterior and left lateral views of the chest, at a comparable radiation level. The device is not intended for mammographic applications.	extremities, and other body parts in patients of all ages. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position and the system is intended for use in all routine radiography exams. Optional image pasting function enables the operator to stitch sequentially acquired radiographs into a single image. The device is not intended for mammographic applications.	
Contraindications	None known.	None known.	Identical
User group	Professional Use Only	Professional Use Only	Identical

Specification	Predicate Device Discovery XR656 HD K191699	Proposed Device Definium Tempo Select K250788	Discussion of differences between Definium Tempo Select and Predicate
Patient Population	All ages	All ages	Identical
System Software Architecture	Distributed software architecture (Atlas)	Distributed software architecture (Atlas)	Identical
Operator I/F	One-LCD monitor, Keyboard, Mouse, Barcode reader	One-LCD monitor, Keyboard, Mouse and Barcode reader	Identical
X-Ray Tube	MX 100	MX 100	Identical
Tube head console	6” LCD touch screen console	12” LCD touch screen console	Changed The same function for motion control and the UI changed with more exam information synced with main UI.
Collimator and Auto FOV	Automatic	Automatic	Identical
DAP	DAP software calculation based on FOV and SID measured by Encoder after Dose calibration	DAP software calculation based on FOV and SID measured by Encoder after Dose calibration	Identical
Camera Workflow	The depth Camera provides: 1. Live video on main UI	The same depth camera provides workflow improvement based on the predicate: 1. Patient size suggestion based on camera depth measurement. 2. Detector and ion chamber outline on video. 3. Patient Snapshot during exam. 4. FOV adjustable from video in Main UI.	New This new feature provides additional observation for patient positioning.
High Voltage Generator	- 50KW or 65KW or 80kW	- 50KW or 65KW or 80kW	Equivalent Same function, different supplier.
DICOM	DICOM 3.0	DICOM 3.0	Identical.
Cabinet	GCC-C4 cabinet as power unit for HV generator and system	GCC-C5 cabinet as power unit for HV generator and system	Equivalent. The GCC-C5 is changed to accommodate the generator.
Detector	FlashPad HD: 10 x 12 detector (K161942) 14 x 17 detector (K161966) 17 x 17 detector (K181526)	FlashPad Select: 17x17 detector (K210314)	Equivalent The proposed device only uses the listed equivalent 17 x 17 detector which is identical to the reference product Definium Pace Select cleared under K231892.

Specification	Predicate Device Discovery XR656 HD K191699	Proposed Device Definium Tempo Select K250788	Discussion of differences between Definium Tempo Select and Predicate
Detector size/ resolution	Three detector Size supported at 100 um resolutions: 17 x 17 inch 14 x 17 inch 10 x 12 inch	One detector Size supported at 100 um resolutions: 17 x 17 inch	Identical Removed 10 x 12 and 14 x 17 detectors.
Detector loading	300kg (distributed loading) 150kg (point loading)	300kg (distributed loading) 150kg (point loading)	Identical
Detector Wireless Connectivity	YES – 802.11 wireless (Personal Area Network)	YES – 802.11 wireless (Personal Area Network)	Identical
Patient Table	Elevating	Elevating	Equivalent The table provides same function with minor travel range and loading change
Wall stand	Motorized	Motorized	Equivalent Minor change on travel range
Overhead Tube Suspension (OTS)	5-axes motion controlled with Auto Positioning overhead tube support (OTS) from console position and local manual control	4-axes motion controlled with Auto Positioning overhead tube support (OTS) from console position and local manual control	Changed Motor and driver changed with minor specification change and the supplier changed
Image Pasting on Table and Wall Stand Mode	Image pasting can be performed at Wall stand mode and Table mode	Image pasting can be performed at Wall stand mode and Table mode. Individual mA adjustable for fixed mode and ion chamber is changeable in sub-image is provided	Changed The function of individual mA adjustable for fixed mode and ion chamber adjustable in sub-images is provided. The registration and image process algorithm are not changed.
Auto Grid Option	Yes Virtual grid function for DC (Digital Cassette) mode	Yes Virtual grid function in Table, WS (Wall stand) and DC (Digital Cassette) mode	Equivalent The Auto-Grid algorithm is the identical to the predicate device whilst only DC (Digital Cassette) mode is used. In the proposed device, we provided Table, WS and DC mode Auto Grid which algorithm is same with the predicate.
Auto tracking for Wall Stand	Auto-tracking between Wall stand and tube stand vertically (OTS tracking WS)	Auto-tracking between Wall stand and tube stand vertically (OTS tracking WS and WS tracking OTS)	Changed The tracking methods are same, just added mutual tracking feature.
Auto tracking for Table	Auto-tracking between Wall stand and tube stand vertically	Auto-tracking between Wall stand and tube stand vertically	Identical The tracking method is same.

Specification	Predicate Device Discovery XR656 HD K191699	Proposed Device Definium Tempo Select K250788	Discussion of differences between Definium Tempo Select and Predicate
Auto Positioning	Tube can be motorized to defined position via motorized 5 axis motion.	Tube can be motorized to defined position via motorized 4 axis motion. Tube can be automatically angulated according to the input on tube head console UI.	Equivalent Auto-position is simpler since the column rotation motorization is removed. The tube angulation is added, and it is a small feature since it is only the tube rotates around its center. But the auto positioning method is equivalent.
Tissue Equalization	The image processing algorithm provides pre-tuned and configurable thick and thin regions to improve contrast and visibility in over-penetrated and under-penetrated regions.	The image processing algorithm uses artificial intelligence to dynamically estimate thick and thin regions to improve contrast and visibility in over-penetrated and under-penetrated regions.	Changed The algorithm is the same but parameters per anatomy/view are determined by artificial intelligence to provide better consistence and easier user interface in the proposed device.

PERFORMANCE DATA: Determination of Substantial Equivalence 21 CFR807(b)(1)

Summary of Non-Clinical Tests:
The following quality assurance measures were applied to the development of Definium Tempo Select system:

1. Risk Analysis
2. Requirements Reviews
3. Design Reviews
4. Testing on unit level (Module verification)
5. Integration testing (System verification)
6. Performance testing (Verification)
7. Safety testing (Verification)
8. Simulated use testing (Validation)

The simulated use test (validation) involved various anatomies and patient sizes using anatomical phantoms (Chest, Abdomen, Spines, Extremities, etc.) encompassing different views and advanced applications (standard radiographic views of AP/PA/Lateral/Oblique as well as Image Pasting) for both Adult and Pediatric applications.

Definium Tempo Select verification and validation testing was performed to confirm that the safety and effectiveness of the device has not been affected. The test plans and results have been executed with acceptable results.

Summary of Clinical testing: 21 CFR 807.92(b)(2)

The AI Tissue Equalization algorithms verification dataset used clinical images retrospectively collected across various anatomies (Abdomen/ Ankle/ Calcaneus /Chest /Spine /Elbow /Femur /Finger/Foot /Hand /HIP /Knee /Leg /Patella /Pelvis /Shoulder/ Skull/ Wrist) and Patient Sizes (Adult Large/ Medium/ Small and Pediatric Large/ Medium/ Small) from locations in the US, Europe, and Asia. The verification tests confirmed that the algorithm meets the performance criteria, and the safety and efficacy of the device has not been affected.

CONCLUSION:

The results of the testing described above demonstrate that the Definium Tempo Select is as safe and effective as the predicate device and supports a determination of substantial equivalence.