October 1, 2024

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

Re: K242678
Trade/Device Name: Definium Pace Select ET
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: KPR, MQB
Dated: September 3, 2024
Received: September 6, 2024

Dear Kenny Ma:

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 Radiologic 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)*

K242678

Device Name

Definium Pace Select ET

Indications for Use *(Describe)*

The Definium Pace Select ET 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.

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.

510K Summary

Definium Pace Select ET

510(k) Summary:

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

Date:	September 6, 2024
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 Pace Select ET
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)	Definium Pace Select (K231892) 21CFR 892.1680 (KPR, MQB) Class 2
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:	Discovery XR656 HD with VolumeRad (K191699) 21CFR 892.1680 (KPR, MQB) Class 2
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 Pace Select ET Radiography X-ray System is designed as a modular system with components that include a 2-axis motorized tube stand with tube and auto collimator assembled on an elevating table, a motorized wall stand, a cabinet with X-ray high voltage generator, a wireless access point, wireless detectors, an acquisition workstation including a monitor and control box with hand-switch. The system generates diagnostic radiographic images which can be reviewed or managed locally and sent through a DICOM network for reviewing, storage and printing. By leveraging platform components / design, Definium Pace Select ET is similar to the predicate Definium Pace Select (K231892) and the reference Discovery XR656 HD (K191699) 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 motorized tube stand (vertical and tube angulation) instead of manual tube stand of the predicate. The high voltage generator is new and is backwards compatible to the predicates high voltage generator. This product also introduced Image Pasting on Table and Wall Stand Mode, Auto tracking for Wall Stand, Auto Angulation, Camera Workflow, DAP software calculation, Siemens LED collimator and LCD touch screen console. The other minor changes include updates to components due to obsolescence.

Indications for Use: 21 CFR 807.92(a)(5)	The Definium Pace Select ET 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 Definium Pace Select	Subject Device Definium Pace Select ET	Discussion of Differences
Intended Use	General Purpose Digital Radiographic Imaging System	General Purpose Digital Radiographic Imaging System	Identical
Indications for Use	The Definium Pace 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	The Definium Pace Select ET 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	Equivalent The optional image pasting function has been cleared in the reference product Discovery XR656 HD under K191699.

Specification	Predicate Device Definium Pace Select	Subject Device Definium Pace Select ET	Discussion of Differences
	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. The device is not intended for mammographic applications.	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 .	None .	Identical
User group	Professional Use Only	Professional Use Only	Identical
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, Barcode reader	Identical
X-Ray Tube	Kailong 300kHU Tube: KL H1080Y	Kailong 300kHU Tube: KL H1080Y	Identical
Tube head console	LED screen display	LCD touch screen console	Changed Besides the previous angle display. This console provides more positioner information and exposure parameter display and adjustment approach from the exam room.
Collimator and Auto FOV	Manual collimator Manual FOV change and light on/off	Siemens AL01CIIeL LED lamp Manual and automatic FOV change and light on/off	Changed The device now provides additional automatic collimation (Auto FOV).
DAP	Physical DAP meter	DAP software calculation based on FOV and SID measured by Encoder after Dose calibration	Changed The system now automatically calculates the DAP instead of providing a physical measurement.

Specification	Predicate Device Definium Pace Select	Subject Device Definium Pace Select ET	Discussion of Differences
Camera Workflow	None	The depth camera provides workflow improvement: 1. Live video on main UI 2. Patient size suggestion based on camera depth measurement; 3. Detector and ion chamber outline on video; 4. FOV adjustable from video	New This new feature provides additional observation for patient positioning.
High Voltage Generator	- Jedi 80 RD 1T - 50KW or 65KW or 80kW	- PSG-HR80S5 - 50KW or 65KW or 80kW	Equivalent Same function, different supplier
DICOM	DICOM 3.0	DICOM 3.0	Identical
OS	Linux OS - SUSE	Linux OS - SUSE	Identical
Detector	IRAY 17x17 detector US (K210314)	IRAY 17x17 detector US (K210314)	Identical
Detector Wireless Connectivity	YES – 802.11 wireless (Personal Area Network)	YES – 802.11 wireless (Personal Area Network)	Identical
Detector size/ resolution	One detector Size supported at 100 um resolutions: 17 x 17 inch	One detector Size supported at 100 um resolutions: 17 x 17 inch	Identical
Detector loading	300kg (distributed loading) 150kg (point loading)	300kg (distributed loading) 150kg (point loading)	Identical
Patient Table	Fixed table height 66cm 220 kg static non-elevating table Longitudinal travel 900mm Transversal travel 220mm	Elevating range 59 – 90 cm Maximum Loading 305kg (672lbs) Elevation speed< 18 seconds with loading 135kg(397lbs) Longitudinal travel 1110mm Transversal travel 220mm	Changed The table now provides motorized elevation with additional tabletop transverse and longitudinal travel range
Tube Support	Floor-mount tube support with longitudinal vertical and angulation manual motion	Floor-mount tube support with longitudinal vertical and angulation manual motion. Additional motorization of vertical and angulation are provided	Changed The vertical and angulation motions are now motorized
Tube to Table Tray Alignment	Alignment between tube stand and table tray is implemented by mechanical connection	Alignment between tube stand and table tray is implemented by automatic electrical control (also called auto alignment)	Equivalent Same function in tube and table tray alignment.
Wall stand	Minimum height from floor to center of panel: 50cm Maximum height from floor to center of panel 176cm	Minimum height from floor to center of panel: 28.5 cm Maximum height from floor to center of panel 180.5 cm	Changed Motorized vertical travel with a minor

Specification	Predicate Device Definium Pace Select	Subject Device Definium Pace Select ET	Discussion of Differences
	Vertical travel 126cm No motorization	Vertical travel: 152 cm. Vertical motorization is provided	change in travel ranges.
Image Pasting on Table and Wall Stand Mode	None	Image pasting can be performed at Wall stand mode and Table mode	New The image pasting function has been cleared in the reference product Discovery XR656 HD under K191699.
Auto Grid Option	Yes Virtual grid function in Table, WS and DC mode	Yes Virtual grid function in Table, WS and DC mode	Identical
Auto tracking for Wall Stand	None	Auto-tracking between Wall stand and tube stand vertically	New This feature is new to Predicate. But it is equivalent to the auto-tracking in the reference Discovery XR656 HD.
Auto Angulation	None	Yes Tube can be automatically angulated according to the input on tube head console UI.	New The tube angulation is now motion controlled.

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 Pace Select ET 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)

Definium Pace Select ET 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 Definium Pace Select ET does not contain clinical testing data.

CONCLUSION:

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