September 12, 2023

GE Hualun Medical Systems Co. Ltd.
℅ Miny Liu
Regulatory Affairs Leader
No. 1 Yong Chang North Road,
Beijing Economic Technological Development Zone
Beijing, Beijing 100176
CHINA

Re: K231892
Trade/Device Name: Definium Pace Select
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: KPR, MQB
Dated: June 5, 2023
Received: June 29, 2023

Dear Miny Liu:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231892

Device Name
Definium Pace Select

Indications for Use *(Describe)*
This product 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.
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.

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510(k) Summary

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

Date:	Jun. 26, 2023
Submitter:	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:	Miny Liu Regulatory Affairs Leader GE Hualun Medical Systems Co., Ltd. Contact Phone Number: +86 (173) 10313927 Email: liuminy@ge.com
Secondary Contact Person:	Christopher Paulik Senior Regulatory Affairs Manager GE HealthCare (GE Medical Systems, LLC) Contact Phone Number: +1 (262) 8945415 Email: christopher.a.paulik@ge.com
Device Trade Name:	Definium Pace Select
Common/Usual Name:	Digital Radiographic System
Regulation, Classification Names: Product Code:	Regulation: 21CFR 892.1680 Classification: Class II Regulation Name: Stationary X-Ray System Product Codes: KPR, MQB

Predicate Device(s):	Discovery XR656 HD clearance (K172869). Regulation: 21CFR 892.1680 Classification: Class II Regulation Name: Stationary X-Ray System Product Codes: KPR, MQB Legal Manufacturer Name: GE Hualun Medical Systems Co., Ltd.
Device Description:	The Definium Pace Select is a Digital Radiographic System designed as a modular system with components that includes fixed table with tube-stand, wallstand, cleared wireless digital detector, X-ray tube, collimator, high kV generator and acquisition workstation in control room. The system generates diagnostic radiographic images which can be sent through a DICOM network for applications including printing, viewing, and storage. The components may be grouped into different configurations to meet specific customer needs.
Intended Use:	General Purpose Digital Radiographic Imaging System
Indication for Use:	This product 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. This device is not intended for mammographic applications.

Technology:	The Definium Pace Select employs the same fundamental scientific technology as its predicate device Discovery XR656 HD. By leveraging platform components/design, it delivers a floor mounted DR system with incremental changes. Technically, Definium Pace Select is similar as Discovery XR656 HD from user operation, i.e., patient worklist access, image acquisition, image processing with same algorithm and image management with DICOM compliance. New image chain components are introduced, including a cleared wireless detector, tube and collimator. Traditional floor mounted positioner is used, that includes fixed table with tube Stand and wallstand. Definium Pace Select has equivalent feature from risk and safety level by comparation with Discovery XR656HD but removing advanced

	application Image pasting. These change from XR656 HD involves: • A cleared detector Mars1717X Wireless Digital Flat Panel Detector (cleared in K210314) is used. It has the same detector size 17"X17", pixel size 100um and same 802.11 wireless technology as the predicate • The tube support is changed. It uses traditional floor mounted tube support instead of Overhead Suspend tube support. The tube support and positioning is equivalent to the predicate. • The patient table is changed. The Definium Pace Select uses a traditional fixed non-elevating table. The patient support function is equivalent to the predicate. • A new X-ray tube is used. It has equivalent functionality with same kV range and slight differences in target angle and focal spot and HU capability • A new manual collimator is used. It has equivalent functionality with the predicate collimator. • Wall stand is changed. The manual Wall Stand function it provides is equivalent to the predicate. • The indication for use is the equivalent with its predicate product. The only difference is the removal of the "image pasting option" (removing an optional feature). No functionalities are added, and the intended use and patient population remains unchanged.
Determination of Substantial Equivalence:	<u>Summary of Non-Clinical Tests:</u> The Definium Pace Select and its applications comply with voluntary standards. • ES 60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance • IEC 60601-1-2:2014[Including AMD 1:2021], Edition 4.1

	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests • IEC 60601-1-3: 2021, Edition 2.2 Medical Electrical Equipment - Part 1-3: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Radiation Protection in Diagnostic X-Ray Equipment • IEC 60601-1-6: 2020, Edition 3.2 Medical electrical equipment - Part 1-6: General requirements for safety - Collateral Standard: Usability • IEC 60601-2-54: 2018, Edition 1.2 Medical Electrical Equipment - Part 2-54: Particular Requirements for The Basic Safety and Essential Performance of X-Ray Equipment for Radiography and Radioscopy • IEC 62366: 2015 + AMD1:2020 Medical devices Part 1: Application of usability engineering to medical devices, including Amendment 1 • ISO 10993-1: 2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process • ISO 10993-5: 2009/(R)2014 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity • ISO 10993-10: 2010/(R)2014 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization • ISO 10993-18 Second edition 2020-01

	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process • PS 3.1 - 3.20: 2022d Digital Imaging and Communications in Medicine (DICOM) set The following quality assurance measures were applied to the development of the system: ▪ Risk Analysis ▪ Requirements Reviews ▪ Design Reviews ▪ Testing on unit level (Module verification) ▪ Integration testing (System verification) ▪ Performance testing (Verification) ▪ Safety testing (Verification) ▪ Simulated use testing (Validation) The risks were evaluated for the newly introduced floor mounted positioners and image chain. These risks were reviewed and mitigated with design controls and labeling. The mitigations were verified and validated as a part of the design verification and validation testing that has been executed with acceptable results. The testing/ documentation we provided for the Definium Pace Select were according to the following FDA guidance documents: • Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices • Content of Premarket Submissions for Management of Cybersecurity in Medical Devices • Pediatric Information for X-ray Imaging Premarket Notifications <u>Summary of Clinical Tests:</u> The subject of this premarket submission, Definium Pace Select, does not require clinical studies to support substantial equivalence for the introduction of the floor mounted positioners and updates to the image chain. Design verification and validation testing was performed to confirm the safety and effectiveness of the device. The test plans and results have been executed with acceptable results.

Conclusion:	The Definium Pace Select use traditional floor mounted positioners and equivalent or same image chain components based on the predicate. This introduction of the Definium Pace Select system does not result in any new potential safety risks, it has the similar technological characteristics, and perform as well as the devices currently on the market. After analyzing design verification and validation testing on the bench it is the conclusion of GE HealthCare that the Definium Pace Select to be as safe, as effective, and performance is substantially equivalent to the predicate device.