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

July 24, 2019

Re: K191699
Trade/Device Name: Discovery XR656 HD with VolumeRad
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: KPR, MQB, IZF
Dated: June 21, 2019
Received: June 25, 2019

Dear Mr. Christopher Paulik:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191699

Device Name
Discovery XR656 HD with VolumeRad

Indications for Use *(Describe)*
The Discovery XR656 HD 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 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.

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 - K191699

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

Date:	June 21, 2019
Submitter:	GE Healthcare, (GE HUALUN MEDICAL SYSTEMS CO. Ltd) No.1 Yong Chang North Road, Beijing Economic Technological Development Zone BEIJING 100176 CHINA
Primary Contact Person:	Chris Paulik Regulatory Affairs Program Manager GE Healthcare 262-548-2010 Christopher.A.Paulik@ge.com
Secondary Contact Person:	Diane Uriell Regulatory Affairs Director GE Healthcare 262-290-8218 Diane.Uriell@ge.com
Device Trade Name:	Discovery XR656 HD with VolumeRad
Common/Usual Name:	Digital Radiographic X-Ray System
Classification Names: Product Code:	Regulation Name: Stationary X-Ray System Regulation: 21 CFR 892.1680 Classification: Class II Product Codes: KPR, MQB, IZF
Predicate Device #1:	Discovery XR656 With VolumeRad (Digital Tomosynthesis) (K132261) Regulation Name: Stationary X-Ray System Regulation: 21 CFR 892.1680 Classification: Class II Product Codes: KPR, MQB, IZF
Predicate Device #2:	Discovery XR656 HD (K172869) Regulation Name: Stationary X-Ray System Regulation: 21 CFR 892.1680 Classification: Class II Product Codes: KPR, MQB
Reference Devices:	Optima XR240amx with AutoGrid (K173602)

	Regulation Name: Mobile X-Ray System Regulation: 21 CFR 892.1720 Classification: Class II Product Codes: IZL MQB
Device Description:	The Discovery XR656 HD Radiography X-ray System is designed as a modular system with components that include an Overhead Tube Suspension with tube/collimator, wallstand, Table, X-ray generator, and cleared wireless digital detectors. The list of detectors verified and validated for use with the Discovery XR656 HD system, including their specifications, are provided in the user documentation. 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 combined in different configurations to meet specific customer needs. In addition, upgrade configurations are available for predicate devices. The optional image pasting function enables the operator to stitch sequentially acquired radiographs into a single image. This 510(k) is to incorporate the VolumeRad advanced application that was currently available on the Discovery XR656 product onto the Discovery XR656 HD, as well as introduce a new Metal Artifact Reduction Algorithm, and an optional standalone console to take any Helix™ acquired images via DICOM (such as from a Discovery XR656 HD, Optima XR646 HD, or Optima XR240amx) and process the images independently of the system it was acquired on.
Intended Use:	General Purpose Digital Radiographic Imaging System
Indications for Use:	The Discovery XR656 HD 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 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.
Technology:	The Discovery XR656 HD with VolumeRad employs the same fundamental scientific technology and software as its predicate devices. The intended use and patient populations are the same between Discovery XR656 HD with VolumeRad and the predicate devices. The indication for use has been updated to include the VolumeRad indications cleared under K132261, as well as the AutoGrid indications cleared under reference device Optima XR240amx with AutoGrid (K173602). The incorporation of the AutoGrid feature is due to the Optima XR240amx and the Discovery XR656 HD both incorporating the Helix™ image processing software, and AutoGrid is embedded within this software. The AutoGrid option is only available for Digital Cassette exposures (when the detector is not docked in the table or wallstand), and when a physical grid is required per the protocol database, but not detected as present. AutoGrid is not intended to be applied when a physical grid has been used to acquire an image. The Discovery XR656 HD with VolumeRad did not change the system software architecture, operator I/F, Tube, or generator. It does incorporate the same 6-axis Overhead Tube Suspension (OTS) and Overhead Bridge that enables the automatic positioning feature and image pasting technique. The differences being introduced are: 1. The incorporation of the VolumeRad feature previously available with the Discovery XR656 (K132261) into the Discovery XR656 HD product 2. An additional Metal Artifact Reduction algorithm for VolumeRad. 3. Helix™ Workstation. The VolumeRad feature allows digital tomographic images of the human body in patients either lying down or standing. Volume RAD involves a series of up to 60 very low dose projection images during a single sweep of the overhead tube assembly (OTS) with the detectors physically docked in the table or wallstand and the tube moving within a limited angular range (up to 40 degrees). The system automatically adjusts collimation throughout the sweep to maintain radiation in the imaging area selected during exam setup. After a VolumeRad acquisition, the system uses a filtered back projection (FBP) technique to reconstruct slices down to a minimum thickness of 1mm parallel to the receptor. The VolumeRad OTS sweep and image reconstruction algorithms are identical between the predicate and proposed products. The difference introduced was in the image acquisition due to the detector resolution change between the Discovery XR656 and the Discovery XR656 HD products. Also, the Discovery XR656 HD with VolumeRad provides an optional Metal Artifact Reduction algorithm to reduce the ripple and ghost artifacts created when metal is present within the anatomy where the images are acquired. The Helix™ Workstation incorporates the PC, Monitor, and software of the Discovery XR656 HD and can be used as a standalone console to take any Helix™ acquired images via DICOM (such as from a Discovery XR656 HD, Optima XR646

	HD, or Optima XR240amx) and process the images independently of the system it was acquired on. The images can then be sent via DICOM to a PACS or other image review station.
Determination of Substantial Equivalence:	<u>Summary of Non-Clinical Tests:</u> The Discovery XR656 HD and its applications comply with voluntary standards: • ES60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance ; • IEC 60601-1-2 Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility - Requirements and Tests ; • IEC 60601-1-3 Medical Elec. Equipment - P. 1: General Req. for Safety 3. Collateral Standard: General Req. for Radiation Protection in Diagnostic XRay Equipment ; • IEC 60601-1-6 Medical electrical equipment - Part 1-6: General requirements for safety - Collateral Standard: Usability ; • IEC 60601-2-54 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 Medical devices - Application of usability engineering to medical Devices ; • PS 3.1 - 3.20 Digital Imaging and Communications in Medicine (DICOM) set. (Radiology). The following quality assurance measures were applied to the development of the 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) New risks were identified for incorporating VolumeRad feature with the updated resolution detectors introduced with Discovery XR656 HD under K172869. These risks were reviewed and mitigated with design controls. 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 Discovery XR656 HD with VolumeRad were according to the following FDA guidance documents:

	• "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices" issued on September 14, 2018. • "Pediatric Information for X-ray Imaging Device Premarket Notifications" issued on November 18, 2017. • "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005. • "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" issued on October 2, 2014. • "Radio Frequency Wireless Technology in Medical Devices" issued on August 14, 2013. • "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices" issued on September 1, 2016. • "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions" issued on April 26, 2019. <u>Summary of Clinical Tests:</u> The subject of this premarket submission, Discovery XR656 HD with VolumeRad, did not require clinical studies to support substantial equivalence for the changes identified. The additional detector used to verify and validate the Discovery XR656 HD with VolumeRad was the Varex Imaging Corporation XRpad2 4343 HWC-M Flat Panel Detector cleared under K181526. The fundamental algorithm to create the VolumeRad image set is identical to the algorithm cleared under K132261, so it was determined that bench testing was sufficient to show the equivalence between the use of this feature on the Discovery XR656 HD with VolumeRad and the predicate Discovery XR656 products. The introduction of the Metal Artifact Reduction algorithm for the VolumeRad images was also evaluated, and it was determined that bench testing using anthropomorphic phantoms was sufficient to provide evidence that it can reduce the ripple and ghost metal artifacts for VolumeRad images acquired with the Discovery XR656 HD product. Design 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.
Conclusion:	The changes identified for the Discovery XR656 HD with VolumeRad do not result in any new potential safety risks, it has the same 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 Discovery XR656 HD with VolumeRad to be as safe, as effective, and performance is substantially equivalent to the predicate devices.