GE HUALUN MEDICAL SYSTEMS CO. Ltd.
% Kenny Ma
Regulatory Affairs Manager
No.1 YongChang North Road,
Economic Technological Development Zone
Beijing, 100176 Beijing
CHINA

October 20, 2017

Re: K172869
Trade/Device Name: Discovery XR656 HD
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR, MQB
Dated: September 14, 2017
Received: September 20, 2017

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 (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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K172869

Device Name
Discovery XR656 HD

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 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:	October 19, 2017
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:	Kenny Ma Regulatory Affairs Manager GE Healthcare, (GE HUALUN MEDICAL SYSTEMS CO. Ltd) Office: +86 18101130591 Email: Kenny.Ma@ge.com
Secondary Contact Person:	Chris Paulik Regulatory Affairs Manager GE Healthcare, (GE Medical Systems, LLC) +1 262-548-2010 Email: Christopher.A.Paulik@ge.com
Device Trade Name:	Discovery XR656 HD
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
Predicate Device:	Optima XR646 (K143270) Regulation Name: Stationary X-Ray System Regulation: 21 CFR 892.1680 Classification: Class II Product Codes: KPR, MQB

Reference Devices:	1) PerkinElmer XRpad2 3025 HWC-M Flat Panel Detector (K161942) Regulation Name: Stationary X-Ray System Regulation: 21 CFR 892.1680 Classification: Class II Product Codes: MQB 2) PerkinElmer XRpad2 4336 HWC-M Flat Panel Detector (K161966) Regulation Name: Stationary X-Ray System Regulation: 21 CFR 892.1680 Classification: Class II Product Codes: MQB 3) 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
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 wireless digital detectors. 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.
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 device is not intended for mammographic applications.
Technology:	The Discovery XR656 HD employs the same fundamental scientific technology as its predicate device. The intended use and patient populations are the same between Discovery XR656 HD and predicate device. The indication for use is the same except that

	Discovery XR656 HD does not include the Dual Energy advanced application that is provided with the predicate device. The Discovery XR656 HD did not change 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 from the referenced Discovery XR656 (K132261), but does not include the VolumeRad indication from this referenced device. The difference being introduced with the Discovery XR656 HD is that exposures can be captured with cleared detectors of multiple sizes. These cleared detectors utilize WiFi (802.11) instead of Ultra Wideband (UWB) technology to transfer the image to the system. To accommodate the cleared wireless detectors, the Discovery XR656 HD changed the following from the predicate device:
	• Wireless communication hardware for detector communication was changed from UWB to WiFi (802.11)
	• Elevating Table and Wallstand Detector Housing geometry and its associated detector charging hardware and firmware to accommodate the 17 inch x 14 inch cleared wireless detectors
	• System software to accomplish the following:
	  ○ WiFi (802.11) association and pairing with the cleared wireless detectors
	  ○ Synchronizing the image acquisition and image retrieval from the cleared wireless detectors
	  ○ Image processing algorithms to accommodate multiple image matrix sizes
	• User interface updates for image acquisition to incorporate the cleared wireless detectors into the user workflow

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 wireless image transfer between the cleared wireless detector and the base system. 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 device Discovery XR656 HD 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 <u>Summary of Clinical Tests:</u> The subject of this premarket submission, Discovery XR656 HD, did not require clinical studies to support substantial equivalence for the incorporation WiFi (802.11) enabled detectors due to these detectors having their own 510(k) clearance. The detectors used to verify and validate the Discovery XR656 HD were the PerkinElmer, Inc. XRpad2 3025 HWC-M Flat Panel Detector cleared under K161942 and the PerkinElmer, Inc. XRpad2 4336 HWC-M Flat Panel Detector cleared under K161966. 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 Discovery XR656 HD device incorporates cleared radiographic detectors to capture radiographic images and utilizes a tether or wireless technology to transfer the images to the base system. This update to this system does 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 to be as safe, as effective, and performance is substantially equivalent to the predicate devices.