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

December 11, 2017

Re: K173612
Trade/Device Name: Optima XR646 HD
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR, MQB
Dated: November 22, 2017
Received: November 22, 2017

Dear Mr. 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

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)*

K173612

Device Name
Optima XR646 HD

Indications for Use *(Describe)*

The Optima XR646 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 prepared:	November 16, 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:	Christopher Paulik Regulatory Affairs Manager GE Healthcare, (GE Medical Systems, LLC) +1 262 548 2010 Email: Christopher.A.Paulik@ge.com
Device Trade Name:	Optima XR646 HD
Common/Usual Name:	Digital Radiographic X-Ray System
Classification Names: Product Code:	Regulation Name: Stationary X-Ray System Regulation: 21CFR 892.1680 Classification: Class II Product Codes: KPR, MQB
Predicate Device:	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 XR646 (K143270) Regulation Name: Stationary X-Ray System Regulation: 21 CFR 892.1680 Classification: Class II Product Codes: KPR, MQB

Device Description:	The Optima XR646 HD is designed to be a lower cost version of the predicate device, the Discovery XR656 HD (K172869). Like the Discovery XR656 HD, the Optima XR646 HD is a radiographic X-ray system capable of generating radiographic images of human anatomy. The Optima XR646 HD is designed to support radiographic applications using previously cleared flat panel wireless digital detectors. The system generates digital images for general radiography by means of its X-Ray image chain. The resulting digital image can be sent through a DICOM network for applications such as printing, viewing and storage.
Intended Use:	General Purpose Digital Radiographic Imaging System
Indication for Use:	The Optima XR646 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 Optima XR646 HD employs the same fundamental scientific technology as its predicate device. The intended use and indications for use are the same between Optima XR646 HD and predicate device. A majority of the Optima XR64 HD hardware is identical to that of the predicate Discovery XR656 HD system. The primary difference is a change from five axis motorized motion to one axis motorized motion in the Overhead Tube Suspension (OTS). The removal of these axes of motion requires the systems image pasting feature to acquire images in a parallel sequence identical to the referenced Optima XR646 (K143270) instead of rotating the x-ray tube like the predicate.

Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: The Optima XR646 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 the modified OTS into the product. 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 Optima XR646 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 Summary of Clinical Tests: The subject of this premarket submission, Optima XR646 HD, does not require clinical studies to support substantial equivalence for the incorporation of a simplified OTS. The image pasting technique utilizing parallel image acquisition is currently incorporated in the Optima XR646 x-ray system cleared under K143270. 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 were executed with acceptable results.
Conclusion:	The Optima XR646 HD device incorporates a simplified OTS used to position the x-ray source within the x-ray system. The changes in the Optima XR646 HD do not result in any new potential safety risks, the product has the same technological characteristics, and performs as well as other devices currently on the market. After analyzing design verification and validation testing on the bench it is the conclusion of GE Healthcare that the Optima XR646 HD is safe and effective, and its performance is substantially equivalent to the predicate devices.