GE Medical Systems, LLC
% Mr. Chris Paulik
Regulatory Affairs Program Manager
3000 N. Grandview Blvd.
WAUKESHAWI 53188

January 12, 2018

Re: K173602
Trade/Device Name: Optima XR240amx with AutoGrid
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL, MQB
Dated: November 20, 2017
Received: November 21, 2017

Dear Mr. 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. 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

Section 4: Indications for Use (FORM FDA 3881)

Optima XR240amx with AutoGrid

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)*

K173602

Device Name
Optima XR240amx with AutoGrid

Indications for Use *(Describe)*

The Optima XR240amx is intended to take exposures utilizing film, computed radiography (CR), or wireless detectors, which are intended to replace radiographic film screen systems in all general purpose diagnostic procedures, for digital radiography (DR).

Optima XR240amx is a self-contained; battery operated mobile radiographic imaging system designed to generate diagnostic radiographic images (medical x-rays) that may increase the ability to detect disease or injury early enough for a medical problem to be managed, treated, or cured. Medical x-rays are used in many types of examinations and procedures, some examples include: x-ray radiography (to find orthopedic damage, tumors, pneumonias, foreign objects).
The Optima XR240amx is indicated for use on adult and pediatric patients for general-purpose diagnostic radiographic examinations and procedures. Its mobility enables general-purpose radiographic procedures throughout the clinical environment, or as needed within the emergency, intensive care, premature birth ward, cardiac and operating departments, for patients that may not be able to be moved or in cases where it is unsafe or impractical to move them to a traditional RAD room.

The system is indicated for taking radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts with the patient sitting, standing, or lying in the prone or supine position.

This device is not intended for mammographic applications.

The Optima XR240amx 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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

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

Date Submitted:	November 20, 2017
Submitter:	GE Medical Systems, LLC 3000 N. Grandview Blvd Waukesha, WI 53188, USA
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:	Optima XR240amx with AutoGrid
Common/Usual Name:	Mobile X-ray system
Regulation, Classification, and Product Code:	Regulation Name: Mobile X-Ray System Regulation: 21 CFR 892.1720 Classification: Class II Product Codes: IZL, MQB

Predicate Device(s):	Optima XR240amx (K162990) Regulation Name: Mobile X-Ray System Regulation: 21 CFR 892.1720 Classification: Class II Product Codes: IZL, MQB
Device Description:	The Optima XR240amx with AutoGrid is intended to take exposures, using a wired or remote exposure switch, utilizing film, computed radiography (CR), or cleared wireless radiographic detectors, which are intended to replace radiographic film screen systems in all general purpose diagnostic procedures, for digital radiography (DR). Optima XR240amx with AutoGrid is a self-contained; battery operated mobile radiographic imaging system designed to generate diagnostic radiographic images (medical x-rays) that may increase the ability to detect disease or injury early enough for a medical problem to be managed, treated, or cured. Medical x-rays are used in many types of examinations and procedures, some examples include: x-ray radiography (to find orthopedic damage, tumors, pneumonias, foreign objects). The Optima XR240amx with AutoGrid system is indicated for use on adult and pediatric patients for general-purpose diagnostic radiographic examinations and procedures. Its mobility enables general-purpose radiographic procedures throughout the clinical environment, or as needed within the emergency, intensive care, premature birth ward, cardiac and operating departments, for patients that may not be able to be moved or in cases where it is unsafe or impractical to move them to a traditional RAD room. The incorporation of AutoGrid software into the Helix Image Processing software on the Optima XR240amx allows the user to improve the image contrast in general radiographic images by reducing the effects of scatter radiation in lieu of incorporating a physical anti-scatter grid onto the cleared wireless detectors. The system is indicated for taking radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts with the patient sitting, standing, or lying in the prone or supine position. This device is not intended for mammographic applications.
Intended Use:	The Optima XR240amx is intended to take exposures utilizing film, computed radiography (CR), or wireless detectors, which are intended to replace radiographic film screen systems in all general purpose diagnostic procedures, for digital radiography (DR).

	Optima XR240amx is a self-contained; battery operated mobile radiographic imaging system designed to generate diagnostic radiographic images (medical x-rays) that may increase the ability to detect disease or injury early enough for a medical problem to be managed, treated, or cured. Medical x-rays are used in many types of examinations and procedures, some examples include: x-ray radiography (to find orthopedic damage, tumors, pneumonias, foreign objects). The Optima XR240amx is indicated for use on adult and pediatric patients for general-purpose diagnostic radiographic examinations and procedures. Its mobility enables general-purpose radiographic procedures throughout the clinical environment, or as needed within the emergency, intensive care, premature birth ward, cardiac and operating departments, for patients that may not be able to be moved or in cases where it is unsafe or impractical to move them to a traditional RAD room. The system is indicated for taking radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts with the patient sitting, standing, or lying in the prone or supine position. This device is not intended for mammographic applications. The Optima XR240amx 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.
Technology:	The Optima XR240amx with AutoGrid employs the same fundamental scientific technology as the predicate device. They are both battery operated mobile x-ray systems that capture exposures utilizing film, CR plates, or a wireless detector. The intended use is the same between the Optima XR240amx with AutoGrid and the predicate device. The Optima XR240amx with AutoGrid did not change the input power, battery subsystem, drive subsystem, x-ray generation, and exposure control from the predicate devices. The difference being introduced is a modification to the Helix image processing software to incorporate an optional image processing software called AutoGrid. AutoGrid can be used in lieu of a physical anti-scatter grid attached to the cleared wireless detectors to improve image contrast in general radiographic images by reducing the effects of scatter radiation. The use of the AutoGrid software can improve user workflow since there is no need to physically incorporate an anti-scatter grid into the image chain. Its use can also alleviate issues caused by the incorrect Source to Image Distance (SID) setup with physical anti-scatter grids, since the AutoGrid software does not require a specific SID to function.

	The AutoGrid software reduces the effect of scatter radiation on the image by estimating the scatter radiation within the image, and then subtracting this scatter estimate from the image. The AutoGrid software can be configured at three global strength options (Low, Medium, and High). The strength indicates the amount of scatter reduction that will occur during image processing. The Low strength corresponds to the amount of scatter reduction that would occur through using a physical 6:1 ratio grid, Medium a physical 8:1 ratio grid, and High a physical 12:1 ratio grid. The AutoGrid software can be used in any application where a physical grid was originally indicated, including both adult and pediatric imaging techniques or protocols. The AutoGrid software is an optional feature that cannot be used in conjunction with a physical grid.
Determination of Substantial Equivalence:	<u>Summary of Non-Clinical Tests:</u> The modification to the Optima XR240amx to include AutoGrid and its applications comply with voluntary standards: • ES60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance ; • IEC 60601-1-3 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: ▪ 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) New risks were identified for incorporating the AutoGrid software into the Helix Image Processing software of the Optima XR240amx. 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. <u>Summary of Clinical Tests:</u> The subject of this premarket submission, Optima XR240amx with AutoGrid, did not require clinical studies to support substantial equivalence of using the AutoGrid software in lieu of a physical anti-scatter grid. Bench testing was sufficient to demonstrate that the AutoGrid software can achieve image contrast equivalent to that of a physical anti-scatter grid. The results of the bench testing are provided in the submission. 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 AutoGrid software that is incorporated into the Helix Image Processing software of the Optima XR240amx can be used in lieu of a physical anti-scatter grid attached to the cleared wireless detectors to improve image contrast in general radiographic images by reducing the effects of scatter radiation. 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 Optima XR240amx with AutoGrid to be as safe, as effective, and performance is substantially equivalent to the predicate devices.