DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 15, 2016

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

Re: K162990
Trade/Device Name: Optima XR240amx
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL, MQB
Dated: October 26, 2016
Received: October 27, 2016

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.

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 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 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 yours,

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

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)*

K162990

Device Name
Optima XR240amx

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.

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.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

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

Date:	October 26, 2016
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
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 XR200amx and Optima XR220amx (K142383) Regulation Name: Mobile X-Ray System Regulation: 21 CFR 892.1720 Classification: Class II Product Codes: IZL, MQB

Device Description:	The Optima XR240amx 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 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 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 cleared flat panel detectors provides increased functionality to enable images of patients of all sizes, and can produce comparable quality images with as little as half the dose of traditional computer radiography (CR), cassettes and other flat panel detectors with lower DQE. The systems are 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. These devices are 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.

Technology:	The Optima XR240amx employs the same fundamental scientific technology as the predicate devices. They are both battery operated mobile x-ray systems that capture exposures utilizing film, CR plates, or a wireless detector. The intended use and the indications for use are the same between the Optima XR240amx and the predicate devices. The Optima XR240amx did not change the input power, battery subsystem, drive subsystem, x-ray generation, and exposure control from the predicate devices. The difference being introduced with the Optima XR240amx 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 base system. To accommodate the cleared wireless detectors, the Optima XR240amx changed the following from the predicate devices:
	
	• Wireless communication hardware for detector communication was changed from UWB to WiFi (802.11)
	
	• Detector storage bin geometry and its associated detector charging hardware and firmware to accommodate multiple sized cleared wireless detectors (17 inch x 14 inch; 10 inch x 12 inch)
	
	• 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:	Summary of Non-Clinical Tests: The Optima XR240amx and its applications comply with voluntary standards. 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 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. Summary of Clinical Tests: The subject of this premarket submission, Optima XR240amx, 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 Optima XR240amx 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 Optima XR240amx 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 Optima XR240amx to be as safe, as effective, and performance is substantially equivalent to the predicate devices.