DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 25, 2014

GE Medical Systems, LLC
% Mr. Christopher Paulik
Regulatory Affairs Leader
3000 N. Grandview Blvd.
WAUKESHA WI 53188

Re: K142383
Trade/Device Name: Optima XR200amx, Optima XR220amx
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL
Dated: August 22, 2014
Received: August 26, 2014

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

Janine M. Morris
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)*

K142383

Device Name
Optima XR200amx and Optima XR220amx

Indications for Use *(Describe)*

The Optima XR200amx and Optima XR220amx are intended to take exposures utilizing film or computed radiography (CR), however the Optima XR220amx utilizes the GE Wireless Detector, which is intended to replace radiographic film screen systems in all general purpose diagnostic procedures, for digital radiography (DR).

Optima XR200amx and Optima XR220amx are self-contained; battery operated mobile radiographic imaging systems 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 XR200amx and Optima XR220amx are 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 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.

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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Attachment A:
Section 5 – 510(k) Summary

Document Name	Document Number	Page Number
Section 5 – 510(k) Summary	N/A	5 Pages

Section 5: 510(k) Summary

Optima XR200amx and Optima XR220amx

510(k) Summary

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

Date:	August 22, 2014
Submitter:	GE Medical Systems, LLC 3000 N. Grandview Blvd Waukesha, WI 53188, USA
Primary Contact Person:	Chris Paulik Regulatory Affairs Leader GE Healthcare 262-548-2010 Christopher.Paulik@med.ge.com
Secondary Contact Person:	John L. Schmidt Regulatory Affairs Manager GE Healthcare 262-548-4964 John.L.Schmidt@med.ge.com
Device Trade Name:	Optima XR200amx and Optima XR220amx
Common/Usual Name:	Optima XR200amx and Optima XR220amx
Classification Names: Product Code:	Class II, System, X-ray, Mobile, 21 CFR 892.1720 IZL
Predicate Device(s):	Brivo XR285amx, Optima XR200amx, and Optima XR220amx K103476
Device Description:	The Optima XR200amx and Optima XR220amx are intended to take exposures, using a wired or remote exposure switch, utilizing film or computed radiography (CR), however the Optima XR220amx utilizes the GE Wireless Detector, which is intended to replace radiographic film screen systems in all general purpose diagnostic procedures, for digital radiography (DR). Optima XR200amx and Optima XR220amx are self-contained; battery

	operated mobile radiographic imaging systems 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 XR200amx and Optima XR220amx systems are 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 flat panel detector 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 digital detector is designed to withstand a distributed load of 352Lbs to accommodate certain larger patients. 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 XR200amx and Optima XR220amx are intended to take exposures utilizing film or computed radiography (CR), however the Optima XR220amx utilizes the GE Wireless Detector, which is intended to replace radiographic film screen systems in all general purpose diagnostic procedures, for digital radiography (DR). Optima XR200amx and Optima XR220amx are self-contained; battery operated mobile radiographic imaging systems 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 series are 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 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.
Technology:	The Optima XR200amx and Optima XR220amx employ the same fundamental scientific technology as the predicate devices. The only difference is that exposures can now be initiated using either a wired or remote exposure switch.
Determination of Substantial Equivalence:	<u>Summary of Non-Clinical Tests:</u> The Optima XR200amx and Optima XR220amx and their 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 risk were identified for potential user error or misuse attributed with the addition of the remote hand switch. 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 XR200amx and Optima XR220amx, did not require clinical studies to support substantial equivalence for the option of initiating x-ray exposures with the use of the remote exposure switch. Design verification and validation testing was performed to confirm that the safety and effectiveness of the devices has not been affected. The test plans and results have been executed with acceptable results.
Conclusion:	The Optima XR200amx and Optima XR220amx devices incorporate a wired as well as a remote hand switch for the user to initiate x-ray exposures. The addition of the optional wireless hand switch to these systems do not result in any new potential safety risks, they have 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 XR200amx and Optima XR220amx to be as safe, as effective, and performance is substantially equivalent to the predicate devices.