JUL 19 2011

GE Healthcare
510(k) Premarket Notification Submission
Optima XR120

510(k) Summary

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

Date:	May 6, 2011
Submitter:	GE Healthcare, (GE Medical Systems, LLC) 3000 N. Grandview Blvd. Waukesha, WI 53188
Primary Contact Person:	Nidhi Chaudhary Regulatory Affairs Leader, X-Ray GE Healthcare, (GE Medical Systems, LLC) Telephone: 414-721-2899; Fax: 414-918-8184 e-mail: Nidhi.Chaudhary@ge.com
Secondary Contact Person:	David Blonski Regulatory Affairs Director, X-Ray GE Healthcare, (GE Medical Systems, LLC) Telephone: 262-513-4072; Fax: 262-364-2509 e-mail: David.Blonski@ge.com
Device: Trade Name:	GE Healthcare Optima™ XR120
Common/Usual Name:	Optima XR120
Classification Names:	Optima XR120
Product Code:	Class II, IZL, System, X-ray, Mobile, 21 CFR 892.1720
Predicate Device(s):	GE Definium AMX700, Model AMX 700 K052897
Intended Use:	The Optima XR120 is indicated for use in generating radiographic images of human anatomy. It is intended for general-purpose diagnostic procedures. It is capable of generating images on film or digitally. This device is not intended for mammographic applications.

Technology: The GE Healthcare Optima™ XR120 employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence: The Optima XR120 and its applications comply with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. 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)

Summary of Clinical Tests:

The subject of this premarket submission, Optima XR120, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the GE Healthcare Optima™ XR120 to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

Ms. Nidhi Chaudhary
Regulatory Affairs Leader, X-ray
GE Medical Systems, LLC
3000 N. Grandview Blvd.
WAUKESHA WI 53188

JUL 19 2011

Re: K111304
Trade/Device Name: Optima XR120
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IXL and MQB
Dated: May 7, 2011
Received: May 9, 2011

Dear Ms. Chaudhary:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

GE Healthcare
510(k) Premarket Notification Submission
Optima XR120

510(k) Number (if known): K111304

Device Name: Optima XR120

Indications for Use:

The Optima XR120 is indicated for use in generating radiographic images of human anatomy. It is intended for general-purpose diagnostic procedures. It is capable of generating images on film or digitally. This device is not intended for mammographic applications.

Prescription Use_X___ AND/OR Over-The-Counter Use_ _
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K111304