K062623

510(k) Summary
For
AXIOM Luminos dRF

AUG 2 2 2007

Submitted by:
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

August 25, 2006

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

1. **Contact Person**

Mr. Gary Johnson
Technical Specialist, Regulatory Affairs, Submissions
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2. **Device Name and Classification**

Trade Name:	AXIOM Luminos dRF
Classification Name:	Image intensified fluoroscopic X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR § 892.1650
Device Class:	Class II
Device Code:	OWB, JAA, OXO

3. **Intended Use**

The AXIOM Luminos dRF is intended to be used as a universal diagnostic imaging system for radiographic and fluoroscopic studies. Using a digital flat detector, it can perform a range of applications including general R/F, angiography and pediatric examinations.

The AXIOM Iconos dRF is a device intended to visualize anatomical structures by converting a pattern of X-ray into a visible image. The system has medical applications ranging from but not limited to gastrointestinal examinations, cranial, skeletal, thoracic and lung exposures as well as examination of the urogenital tract. The units may also be used in lymphography, endoscopy, myelography, venography, pediatrics, arthrography, interventional radiology, digital angiography and digital subtraction angiography (DSA).

AXIOM Luminos dRF may be used for outpatient and emergency treatment, as well as for mobile transport (wheelchair and bed) examinations.

4. Substantial Equivalence

The AXIOM Luminos dRF with Flat Detector is substantially equivalent to the commercially available Siemens system, the URF Digital OT.
The URF Digital OT, marketed as AXIOM Iconos was described in premarket notification K992660 which received FDA Clearance on November 5, 1999.

The Flat Detector Pixium 5100 equipped with AXIOM Luminos dRF is an improved detector and substantial equivalent to the Pixium 4600 used with AXIOM Aristos FX Plus and substantial equivalent to the Pixium 4800 used with AXIOM Artis modular Angiography system. The AXIOM Aristos FX Plus was described in premarket notification K061054 which received FDA Clearance on May 09, 2006.
The AXIOM Artis Modular Angiography system was described in premarket notification K021021 which received FDA Clearance on June 06, 2002.

5. Device Description

AXIOM Luminos dRF is a universal fluoroscopic x-ray diagnostic system (R/F system), with an overtable X-ray tube assembly. This system is a modified and upgraded version of the URF Digital OT, which now is equipped with a Flat detector instead of an image intensifier.

AXIOM Luminos dRF can be configured as a single tube system, with only an overtable tube or it can be combined with an additional 3D overhead tube crane, that can be moved longitudinally and laterally as well as vertically and a bucky wall stand.
For processing the digital images from the Digital Imaging System the AXIOM Luminos dRF is equipped with the Fluorospot COMPACT digital imaging system.

6. Summary of Technological Characteristics of the Principal Device as Compared with the Predicate Device

AXIOM Luminos dRF is not a stand-alone device, but functions as the platform for specific X-ray components, X-ray tube and housing, flat detector, digital imaging system, Bucky wall stand, collimator, generator etc.
Many of the components used in AXIOM Luminos dRF are either commercially available with current Siemens systems or include minor modifications to existing components.

7. General Safety and Effectiveness Concerns

Instructions for use are included within the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner. Several safety features including visual and audible warnings are incorporated into the system design. In addition the AXIOM Luminos dRF is continually monitored, and if an error occurs, the system functions will be blocked and an error message will be displayed.

Furthermore the operators are health care professionals familiar with, and responsible for, the X-ray examinations to be performed. To minimize electrical, mechanical and radiation hazards, Siemens adheres to recognized and established industry practice, and all equipment is subject to final performance testing.

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

Mr. Gary Johnson
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MALVERN PA 19355

JUL 30 2012

Re: K062623
Trade/Device Name: AXIOM Luminos dRF
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, JAA and OXO
Dated: July 10, 2007
Received: July 24, 2007

Dear Mr. Johnson

This letter corrects our substantially equivalent letter of August 22, 2007.

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,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

SECTION 3

INDICATIONS FOR USE

510(k) Number (if known): K062623

Device Name: AXIOM Luminos dRF

Indications for Use:

The AXIOM Luminos dRF is intended to be used as a universal diagnostic imaging system for radiographic and fluoroscopic studies. Using a digital flat detector, it can perform a range of applications including general R/F, angiography and pediatric examinations.

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Concurrence of the CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K062623

Prescription Use X OR Over-The-Counter Use _____

(per 21 CFR 801.109)