JUL 7 - 2005

K051602

510(k) Summary
For
AXIOM Sireskop SD

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

June 13, 2005

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
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Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway E-50
Malvern, PA 19355
Phone: (610) 448 1778 Fax: (610) 448-1787

2. Device Name and Classification

Trade Name:	AXIOM Sireskop SD
Classification Name:	Image intensified fluoroscopic X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR § 892.1650
Device Class:	Class II
Device Code:	MQB

3. Intended Use

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

AXIOM Sireskop SD is applicable for emergency treatment on an outpatient basis, as well as for bedside examinations.

4. **Substantial Equivalence**

The AXIOM Sireskop SD with Mobile Flat Detector is substantially equivalent to the commercially available Siemens systems, the AXIOM Sireskop SD (Sireskop SX), and the AXIOM ICONOS R200 (URF Digital OT). The Sireskop SX, marketed as AXIOM Sireskop SD was described in premarket notification K951358 which received FDA Clearance on May 15, 1995. The URF Digital OT, marketed as AXIOM ICONOS R200 was described in premarket notification K992660 and received FDA clearance on April 21, 1997.

5. **Device Description**

AXIOM Sireskop SD is a floor-mounted universal fluoroscopic x-ray diagnostic system (R/F system), that was developed for tableside examinations in combination with an explorator. The explorator holds an image intensifier and the CCD camera.

AXIOM Sireskop SD can be configured as a single tube system, with only an undertable tube or a dual tube system which contains an additional 3D overhead tube crane, that can be moved longitudinally and laterally as well as vertically. The dual x-ray tubes allow a quick change between undertable and overtable exposure modes. The undertable tube is used for fluoroscopy and radiographic exposures taken with the Digital Imaging System. The overtable tube is suspended from an overhead tube support for exposures with a table bucky or bucky wall stand, either with film cassettes or a mobile Flat Detector. For processing the digital images from the Digital Imaging System or digital mobile Flat Detector, the AXIOM Sireskop SD 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 Sireskop SD is not a stand-alone device, but functions as the platform for specific X-ray components (image intensifier, X-ray tube and housing, explorator, mobile flat detector, digital imaging system, Bucky cassette holder, Bucky detector holder, Bucky wall stand, collimator, generator etc.) and television camera systems (Videomed DH/ DHC) to create a flexible universal fluoroscopic X-ray system (R/F system)

Many of the components used in AXIOM Sireskop SD 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 Sireskop SD 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

AUG 20 2013

Mr. Gary Johnson
Technical Specialist, Regulatory Affairs, Submissions
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway, E-50
MALVERN PA 19355

Re: K051602
Trade/Device Name: AXIOM Sireskop SD
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: JAA
Dated: June 13, 2005
Received: June 16, 2005

Dear Mr. Johnson:

This letter corrects our substantially equivalent letter of June 7, 2005.

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): K051602

Device Name: AXIOM Sireskop SD

Indications for Use:

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

AXIOM Sireskop SD may be used for emergency treatment on an outpatient basis, as well as for bedside examinations.

(Please do not write below this line – continue on another page if needed)

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

Prescription Use ✓ OR Over-The-Counter Use _____

(per 21 CFR 801.109)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051602