K061054

510(K) SUMMARY
FOR
SIEMENS AXIOM ARISTOS FX PLUS
WIRELESS REMOTE CONTROL

MAY - 9 2006

Submitted by:

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

April 14, 2006

This summary of 510(k) 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

Siemens Medical Solutions USA, Inc
51 Valley Stream Parkway E-50
Malvern, PA 19355-1406
Phone:(601) 448-1778 Fax: (610) 448-1787

2. Device Name and Classification

Product Name:	AXIOM Aristos FX Plus
Classification Name:	Solid State X-ray Imager (SSXI)
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1680
Device Class:	Class II
Product Code:	90MQB

3. Intended Use:

The AXIOM Aristos FX Plus is a dedicated x-ray system with a flat panel detector which allows the acquisition of x-ray exposures without the use of conventional film/screen systems. The MPRS allows radiographic exposures of the whole body including skull, spinal column, chest, abdomen, and extremities. It is not designed for mammography use. Radiographic exposures may be taken with the patient in the sitting, standing, or supine positions. The intended use and indications for use of this modified device as described in its labeling have not changed from its predicate device.

4. Device Description:

The AXIOM Aristos FX Plus is designed as a set of two ceiling mounted telescoping arms. One arm is supporting the x-ray tube with the collimator; the other arm is supporting the FD (Flat panel detector) with new detector housing and two hand grips. Different table tops, including a painted one for children are available. Radiographic exposures may be taken with the patient in the sitting, standing, or supine positions.

A Wireless Remote Control using RF technology has been designed to allow the clincian to remotely operate the system movements from virtually anywhere in the room through a short-range, low-power radio communication link between a hand held transmitter and the receiver. Additional hardware (independent of microcontroller) and Siemens own communication protocol layers will provide a safety-oriented signal transmission.

5. Substantial Equivalence:

The AXIOM Aristos FX Plus stationary x-ray system is designed with a Flat Panel Detector. The ceiling mounted configuration allows acquisition of radiographic exposures of various anatomical regions of the body. It is substantially equivalent to the following SIEMENS Medical Systems devices:

AXIOM Aristos FX	K013826, cleared on 2/4/02

The Wireless Remote Control is substantially equivalent to the wireless footswitch for AXIOM Artis system.

AXIOM Artis with Wireless Footswitch	K052202, cleared on 3/7/06

A detailed Substantial Equivalence Comparison is provided in Section 5.

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

Many of the components (Generator, X-ray tube, Imaging system, Collimator, FD detector, Wireless Remote Control) used in the AXIOM Aristos FX Plus are either commercially available with current Siemens AXIOM Aristos FX system 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 Aristos FX Plus System is continually monitored, and if an error occurs 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

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY - 9 2006

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

Re: K061054
Trade/Device Name: AXIOM Aristos FX Plus
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: April 14, 2006
Received: April 17, 2006

Dear Mr. Johnson:

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 either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 3
INDICATION FOR USE

510(k) Number (if known): K061054

Device Name: **AXIOM Aristos FX Plus**

AXIOM Aristos FX Plus is a dedicated x-ray system with a flat panel detector, which allows the acquisition of x-ray exposures without the use of conventional film/screen systems. The AXIOM Aristos FX Plus allows radiographic exposures of the whole body including skull, spinal column, chest, abdomen, extremities, excluding mammography. Radiographic exposures may be taken with the patient in the sitting, standing, or lying positions. The intended use and indications for use of this modified device as described in its labeling have not changed from its predicate device.

(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)

David R. Hoyem

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061054