FEB 01 2002

# 510(K) SUMMARY

K013826

Submitted by:
Siemens Medical Systems, Inc.
186 Wood Avenue South
Iselin, NJ 08830

August 02, 2001

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**

Ms. Sandra Robinson
Phone: (732) 321-3243 Fax: (732) 321-4841

2. **Device Name and Classification**

| | |
|---|---|
| Trade Name: | AXIOM Aristos FX (*Multipurpose Radiography System*) |
| Internal name of R&D: | MPRS (*Multipurpose Radiography System*) |
| Classification Name: | Solid State x-ray Imager |
| Classification Panel: | Radiology |
| CFR Section: | 21 CFR § 892.1680 |
| | Stationary X-ray System |
| Device Class: | Class II |
| Device Code: | 90MQB |

3. **Intended Use**

MPRS 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, extremities, and excluding mammography. 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. **Substantial Equivalence**

The MPRS stationary x-ray system is a modified version of the current, commercially available SIEMENS Medical Systems:

| | |
|---|---|
| Thorax FD | K983732, cleared on 4/21/99 |
| Multix FD | K983732, cleared on 4/21/99 |

The table is a modified version of the Koordinat M , K951176, cleared on 3/16/95

Information that substantiates this claim of equivalence is provided throughout this 510(k) submission and specific equivalence information is provided in Attachment 1.

5. **Device Description**

The MPRS *Multipurpose Radiography System* is designed as a set of two ceiling mounted telescoping arms. One arm is supplying the x-ray tube with the collimator; the other arm is supplying the FD (Flat panel detector), which replaces the conventional film/cassette system. A modified patient table is provided, which is based on the Siemens Koordinat M Radiographic X-ray table. Radiographic exposures may be taken with the patient in the sitting, standing, or supine positions.

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) used in MPRS *Multipurpose Radiography System* 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 trained healthcare professional to operate the device in a safe and efficacious manner. 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.

8. **Substantial Equivalence**
In the opinion of Siemens Medical Systems, Inc., the hardware and software documentation and the substantial equivalence comparison matrix proves that the MPRS *Multipurpose Radiography System* is substantially equivalent to the Siemens Medical Systems, Inc. predicate Radiography systems – Thorax FD, and Multix FD.

Kathleen Rutherford
Manager, Regulatory Submissions
Siemens Medical Systems, Inc.

8/8/01
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 01 2002

Ms. Sandra Robinson
Technical Specialist,
Regulatory Submissions
Siemens Medical Systems, Inc.
186 Wood Avenue South
ISELIN NJ 08830

Re: K013826
Trade/Device Name: AXIOM Aristos FX
Regulation Number: 21 CFR 892.1630
Regulation Name: Electrostatic x-ray imaging system
Product Code: 90 MQB
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Product Code: 90 KPR
Regulatory Class: II
Dated: August 6, 2001
Received: November 19, 2001

Dear Ms. Robinson:

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 (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); 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 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:

| | |
|---|---|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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

## INDICATIONS FOR USE

**510(k) Number (if known):** K013826

**Device Name:** (MPRS Multi Purpose Radiology System) AXIOM ARISTOS FX

**Indications for Use:**

MPRS 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, extremities, excluding mammography. 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.

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

Prescription Use ✓ OR Over-The-Counter Use _____
(per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013826