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510(K) SUMMARY

K040675

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

March 1, 2004

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. Debra Peacock
Technical Specialist
Phone: (610) 448-1773 Fax:: (610) 448-1787

2. **Device Name and Classification**

Trade Name:	AXIOM Artis U
Classification Name:	Angiographic X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR § 892.1600 , 892.1720 + 892.1650
Device Class:	Class II
Device Code:	OWB, OXO, JAA, & IZI

3. **Intended Use**

AXIOM Artis U is an angiography system developed for diagnostic imaging and interventional procedures.
Procedures that can be performed with the AXIOM Artis U include cardiac angiography, neuro-angiography, general angiography, operating room angiography, multipurpose angiography and radiographic/fluoroscopic procedures eg. Gastro-intestinal imaging, Skeletal imaging etc.

4. **Substantial Equivalence**

The AXIOM Artis U is substantially equivalent to the currently, commercially available Siemens system, the AXIOM ICONOS R200 (URF Digital OT), the Powermobil and the AXIOM Artis FC.
The URF Digital OT, market as AXIOM ICONOS R200 was described in premarket notification K992660 and received FDA clearance on April 21, 1997. The Siremobil C02, market as Powermobil was described in premarket notification K973598 which received FDA Clearance on November 10, 1997. The AXIOM Artis FC was described in premarket notification K010721 which received FDA Clearance on March 30, 2001.

Information that substantiates this claim of equivalence is provided throughout this 510(k) submission and specific equivalence information is provided in Attachment 4.

5. **Device Description**
The AXIOM Artis U Angiography System is designed of components used from existing Siemens Angiography Systems (i.e., AXIOM Iconos R200, Powermobil, AXIOM Artis FC).

AXIOM Artis U covers the complete range of angiographic applications which are currently possible with commercially available Siemens Angiography systems.

AXIOM Artis U system consists of a mobil C-arm upon connected with other components (i.e. generator, x-ray tube, collimator, image intensifier, television system, digital imaging system, etc). Many of the components used in AXIOM Artis U are either commercially available with current Siemens systems or include minor modifications to existing components. The stand is a mobile C-arm which allows manual angulations and movements. The vertical lift is the only motorized movement.

6. **Summary of Technological Characteristics of the Principal Device as Compared with the Predicate Device**
Many of the components used in AXIOM Artis U 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 AXIOM Artis U system is substantially equivalent to the Siemens Medical Systems, Inc. predicate Angiography systems - the AXIOM ICONOS R200 (URF Digital OT), the Powermobil and the AXIOM Artis FC.

Debra Peacock — March 9, 2004

Débra Peacock — Date

TECHNICAL SPECIALIST, REGULATORY AFFAIRS

Siemens Medical Systems, Inc.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Ms. Debra A. Peacock
Technical Specialist, Regulatory Affairs
Siemens Medical Systems, Inc.
51 Valley Stream Parkway
MALVERN PA 19355

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Re: K040675
Trade/Device Name: AXIOM Artis U
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, OXO, JAA, and IZI
Dated: March 8, 2004
Received: March 12, 2004

Dear Ms. Peacock:

This letter corrects our substantially equivalent letter of November 14, 2011.

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

INDICATIONS FOR USE

510(k) Number (if known): K040675

Device Name: AXIOM Artis U

Indications for Use:

AXIOM Artis U is an angiography system developed for diagnostic imaging and interventional procedures.

Procedures that can be performed with the AXIOM Artis U include cardiac angiography, neuro-angiography, general angiography, operating room angiography, multipurpose angiography and radiographic/fluoroscopic procedures e.g., Gastro-intestinal imaging, Skeletal imaging etc.

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

Prescription Use ✓ OR Over-The-Counter Use _____
(per 21 CFR 801.10Attachment 2

David R. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K040675

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