MAR 7 2006

510(K) SUMMARY

FOR

SIEMENS AXIOM ARTIS

WIRELESS FOOTSWITCH AND VOICE CONTROL

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

August 1, 2005

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 Artis - Modular Angiographic System
Classification Name:	Angiographic X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1600
Device Class:	Class II
Product Code:	90 JAA (90 IZI with flat Panel Detector)

3. Intended Use:

AXIOM Artis is a family of dedicated angiography systems developed for single and biplane diagnostic imaging and interventional procedures.

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

AXIOM Artis can also support the acquisition of position triggered imaging for spatial data synthesis.

The intended use and indications for use of the AXIOM Artis with wireless footswitch and with voice control as described in its labeling have not changed from its predicate device the AXIOM Artis Modular Angiographic System.

4. Device Description:

The Wireless Footswitch uses RF technology in order to establish a short-range, low-power radio communication link between the footswitch (transmitter) and AXIOM Artis system (receiver). Additional hardware (independent of microcontroller) and Siemens own communication protocol layers will provide a safety-oriented signal transmission.

The Voice Control for the AXIOM Artis family allows for the control of selected functions by voice commands. The primary focus will be on image processing functions. Safety relevant functions such as X-ray release and movement control will not be included in the voice control functions.

Both Wireless Footswitch and Voice Control will be made available on the currently marketed Siemens AXIOM Artis family of products.

5. Substantial Equivalence:

The Wireless Footswitch and Voice Control are designed for use with the commercially available AXIOM Artis Modular Angiographic systems.

The Siemens wireless footswitch is substantially equivalent to the Stryker Wireless footswitch, 510(k), K033135, with a clearance date of August 9, 2004.

Siemens Voice Control is substantially equivalent to the voice control used on the SIOS – Siemens Integrated Operation System discussed in 510(k) K994231 cleared on August 10, 2000 and the Philips iU22 Ultrasound System, 510(k) K042540 with a clearance date of October 04, 2004.

These systems will be incorporated for use with SIEMENS AXIOM Artis Modular Angiographic System cleared via 510(k), K010721 on March 30, 2001 and the SIEMENS AXIOM Artis with FD, 510(k) K021021 with a clearance date of June 6, 2002. The Indication for use of the AXIOM Artis does not change with the above-mentioned additions.

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

A Wireless Footswitch and a Voice Control will be made available for the AXIOM Artis family. Many of the components used in AXIOM Artis with the Wireless Footswitch and Voice Control 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 Artis Modular Angiography System 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
9200 Corporate Boulevard
Rockville MD 20850

MAR 7 2006

Mr. Gary Johnson
Technical Specialist, Regulatory Submissions
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway E-50
MALVERN PA 19355-1406

Re: K052202
Trade/Device Name: AXIOM Artis with Wireless Footswitch and Voice Control
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: II
Product Code: IZI and JAA
Dated: February 16, 2006
Received: February 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): K052202

Device Name: **AXIOM Artis with Wireless Footswitch and Voice Control**

AXIOM Artis is a family of dedicated angiography systems developed for single and biplane diagnostic imaging and interventional procedures.

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

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

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

Prescription Use ___X___ 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 K052202