## 510(k) Summary: Artis Q and Artis Q.zen

FEB 26 2013

**Company:** Siemens Medical Systems, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

**Date Prepared:** November 14, 2012

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. **General Information:**

**Importer / Distributor:**
Siemens Medical Systems, Inc.
51 Valley Stream Parkway
Malvern, PA 19355
**Establishment Registration Number:**
2240869

**Manufacturing Site:**
SIEMENS AG Sector Healthcare
Siemensstraße 1
D-91301 Forchheim, Germany
**Establishment Registration Number:**
2240869

2. **Contact Person:**
Ms. Patricia D Jones
Technical Specialist, Regulatory Submissions
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway D-02
Malvern, PA 19355
Phone: (610) 448 -3536 Fax: (610) 448-1787
Email: patricia.d.jones@siemens.com

3. **Device Name and Classification:**

| | |
|---|---|
| **Trade Name:** | Artis Q and Q.zen - Modular Angiographic System |
| **Classification Name:** | Angiographic X-Ray System<br>Image intensified fluoroscopic x-ray system |
| **Classification Panel:** | Radiology |
| **Classification Regulation:** | 21 CFR §892.1600<br>21 CFR §892.1650 |

| | |
|---|---|
| **Device Class:** | Class II |
| **Product Code:** | OWB, JAA, IZI |

**4. Legally Marketed Predicate Device**

| | |
|---|---|
| **Trade Name:** | Artis zee and Artis zeego - Modular Angiographic System |
| **510(k) Clearance** | K090745 |
| **Clearance Date** | June 18, 2009 |
| **Classification Name:** | Angiographic X-Ray System |
| **Classification Panel:** | Radiology |
| **CFR Section:** | 21 CFR §892.1600 |
| **Device Class:** | Class II |
| **Product Code:** | 90 IZI |

**5. Device Description:**

The Artis Q and Artis Q.zen Modular Angiography System is a further development of the Artis zee / zeego Modular Angiography System. It is designed as a set of components that may be combined into different configurations to provide specialized angiography systems. New Flat Panel detectors, a new x-ray tube are implemented and system improvements were performed to the systems.

The Artis Q and Artis Q.zen Modular Angiography System is substantially equivalent to the Artis zee / zeego Modular Angiography System VC14 with all its components as described in the Device Description, **Section 10** and the Substantial Equivalence **Section 11**.

**6. Indication for Use:**

Artis is a family of dedicated angiography systems developed for single and biplane diagnostic imaging and interventional procedures including, but not limited to, pediatric and obese patients.

Procedures that can be performed with the Artis family include cardiac angiography, neuro-angiography, general angiography, rotational angiography, multipurpose angiography and whole body radiographic/fluoroscopic procedures as well as procedures next to the table for i.e. patient extremities.

Additional procedures that can be performed include angiography in the operating room, image guided surgery by X-ray, by image fusion, and by navigation systems. The examination table as an integrated part of the system can be used for X-ray imaging, surgery and interventions.

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

DynaCT is an x-ray imaging software option, which allows the reconstruction of two-dimensional images acquired with a standard angiographic C-arm device into a three-dimensional image format.

DynaCT is intended for imaging both hard and soft tissues as well as other internal body structures for diagnosis, surgical planning, interventional procedures and treatment follow-up.

7. **Substantial Equivalence:**
The Artis Q and Artis Q.zen Modular Angiography System is a modification of a legally marketed device and substantial equivalent to Artis zee, Artis zeego systems as listed below.

| 510(k) Number | Date of Clearance | Device Name |
|---|---|---|
| K090745 | June 18, 2009 | Artis zee, Artis zeego Angiographic X-ray Systems |

8. **Summary of Technological Characteristics of the Subject Device as Compared with the Predicate Device:**
Artis Q and Artis Q.zen Modular Angiography System is designed as a set of components (C-arm, X-ray tube and housing, flat detector, digital imaging system, collimator, generator etc.) that may be combined into different configurations to provide specialized angiography systems. Many of the components used with Artis Q and Artis Q.zen are either commercially available with current Siemens systems or include minor modifications to existing components. New or modified features provided with Artis Q and Artis Q.zen are provided in the Device Description.

9. **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.

Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. To minimize electrical, mechanical and radiation hazards, Siemens adheres to recognized and established industry practice, and all equipment is subject to final performance testing. Furthermore the operators are health care

professionals familiar with and responsible for the evaluating and post processing of X-ray images.

**10. Conclusion as to Substantial Equivalence:**

The Artis Q and Artis Q.zen Modular Angiography System has the same indication for use as the predicate device Artis zee / zeego with software VC14 and SW VD10. The new detectors are designed to provide fluoroscopic and spot-film radiographic images of human anatomy during diagnostic, surgical and interventional procedures.

The functionality of Artis Q and Artis Q.zen Modular Angiography System is similar to the predicate device. It is Siemens opinion, that the Artis Q and Artis Q.zen Modular Angiography System is substantially equivalent to the Artis zee / zeego Modular Angiography System (K090745).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

February 26, 2013

Siemens Medical Solutions USA, Inc.
C/O Patricia D. Jones
51 Valley Stream Parkway, D-02
Malvern, PA 19355

Re: K123529
Trade/Device Name: The Artis Q and Q.zen - Modular Angiographic System
Regulation Number: 21 CFR 892.1600
Regulation Name: Image intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, JAA, IZI
Dated: February 4, 2013
Received: February 5, 2013

Dear Ms. Jones:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

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* Diagnostics and Radiological Health 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,

for

Janine M. Morris
Director
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

# Indications for Use Statement

510(k) Number (if known): K123529

Device Name: Artis Q and Artis Q.zen - Modular Angiographic System

Indications for Use:

Artis is a family of dedicated angiography systems developed for single and biplane diagnostic imaging and interventional procedures including, but not limited to, pediatric and obese patients.

Procedures that can be performed with the Artis family include cardiac angiography, neuro-angiography, general angiography, rotational angiography, multipurpose angiography and whole body radiographic/fluoroscopic procedures as well as procedures next to the table for i.e. patient extremities.

Additional procedures that can be performed include angiography in the operating room, image guided surgery by X-ray, by image fusion, and by navigation systems. The examination table as an integrated part of the system can be used for X-ray imaging, surgery and interventions.

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

The Artis Q and Artis Q.zen include also the software option DynaCT with following IFU:

DynaCT is an x-ray imaging software option, which allows the reconstruction of two-dimensional images acquired with a standard angiographic C-arm device into a three-dimensional image format.

DynaCT is intended for imaging both hard and soft tissues as well as other internal body structures for diagnosis, surgical planning, interventional procedures and treatment follow-up.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

**(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)**

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)



(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k) K123529