NOV 2 2 2011 K113027

510(k) Summary: syngo Aortic ValveGuide Software

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

Date Prepared: October 7, 2011

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 Solutions, Inc.
51 Valley Stream Parkway, E-50
Malvern, PA 19355
Establishment Registration Number:
2240869

Manufacturing Site:
SIEMENS AG Sector Healthcare
Siemensstraße 1
D-91301 Forchheim, Germany

2. Contact Person:

Ms. Patricia D Jones
Technical Specialist, Regulatory Submissions
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway G-01
Malvern, PA 19355
Phone: (610) 448 -3536 Fax: (610) 448-1787
Email: patricia.d.jones@siemens.com

3. Device Name and Classification:

Trade Name:	syngo Aortic ValveGuide Software
Classification Name:	Accessory to Angiographic X-Ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1600
Device Class:	Class II
Product Code:	90JAA & OWB

4. Legally Marketed Predicate Device

Trade Name:	InSpace 3D Software Option

510(k) #:	K011447
Clearance Date:	August 3, 2001
Classification Name:	Accessory to Angiographic X-Ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1600
Device Class:	Class II
Product Code:	90JAA

5. **Device Description:**
The *syngo* Aortic ValveGuide software is an add-on to the 510(k) cleared InSpace 3D software and a workflow improvement. This software visually assists the physician in localizing the aortic root plane by exact C-arm adjustment. The Inspace 3D application was originally cleared under Premarket Notification K011447 on 08/03/2001.

syngo Aortic ValveGuide software offers fast and precise 3D image viewing information of the aortic root anatomy during the procedure, thus providing excellent viewing support of the aortic root plane.

This software modification does not affect the intended use of the device nor does it alter its fundamental scientific technology.

6. **Indication for Use:**
The *syngo* Aortic ValveGuide software is an add-on option to InSpace 3D software with an enhanced algorithm to display the aortic root and to visually assist the physician by placing the C-arm in an orthogonal position to the aortic root plane.

The *syngo* Aortic ValveGuide software is intended for imaging soft tissues (heart) for diagnosis, surgical planning, interventional procedures and treatment follow-up.

This software is also designed to visually assist physicians in the diagnosis and treatment of vessel malformations (i.e. Aneurysms, AVM's and Stenoses)

7. **Substantial Equivalence:**
The Aortic ValveGuide Software application is substantially equivalent to the commercially available Siemens software application, Inspace 3D. The Inspace 3D software option was described in premarket notification K011447 which received FDA Clearance on August 03, 2001.

The *syngo* Aortic ValveGuide software is an add-on to InSpace 3D and uses the same hardware and software components as the InSpace 3D software.

8. **Summary of Technological Characteristics of the Subject Device as Compared with the Predicate Device:**
   syngo Aortic ValveGuide is a software add-on to Inspace 3D. The subject device *syngo* Aortic ValveGuide features the same post processing software, user interface, archiving and communication as the predicate Inspace 3D. The syngo Aortic ValveGuide software is not a stand-alone software. It interfaces with InSpace 3D. syngo Aortic ValveGuide user function keys are integrated into the InSpace 3D task card. The user function is similar to Inspace 3D task card except for an additional activation button for the syngo Aortic ValveGuide software features.

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:**
    syngo Aortic ValveGuide is intended for similar indications as cleared in the predicate Inspace 3D. The *syngo* Aortic ValveGuide Software add-on application is designed for use with the Inspace 3D (K011447) and a workflow improvement which helps during visualizing and localizing the aortic root plane by exact C-arm adjustment.

    The functionality of syngo Aortic ValveGuide Sotware is similar to the predicate device. It is Siemens opinion, that the *syngo* Aortic ValveGuide add-on software is substantially equivalent to the Inspace 3D software (K011447).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Ms. Patricia D. Jones
Technical Regulatory Specialist
Siemens Medical Solutions, USA, Inc.
51 Valley Stream Parkway
MELVERN PA 19355

MAY - 7 2012

Re: K113027
Trade/Device Name: syngo Aortic ValveGuide Software
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB and JAA
Dated: November 10, 2011
Received: November 14, 2011

Dear Ms. Jones:

This letter corrects our substantially equivalent letter of November 22, 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.

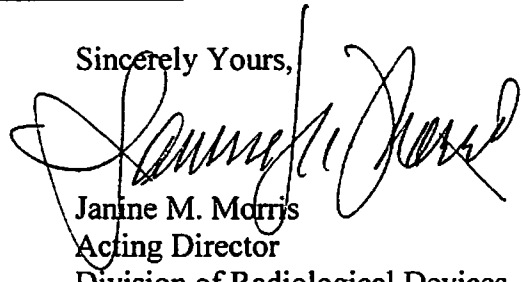
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 Statement

510(k) Number (if known): K113027

Device Name: syngo Aortic ValveGuide Software

Indications for Use:

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation
and Safety

510(k) K113027