



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Siemens Medical Solutions USA, Inc.
% Ms. Kimberly Mangum
Regulatory Affairs Specialist
51 Valley Stream Parkway
MALVERN PA 19355

September 16, 2015

Re: K151887
Trade/Device Name: syngo VSim
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: June 15, 2015
Received: July 10, 2015

Dear Ms. Mangum:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style. Behind the signature, there is a faint, large watermark of the letters "FDA" in a stylized font.

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K151887

Device Name

syngo VSim

Indications for Use (Describe)

VSim is a software solution to prepare anatomical data (CT) for the planning of external beam radiation therapy treatment.

VSim provides features to define anatomical regions, reference points and geometric treatment plans prior to dosimetric planning with a treatment planning system.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

FOR

syngo VSim

Submitted by:

Siemens Medical Solutions USA, Inc.

40 Liberty Boulevard

Malvern, PA 19355

Date Prepared: September 2, 2015

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. General Information

Importer/Distributor Establishment:

Registration No: 2240869

Siemens Medical Solutions USA, Inc.

40 Liberty Boulevard

Malvern, PA 19355

Manufacturing Facility:

Siemens AG

Medical Solutions

Doris-Ruppenstein Straße 4

D-91052 Erlangen, Germany

Establishment Registration Number:

3004977335

2. Contact Person:

Kimberly Mangum

Regulatory Affairs Specialist

Siemens Medical Solutions, Inc. USA

40 Liberty Boulevard

Malvern, PA 19355

Phone: (610) 448-6477

Fax: (610) 640-4481

Email: kimberly.mangum@siemens.com

3. Device Name and Classification

Product Name: syngo VSim

Propriety Trade Name: syngo VSim

Classification Name: System, Planning, Radiation Therapy Treatment

Classification Panel: Radiology

CFR Section: 21 CFR §892.5050

Device Class: Class II

Product Code: MUJ

4. Legally Marketed Primary Predicate Device:

Product Name: syngo Dosimetrist Workspace v2.7
Propriety Trade Name: syngo Dosimetrist Workspace v2.7
Classification Name: System, Planning, Radiation Therapy Treatment
Classification Panel: Radiology
CFR Section: 21 CFR § 892.5050
Device Class: Class II
Product Code: MUJ
510(k) Number: K101119

5. Indications for Use

VSim is a software solution to prepare anatomical data (CT) for the planning of external beam radiation therapy treatment.

VSim provides features to define anatomical regions, reference points and geometric treatment plans prior to dosimetric planning with a treatment planning system.

6. Substantial Equivalence:

The subject device syngo VSim is substantially equivalent to following medical devices in commercial distribution as listed in **Table 1**:

Table 1: Predicate Devices

| Manufacturer | Predicate Device | 510(k) | Clearance Date |
|--------------|----------------------------------|---------|----------------|
| Siemens | syngo Dosimetrist Workspace v2.7 | K101119 | June 16, 2010 |

7. Device Description:

Virtual simulation, the most basic form of planning, allows more accurate placement of radiation beams than is possible using conventional X-ray imaging, where soft-tissue structures are often difficult to assess and normal tissues difficult to protect. The virtual simulation application syngo VSim allows the use of contouring and segmentation tools to assist in the drawing of the borders of the treatment volume and organ at risk.

syngo VSim is a software application that runs on a syngo® based workspace. It is a 3D-post-processing software application that uses CT planning images as input and creates as output DICOM-RT Structures and DICOM RT Plans for treatment planning.

syngo VSim is used to create 3D-models of target volumes and organs at risk. The main functionalities of syngo VSim are segmentation of organs, management of reference points and placement of geometrical treatment beams.

8. Summary of Technical Characteristics of the Subject Device as Compared with the Predicate Device:

The subject device syngo VSim application does not differ in intended use from the 510(k) cleared predicate device syngo® Dosimetrist Workspace 2.7 (K101119, clearance date 06/16/2010). A comparison of the technical characteristics for the subject device and the predicate device is provided in **Table 2** below.

Table 2: Predicate and Subject Device Comparable Technological Characteristics

| Property | Subject Device | Primary Predicate Device K101119 |
|----------------------------|---|--|
| Indications for Use | Modified to reflect syngo VSim as a standalone software device. There is no change in the intended use from the predicate device. | Indications for use reflects syngo VSim as a component of syngo® Dosimetrist Workspace 2.7 |
| VSim software | Stand alone software device to be marketed as syngo VSim. | Component of syngo® Dosimetrist Workspace 2.7 |

The basic operating principle remains unchanged from the predicate device. Furthermore, there are no changes in regard to the features of VSim (Segmentation, Reference Point Management, Simulation) compared to the predicate device.

Testing and validation is completed. Test results show that the subject device, syngo VSim, is comparable to the VSim task card of the predicate device and therefore Siemens believes it substantially equivalent.

9. Nonclinical Testing:

syngo VSim is designed to fulfill the requirements of the following safety and performance standards listed in **Table 3** below:

Table 3: Performance Standards

| Recognition Number | Product Area | Title of Standard | Reference Number and Date | Publication Date | Standards Development Organization |
|--------------------|--------------|---|---|------------------|------------------------------------|
| N/A | General | General Requirements for Collateral Standard: Programmable Electrical Medical Systems | IEC 60601-1-4:2000, Consol. Ed. 1.1, Medical Electrical Equipment - Part 1-4: | 09/08/2009 | IEC |
| 12-217 | Radiology | Medical Electrical Equipment – Requirements for the | 62083 Edition 2.0 2009-09 | 03/18/2011 | IEC |

| Recognition Number | Product Area | Title of Standard | Reference Number and Date | Publication Date | Standards Development Organization |
|--------------------|--------------|---|---------------------------------|------------------|------------------------------------|
| | | Safety of Radiotherapy Treatment Planning Systems | | | |
| N/A | Software | Medical device software – Software life cycle processes | IEC 62304 First Edition 2006-05 | 09/09/2008 | IEC |
| N/A | General | Medical devices - Application of usability engineering to medical devices (General) | EN/IEC 62366 | 09/08/2009 | IEC |
| N/A | Radiology | Digital Imaging and Communications in Medicine (DICOM) Set | PS 3.1 – 3.18 | 03/16/2012 | NEMA |
| 5-40 | General | Medical devices – Application of risk management to medical devices | 14971 Second Edition 2007-03-01 | 08/20/2012 | ISO |
| N/A | General | Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance -- Collateral Standard: Usability | 60601-1-6:2004 | 1/30/2014 | IEC |
| 12-267 | Radiology | Radiotherapy equipment - Coordinates, movements, and scales | 61217 Edition 2.0 2011-12 | 01/30/2014 | IEC |

This submission contains performance data to demonstrate continued conformance with special controls for medical devices containing software. Non clinical tests (integration and functional) were conducted for syngo VSim during product development. The modifications described in this Premarket Notification were supported with verification/validation testing.

The risk analysis was completed and risk control implemented to mitigate identified hazards. The testing results support that all the software specifications have met the acceptance criteria. Testing for verification and validation of the device was found acceptable to support the claims of substantial equivalence.

Software Verification and Validation

Software Documentation for a Moderate Level of Concern software per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for



Software Contained in Medical Devices” issued on May 11, 2005 is also included as part of this submission.

Non-Clinical Testing Summary

Performance tests were conducted to test the functionality of the syngo VSim. These tests have been performed to test the ability of the included features of the subject device. The results of these tests demonstrate that the subject device performs as intended. The result of all conducted testing was found acceptable to support the claim of substantial equivalence.

10. General Safety and Effectiveness Concerns:

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device. Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled during development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

11. Conclusion as to Substantial Equivalence

syngo VSim has the same intended use and comparable indications for use as the predicate device. The technical characteristics of the VSim component remain unchanged from the predicate device. Any technological differences between the subject device and predicate device do not raise different questions of safety or effectiveness.

The predicate device was cleared based on non-clinical supportive information. The subject device non-clinical test data similarly supports the safety of the software with verification and validation testing. Verification and validation testing demonstrates that the subject device syngo VSim performs as intended. The non-clinical test data demonstrates that syngo VSim device performance is comparable to the predicate device that is currently marketed for the same intended use.

In summary, Siemens is of the opinion that the syngo VSim does not introduce any new potential safety risk and is substantially equivalent to and performs as well as the predicate devices.