Siemens Medical Solutions USA, Inc.
Radiation Oncology

Section 5

510(k) Summary

Submitter: Siemens Medical Solutions USA, Inc.
Radiation Oncology
4040 Nelson Avenue
Concord, CA 94520

Contact: Christine Dunbar
Senior Manager, Regulatory Affairs

Phone: (925)602-8157
Fax: (925)602-8008
Email: christine.dunbar@siemens.com

Proprietary Name: *syngo®* RT Interface

Common Name: System, Planning, Radiation Therapy Treatment (accessory to)

Classification: 892.5050

Product Code: MUJ

Substantial Equivalence Claimed To:

PRODUCT	Clearance	Claim of Equivalence For:
Syngo® Dosimetrist v2.7 Segmentation and contouring features on "syngo classic".	K101119	*syngo®* RT Interface supports the RT Connect features which includes: Segmentation, (contours) Image fusion, Plan review Conversion to DICOM® RT Structure Sets.
Syngo® PET & CT application (market name: MM Oncology) – Software Pkg	K093621	*syngo®* RT Interface as a plug-in into the MM Oncology Reading feature and clinically focused image review applications including *syngo* TrueD™, Findings Navigator and Image post processing applications.
Syngo®.X (market name *syngo®*.via)	K092519	*Syngo®* classic to the *Syngo.via* software development for client / server architecture.

The *syngo®* RT Interface as described in this premarket notification has similar intended use and fundamental scientific technical characteristics as the predicate devices listed above.

Description Summary for the *syngo*® RT Interface:

Technological Characteristics:

The *syngo*® RT Interface offers the segmentation tools, which are currently cleared in the Virtual Simulation [VSIM] module of the *syngo*® Dosimetrist v2.7 workspace, to be available from the RT Connect workflow on the MM Oncology Reading pane. The *syngo*® RT Interface software is based on the currently cleared SIEMENS *syngo.via* software's client /server architecture and is intended to be marketed as a licensable plug-in to the currently cleared *syngo.via* MM Oncology™ workspace. The basic design, safety features and function of the segmentation tools supported within the *syngo*® RT Interface remain unchanged from their currently cleared intended use and functions, however, the segmentation tools have been modified to run on the *syngo.via* architecture.

The *syngo*® RT Interface supports the RT Connect workflow application within the MM Oncology Reading pane that provides access to patient imaging data. The clinician can view and make clinical assessments of the area of medical interest (findings) using a variety of digital diagnostic radiographic [DDR] and other imaging modality images such as PET, CT, MR, and SPECT that conform to the DICOM standard.

The RT Connect workflow on the MM Oncology workspace supports the segmentation tools for use on a three dimensional view allowing for a virtual setup of the patient's preliminary treatment planning. A variety of segmentation tools are supplied to assist in the delineation of structures for contouring and placement on target organ(s) or findings prior to the data transfer for use by the third party treatment planning systems [TPS].

Additionally, the segmentation tools available through the *syngo*® RT Interface supports a workflow that enables the user to delineate, edit, or delete contours, and automatically convert them to DICOM RT structures. The DICOM RT Structure objects can be transfer to a currently cleared and commercial DICOM compatible treatment planning system to be used in the development of the treatment plan by the clinician or archived.

Syngo.via:

The *syngo*® RT Interface software utilizes the SIEMENS proprietary *syngo.via* software client/server architecture and allows for a standardized graphical user interface across SIEMENS medical products. The *syngo*.via -based software design consists of a unified user interface with clinical focused workflow options (clinically based engines) allowing for a selection and use of modules of common software applications for image acquisition, reconstruction, post-processing, display, and archiving across the Siemens Healthcare imaging and radiation therapy product lines.

Refer to Section 11- Design Description, for the System and Sub-System Requirements Specifications regarding these specific requirements.

General Safety and Effectiveness:

The device labeling contains instructions for use, on-line help and any necessary cautions and warnings, to provide for safe and effective use of the device.

Risk management is ensured via a risk analysis, which is used to identify potential hazards and mitigations. These potential hazards are controlled by software means, user instructions, verification of requirements and validation of the clinical workflow to ensure that the product meets its intended uses. To minimize electrical, mechanical and radiation hazards, SIEMENS adheres to recognized and established industry practice and relevant international standards.

Intended Use:

The *syngo®* RT Interface is as an accessory to the linear accelerator system to provide input to the planning for the delivery of x-ray photon and electron radiation for the therapeutic treatment of cancer where indicated.

The *syngo®* RT Interface supports the oncology workflow as a medical application for viewing, manipulation, contouring, 3D visualization and comparison of medical images from multiple imaging modalities.

This application allows the user to convert, store and export volume of interest (VOI) structures in DICOM RT format for use in radiation therapy planning.

Summary:

In summary, SIEMENS is of the opinion that the *syngo®* RT Interface update does not introduce any new potential safety risks and is substantially equivalent to, and performs as well as, the predicate devices.

Ms. Christine Dunbar
Senior Manager, Regulatory Affairs
Siemens Medical Solutions USA, Inc.
Radiation Oncology
4040 Nelson Avenue
CONCORD CA 94520

MAR 2 0 2012

Re: K120363
    Trade/Device Name: *syngo®* RT Interface
    Regulation Number: 21 CFR 892.5050
    Regulation Name: Medical charged-particle radiation therapy system
    Regulatory Class: II
    Product Code: MUJ, LLZ
    Dated: January 31, 2012
    Received: February 6, 2012

Dear Ms. Dunbar:

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,
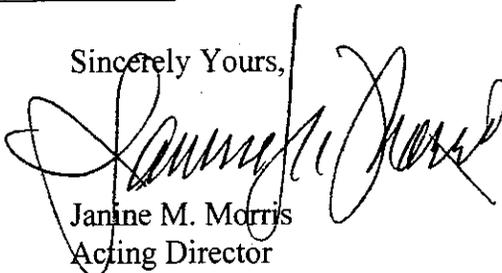
Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
 Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Section 4

Indication For Use Statement

510(k) Number (if known): ___K12 0363___

Device Name: *syngo®* RT Interface

Indications for Use:

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This application allows the user to convert, store and export volume of interest (VOI) structures in DICOM® RT format for use in radiation therapy planning.

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

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

~~Mary S Pastel~~
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K ___K120363___

Prescription Use_____   OR   Over-the-Counter Use_____
(Per 21 CFR 801.109)

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