K101749

510(k) Summary

AUG 1 6 2010

This summary of 510(k) safety and effectiveness is provided in accordance with the requirements of SMDA 1990 and 21 CFR §807.92

Date Prepared; May 20th, 2010

General Information

Manufacturer Facility (Developer/manufacturer)
Siemens Medical Solutions USA, Inc.
20 Valley Stream Pkwy
Malvern, PA 19355
Establishment Registration Number: 3002329443

Contact Person
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Device Name and Classification

Trade Name:	*syngo™TrueD Software*
Classification Name:	Picture Archiving and Communications System
CFR Section:	21 CFR §892.2050
Device Class:	Class II
Product Code:	LLZ

Safety and Effectiveness Information Supporting the Substantial Equivalence Determination

Device Description and Intended Use

syngo TrueD is a medical diagnostic application for viewing, manipulation, 3D- visualization and comparison of medical images from multiple imaging modalities and/or multiple time-points. The application supports functional data, such as PET or SPECT as well as anatomical datasets, such as CT or MR. The images can be viewed in a number of output formats including MIP and volume rendering.

syngo TrueD enables visualization of information that would otherwise have to be visually compared disjointedly. *syngo* TrueD provides analytical tools to help the user assess, and document changes in morphological or functional activity at diagnostic and therapy follow-up examinations.

syngo TrueD is designed to support the oncological workflow by helping the user to confirm the absence or presence of lesions, including evaluation, quantification, follow-up and documentation of any such lesions. The application allows to store and export volume of interest (VOI) structures in DICOM RT format for use in radiation therapy planning systems.

syngo TrueD allows visualization and analysis of respiratory gated studies to support accurate delineation of the target or treatment volume over a defined phase of the respiratory cycle and thus provide information for radiation therapy planning.

Technological Characteristics

TrueD will be marketed as a software only solution for the end-user (with recommended hardware requirements) .It will be installed by Siemens service engineers. The TrueD described supports DICOM formatted images and information. It is based on the Windows XP operating system.

Safety Information / Nonclinical Testing

The following nonclinical testing has been completed in compliance to the following;

- DICOM (Digital Imaging and Communications in Medicine) Standard:2003 – Developed by the American College of Radiology and the National Electrical Manufacturers Association. Specifies the format for the communication of digital images between individual devices and over networks.

- ISO 14971:2007 - Medical Devices – Application of risk management to medical devices

A summary of the software design description, hazard analysis, validation testing, and technical and safety information can be found in the attached submission. The results of the hazard analysis and validation, combined with the appropriate preventive measures taken indicate the device is of minor level of concern, as per *Guidance for the Content of Premarket Submission for Software Contained in Medical Devices, May 2005*

The device has no patient contacting materials and is utilized only by trained professionals. The output of the device is evaluated by trained professionals allowing sufficient review for identification and intervention in the event of a malfunction. Device output and analysis is used to indicate the appropriateness of a referral. The device does not impact the quality or status of the original acquired data.

Substantial Equivalence:
The *syngo TrueD Software* is substantially equivalent, both in intended use and technically, to the following device:

#	New Feature	Comparison	Predicate
1	**Support Dynamic PET data** Features: - Dynamic PET in one of the three time-points - Rotating MIP of a timeslice in dynamic study	The new version is extending the functionality of syngo TrueD from loading static as well as respiratory gated PET data to loading dynamic PET data. Dynamic PET data are technically equivalent to static PET data with the only difference that dynamic PET datasets consist of multiple time-slices,	TrueD VC60A K091373

	- Cine of dynamic PET studies - Copy VOI to another time-slice of the same dynamic data - Display dynamic data information - Time activity curve for dynamic studies - Add time activity table and table data to report	which is similar to respiratory gated PET studies which have been cleared in TrueD (k071950) Similar to static and respiratory-gated PET, TrueD can perform a rotating MIP for each time-slice. Similar to respiratory-gated PET data, TrueD can perform cine for dynamic PET data. Similar to creating VOIs in one respiratory gate and copying VOIs across respiratory gates, TrueD allows creating VOIs in one time-slice and copying to other time-slices. This new feature has been fully validated and adds no additional unmitigated risk or functionality that would affect the safe and effective use of this device in comparison to its predicate	
2	**Respiratory gated data with multiple bed positions.**	The VE10A version of TrueD is extended to allow respiratory gated studies with multiple bed positions to be loaded into the application, rather than single bed positions as in TrueD VC60A (k091373). The respiratory gating functionality remains otherwise unchanged.	TrueD VC60A K091373
3	**Enabling PERCIST workflow:** Features: - Peak sphere - Peak sphere diameter - Provide SUV peak quantification - Peak value - PERCIST Reference VOI - PERCIST threshold - Peak trending - Highest peak trending	TrueD VE10A is extending the volume of interest (VOI) quantification functionality previously cleared in k091373 by enabling the user to apply the PERCIST (PET Response Criteria in Solid Tumors). The interpretation of the quantification results according to the PERCIST criteria remains the responsibility of the physician. The peak sphere is a 3D sphere VOI which is placed inside a larger 3D VOI at the location of the highest average SUV value in the VOI which is called the 'peak SUV value'. This is an extension to previously cleared technology where TrueD is searching for the highest SUV value in a VOI.	TrueD VC60A K091373

		For each peak sphere, the application displays a peak sphere diameter which is technically the same as a sphere diameter. The application is extended to allow users to create PERCIST reference VOIs in the liver or blood pool: a 3 cm spherical ROI (VOI) should be manually placed by the user in the normal right lobe of the liver (if the liver is abnormal a 1 cm diameter ROI should be positioned in the descending thoracic aorta extending 2 cm along z-axis). The VOI technology used for PERCIST reference VOIs is equivalent to existing VOIs in TrueD. In addition to the usual quantification parameters, the PERCIST Reference VOIs provide a PERCIST threshold value which is calculated based on a defined mathematical formula which is provided to the user in the user documentation of the application. The application provides peak quantification trending in the same manner as for other quantification parameters. The trending is extended to allow users to see trending values between the highest values for each time point for Peak, which may not be the same lesions in each time-point.	

Summary

In summary, Siemens is of the opinion that the indicated changes to the syngo TrueD software, as described within this submission does not introduce any new potential safety risks and is substantially equivalent to and performs as well as the predicate device.

REV B

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Siemens Medical Solutions USA, Inc.
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Senior Project Engineer
Underwriters Laboratories, Inc.
1285 Walt Whitman Rd.
MELVILLE NY 11747

AUG 1 6 2010

Re: K101749
Trade/Device Name: syngo™ TrueD
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: LLZ
Dated: July 29, 2010
Received: August 2, 2010

Dear Mr. Conry:

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,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K101749

Indications for Use Form

510(k) Number (if known): K101749

Device Name: **Syngo™ TrueD**

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syngo TrueD allows visualization and analysis of respiratory gated studies to support accurate delineation of the target or treatment volume over a defined phase of the respiratory cycle and thus provide information for radiation therapy planning.

Note: The clinician retains the ultimate responsibility for making the pertinent diagnosis based on their standard practices and visual comparison of the separate unregistered images. *syngo* TrueD is a complement to these standard procedures.

Prescription Use ___✓___ (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 OF 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) K101749