K041484

JUL 3 0 2004

510(k) Summary

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

General Information

Manufacturer Facility (Developer)
Siemens Medical Solutions USA, Inc.
51 Valley Stream Pkwy
Malvern, PA 19355
Establishment Registration Number: 2240869

Manufacturer Facility (Contract Manufacturer)
Siemens Medical Solutions USA, Inc.
2501 North Barrington Rd.
Hoffman Estates, IL 60195-7372
Establishment Registration Number: 1423253

Contact Person
Richard Andersen
Manager of Quality Assurance
Phone: (610) 448-4362 Fax: (610) 448-4274

Device Name and Classification

Trade Name:	*syngo* TrueD
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 image manipulation software that is intended to assemble existing datasets from imaging modalities into a single dataset that accurately represents the information from the initial data. This "fusion" of data from multiple modalities will be performed on 3D volume datasets and may be represented in a number of output formats including MIP and volume rendering. Additionally, simple quantitative measurements may be made and subsequently compared to a dataset acquired at a different point in time.

More detailed information regarding the device can be found in the System Description included in Section 2 as well as in the technical information in Section 4.

Technological Characteristics
syngo 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.

syngo TrueD supports DICOM formatted images and information. It is based on the Windows XP operating system.

Safety Information
A summary of the software design description, hazard analysis, and technical and safety information can be found in the attached submission. The results of the hazard analysis, combined with the appropriate preventive measures taken indicate the device is of minor level of concern, as per the August 29, 1991 issue of the "*Reviewers Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review*".

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:
syngo TrueD is substantially equivalent, both in intended use and technically, to the following devices:

Predicate Device Name	*FDA Clearance Number*
syngo Multimodality Workstation	K010938
Lung CARE CT Software Package	K033374
Advantage Windows CT/PET Fusion	K010336
Leonardo Workstation	K040970 (in review)

In summary, Siemens is of the opinion that *syngo* TrueD does not introduce any new potential safety risks and is substantially equivalent to and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 2004

Siemens Medical Solutions USA, Inc.
c/o Mr. Glenn Luchen
Staff Engineer
Underwriters Laboratories, Inc.
1285 Walt Whitman Rd.
MELVILLE NY 11747-3081

Re: K041484
Trade/Device Name: syngo TrueD
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: July 14, 2004
Received: July 15, 2004

Dear Mr. Luchen:

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); 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.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K041484
Device Name: *syngo* TrueD

Indications For Use:

syngo TrueD is a medical diagnostic application for viewing, image manipulation, 3D-visualization and comparison of medical images. *syngo* TrueD is intended for combining datasets from multiple imaging modalities and/or multiple time-points into a single dataset that accurately represents the information from the initial data. The input datasets could be functional 3D volumes (e.g. PET and SPECT) and/or anatomic 3D volumes (e.g. CT and MRI). This "fusion" of data may 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 any 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.

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.

(Please do not write below this line - continue on another page if needed)

Concurrence of the CDRH, Office of Device Evaluation (ODE)

Prescription Use √ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K041484