JUL 16 2002

K022013

510(k) Summary of Safety and Effectiveness

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.

I. General Information

Device Name and Classification

Product Name:	LungCARE CT software package
Common Name	3D CT Reconstruction Software
Classification Name:	Accessory to Computed Tomography System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	90 JAK

Establishment:

Importer/Distributor:

Siemens Medical Solutions, Inc.
186 Wood Avenue South
Iselin, NJ 08830

Registration Number: 2240869

Manufacturing Facility:

Siemens AG
Medical Solutions
Henkestrasse 127
D-91052 Erlangen, Germany
***syngo* is a registered trademark of Siemens AG**

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Technical Specialist
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Date of Preparation of Summary: May 10th 2002

II. Safety and Effectiveness Information Supporting the Substantial Equivalence Determination

Device Description and Intended Use:

This premarket notification covers Siemens LungCARE CT software package. It is based on Siemens *syngo* software platform.

Lung CARE CT is a self-contained image analysis software package for evaluating CT volume data sets. Combining enhanced commercially available digital image processing tools (MIP, MPR, SSD, VRT), evaluation tools (volumetric estimation using consistent standardized measurement protocol, comparator tool for nodule matching by synchronization of two datasets, classification of nodules using configurable descriptors) and reporting tools (targeted presets, saved lesion location) with optimized workflow palette, the software package is designed to support the physician in confirming the presence or absence of physician identified lung lesions (eg. nodules) in addition to evaluation, documentation and follow-up of any such lesions using standard or low-dose spiral CT scanning. This visualization tool allows for volumetric analysis of pulmonary nodule or lesion size over time, helping the Physician to assess the changes in their growth. It is also designed to help the physician classify conspicuous regions of tissue unambiguously, with respect to their size, dimensions, shape and position.

General Safety and Effectiveness Concerns:
The device labeling contains instructions for use and any necessary cautions and warning, 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 via software development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

Summary of Pre-clinical and Clinical Information:
Kohl et al., performed a Lung Phantom bench testing study to determine the influence of the scanning and reconstruction parameters on reproducibility of volume measurements using LungCARE CT.
The results indicate that that the reproducibility of volumetric measurements is independent of reconstructed field of view but is slightly dependent on the reconstruction kernel used to perform the evaluation. The results also clearly demonstrate the advantage of using thin slice collimations for better reproducibility of volume measurements. Comparison of volumetric measurements performed at various dose levels clearly demonstrates that the usage of normal dose versus low dose brings no additional benefit to the volume estimation.
In conclusion, the authors propose that the end-user should use thin slice collimations, medium kernel, low radiation dose with a full field of view reconstruction and last but not the least consistently use the same protocol for the best reproducibility of volumetric estimation.

Wormanns et al., performed a clinical evaluation of the reproducibility of volumetric measurements using LungCARE CT in 10 patients with pulmonary metastatic disease. In total 150 pulmonary nodules were manually marked and then evaluated. Volume and diameter of the nodules was calculated with the LungCARE CT software package. The proposed segmentation results, provided by the software package, were not modified by the user.

The results indicate that the clearly defined compact type of pulmonary nodules have a better volume reproducibility, than the ill-defined types of nodules with multiple connections to pleura and/or vessels without user intervention by modifying the segmentation results.
The authors concluded that they had evaluated a method that allows for the reliable estimation of volume growth but the user is cautioned to carry out the evaluation carefully and always critically assess the visual representation of the software proposed segmentation results especially for ill-defined nodules.

Substantial Equivalence:
The LungCARE CT software package, addressed in this premarket notification, is substantially equivalent to the following commercially available software package:

Manufacturer	Product	510(k)	Clearance date
GE Medical	Advanced Lung Analysis-I	K013381	10/26/01

The LungCARE CT software package described in this 510(k) has the same intended use and similar technical characteristics as the commercially available software listed above.

In addition, the image processing, display and evaluation components of LungCARE are currently available software components on CT systems like Siemens Somatom Plus 4 with Volume Zoom option, K941546, cleared on September 20th, 1994, software options like the Volume Rendering Technique option, K923524/S2, cleared on May 17th 1994 and the Calcium Scoring Software package, K990426 cleared on 04/30/99, and Workstations like the Siemens RealTime 3D Diagnostic Workstation (3D Virtuoso), K973010, which received clearance on Nov 10th 1997 and the syngo Multimodality Workstation, K010938, cleared on 26th June 2001. LungCARE packages these image processing and image display components in an optimized workflow palette.

In summary, Siemens is of the opinion that LungCARE CT software package does not introduce any new potential safety risks and is substantially equivalent to and performs as well as the predicate software components and the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 2002

Siemens Medical Solutions, Inc.
% Mr. Wolfram Gmelin
Technical Manager
TÜV Rheinland of North America
12 Commerce Road
NEWTON CT 06470

Re: K022013
Trade/Device Name: LungCARE CT Software Package
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: June 27, 2002
Received: July 2, 2002

Dear Mr. Gmelin:

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 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 this 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" (21 CFR Part 807.97). 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

Indication for use

510(k) Number (if known): K022013

Device Name: Lung CARE CT Software Package

Lung CARE CT is a self-contained image analysis software package for evaluating CT volume data sets. Combining enhanced commercially available digital image processing tools with optimized workflow and reporting tools, the software is designed to support the physician in confirming the presence or absence of physician-identified lung lesions (eg. nodules) in addition to evaluation, documentation and follow-up of any such lesions using standard or low-dose spiral CT scanning. This evaluation tool allows for volumetric analysis of pulmonary nodule or lesion size over time, helping the Physician to assess the changes in their growth. It is also designed to help the physician classify conspicuous regions of tissue unambiguously, with respect to their size, dimensions, shape and position.

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

David A. Lepay

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022013

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