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K042694

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

Submitter Larry A. Kroger, Ph.D.
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3000 North Grandview Blvd.
Waukesha, WI 53188 USA
Date Prepared: July 15, 2004

PRODUCT IDENTIFICATION

Name: Advanced Lung Analysis II
Classification Name: Accessory to Computed Tomography System
Manufacturer: General Electric Medical Systems
283, rue de la Minière
78533 Buc Cedex, FRANCE
Distributor: General Electric Medical Systems, Buc, France.

Marketed Devices The Advanced Lung Analysis II is substantially equivalent to the devices listed below:

- Model: Advanced Lung Analysis I
- Manufacturer: General Electric Medical Systems, Buc - France
  510(k) #: K013381

- Model: LungCare CT
- Manufacturer: Siemens, Malvern - PA19355
  510(k) #: K033374

Device Description: K042694

CT Advanced Lung Analysis (ALA 2 / ALA II) is a post processing analysis software package designed to assist radiologists and other clinicians in the evaluation and assessment of nodules and other lesions in the lung.

Advanced Lung Analysis II provides an effective solution for providing quick analysis and measurements to help differentiate the radiologist's findings during the primary read. The software assesses and measures all lung nodule types, including measuring volume and their changes over time. Following a CT scan, the user clicks on a specific nodule and the software automatically calculates and displays a 3-dimensional volume and rendering of the nodule as well as the associated measurements. Advanced Lung Analysis II also offers functionality for quick comparisons between the current and previous patient procedures.

The Digital Contrast Agent (DCA) option will further compliment the Radiologist's diagnostic capability by highlighting spherical (S) and cylindrical (C) anatomical regions, such as nodules, cysts, scars, and vessels.

ALA II and DCA are software options that operate on the GE family of LightSpeed multi-slice CT scanners, Advantage Workstation 4.2 (or higher), and GE PACS systems.

Indications for Use:

Advanced Lung Analysis II is intended to provide an optimized non-invasive application to measure abnormalities in the lung (for example, nodules, lesions, etc.) from a set of Computed Tomography (CT) images.

The software is designed to support the physician in confirming the presence or absence of physician identified lung lesions (e.g. nodules). The software allows measurement of volume over time using a consistent standardized measurement protocol, thus providing an estimation of the volume doubling time. ALA II software allows analysis and displays statistics for nodule characterization all the different nodule types.

ALA II optional Digital Contrast Agent (DCA) module is an automated highlight feature for the visual identification of possible lesions. Digital Contrast Agent (DCA) is a 3D filter that produces images that highlight spherical (S) and cylindrical (C) anatomical regions, such as nodules, cysts, scars, and vessels. Images are made available to the physician to aid in characterization of suspicious nodules and thus, the patient management care decision process.

ALA II provides to physician with additional information, meant to complement diagnosis based on classical techniques.

Comparison with Predicate: K042694

The functional features of Advanced Lung Analysis II software package are substantially equivalent to that of the following device:

Device Name	FDA Clearance Number
Advanced Lung Analysis I	K013381
LungCare CT	K033374

Adverse Effects on Health:

The potential hazards are identified in a risk management summary (hazard analysis) and are controlled by:

- Software Development, Validation and Verification Process to ensure performance to specifications, Federal Regulations and user requirements.
- Adherence to industry and international standards.

Conclusions:

The Advanced Lung Analysis II does not result in any new potential safety risks and performs as well as devices currently on the market. GE considers features of the Advanced Lung analysis II to be equivalent to those of Advanced Lung Analysis I (K013381) and LungCare CT (K033374).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 11 2009

GE Medical Systems
% Mr. Daniel W. Lehtonen
Staff Engineer
Intertek Testing Services
70 Codman Hill Road
BOXBOROUGH MA 01719

Re: K042694
Trade/Device Name: Advanced Lung Analysis II
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: OEB
Dated: November 8, 2004
Received: November 9, 2004

Dear Mr. Lehtonen:

This letter corrects our substantially equivalent letter of November 18, 2004.

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 such 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 os 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.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

for Janine M. Morris
Acting 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): K042694

Device Name: ADVANCED LUNG ANALYSIS II

Indications for Use:

Advanced Lung Analysis II is intended to provide an optimized non-invasive application to measure abnormalities in the lung (for example, nodules, lesions, etc.) from a set of Computed Tomography (CT) images.

The software is designed to support the physician in confirming the presence or absence of physician identified lung lesions (e.g. nodules). The software allows measurement of volume over time using a consistent standardized measurement protocol, thus providing an estimation of the volume doubling time. ALA II software allows analysis and displays statistics for nodule characterization all the different nodule types.

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Prescription Use (Part 21 CFR 801 Subpart D)	X	~~AND~~/OR	Over-The-Counter-Use (Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K042694

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