JAN 2 2 2004

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K040028

510(k) Summary of Safety and Effectiveness
Prepared October 20th 2003

Submitted by: R2 Technology, Inc.
1195 W. Fremont Avenue
Sunnyvale, CA 94087

Contact Person: Kathy O'Shaughnessy
Vice President, Regulatory Affairs

Product Name: CA-1500

Common Name: Comprehensive Chest Analysis Tools (C-CAT)

Classification: LLZ, Class II; CFR 21 892.2050

Predicate Devices:

Product	Company	510(k) Number	Product Classification
ImageChecker CT Workstation	R2 Technology Inc.	K023003	LLZ, Class II
Advanced Lung Analysis-1	General Electric Medical Systems	K013381	JAK, Class II
LungCARE CT Software Package	Siemens Medical Solutions	K022013	JAK, Class II

Device Description:

The C-CAT software is dedicated to assist the radiologist in assessing multiple CT case studies as well as any selected abnormal thoracic regions of interest (ROI's), such as pulmonary lesions, nodules, etc. It enables:

a) a detailed visualization and analysis of the CT slices using tools such as Multi-Planar Reformat and Sliding Maximum Image Projection;
b) a comparative analysis of the aligned, simultaneously presented current and previous CT images with findings and selected ROIs with their size (volumetric and diameter) measurement displayed for assessment of volume change and doubling time; and

c) review of software-generated comparative reports that present information such as development of new lesions, prior lesion's progression and doubling time.

This software tools package is designed for use with the ImageChecker CT Workstation (K023003, cleared 11/20/02) and other CT workstations that utilize the ImageChecker CT Workstation software tools.

Summary of Intended Use:

The Comprehensive Chest Analysis Tools (C-CAT) package is intended to provide the radiologist the ability to visualize thoracic CT series with enhanced imaging tools such as MPR and MIP; analyze, automatically/manually align and compare simultaneously presented current and previous thoracic CT images and selected "candidate" regions of interest (ROIs).

Comparison with Predicate Devices:

Hardware Platform Predicate:

R2 Technology's Comprehensive Chest Analysis Tools (C-CAT) package will reside in the ImageChecker CT Workstation hardware or any cleared CT workstation that has the ImageChecker CT Workstation software. The ImageChecker CT Workstation is the predicate for the hardware platform for this product.

Software Component Predicates:

R2 Technology's Comprehensive Chest Analysis Tools (C-CAT) package, GE's Advanced Lung Analysis (ALA-1) software package and Siemens LungCARE CT software package enable radiologists to view, analyze, register and compare current and prior thoracic CT series. These software packages allow the radiologist to examine segmented candidate chest lesions found in the CT case studies. These software packages also enable the radiologist to determine volumetric growth and doubling time of these lesions over time. Thus, their functional features are substantially equivalent.

Studies:

The Comprehensive Chest Analysis Tools package will undergo design verification tests for conformance with specifications.

Conclusion:

The Comprehensive Chest Analysis Tools package has the same intended use as the two software predicate devices identified in this section. Any technological differences in the Comprehensive Chest Analysis Tools package and the predicate devices do not raise any new questions regarding safety or effectiveness. Thus, R2 Technology's Comprehensive Chest Analysis Tools package is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 2 2004

R2 Technology, Inc.
% Ms. Denise Leung Klinker
Reviewer
Underwriters Laboratories, Inc.
1655 Scott Boulevard
SANTA CLARA CA 95050-4169

Re: K040028
Trade/Device Name: CA-1500, Comprehensive Chest Analysis tools (C-CAT) Package
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: January 6, 2003
Received: January 8, 2003

Dear Ms. Klinker:

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 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

K040028

Indications for Use:

The Comprehensive Chest Analysis Tools (C-CAT) package consists of software that enables radiologists to view, analyze, register and compare new and previous series of thoracic CT images. The software package assists the radiologists by calculating volume change and doubling time of selected segmented candidate thoracic abnormalities, such as pulmonary and pleural nodules and lesions, found on these images.

The software is designed to assist the radiologists in characterization and classification of these suspicious candidate thoracic abnormalities in terms of size, dimension, shape and position and thus aid in the patient management care decision process.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: x -OR- Over-The-Counter: _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040028