Section 1

K024149

FEB 21 2003

510(K) Summary

(as required by 21 CFR § 807.92)

Date:

A. Submitter's Information:

Name:	AccuImage Diagnostics Corporation
Address:	400 Grandview Drive South San Francisco, CA 94080
Telephone Number:	(650) 875-0192
Fax Number:	(650) 875-0194
Contact Name:	Oscar Gils Carbó
Contact Email address:	oscar@accuimage.com

B. Device Information:

Proprietary Name:	PrimeLung
Common or Usual Name:	Lung nodule visualization and analysis software package.
Classification:	Class II 21 CFR 892.2050 LLZ
Substantial Equivalence:	The AccuImage PrimeLung option is Substantially Equivalent to the Siemens Medical Solutions Lungcare CT Software Package, to the GE Medical Systems Advanced Lung Analysis, and to the AccuImage AccuView Workstation with AccuScore software module.
Device Description:	The AccuImage PrimeLung software module is an additional software option to K990241, AccuView Diagnostics Imaging Workstation with AccuScore, AccuAnalyze, AccuShade, AccuVRT and AccuMIP plug-ins. The AccuShade plug-in is not currently marketed, the AccuMIP plug-in is currently marketed with the name ProjectorPro. The AccuImage PrimeLung plug-in provides visualization and analysis tools for viewing regions of the lung, and generating reports with patient information, images, results and recommendations.

K024149

Intended Use:

PrimeLung is a comprehensive software package for visualization and analysis of thoracic CT datasets, which is intended to help the user to analyze lung nodules and other lung parameters, and to generate an automatic report.

C. Technological Characteristics of the Device as compared to Predicate Devices:

Substantial Equivalence Comparison Chart

Manufacturer	Siemens Medical Solutions	GE Medical Systems	AccuImage Diagnostics Corp.	AccuImage Diagnostics Corp.
Product Name	LungCare CT Software	Advanced Lung Analysis	AccuView Workstation with AccuScore, etc.	PrimeLung
510(k) Number	K022013	K013381	K990241/ K012106	
Computer Platform	PC Workstation with Windows Operating System	Sun Workstation	PC Workstation with Windows Operating System	PC Workstation with Windows Operating System
Type of CT Scanner for which it is applicable	Standard or low-dose spiral CT scanners	At least helical CT scanners	Helical, Multidetector and Electron Beam CT scanners	Helical, Multidetector and Electron Beam CT scanners
Draw, Edit, Delete ROI (possible nodules	Yes	Yes	Yes	Yes
Image Processing Tools	MIP, MPR, 3D Volume Rendering	Yes	MIP, MPR, 3D Volume Rendering	MIP, MPR, 3D Volume Rendering
Segmentation of lung nodule	Yes	Yes	n/a	Yes
Volume measurements, Comparator tool for nodule matching	Yes	Yes	n/a	Yes
Report Generator	Yes	Unknown	Yes	Yes

D. Brief Discussion of Test Results Submitted:

The test plan covers all aspects of the functionality, exercising every user interface button, all menus and sub-menus, as well as all configurable items, including the measurement tool, segmentation tool and report generator tool.

E. Conclusions from Test Results:

From the Graphic User Interface test results:
The Graphic User Interface, its menus and buttons conform as per the PrimeLung functional specification.

From a functionality point of view, all functionality works as described in the PrimeLung Functional Specification.

From Comparison Tool test results:
The testing performed showed that auto-matching comparison tool provides very reliable results with 100% of matching accuracy on the specified data sets.

From Report Generator Test results:
Tests results show that the report generator can be created and results can be printed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2003

Mr. Oscar Gils Carbó
Vice President
Acculmage Diagnostics Corporation
400 Grandview Drive
SOUTH SAN FRANCISCO CA 94080

Re: K024149
Trade/Device Name: PrimeLung
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: December 6, 2002
Received: December 16, 2002

Dear Mr. Carbó:

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

Section 1.1

K024149

INDICATIONS FOR USE

Applicant: AccuImage Diagnostics Corporation

510(k) Number: K024149

Device Name: PrimeLung

Indications for Use:

Comprehensive software package for visualization and analysis of thoracic CT datasets, which is intended to help the reading physician to analyze regions of the lung, such as nodules and other lung parameters, and to generate an automatic report.

Prescription Use ✓
(Per 21 CFR 801.109)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K024149