

MAY 11 1998

# 510(k) Summary

## 1. Company Identification

**Lumisys Inc.**  
225 Humboldt Court  
Sunnyvale, CA 94089  
Tel. (408) 733-6565  
Fax (408) 733-6567

## 2. Official Correspondent

Gary J. Allsebrook  
Regulatory Affairs

## 3. Date of Submission

February 28, 1998

## 4. Device Name

Classification Name:	Image Digitizer
Common/Usual Name:	Phosphor Plate Digitizer
Proprietary Name:	Lumiscan 135 Phosphor Plate Digitizer (PPD)

## 5. Substantial Equivalence

*Fuji, Computed Radiography FCR AC-3, K944046; Kodak, System 400 Reader, 510(k) # Not Known, Agfa ADC Digitizer, 510(k) # Not Known*

## 6. Device Description and Intended Use

The LUMISCAN 135 system is a laser phosphor plate digitizer designed for darkroom operation to read recorded patient radiation patterns in the plate and a plate eraser system to prepare the plate for re-use. The system is based on a fixed size scanning spot and is characterized by high spatial resolution and a wide gray scale dynamic range. This is achieved with a high intensity spot of light derived from a solid-state laser that is scanned across the plate as the plate is moved perpendicular to the beam scan. As the laser scans the plate, the phosphor's stored x-ray attenuated equivalent energy is released as a different light wavelength. The emitted light is collected and

digitized to provide an image that can be stored on disk, transmitted to other systems for processing and manipulation, archived or printed onto film. After the plate has been read, it is placed on a high intensity sealed lightbox for erasure. Erasing the plate brings all the phosphors down to a ground state from which the plate is now ready to be reused to record a patient's anatomy from x-ray.

The LUMISCAN 135 houses a plate transport system, optics module and reading electronics. Separate from the LUMISCAN 135 is the eraser unit, Lumisys 135E, which incorporates high intensity lamps with a light-tight lid for returning the phosphors to zero.

The LUMISCAN 135 uses a solid state laser diode as the beam source. The laser is conditioned by a lens for beam forming and coupled to a fiber. From the fiber, the energy is directed to a scanning galvanometer. The galvanometer has a mirror that is oscillating precisely across the width of the plate and irradiating the plate with laser light. As the light impinges the plate, stored energy from the plate is emitted and collected in an integrating cylinder. The collected light is detected by a photomultiplier, converted to an analog signal which is logarithmically amplified, corrected for spatial variations in the integrating cylinder, and then digitized by an A/D converter.

## **7. Hazard Analysis**

Potential hazards as a result of equipment malfunction are:

1. Phosphor plate may not digitize
2. Phosphor plate may digitize partially.
3. Image artifacts, and
4. Phosphor plate may not completely erase.

The software has been designed to provide a user with system messages in case of equipment malfunction. These messages are listed in the Operators' Reference Guide and include a probable cause with any recommended action(s). Any artifacts that may be introduced into a digitized image, such as vertical lines resulting from dirt on the optics, are obvious to a physician or technologist.

## 8. Safety Concerns

The hardware complies with one or more of the following safety standards (or the most current revision at the time of testing):

UL 1950  
 CAN/CSA-C22.2 No. 950-93  
 TUV:  
 EN 60950/08.92  
 EN 60950 A1/01.93  
 EN 60950 A2/08.93  
 EN 60825-1/03.94

Additionally, the hardware complies with CFR 47, Part 15 and DHHS Radiation performance standards (21 CFR Subchapter J) as appropriate.

## 9.0 Substantial Equivalence

The following products provide functions, which are substantially equivalent to this product:

	Lumisys	Fuji	Kodak	Agfa
Product Name	Lumiscan 135	Fuji FCR AC-3	System 400 Reader	ADC Digitizer
510(k) Number		K944046	Not Known	Not Known
Dimensions (WxHxD) (cm)	53x33x69	71x105x68	108x141x101	165x180x180
Weight (kg)	165	180	270	500
Power (VAC/A/Hz)	120/2/60 or 220/1/50	120/2/60	120/2/60 220/1/50	220/14/60
Scan Size (max) (WxL) (cm)	35 x 43	35 x 43	35 x 43	35 x 43
Spot Size (microns)	100	Not Known	100	120
Dynamic Range	5 Decades	Not Known	Not Known	Not Known
Gray Scale	12 Bit	10 Bit	12 Bit	12 Bit
Digitizing Rate	60 per hour	70 per hour	50	70 per hour
Laser	30 mW Solid State	Not Known	30 mW HeNe	35 mW HeNe
Beam Scan	Galvanometer	Polygonal Mirror	Galvanometer	Galvanometer
Resolution X/Y	2.85 - 5 LP/mm	Not Known	Not Known	3-4.5 LP/mm
Pixels per mm (35 x 43)	5-10	5-10	Not Known	Not Known
Interface	PC, ISA or SCSI	Proprietary	Proprietary	Proprietary



MAY 11 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Lumisys, Inc.  
c/o Regulatory Management Services  
Gary J. Allsebrook  
Official Correspondent  
16303 Panoramic Way  
San Leandro, CA 94578

Re: K980809  
Lumiscan 135 Phosphor Plate Digitizer  
Lumiscan 135E Eraser  
Dated: February 28, 1998  
Received: March 3, 1998  
Regulatory class: Unclassified  
Procode: 90 LMA

Dear Mr. Allsebrook:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K980809

510(k) Number (if known):

Device Name: Lumiscan 135 Phosphor Plate Digitizer (PPD) and Lumisys 135E Eraser.

Indications For Use:

The LUMISCAN 135 system is a laser phosphor plate digitizer designed for darkroom operation to read recorded patient radiation patterns in the plate and a plate eraser system to prepare the plate for re-use. The system is based on a fixed size scanning spot and is characterized by high spatial resolution and a wide gray scale dynamic range. This is achieved with a high intensity spot of light derived from a solid-state laser that is scanned across the plate as the plate is moved perpendicular to the beam scan. As the laser scans the plate, the phosphor's stored x-ray attenuated equivalent energy is released as a different light wavelength. The emitted light is collected and digitized to provide an image that can be stored on disk, transmitted to other systems for processing and manipulation, archived or printed onto film. After the plate has been read, it is placed on a high intensity sealed lightbox for erasure. Erasing the plate brings all the phosphors down to a ground state from which the plate is now ready to be reused to record a patient's anatomy from x-ray.

The LUMISCAN 135 houses a plate transport system, optics module and reading electronics. Separate from the LUMISCAN 135 is the eraser unit, Lumisys 135E, which incorporates high intensity lamps with a light-tight lid for returning the phosphors to zero.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  (Per 21 CFR 901.109)

OR

Over-the-Counter Use

(Optional Format 1-2-96)

*David L. ...*  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K980809