K020243

Appendix A. 510(k) Summary of Safety and Effectiveness
(See next page)

MAR 5 2002

Per Title 21 CFR 807 . 92, the following is the 510(k) Summary for the Laser Film Digitizer manufactured by Clinical Laser Systems and marketed by eRadLink Inc. under the trade-name eRadLink LaserPro 16:

(1) SUBMITTER:

eRadLink Inc.
22750 Hawthorne Blvd.
Torrance, California 90505-
Phone: 310-373-5673
Fax: 310-373-9763

CONTACT:

Albert Kouba
Regulatory Affairs
19529 Chaparral Circle
Penn Valley, California 95946
Phone: 530-432-3791
Fax: 530-432-4046

SUBMISSION DATE: 18 DEC 2001

(2) DEVICE NAME:

TRADE NAME: eRadLink LaserPro 16

COMMON NAME: Laser Film Digitizer

CLASSIFICATION NAME: Digitizer, Image, Radiological (per regulation 21 CFR 892.2030) (Class II device)

PRODUCT CODE: LMA

(3) PREDICATE DEVICE: Lumiscan 75 (510(k) number Not Known)
DI-2000 (Software application – 510(k) Number K980213)
Lumisys Inc.
225 Humboldt Court
Sunnyvale, California 94089

(4) DEVICE DESCRIPTION:

The eRadLink LaserPro 16 is a digitizing scanner that converts radiographic film transparency images to digital format. This is accomplished by utilizing a laser beam light source and a proprietary sealed optic path. There are no internal lenses, mirrors, or electro-optic devices. The new technology provides superior image quality, requires no internal optics cleaning, no optical alignment and is inherently highly accurate and reliable.

Film, from a minimum of 2 inches to a maximum of 14 inches in width and, from a minimum of 2 inches to a maximum of over 52 inches in length is driven passed the scanning laser beam by a clocked, stepping motor. Scanned data is electronically converted from analog to 16 bit digital gray scale and transmitted to the host computer in DICOM format.

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(5) INTENDED USE OF DEVICE

The LaserPro 16 Laser Film Digitizer is intended to be used in a Radiological Laboratory or Doctors office to read and digitize gray scale images from conventional x-rays for transmission to PC computer. The receiving computer allows the technician to add patient identification, review the x-ray at various rotations and options and compress the image using industry accepted techniques to an average file size of less than one megabyte. Compressed images are encapsulated in DICOM (Digital Imaging and Communications in Medicine) format, which then may be transmitted via various communication protocols to other sites or archived by a PACS host.

(6) SUBSTANTIAL EQUIVALENCE TO PREDICATE DEVICE - HARDWARE

Table – A illustrates the comparative equivalence of the LaserPro 16 to the Predicate device Hardware.

Table A – Hardware Comparison of LaserPro 16 to Predicate Devices

Feature	eRadLink	Lumisys
Product Name	**LaserPro 16**	**Lumiscan 75**
510(k) Number	-	Not Known
Dimensions	12"(h) x 18"(w) x 12"(d)	16"(h) x 21"(w) x 29"(d)
Weight	30 lbs. (13.6 kg)	90 lbs. (40.9 kg)
Power	85-264vac 2.8A 47-63 Hz	110-120vac 1A 50/60 Hz
Scan Size	2" x 2" (min), 14" x 15' (max)	7" x 7" (min), 14" x 36"
Spot Size	116 µm	100 µm
Dynamic Range	0.0 – 4.1 OD	0.5 – 3.8 OD
Gray Scale	8, 12, or 16 bits	12 bits
Digitizing Rate	100 lines/sec (16 bit gray scale)	115 lines/sec
Laser	35 mw Solid State	He-Ne Laser
Beam Scan	Fiber Optics	Galvanometer
Pixel/mm	8.6	10.09
Interface	USB or Ethernet	PCISA or SCSI

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(7) SUBSTANTIAL EQUIVALENCE TO PREDICATE DEVICE - SOFTWARE

Table B illustrates the comparative equivalence of the LaserPro 16 to the Predicate device Software.

Table B – Software Comparison of LaserPro 16 to Predicate Devices

Features	eRadLink	Lumisys
Product Name	eRadLink Medical Internet Image & Management System	DI-2000
510(k) Number	-	K980213
Patient Information – Add/Modify/Delete	Y	Y
Fax Report	N[1]	Y
Print Dicom Image	N[1]	Y
Image Rotate and Flip	Y	Y
Black/White Inversion	Y	Y
Multiple Image Display	N[2]	Y
Dicom Send/Receive/Echo	Y	Y
Dicom Query User/Provider	Y	Y
Dicom Retrieve User/Provider	Y	Y
Dicom Print	N[3]	Y
JPEG Compression lossy/lossless	Y	Y
iJPEG Compression	Y	Y
Wavelet Compression	Y	Y
Industry Standard Digital Communication Support	Y	Y
Color Images	N	Y
Cine Loop Viewing	N	Y
Dicom Removable Media Support	N	Y
Measurement Tools	N[4]	Y
Communication protocols	Y[5]	Y[5]

[1] In progress
[2] Dicom Viewer
[3] Display only
[4] Dicom Viewer
[5] ADSL, Cable and Analog Modems and Phone Lines, ATM, ISDN, FDDL, Ethernet, Token Ring

(8) EFFECTIVENESS

Program testing and calibration using Stoeffer T4110 gray-scale strip, linearity test patterns and typical x-ray film samples has demonstrated the LaserPro's 16's conformance to its defined specifications.

(9) SAFETY

The LaserPro 16 is powered by an external power supply, which is UL260, CSA 22.2, TUV and IEC 601-1 approved for safety and CISPR11 Class B for EMT requirements. Features include 4000VAC isolation, operating range from 0 to 70° C, overvoltage and overcurrent protection and line regulation of ±0.5% maximum at full load.

The LaserPro 16 Scanner is currently under test for FCC Class A EMT, RFI and UL safety compliance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 5 2002

Mr. Albert J. Kouba
Regulatory Affairs
eRadLink, Inc.
19529 Chaparral Circle
PENN VALLEY CA 95946-9443

Re: K020243
Trade/Device Name: LaserPro 16 Laser Digitizing Scanner
Regulation Number: 21 CFR 892.2030
Regulation Name: Medical image digitizer
Regulatory Class: II
Product Code: 90 LMA
Dated: January 22, 2002
Received: January 23, 2002

Dear Mr. Kouba:

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

510(k) Number (if known): K020243

Device Name: eRadLink LaserPro 16

Indications for Use

The LaserPro 16 is a desk top laser image digitizer intended to produce digital copies of radiological film in 16 levels of gray scale. The digital copies are transmitted to a Pentium based personal computer (PC) where they may be displayed, processed, or compressed for archiving or transmission via computer networks to other medical facility sites.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020243

Prescription Use √ OR Over-the-Counter Use _____
(Per 21 CFR 901.109)

(Optional Format 1-2-96)