K052938 NOV 17 2005

Per Title 21 CFR 807. 92, the following is the 510(k) Summary for the Solid State X-ray Imager manufactured and marketed by eRadlink Inc. under the trade-name eRadlink CR-Pro:

(1) **SUBMITTER:**

eRadlink Inc.
22760 Hawthorne Blvd.
Torrance, California 90505-3664
Phone: 310-373-5673
Fax: 310-373-9763

CONTACT: Albert Kouba
Manager, Regulatory Affairs
22760 Hawthorne Blvd.
Torrance, California 90505-3664
Phone: 310-373-5673
Fax: 310-373-9763

SUBMISSION DATE: 30 September 2005

(2) **DEVICE NAME:**

TRADE NAME: eRadlink CR-Pro

COMMON NAME: Storage Phosphor Reader with Software Modification

CLASSIFICATION NAME: Solid State X-ray Imager (per regulation 21 CFR 892.1650) (Class II device)

PRODUCT CODE: MQB

(3) **PREDICATE DEVICE:** OREX PcCR (K003256)
49 Plain St.
Attleboro, MA 02760

(4) **DEVICE DESCRIPTION:**

The eRadlink CR-Pro 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 path of fiber optics. The new technology provides superior image quality, requires no internal optics cleaning, no optical alignment and is inherently highly accurate and reliable.

Phosphor plates from a minimum of 10 inches to a maximum of 14 inches in width, is driven past the digitizing laser beam by a clocked, stepping motor. Scanned data is electronically converted from analog to 16 bit digital gray scale and transmitted to the internal computer for processing.

(5) **INTENDED USE OF DEVICE**

The CR-Pro is a free standing, laser driven, image digitizer intended to produce digital copies of phosphor plate recorded images in 16 levels of gray scale. The digital copies are transmitted to an internal Intel Pentium 4 based personal computer (PC) where they may be displayed,

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processed, or compressed for archiving or transmission via computer networks to other medical facility sites.

This device is not to be used for primary imaging diagnosis in mammography.

(6) SUBSTANTIAL EQUIVALENCE TO PREDICATE DEVICE - HARDWARE

Table – A illustrates the comparative equivalence of the CR-Pro to the Predicate device Hardware.

Table A – Hardware Comparison of CR-Pro to Predicate Devices

Feature	eRadlink	OREX
Product Name	CR-Pro	PcCR
510(k) Number	Not Issued	K003256
Dimensions	40in (h) x 24in(w) x 18in9(d)	16"(h) x 21"(w) x 29"(d)
Weight	98lbs (44.5kg)	90 lbs. (40.9 kg)
Power	90-227vac 10A 47-63Hz	110-120vac 1A 50/60 Hz
Scan Size	8" x 10" (min) 14"x 17" (max)	7" x 7" (min), 14" x 36"
Spot Size	100µm	100 µm
Dynamic Range	0.0 – 3.5 OD	0.5 – 3.8 OD
Gray Scale	16 (Transmitted)	8 or 12 bits
Digitizing Rate	100 lines/sec	115 lines/sec
Laser	35 mw Solid State	He-Ne Laser
Beam Scan	Fiber Optics	Galvanometer
Pixel/mm	8.0	10.09
Plate Size	14" x 17"	14" x 17"
	14" x 14"	14" x 14"
	10" x 12"	10" x 12"
	8" x 10"	8" x 10"
Interface	USB 2 (Diagnostic), Ethernet	USB 1.1
Computer	Pentium 4 2.8 GH	Pentium 4 1.8 GH
Ram	512 MB	512 MB
Hard Drive	80GB	20 GB
Video Card	2 MB 1024 X 760 Resolution	1024 X 760 Resolution
Monitor	1024 x 760	1024 x 760
Operating System	Windows XP Pro	Windows 2000
Electrical Safety	IEC 60601-1, 2	IEC 60601-1, 2

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(7) SUBSTANTIAL EQUIVALENCE TO PREDICATE DEVICE - SOFTWARE

Table B illustrates the comparative equivalence of the CR-Pro to the Predicate device Software.

Table B – Software Comparison of CR-Pro to Predicate Devices

Features	eRadlink	OREX	eRadlink[2]
Product Name	CR-Pro	PcCR	LS-16
510(k) Number	-	K003256	K020243
Patient Information – Add/Modify/Delete	Y	Y	Y
Fax Report	Y	Y	Y
Print Dicom Image	Y	Y	Y
Image Rotate and Flip	Y	Y	Y
Black/White Inversion	Y	Y	Y
Multiple Image Display	Y	Y	Y
Dicom Send/Receive/Echo	Y	Y	Y
Dicom Query User/Provider	Y	Y	Y
Dicom Retrieve User/Provider	Y	Y	Y
Dicom Print	Y	Y	Y
JPEG Compression lossy/lossless	Y	Y	Y
iJPEG Compression	Y	Y	Y
Wavelet Compression	Y	Y	Y
Industry Standard Digital Communication Support	Y	Y	Y
Color Images	N	Y	N
Cine Loop Viewing	N	Y	N
Dicom Removable Media Support	Y	Y	Y
Measurement Tools	Y	Y	Y
Communication protocols	Y[1]	Y[1]	Y[1]

[1] ADSL, Cable and Analog Modems and Phone Lines, ATM, ISDN, FDDL, Ethernet, Token Ring

[2] The LaserPro 16 (an earlier product of eRadlink) is cited as a Predicate Device as the application software utilized in that device is the same software used in the CR-Pro with minor start-up; phosphor plate handling and erasing modifications.

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Color Images	N	Y	N
Cine Loop Viewing	N	Y	N
Dicom Removable Media Support	Y	Y	Y
Measurement Tools	Y	Y	Y
Communication protocols	Y[1]	Y[1]	Y[1]

[1] ADSL, Cable and Analog Modems and Phone Lines, ATM, ISDN, FDDL, Ethernet, Token Ring

[2] The LaserPro 16 (an earlier product of eRadlink) is cited as a Predicate Device as the application software utilized in that device is the same software used in the CR-Pro with minor start-up; phosphor plate handling and erasing modifications.

(8) EFFECTIVENESS

Program testing and calibration using Beryllium gray-scale wedge, body part phantoms and typical x-ray plate samples has demonstrated the CR-Pro's conformance to its defined specifications.

(9) SAFETY

The CR-Pro complies with the following standards:

Standard:year	**Name**
21CFR1040.10	PERFORMANCE STANDARDS FOR LIGHT-EMITTING PRODUCTS: Laser products
DICOM 3:2004	Digital Imaging and Communications in Medicine (including JPEG coding per section 3.6)
EN55022:1998 including A1:2000	Information technology equipment — Radio disturbance characteristics — Limits and methods of measurement
EN55024:1998 including A1:2001 and A2:2003	Information technology equipment — Immunity characteristics — Limits and methods of measurement
EN61000-3-2:2000	Electromagnetic compatibility (EMC) — Part 3-2: Limits — Limits for harmonic current emissions (equipment input current up to and including 16 A per phase)
EN61000-3-3:1995 including A1:2001	Electromagnetic compatibility (EMC) — Part 3-3: Limits — Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection
IEC 60601-1:1988 including am1:1991 and am2:1995	Medical electrical equipment - Part 1: General requirements for safety
IEC 60601-1-2 (2001-09)	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility – Requirements and tests
SMPTE RP 215-2001	Encoding Film Transfer Information into Vertical Ancillary Data for SMPTE 292M Bit-Serial Interface
SMPTE 349M-2001	Television – Transport of Alternate Source Image Formats through SMPTE 292M

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 17 2005

eRadlink, Inc.
% Mr. Ned Devine
Responsible Third Party Official
Intertek Testing Services NA, Inc.
70 Codman Hill Road
BOXBOROUGH MA 01719

Re: K052938
Trade/Device Name: eRadlink CR-Pro
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: MQB
Dated: November 3, 2005
Received: November 4, 2005

Dear Mr. Devine:

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 (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 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 this letter:

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.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

Indications for Use

510(k) Number (if known): K052938

Device Name: eRadlink CR-Pro

Indications for Use:

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This device is not to be used for primary imaging diagnosis in mammography.

Prescription Use ✓ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Legarm

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052938

Software Certification Statement