DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Radlink, Inc.
% Mr. Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Court
NAPLES FL 34114

December 17, 2014

Re: K142718
Trade/Device Name: Radlink GPS
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: November 14, 2014
Received: November 21, 2014

Dear Mr. Kamm:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert A. Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142718

Device Name
Radlink GPS

Indications for Use *(Describe)*
Radlink GPS is intended for digital image capture use in general radiographic examinations, whenever conventional screen-film systems may be used. Radlink GPS allows imaging of the pelvis, knee, skull, chest, shoulder, spine, abdomen and extremities. The digital images are transmitted from the panel or from a connection to PACS via computer networks or from a video input port to a personal computer (PC) where they may be displayed, processed, altered, overlaid with templates, compressed for archiving or transmission via computer networks to other medical facility sites. Not for mammography.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Food and Drug Administration
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Attachment 2– 510(k) Summary

Per Title CFR 807.92, the following is the 510(k) Summary for the DR system manufactured and marketed by Radlink Inc. under the trade name Radlink GPS:

(1) SUBMITTER

Radlink, Inc.
815 N Nash st
El Segundo, CA, 90245
Phone: 310 643 6900 Fax: 310 364 3150
Establishment Registration Number: 3005560996
Prepared by: Brian Kordich, Quality Manager
Date Prepared: November 14, 2014

(2) DEVICE NAME

TRADE NAME: Radlink GPS
COMMON NAME: Digital X-Ray Receptor Panel
CLASSIFICATION NAME: Stationary X-ray system (Class 2 Device)
PRODUCT CODE: MQB. Regulation 892.1680

(3) PREDICATE DEVICE: K141440, dicomPACS DX-R, O&R

(4) DEVICE DESCRIPTION

The Radlink GPS system represents the straightforward integration of digital x-ray receptor panels with their own FDA 510(k) clearance and our acquisition software that has been previously cleared by the FDA for use with our Radlink CR-Pro Solid State X-ray Imager (K052938) and Radlink LaserPro-16 (K020243). The Radlink GPS is compatible with the following digital x-ray receptor panels:

- Vieworks VIVIX-S (K120020) and VIVIX-S Wireless (K122865)
- Trixell Artpix Mobile EZ2GO with portable PIXIUM 3543EZ (K110849)
- Perkin Elmer XRpad 4336 MED (K140551)

Radlink GPS is a Digital Radiography (DR) system, featuring an integrated flat panel digital detector (FPD). Radlink GPS is designed to perform digital radiographic examinations as a replacement for conventional film. This integrated platform provides the benefits of PACS with the advantages of digital radiography for a filmless environment and improves cost effectiveness. The major functions and principle of operations of the Radlink CR Pro acquisition software and PACS were not changed. The digital copies are transmitted to an internal personal computer (PC) where they may be displayed, processed, compressed for archiving or transmission via computer networks to other medical facility sites. Images can be rotated, flipped, cropped, zoomed, window level, overlaid and annotated (markers, text, freestyle, line distance measurements, angles). Digital images may be received via the flat panel digital detector (FPD), from a connection to PACS via computer networks or from a video input port.

(5) INDICATIONS FOR USE

Radlink GPS is intended for digital image capture use in general radiographic examinations, whenever conventional screen-film systems may be used. Radlink GPS allows imaging of the pelvis, knee, skull, chest, shoulder, spine, abdomen and extremities. The digital images are transmitted from the panel or from a connection to PACS via computer networks or from a video input port to a personal computer (PC) where they may be displayed, processed, altered, overlaid with templates, compressed for archiving or transmission via computer networks to other medical facility sites. Not for mammography.

(6) SUBSTANTIAL EQUIVALENCE TO PREDICATE DEVICE

The Radlink GPS is the functional equal to the above named predicate device AND our Radlink CR-Pro product, K052938 and it adds compatibility with 510(k) cleared digital panels which came out after our original submission. The Radlink Digital Radiography System uses the following cleared digital panels: (Supplied unmodified):

- Vieworks VIVIX-S (K120020) and VIVIX-S Wireless (K122865)
- Trixell Artpix Mobile EZ2GO with portable PIXIUM 3543EZ (K110849)
- Perkin Elmer XRpad 4336 MED (K140551)

The Radlink digital radiography system uses the Radlink software which controls image acquisition, processing, storage, transfer, display, and measurement functions that were previously certified with both the Radlink CR-Pro (FDA 510(k): K052938) and the Radlink LaserPro (FDA 510(k): K020243) products.

Table 1: Substantial Equivalence Table: Software: Comparison to our previous software.

Features/Company	Radlink [2]	Radlink [2]
Product Name	CR-Pro	GPS
FDA 510(k) #	K052938	-
Patient Information (Add/Modify/Delete)	Yes	Yes
Fax Report	Yes	Yes
Print DICOM Image	Yes	Yes
Image Rotate & Flip	Yes	Yes
Black/White Inversion	Yes	Yes
Multiple Image Display	Yes	Yes
DICOM Send/Receive/Echo	Yes	Yes
DICOM Query User/Provider	Yes	Yes
DICOM Retrieve User/Provider	Yes	Yes
DICOM Print	Yes	Yes
JPEG Compression lossy/lossless	Yes	Yes
JPEG Compression	Yes	Yes
Wavelet Compression	Yes	Yes
Industry Standard Digital Communication Support	Yes	Yes
Color Images	No	No
Cine Loop Viewing	No	No
DICOM Removable Media Support	Yes	Yes
Measurement Tools	Yes	Yes
Communication Protocols	Yes [1]	Yes [1]

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

[2] The LaserPro-16 and CR-Pro are previously cleared software products of Radlink, Inc. These are cited as a Predicate Device because the application software utilized in the Radlink DR System is the exact same software used in the LaserPro-16 and CR-Pro units with very minor work-flow changes.

Table 2: Substantial Equivalence Table: Digital Panel Upgrade Kit

Item	K141440, dicomPACS DX-R, O&R	Radlink GPS
Indications for Use	The dicomPACS DX-R with flat panel digital imaging system is intended for use in generating radiographic images of human anatomy. This device is intended to replace film/screen systems in all general purpose diagnostic procedures. This device is not intended for mammography applications. This device is intended for use by qualified medical personnel and is contraindicated when, in the judgment of the physician, procedures would be contrary to the best interest of the patient.	Radlink GPS is intended for digital image capture use in general radiographic examinations, whenever conventional screen-film systems may be used. Radlink GPS allows imaging of the pelvis, knee, skull, chest, shoulder, spine, abdomen and extremities. The digital images are transmitted from the panel or from a connection to PACS via computer networks or from a video input port to a personal computer (PC) where they may be displayed, processed, altered, overlaid with templates, compressed for archiving or transmission via computer networks to other medical facility sites. Not for mammography.
Compatible Digital Panels	Toshiba FDX4343R, Toshiba FDX3543RP, Konica Minolta AeroDR P-11 (1417HQ). Pixium Portable 2430 EZ (wireless) Pixium Portable 3543 EZ (wireless) Perkin Elmer 4336 XRpad (wireless) :	Vieworks VIVIX-S (K120020) Vieworks VIVIX-S Wireless (K122865) PIXIUM 3543EZ (K110849) (wireless) Perkin Elmer XRpad 4336 MED (K140551) (wireless)
DICOM	YES	YES
Templating	NO	YES

(6) Summary of Non-clinical testing. Program testing and calibration using gray-scale wedge and a line resolution phantom and has demonstrated the Radlink GPS conformance to its defined specifications. Proper acquisition of digital x-ray images was verified with each of the three available digital panels. All panels have been tested to meet the requirements of IEC 60601-1 (Medical Device Safety) and IEC 60601-1-2 (Electromagnetic Compatibility). All panels have already been cleared by FDA. DICOM compatibility has been verified. Software validation and risk analysis was performed. The templating features software has been validated.

(7) Summary of Clinical testing. Human images were obtained from each of the panels. They were reviewed by a Board Certified Radiologist and found to be of good diagnostic quality. Physician Evaluation of the Templating Software was performed successfully.

(8) Conclusion: Based on the non-clinical and clinical testing, and a comparison of software features (Tables above) and the fact that all three proposed compatible panels have already undergone successful FDA review, we conclude that the Radlink GPS product is as safe and effective as products currently legally for sale in the USA and is therefore substantially equivalent to predicate devices.