March 18, 2025

Radlink, Inc.
℅ Victoria Nadershahi
Director of Regulatory Affairs
2101 E El Segundo Blvd., Suite 104
EL SEGUNDO, CA 90245

Re: K242161
Trade/Device Name: Radlink GPS Pro Imaging
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: February 10, 2025
Received: February 10, 2025

Dear Victoria Nadershahi:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242161

Device Name
Radlink GPS Pro Imaging

Indications for Use *(Describe)*
Radlink GPS Pro Imaging is an image-processing software intended to assist in hip procedures by measuring the acetabulum's position relative to local bone structures identified from radiological images. The device allows for overlaying digital annotations on radiological images and includes tools for performing measurements using the images and digital annotations. Clinical judgment and experience are required to properly use the software. The software is not for primary image interpretation. The software is not for use on mobile phones.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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K242161 510(k) Summary

Applicant Name: Radlink, Inc.
2101 E. El Segundo Blvd., Suite 104
El Segundo, CA 90245

Applicant Contact: Victoria Nadershahi

Email: vnadershahi@radlink.com

Phone: (310)717-5822

Date Prepared: March 13, 2025

Device Information:

- **Device Trade Name:** *Radlink GPS Pro Imaging*
- **Common Name:** Medical image management and processing system
- **Regulation Number:** 892.2050
- **Device Class:** II
- **Product Code:** LLZ

Predicate & Reference Devices:

- Primary Predicate Device: CUPTIMIZE™ Advanced (K231503), Regulation Number: 892.2050, Product Code: LLZ
- Secondary Predicate Device: Radlink® GPS (K142718), Regulation Number: 892.1680, Product Code: LLZ/MQB
- **Reference Device:** K233761

Indications for Use:

Radlink GPS Pro Imaging is an image-processing software intended to assist in hip procedures by measuring the acetabulum's position relative to local bone structures identified from radiological images. The device allows for overlaying digital annotations on radiological images and includes tools for performing measurements using the images and digital annotations. Clinical judgment and experience are required to properly use the software. The software is not for primary image interpretation. The software is not for use on mobile phones.

Device Description:

The *Radlink® GPS Pro Imaging* is an image processing software designed to assist orthopedic surgeons in positioning hip, knee, and trauma components. The software leverages advanced geographic measurement and

stitching technologies, which have been previously FDA cleared, ensuring precise and reliable image handling. These foundational technologies continue to be the primary features of software.

Additionally, Radlink GPS Pro Imaging software supports complete image acquisition and DICOM transmission capabilities, facilitating seamless integration with existing hospital systems. It is compatible with Windows operating system, and requires minimal hardware specifications, making it a versatile solution for different clinical setups.

Substantial Equivalence:

Table 1: Predicate Comparison Table

Feature	Subject Device	Primary Predicate Device	Secondary Predicate Device
Company	Radlink, Inc.	DePuy Orthopedics, Inc.	Radlink, Inc.
Device Name	Radlink GPS Pro Imaging	Cuptimize™ Advanced	Radlink GPS
FDA 510(k) #	K242161	K231503	K142718
Regulatory Number	892.2050	892.2050	892.1680
Product Code	LLZ	LLZ	LLZ/MQB
Device Class	II	II	II
Intended Use	Radlink GPS Pro Imaging is an image-processing software intended to assist in hip procedures by measuring the acetabulum's position relative to local bone structures identified from radiological images. The device allows for overlaying digital annotations on radiological images and includes tools for performing measurements using the images and digital annotations. Clinical judgment and experience are required to properly use the software. The software is not for primary image interpretation. The software is not for use on mobile phones.	Preoperative templating for orthopedic procedures and intraoperative data for total hip arthroplasties (THA) to provide the following: • Accurate digital templating by allowing 'real time' templating in the OR using direct measurement and template rescaling. • Intraoperative surgical guidance, including offset, leg length, anteversion and abduction angle data.	Preoperative templating for orthopedic procedures to provide the following: • Accurate digital templating by allowing 'real time' templating in the OR using direct measurement and template rescaling. (OrthoPlan®) • Intraoperative surgical guidance, including offset, leg length, anteversion and abduction angle data.
PACS Image Compatibility	C-Arm, X-Ray, CT	C-Arm, X-Ray	C-Arm, X-Ray
Operating System	Windows	Windows, iOS	Windows
Cybersecurity Enhancements	Yes	Stated, but details unavailable	Limited

Performance Data

Comprehensive cybersecurity testing and software verification/validation activities were conducted in accordance with applicable FDA guidance and recognized standards. These assessments confirm that the device's software meets the required performance, safety, and security criteria.

Conclusion:

The Radlink Pro Imaging Software has been demonstrated to be substantially equivalent to the predicate devices Cuptimize™ Advanced (K231503) and Radlink GPS (K142718). The subject device shares the same intended use and fundamental technology, while incorporating enhancements that do not raise new or different questions of safety and effectiveness.

The verification and validation testing, including software performance, segmentation accuracy, usability evaluation, and cybersecurity assessment, confirms that the subject device performs as safely and effectively as the predicate devices.