JLK, Inc.
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

February 25, 2025

Re: K250348
Trade/Device Name: JLK-AILink
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: February 6, 2025
Received: February 6, 2025

Dear Dave Yungvirt:

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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT 8B: 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)*
K250348

Device Name
JLK-AILink

Indications for Use *(Describe)*
JLK-AILink is a software that receives digital images and data from various sources (i.e., CT scanners, MR scanners, ultrasound systems, computed & direct radiographic devices, secondary capture devices, scanners, imaging gateways, or other imaging sources). Images and analyzed data with optional modules can be stored, communicated, processed, and displayed within the system and or across computer networks at distributed locations. Typical users of this system are trained professionals including but not limited to physicians and medical technicians. The device is not intended 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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February 22, 2025

K250348

510(k) Summary

1. Contact Details *(21 CFR 807.92(a)(1))*

- Applicant Name: JLK, Inc.
- Applicant Address: JLK Tower, 5, Teheran-ro 33-gil Gangnam-gu Seoul n/a 06141 Korea, South
- Applicant Contact Telephone: (+82)1038507933
- Applicant Contact: Dr. Dongmin Kim
- Applicant Contact Email: dmkim@jlkgroup.com

- Correspondent Name: JLK, Inc.
- Correspondent Address: JLK Tower, 5, Teheran-ro 33-gil Gangnam-gu Seoul n/a 06141 Korea, South
- Correspondent Contact Telephone: (+82)1027905959
- Correspondent Contact: Ms. Sunyoung Jang
- Correspondent Contact Email: syjang@jlkgroup.com

2. Device Name *(21 CFR 807.92(a)(2))*

Device Trade Name	JLK-AILink
Common Name	Medical image management and processing system
Classification Name	System, Image Processing, Radiological
Regulation Number	892.2050
Product Code(s)	LLZ

3. Legally Marketed Predicate Devices *(21 CFR 807.92(a)(3))*

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K031013	STARPACS™	LLZ

4. Device Description Summary *(21 CFR 807.92(a)(4))*

JLK-AILink is a software designed to streamline the management, visualization, and communication of medical imaging data within clinical workflows. It facilitates bidirectional communication with hospital PACS systems or imaging equipment such as MR, CT, or X-ray scanners, enabling the communication of DICOM images. This functionality ensures seamless integration with existing hospital IT infrastructure while adhering to DICOM communication standards.

The software includes a DICOM viewer that offers tools for image manipulation and annotation, such as zoom, magnify, contrast adjustment, cobb angle measurement, and annotation tools, making it an efficient and user-friendly interface for medical professionals. The modular architecture allows healthcare institutions to integrate optional analysis solutions with DICOM communication to expand its image analysis capabilities as needed.

JLK-AILink also supports mobile access, enabling clinicians to view images, interact with annotations, and receive critical alerts remotely. With a focus on interoperability, the software ensures compatibility not only with PACS systems but also with containerized environments, allowing for secure and data management.

This combination of DICOM functionalities, modular integration, and mobile accessibility makes JLK-AILink a clinical tool for enhancing clinical workflows and improving the efficiency of medical imaging data usage in diverse healthcare settings.

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5. Intended Use/Indications for Use *(21 CFR 807.92(a)(5))*

JLK-AILink is a software that receives digital images and data from various sources (i.e., CT scanners, MR scanners, ultrasound systems, computed & direct radiographic devices, secondary capture devices, scanners, imaging gateways, or other imaging sources). Images and analyzed data with optional modules can be stored, communicated, processed, and displayed within the system and or across computer networks at distributed locations. Typical users of this system are trained professionals including but not limited to physicians and medical technicians. The device is not intended for mammography.

6. Indications for Use Comparison *(21 CFR 807.92(a)(5))*

Both JLK-AILink and STARPACS™ are designed as software applications for managing, processing, storing, and displaying medical images and associated data. These systems support healthcare professionals in clinical environments by facilitating the interpretation and management of digital images from various imaging modalities, such as CT, MRI, ultrasound, and radiographic devices. Neither device is intended to provide a clinical diagnosis independently but serves as a supportive tool for trained professionals.

7. Technological Comparison *(21 CFR 807.92(a)(6))*

Both JLK-AILink and STARPACS™ are software-based systems designed for medical image management and processing. These systems receive digital images and data from various imaging modalities, including CT, MRI, ultrasound, and radiographic devices. The images and data are stored, communicated, processed, and displayed within the system or across distributed computer networks to assist healthcare professionals in clinical workflows.
In summary, JLK-AILink and STARPACS™ share technological characteristics and meet equivalent safety and performance standards, ensuring their substantial equivalence for regulatory purposes.

8. Non-Clinical and/or Clinical Tests Summary & Conclusions (*21 CFR 807.92(b)*)

JLK-AILink was designed and developed according to the standards required for software development. For software evaluation, software functionality, risk management, cybersecurity, verification, validation, and requirements were addressed. The evaluation was tested according to the verification and validation processes and planning, and the test results support that all system requirements have met their acceptance criteria and are adequate for their intended use.
JLK, Inc. conducted extensive software verification and validation test of the JLK-AILink. This v&v testing demonstrated that the JLK-AILink system accurately represents key processing parameters under a range of clinically relevant parameters and perturbations associated with the intended use of the software. The documentation was provided as recommended by FDA's Guidance for Industry and FDA staff, "Content of Premarket Submissions for Device Software Functions," June 14, 2023.
In conclusion, JLK-AILink, is substantially equivalent to the legally marketed predicate device, STARPACS™ (K031013).