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

October 16, 2024

Re: K242556
Trade/Device Name: JLK-CTP
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: October 5, 2024
Received: October 7, 2024

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
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)*
K242556

Device Name
JLK-CTP

Indications for Use *(Describe)*
JLK-CTP is an image processing software package to be used by trained professionals, including but not limited to physicians and medical technicians.
The software runs on a standard "off-the-shelf" computer or a virtual platform, such as VMware, and can be used to perform image viewing, processing, and analysis of CT perfusion images for the brain.
Data and images are acquired through DICOM compliant imaging devices.
JLK-CTP provides both viewing and analysis capabilities for dynamic imaging datasets obtained through CT Perfusion protocols.
The analysis is for visualization and examination of imaging data, revealing characteristics of contrast changes over time. This functionality includes the calculation of CT perfusion parameters associated with tissue flow (perfusion) and tissue blood volume.

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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October 16, 2024

510(k) Summary K242556

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

- Applicant Name: JLK, Inc.
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- Applicant Contact Telephone: (+82)1038507933
- Applicant Contact: Dr. Dongmin Kim
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- Correspondent Name: JLK, Inc.
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- 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-CTP
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
K121447	iSchemaView RAPID	LLZ

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

JLK-CTP is image processing software designed to analyze CT perfusion (CTP) images. Using the analyzed perfusion map, the software calculates the volume of the reduced cerebral blood flow (CBF) area and the volume of the delayed Tmax area in the CTP images.

JLK-CTP can be used to communicate with a DICOM-compliant device or a PACS server to receive CTP images. The software is designed to automatically receive and analyze a head CTP image with DICOM image data. The analyzed perfusion parametric maps, which are related to the tissue blood flow and volume, are written to the source DICOM and stored in the data storage. Users can review the analysis results through the implemented user interface (UI) or a connected PACS server.

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

JLK-CTP is an image processing software package to be used by trained professionals, including but not limited to physicians and medical technicians.

The software runs on a standard "off-the-shelf" computer or a virtual platform, such as VMware, and can be used to perform image viewing, processing, and analysis of CT perfusion images for the brain.

Data and images are acquired through DICOM compliant imaging devices.

JLK-CTP provides both viewing and analysis capabilities for dynamic imaging datasets obtained through CT Perfusion protocols.
The analysis is for visualization and examination of imaging data, revealing characteristics of contrast changes over time.
This functionality includes the calculation of CT perfusion parameters associated with tissue flow (perfusion) and tissue blood volume.

6. Indications for Use Comparison *(21 CFR 807.92(a)(5))*
As detailed below, JLK-CTP is an image processing software package that is substantially equivalent to iSchemaView Inc.'s RAPID (K121447), which is a previously cleared predicate device. Both devices share the same intended use, similar indications, technological characteristics, and principles of operation.

7. Technological Comparison *(21 CFR 807.92(a)(6))*
The proposed and predicate devices are brain CT perfusion analysis tools designed to support trained medical professionals. JLK-CTP integrates seamlessly with the hospital's CT equipment or PACS server, receiving CT perfusion DICOM images and analyzing perfusion parameters such as Cerebral Blood Flow (CBF), Cerebral Blood Volume (CBV), Mean Transit Time (MTT), and Residue function time-to-peak (TMax).
The proposed and predicate devices are both intended for use as analysis tools in image processing for a CT perfusion study. Both devices run on standard physical and/or virtual servers installed within the hospital's network and protected by the firewall.

8. Non-Clinical and/or Clinical Tests Summary & Conclusions (*21 CFR 807.92(b)*)
JLK-CTP 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 verification 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 performance validation testing and software verification of the JLK-CTP system. This performance validation testing demonstrated that the JLK-CTP 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.
JLK-CTP demonstrated reliable and accurate performance in calculating the reduced blood flow and delayed Tmax tissue volumes. The software's results were substantially equivalent to those obtained using RAPID. These results indicate that JLK-CTP meets the predetermined performance criteria, validating its reliability and accuracy in analyzing CT perfusion images.
In conclusion, JLK-CTP, is substantially equivalent to the legally marketed predicate device, iSchemaView RAPID (K121447).