JLK, Inc.
% John Smith
M.D, J.D. - Global Regulatory Partner
Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street NW
Washington, District of Columbia 20004

January 3, 2025

Re: K243363
Trade/Device Name: Jlk-ich
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological Computer Aided Triage And Notification Software
Regulatory Class: Class II
Product Code: QAS
Dated: October 29, 2024
Received: October 29, 2024

Dear John Smith:

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
Assistant Director
DHT8B: Division of Radiologic 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.*

Submission Number *(if known)*

K243363

Device Name

JLK-ICH

Indications for Use *(Describe)*

JLK-ICH is a radiological computer-aided triage and notification software indicated for use in the analysis of non-contrast CT images. JLK-ICH is a notification-only, parallel workflow tool that is intended to assist hospital networks and trained clinicians to identify and communicate images of specific patients to specialists, independent of the standard of care workflow.

JLK-ICH uses an artificial intelligence algorithm to analyze images for findings suggestive of pre-specified clinical conditions and promptly notifies the appropriate medical specialists of these findings in parallel with the standard of care image interpretation. Identification of suspected findings is not for diagnostic use beyond notification. Specifically, the device analyzes non-contrast CT images of the head to detect intracranial hemorrhage (ICH). The system sends a notification to a clinician that a suspected ICH has been identified and recommends a review of those images. Images can be previewed and compressed through a mobile application.

Notified clinicians are responsible for viewing non-compressed images on a diagnostic viewer and engaging in appropriate patient evaluation and relevant discussion with a treating clinician before making care-related decisions or requests.

JLK-ICH is limited to the analysis of imaging data and should not be used in lieu of full patient evaluation or relied upon to make or confirm the diagnosis.

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.**

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K243363

**510(k) SUMMARY**
**JLK, Inc.'s JLK-ICH**
**K243363**

**Applicant Name:** JLK, Inc.
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**Date Prepared:** January 3, 2025

## Device Name and Classification

- Name of Device: JLK-ICH
- Common or Usual Name: Radiological Computer-Assisted Triage and Notification Software
- Classification Panel: Radiology
- Regulation No: 21 C.F.R. § 892.2080
- Regulatory Class: Class II
- Product Code: QAS

## Predicate Device

| Manufacturer | Predicate Trade Name | Application No. | Product Code |
|---|---|---|---|
| Viz.ai, Inc. | Viz ICH | K193658 | QAS |

## Device Description

JLK-ICH is a radiological computer-assisted triage and notification (CADt) software that adheres to the DICOM standard. The device functions as a Non-Contrast Computed Tomography (NCCT) processing module, providing triage and notification prioritization for suspected hemispheric intracranial hemorrhage (ICH). This software acts as a notification-only, parallel workflow tool for hospital networks and trained clinicians, enabling the identification and communication of suspected patient images to relevant specialists, independent of the standard care workflow. JLK-ICH processes non-contrast computed tomography (NCCT) scans, prioritizing triage and notification for suspected hemispheric intracranial hemorrhage (ICH). The system utilizes advanced artificial intelligence to automatically analyze NCCT scans for indicators of ICH and promptly notify appropriate medical specialists of potential cases.

JLK-ICH comprises an image analysis algorithm hosted on JLK servers and a mobile application for notification management. The AI/ML-based algorithm is designed to analyze NCCT of the head scans forwarded from CT scanners to the JLK servers. The mobile software module enables users to receive and toggle notifications for suspected ICH cases identified by the JLK-ICH Image Analysis Algorithm. Users can view a patient list and non-diagnostic CT scans through the mobile application. Image viewing through the mobile application interface is for non-diagnostic purposes only.

The JLK-ICH AI model was trained using a dataset that includes 14,462 ICH cases from various institutions, divided between US-based and Out-of-US sources. In total, the US-based datasets contributed 14,998 cases, of which 7,499 were ICH cases and 7,499 were normal cases. These datasets were sourced from institutions including Stanford University and Thomas Jefferson University Hospital. The Out-of-US datasets provided 13,926 cases, evenly split between 6,963 normal cases and 6,963 ICH cases, collected from institutions such as Universidale Federal de Sao Paulo, Seoul St. Mary's Hospital, and five other institutions. This broad collection of both US and Out-of-US data ensures that the AI model is trained on a diverse set of cases, enhancing its applicability across different populations and clinical environments. All cases are carefully separated from the clinical performance datasets.

The algorithm’s performance was validated through a standalone performance evaluation using an independent dataset, distinct from the one for algorithm training data. Each case output from the JLK-ICH device was compared with a ground truth standard determined by two ground truthers, with a third ground truther intervening in cases of disagreement (i.e., 2+1 truther scheme). All truthers were US board-certified neuroradiologists.

**Intended Use/Indications for Use**

JLK-ICH is a radiological computer-aided triage and notification software indicated for use in the analysis of non-contrast CT images. JLK-ICH is a notification-only, parallel workflow tool that is intended to assist hospital networks and trained clinicians to identify and communicate images of specific patients to specialists, independent of the standard of care workflow.

JLK-ICH uses an artificial intelligence algorithm to analyze images for findings suggestive of pre-specified clinical conditions and promptly notifies the appropriate medical specialists of these findings in parallel with the standard of care image interpretation. Identification of suspected findings is not for diagnostic use beyond notification. Specifically, the device analyzes non-contrast CT images of the head to detect intracranial hemorrhage (ICH). The system sends a notification to a clinician that a suspected ICH has been identified and recommends a review of those images. Images can be previewed and compressed through a mobile application.

Notified clinicians are responsible for viewing non-compressed images on a diagnostic viewer and engaging in appropriate patient evaluation and relevant discussion with a treating clinician before making care-related decisions or requests.

JLK-ICH is limited to the analysis of imaging data and should not be used in lieu of full patient evaluation or relied upon to make or confirm the diagnosis.

**Summary of Technological Characteristics**

Both the subject and predicate devices utilize artificial intelligence and machine learning (AI/ML) algorithms and mobile notification software to identify and notify specialists, respectively, of patients with the presence of suspected intracranial hemorrhage (ICH) on non-contrast CT imaging of the head. JLK-ICH operates in parallel to standard of care without removing the cases from normal clinical workflow. The subject and predicate devices both include a mobile application with the same mobile software functions and outputs.

The software algorithms used in the subject device and predicate device are hosted on similar architectures that automatically receive imaging in the same DICOM format and use similar mechanisms to identify applicable imaging for analysis. Both the subject and the predicate devices include mobile application software that allows users to receive push notifications for patients identified with a suspected ICH. Users can view a unique list of patients with suspected ICH and examine the non-contrast CT scan of the patient through the mobile application. The imaging viewing of NCCT scans analyzed by both the subject and predicate devices are intended solely for informational and prioritization review purposes only (i.e., triage and notification) and are not intended for diagnostic use. Both devices interface with a non-diagnostic mobile DICOM image viewer, which allows the specialist to preview non-diagnostic images and view patient details associated with a series. The outputs of the subject and predicate devices are the same; both devices identify suspected ICH and send notifications of suspected ICH findings from the same server.

The average total NCCT-to-notification time for the JLK-ICH system is 0.19 ± 0.04 minutes. This performance is comparable to the predicate device, Viz ICH (K193658), which reported a mean time of 0.49 ± 0.15 minutes. JLK-ICH successfully meets the target time-to-notification of ≤ 0.49 ± 0.15 minutes set by the predicate device.

The JLK-ICH is as safe and effective as the predicate device Viz ICH (K193658). JLK-ICH device has the same intended use and similar indications, technological characteristics, principles of operation, and performance characteristics as the legally marketed predicate device. Performance data demonstrates that JLK-ICH is as safe and effective as the predicate device, the previously cleared Viz ICH. Thus, JLK-ICH is substantially equivalent.

| | **Viz ICH** | **JLK-ICH** |
|---|---|---|
| **Image Analysis** | | |
| Supported Imaging Modality | Non-contrast CT (NCCT) | Non-contrast CT (NCCT) |
| Alteration of Original Image Database | No | No |
| Results of Image Analysis | Internal, no image marking | Internal, no image marking |
| **Image Viewing Functionality** | | |
| Preview Images | Initial assessment, non-diagnostic purposes | Initial assessment, non-diagnostic purposes |

| | | |
|---|---|---|
| View DICOM Data | DICOM Information about the patient, study and current image. | DICOM Information about the patient, study and current image. |
| Image viewing and any manipulation (window, pan, level, zoom) | Yes | Yes |
| Segmentation of region of interest | No; device does not mark, highlight, or direct users' attention to a specific location in the original image. | No; device does not mark, highlight, or direct users' attention to a specific location in the original image. |
| **Technological Characteristics** | | |
| Compatibility with the environment and other devices | DICOM Compatible | DICOM Compatible |
| Transfer, store, and process DICOM images | Yes | Yes |
| Technical Implementation | Artificial intelligence algorithm with database of images | Artificial intelligence algorithm with database of images |
| Interference with standard workflow | No. Cases are not removed from worklist or deprioritized. | No. Cases are not removed from worklist or deprioritized. |
| Data acquisition | Acquires medical image data from DICOM-compliant imaging devices and modalities | Acquires medical image data from DICOM-compliant imaging devices and modalities |
| Time to Notification | 0.49±0.15 minutes | 0.19 ±0.04 minutes |

**Performance Data**

JLK, Inc. conducted extensive performance validation testing and software verification of the JLK-ICH system. This performance validation testing demonstrated that the JLK-ICH system accurately represents key processing parameters under a range of clinically relevant parameters and perturbations associated with the software's intended use. 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 addition to the software verification and validation testing described in the sections above, JLK, Inc. performed a standalone performance in accordance with the §892.2080 special controls to demonstrate adequate clinical performance of the JLK-ICH module. The test dataset used during the standalone performance evaluation was newly acquired, and appropriate steps were taken to ensure it was independent of the training dataset used in model development.

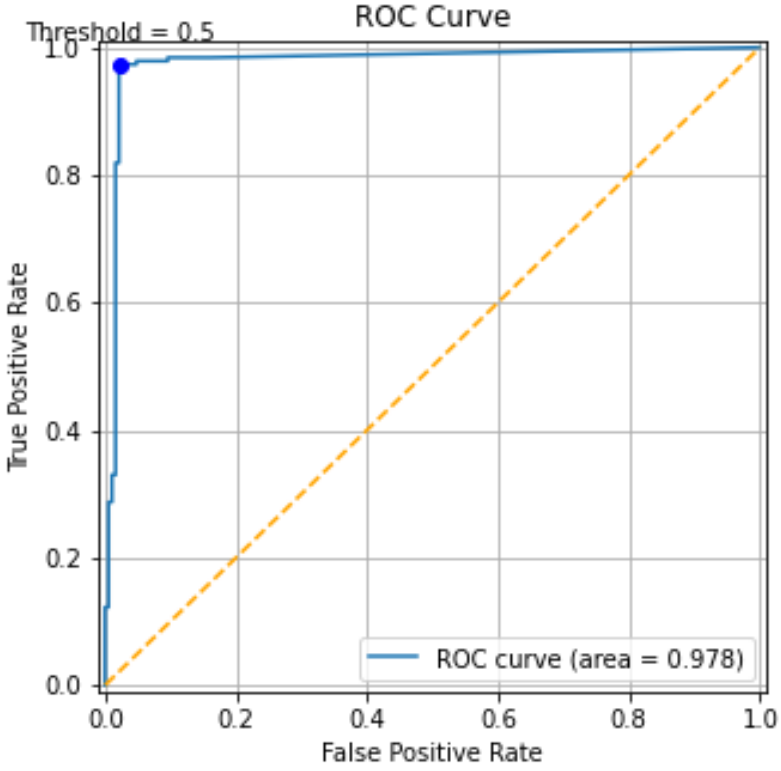
A retrospective study was conducted to assess the sensitivity and the standalone performance of the image analysis algorithm and notification functionality of Triage intracranial hemorrhage (ICH). Specifically, the study evaluated the Triage ICH image analysis in terms of sensitivity and specificity with respect to ground truth (as established by US board-certified neuro-radiologists), in detecting ICH in the head.

376 NCCT scans were obtained from various regions in the U.S. The analysis included 188 ICH-positive and 188 ICH-negative cases. Note that there were 30 cases sent to the third truther (i.e., tie-breaker interpreter) due to disagreements between the first two truthers. The

patient cohort was enriched to promote the generalizability of clinical and demographic variables (e.g., age, gender, and race-ethnicity) to the target patient population. Ground truth was determined by two American Board of Radiologists (ABR)-certified neuroradiologists, with a consensus reached by a third in case of disagreement.

The primary endpoints, sensitivity and specificity, both exceeded 80%. Specifically, the sensitivity was 97.3% with a 95% confidence interval (CI) of 94.8% to 99.5%. The specificity was 97.9% with a 95% CI of 95.5% to 99.5%. The area under the curve (AUC) was 0.978 with a 95% CI of 0.959 to 0.992.

JLK-ICH ROC curve




As part of a secondary analysis, the company stratified the performance of the device by various confounding variables:

| Performance Metrics Overview for Patients Categorized by Age | | | |
|---|---|---|---|
| **Age Range (Years)** | **N** | **Sensitivity [95% CI]** | **Specificity [95% CI]** |
| <50 | 74 | 0.94 [0.86, 1.00] | 0.97 [0.91, 1.00] |
| 50-70 | 146 | 0.95 [0.89, 1.00] | 1.0 [1.00, 1.00] |
| 70< | 156 | 1.0 [1.00, 1.00] | 0.96 [0.90, 1.00] |

| Performance Metrics Overview for Patients Categorized by Gender | | | |
|---|---|---|---|
| **Gender** | **N** | **Sensitivity [95% CI]** | **Specificity [95% CI]** |
| Male | 188 | 0.98 [0.95, 1.00] | 0.97 [0.92, 1.00] |
| Female | 187 | 0.97 [0.92, 1.00] | 0.99 [0.97, 1.00] |
| Unknown | 1 | 1.0 [1.00, 1.00] | - |

| Performance Metrics Overview for Patients Categorized by Race-Ethnicity | | | |
|---|---|---|---|
| **Race-Ethnicity** | **N** | **Sensitivity [95% CI]** | **Specificity [95% CI]** |
| Non-Hispanic White | 263 | 0.99 [0.97, 1.00] | 0.97 [0.94, 1.00] |
| Hispanic or Latino | 35 | 1.0 [1.00, 1.00] | 1.0 [1.00, 1.00] |
| Black or African American | 60 | 0.9 [0.76, 1.00] | 0.97 [0.92, 1.00] |
| Asian & Pacific Islander | 8 | 0.83 [0.50, 1.00] | 1.0 [0.00, 1.00] |
| Unknown / Refused | 10 | 1.0 [0.00, 1.00] | 1.0 [1.00, 1.00] |

| Performance Metrics Overview for Patients Categorized by Scanner Manufacturer | | | |
|---|---|---|---|
| **Manufacturer** | **N** | **Sensitivity [95% CI]** | **Specificity [95% CI]** |
| General Electric | 118 | 0.96 [0.90, 1.00] | 0.98 [0.95, 1.00] |
| Siemens | 161 | 0.98 [0.95, 1.00] | 0.97 [0.93, 1.00] |
| Philips | 77 | 0.97 [0.90, 1.00] | 0.98 [0.93, 1.00] |
| Toshiba / Canon | 20 | 1.0 [1.00, 1.00] | 1.0 [1.00, 1.00] |

| Performance Metrics Overview for Patients Categorized by Slice Thickness | | | |
|---|---|---|---|
| **Slice Thickness** | **N** | **Sensitivity [95% CI]** | **Specificity [95% CI]** |
| 2.5mm≤Slice thickness <3.5mm | 62 | 1.0 [0.00, 1.00] | 1.0 [1.00, 1.00] |
| 3.5mm≤Slice thickness ≤5mm | 314 | 0.97 [0.95, 0.99] | 0.97 [0.94, 0.99] |

| Performance Metrics Overview for Patients Categorized by ICH Subtype | | |
|---|---|---|
| **ICH Subtype** | **N** | **Sensitivity [95% CI]** |
| Intraparenchymal Hemorrhage (IPH) | 36 | 1.0 [1.00, 1.00] |
| Intraventricular Hemorrhage (IVH) | 12 | 0.92 [0.75, 1.00] |
| Subarachnoid Hemorrhage (SAH) | 32 | 0.97 [0.91, 1.00] |
| Subdural Hemorrhage (SDH) | 22 | 0.95 [0.86, 1.00] |
| Epidural Hemorrhage (EDH) | 3 | 0.67 [0.00, 1.00] |
| SDH or EDH* | 15 | 1.0 [1.00, 1.00] |
| Multiple | 68 | 0.99 [0.96, 1.00] |

* In situations where a definitive determination is not possible, individuals responsible for establishing the truth select 'SDH or EDH' to denote that the case is considered to be either a subdural hematoma or an epidural hematoma.

| Performance Metrics Overview for Patients Categorized by ICH Volume | | |
|---|---|---|
| **Volume (mL)** | **N** | **Sensitivity [95% CI]** |
| Volume < 1 | 20 | 0.8 [0.60, 0.95] |
| 1 ≤ Volume < 5 | 33 | 1.0 [1.00, 1.00] |
| 5 ≤ Volume < 10 | 28 | 1.0 [1.00, 1.00] |
| Volume ≥ 10 | 107 | 0.99 [0.97, 1.00] |

A secondary endpoint of time-to-notification from non-contrast CT scans to notification for ICH-positive cases was also evaluated.

| NCCT-to-notification | Mean Estimate | 95% Lower CI | 95% Upper CI | Median |
|---|---|---|---|---|
| K193658, Viz ICH | 0.49 | 0.47 | 0.51 | n/a |
| JLK-ICH | 0.19 | 0.186 | 0.197 | 0.20 |

The JLK-ICH system for ICH-positive cases demonstrated efficient triage with a total NCCT-to-notification time ranging from an average of 0.19±0.04 minutes, which successfully meets the target of 0.49±0.15 minutes established by the predicate device, Viz ICH (K193658). These results affirm that the JLK-ICH system meets the time-to-notification goal, underscoring its effectiveness in timely triage and notification.

## Conclusions

JLK-ICH, which has the same intended use and exhibits substantially equivalent technological, safety, and performance characteristics, is comparable to the legally marketed predicate device, Viz ICH (K193658). Therefore, JLK-ICH is substantially equivalent to the selected predicate device and raises no questions regarding safety or effectiveness.