



March 24, 2026

JLK, Inc.
% John Smith
Partner
Hogan Lovells
555 Thirteenth Street NW
WASHINGTON, DC 20004

Re: K252421

Trade/Device Name: JLK-NCCT
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological Computer Aided Triage And Notification Software
Regulatory Class: Class II
Product Code: QAS
Dated: July 25, 2025
Received: February 19, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

 for

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K252421

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Please provide the device trade name(s).

?

JLK-NCCT

Please provide your Indications for Use below.

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JLK-NCCT is a radiological computer-aided triage and notification software designed for analyzing non-contrast head CT (NCCT) images. The software assists hospital networks and trained clinicians by flagging and communicating them of findings suggestive of (1) Intracranial Hemorrhage (ICH) and (2) large vessel occlusion (LVO) involving the internal carotid artery (ICA), middle cerebral artery M1 (MCA-M1) and middle cerebral artery M2 (MCA-M2) on NCCT images.

JLK-NCCT employs an artificial intelligence (AI) algorithm to analyze images and highlight cases with detected (1) ICH or (2) LVO on an on-premises or cloud-based JLK server. This occurs in parallel with the ongoing standard of care image interpretation. Users receive notifications for cases with suspected ICH and LVO findings via mobile devices. Notifications include compressed preview images for informational purposes only and not intended for diagnostic use beyond notification.

The device does not modify the original medical image, and is not intended to be used as a primary diagnostic device. The results of JLK-NCCT are intended to be used in conjunction with other patient information and professional judgment to assist with triage and prioritization of medical images. Clinicians who receive notifications are responsible for reviewing full images per the standard of care. JLK-NCCT is intended for adults use only.

Limitations and warnings:

- All patients should receive appropriate care, including a CT angiography (CTA) and/or relevant treatments as part of the standard stroke workup. The device is not intended to rule out any medical conditions, therefore, cases without a "Suspected ICH" or "Suspected LVO" notification should not be assumed to exclude ICH or LVO. All cases should undergo a CTA as part of the standard stroke workup.
- The device does not replace the need for CTA or MRA in ischemic stroke workup, it provides workflow prioritization and notification only.

Contraindications/Exclusions:

- Patient Motion: excessive motion leading to artifacts that make the scan technically inadequate.
- Hemorrhagic Transformation
- Very thin or no Ventricles

Please select the types of uses (select one or both, as applicable).

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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**510(k) SUMMARY
JLK, Inc.'s JLK-NCCT
K252421**

Prepared on: 2026-02-19

Contact Details 21 CFR 807.92(a)(1)

Applicant

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

Correspondent

- Name Hogan Lovells
- Address 555 Thirteenth Street NW Washington D/C 20004
United States
- Contact Telephone (+1)2026373638
- Contact Dr. John Smith
- Contact Email john.smith@hoganlovells.com

Device Name 21 CFR 807.92(a)(2)

- Device Trade Name JLK-NCCT
- Common Name Radiological computer aided triage and notification
software
- Classification Name Radiological computer aided triage and notification
software
- Regulation Number 892.2080
- Product Code(s) QAS

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

- Predicate # K222884
- Predicate Trade Name Rapid NCCT Stroke
- Product Code QAS



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

JLK-NCCT is a radiological computer-assisted triage and notification (CADt) software that complies with the DICOM standard. It functions as a Non-Contrast Computed Tomography (NCCT) processing module, prioritizing triage, and notification for suspected intracranial hemorrhage (ICH) and large vessel occlusion (LVO). Operating as a notification-only tool, it assists hospital networks and clinicians by flagging critical cases and alerting specialists independent of standard workflows. JLK-NCCT's AI algorithm analyzes NCCT scans for ICH and LVO indicators and provides automated notifications to streamline clinical decision-making.

JLK-NCCT consists of an AI-based image analysis algorithm hosted on JLK servers either on-premises or cloud-based and a mobile software module for notification management. The AI processes NCCT head scans, detecting suspected ICH and LVO, and transmits mobile notifications with compressed preview images for triage. PACS integration is optional and supported when available. The system does not modify original medical images and is not intended for diagnostic use. JLK-NCCT integrates the JLK-ICH Model (ICH detection), LVO score Model (ischemic assessment), and HAS Model (Hyperdense Artery Sign detection), supporting real-time alerts and prioritization within hospital workflows (the ICH algorithm is the same as the device cleared under K243363).

JLK-NCCT was trained using clinical datasets from the U.S. and South Korea, totaling 3,067 cases, sourced from multiple institutions to ensure diversity and robustness. The dataset included NCCT scans acquired using imaging equipment from various manufacturers, such as GE, Siemens, Philips, and Toshiba, covering a range of scanning parameters to enhance model generalizability. Data were collected from institutions across different geographic locations, including hospitals in North Carolina and Texas in the U.S., as well as Seoul St. Mary's Hospital and other South Korean medical centers. All imaging studies were labeled by board-certified neuroradiologists. This diverse dataset strengthens the AI model's applicability across various clinical environments, supporting its role as a triage and notification tool for assisting clinicians in early detection and prioritization of suspected ICH and LVO cases.

The performance of the device's AI algorithms was validated in a standalone performance evaluation using an independent dataset different from the one used for algorithm training. Each case output from the JLK-NCCT 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 21 CFR 807.92(a)(5)

JLK-NCCT is a radiological computer-aided triage and notification software designed for analyzing non-contrast head CT (NCCT) images. The software assists hospital networks and trained clinicians by flagging and communicating them of findings suggestive of (1) Intracranial Hemorrhage (ICH) and (2) large vessel occlusion (LVO) involving the internal carotid artery (ICA), middle cerebral artery M1 (MCA-M1) and middle cerebral artery M2 (MCA-M2) on NCCT images.

JLK-NCCT employs an artificial intelligence (AI) algorithm to analyze images and highlight cases with detected (1) ICH or (2) LVO on an on-premises or cloud-based JLK server. This occurs in parallel with the ongoing standard of care image interpretation. Users receive notifications for cases with suspected ICH and LVO findings via mobile devices. Notifications include compressed preview images for informational purposes only and not intended for diagnostic use beyond notification.

The device does not modify the original medical image, and is not intended to be used as a primary diagnostic device. The results of JLK-NCCT are intended to be used in conjunction with other patient



information and professional judgment to assist with triage and prioritization of medical images. Clinicians who receive notifications are responsible for reviewing full images per the standard of care. JLK-NCCT is intended for adults use only.

Limitations and warnings:

- All patients should receive appropriate care, including a CT angiography (CTA) and/or relevant treatments as part of the standard stroke workup. The device is not intended to rule out any medical conditions, therefore, cases without a “Suspected ICH” or “Suspected LVO” notification should not be assumed to exclude ICH or LVO. All cases should undergo a CTA as part of the standard stroke workup.
- The device does not replace the need for CTA or MRA in ischemic stroke workup, it provides workflow prioritization and notification only.

Contraindications/Exclusions:

- Patient Motion: excessive motion leading to artifacts that make the scan technically inadequate.
- Hemorrhagic Transformation
- Very thin or no Ventricles

Indications for Use Comparison 21 CFR 807.92(a)(5)

Both the subject and predicate device have the same intended use, namely, to assist clinicians in identifying and communicating images of specific patients to a specialist, independent of the standard of care workflow, act solely as notification tools, and do not modify original medical images, instead providing compressed preview images for triage.

Both JLK-NCCT and the predicate device employ advanced artificial intelligence and machine learning (AI/ML) algorithms to analyze non-contrast CT (NCCT) imaging of the head. However, the primary differences lie in notification channels. While the predicate device supports PACS, email, and mobile notifications, JLK-NCCT uses only mobile alerts, aligning with standard hospital workflows. These differences do not impact safety or effectiveness.

Technological Comparison 21 CFR 807.92(a)(6)

The JLK-NCCT software is designed with an architecture similar to the predicate device, Rapid NCCT Stroke (K222884). Both systems process non-contrast CT (NCCT) images in DICOM format using artificial intelligence (AI) and machine learning (ML) algorithms to detect suspected conditions and prioritize workflow through automated notifications. These notifications assist clinicians in identifying potential cases of LVO and ICH, facilitating early intervention while maintaining standard clinical workflows. The devices do not replace standard diagnostic methods but serve as adjunct tools to streamline decision-making in acute care settings.

Both JLK-NCCT and the predicate device integrate mobile software applications, allowing clinicians to receive real-time notifications, access lists of flagged cases, and review compressed, non-diagnostic CT scans for triage purposes only. These systems operate in parallel to standard care and do not alter the original medical images, ensuring that their outputs serve solely for informational purposes without interfering with the diagnostic integrity of radiological assessments.

While the fundamental operational framework remains consistent between JLK-NCCT and the predicate device, key distinctions exist in their detection scope and its algorithms. The predicate device detects LVO in the internal carotid artery (ICA) and middle cerebral artery segment M1 (MCA-M1), whereas JLK-NCCT expands LVO detection to include ICA, MCA-M1, and also MCA-M2. This broader detection capability enables identification of vascular occlusions in an additional anatomical region.



Additionally, JLK-NCCT and the predicate device employ different AI/ML algorithms for NCCT image analysis. JLK-NCCT incorporates JLK-ICH, hypodensity detection and HAS models, whereas the predicate device utilizes hypodensity detection and Hyperdense Vessel Sign (HVS) models.

JLK-NCCT remains technologically and functionally equivalent to the predicate device. The differences in AI/ML algorithms and notification channels between JLK-NCCT and the predicate device do not introduce any new questions regarding safety or effectiveness.

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

JLK, Inc. conducted extensive performance validation testing and software verification of the JLK-NCCT system. This performance validation testing demonstrated that the JLK-NCCT 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 and Reader Performance in accordance with the §892.2080 special controls to demonstrate adequate clinical performance of the JLK-NCCT module. The test dataset used during the Standalone Performance and Reader 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 standalone performance of the image analysis algorithm and notification functionality of Triage NCCT head images containing large vessel occlusion (LVO) findings. The standalone evaluation included a total of 288 cases (LVO Positive: 144, LVO negative: 144).

Although the Triage NCCT system is originally designed as a cascade model that sequentially analyzes both intracranial hemorrhage (ICH) and large vessel occlusion (LVO), this clinical study focuses solely on the evaluation of LVO detection performance. This is because the ICH detection algorithm is identical to that of a previously FDA-cleared device under 510(k) number K243363, and thus does not require additional clinical validation. Specifically, the study evaluated the Triage LVO image analysis in terms of sensitivity and specificity with respect to ground truth (as established by U.S. board-certified neuroradiologists) in detecting suspected LVO in the head.

In the standalone performance evaluation, the JLK-NCCT system successfully met its primary endpoints on the standalone performance evaluation, the observed sensitivity was 78.5% (95% Confidence Interval [CI]: 71.9%–84.7%) and the specificity was 90.3% (95% CI: 85.1%–94.7%). The area under the curve (AUC) was 0.880 with a 95% CI of 0.837–0.920.

The secondary endpoint of the standalone performance, evaluated the time-to-notification performance of the JLK-NCCT system. This analysis includes the time required to retrieve the DICOM exam, de-identify it (if necessary), perform image analysis, and transmit the notification to both the PACS and the mobile device. For suspected LVO cases, the system demonstrated triage with an average NCCT-to-notification time of 1.67 ± 0.10 minutes. This result successfully meets the predefined performance goal of 2.5 ± 0.1 minutes established by the predicate device, Rapid NCCT Stroke (K222884). These findings support the effectiveness of the JLK-NCCT system in timely notification, confirming that it satisfies the study's secondary endpoints.



In addition, a reader performance was conducted to explore Neuroradiologist non-inferiority and General Radiologist superiority. JLK-NCCT satisfied both criteria show General Radiologist superiority and Neuroradiologist non-inferiority. JLK-NCCT demonstrated a sensitivity of 0.792 and passed the conditions compared to all readers (Neuroradiologist and General Radiologist) whose average sensitivity was 0.568, with difference in Se between NCCT Stroke and all readers of 0.224 (95%CI: 0.144–0.306); Se for general radiologists of 0.633, with difference in Se of 0.159 (95%CI: 0.083–0.237); Se for Neuroradiologist of 0.525, with difference in Se of 0.267 (95%CI: 0.174–0.356)

Also, JLK-NCCT demonstrated a specificity of 0.933 and passed the conditions compared to all readers (Neuroradiologist and General Radiologist) whose average specificity was 0.840, with difference in Sp between NCCT Stroke and all readers of 0.093 (95%CI: 0.038–0.150); Sp for general radiologists of 0.796, with difference in Sp of 0.137 (95%CI: 0.070–0.205); Sp for Neuroradiologist of 0.869, with difference in Sp of 0.064 (95%CI: 0.005–0.126). These results confirm that the predefined clinical hypothesis was fully met.

In conclusion, JLK-NCCT has the same intended use and similar technological, safety, and performance characteristics as the legally marketed predicate device, Rapid NCCT Stroke (K222884). Therefore, JLK-NCCT is substantially equivalent to the selected predicate device.