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

September 27, 2024

Re: K241480
Trade/Device Name: JBS-LVO
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological Computer Aided Triage And Notification Software
Regulatory Class: Class II
Product Code: QAS
Dated: August 30, 2024
Received: August 30, 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, Ph.D.
Assistant Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K241480

Device Name
JBS-LVO

Indications for Use *(Describe)*
JBS-LVO is a notification-only, parallel workflow tool for use by hospital networks and trained clinicians to identify and communicate images of specific patients to a specialist, independent of standard of care workflow.

JBS-LVO uses an artificial intelligence algorithm to analyze images for findings suggestive of a pre-specified clinical condition and to notify an appropriate medical specialist of these findings in parallel to standard of care image interpretation. Identification of suspected positive findings is not for diagnostic use beyond notification. Specifically, the device analyzes CT angiogram images of the brain acquired in the acute setting and sends notifications to a neurovascular specialist that a suspected large vessel occlusion has been identified and recommends a review of those images. Images can be previewed through a mobile application. JBS-LVO is intended to analyze terminal ICA and MCA-M1 vessels for LVOs.

Images that are previewed through the mobile application are compressed and for informational purposes only. They are not intended for diagnostic use beyond notification. The JBS-LVO device does not alter the original medical image. 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 physician before making care-related decisions or requests. JBS-LVO 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 a diagnosis.

Limitations:
The device does not process scans containing metallic artifacts.

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.

510(k)#: K241480

510(k) Summary

Prepared on: 2024-09-26

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	JLK, Inc.
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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	JBS-LVO
Common Name	Radiological computer aided triage and notification software
Classification Name	Radiological Computer-Assisted Triage And Notification Software
Regulation Number	892.2080
Product Code(s)	QAS

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K223042	Viz LVO	QAS
K221248	Rapid LVO	QAS

Device Description Summary

21 CFR 807.92(a)(4)

JBS-LVO is a radiological computer aided triage and notification (CADt) software package compliant with the DICOM standard. JBS-LVO is a notification-only, parallel workflow tool for use by hospital networks and trained clinicians to analyze computed tomography angiography (CTA) images for findings suggestive of a suspected large vessel occlusion (LVO) and to notify an appropriate medical specialist of these findings in parallel to standard of care image interpretation. Specifically, JBS-LVO is optimized to evaluate occlusions of the intracranial carotid artery (ICA) and proximal middle cerebral artery (MCA-M1 segment). It is important to clarify that this quantification is solely used within the device's AI module to facilitate a refined classification process. The output provided to healthcare professionals is strictly a flag indicating the presence (positive) of an LVO, in accordance with regulatory guidelines.

The images used to train the algorithm were sourced from datasets that included equipment from various manufacturers, such as Siemens,

Philips, Toshiba, and GE. This dataset, containing over 2,000 CT brain imaging studies, was labeled by trained radiologists to identify the presence of LVO. The performance of the device's AI algorithms was validated in a standalone performance evaluation, utilizing an independent dataset different from the one used for algorithm training. In this standalone performance evaluation, each case output from the JBS-LVO device was compared with a ground truth standard which was determined by two ground truthers, with a third ground truther intervening in cases of disagreement. All truthers were US board-certified neuroradiologists.

JBS-LVO is a combination of software modules that allow for detection and notification of patients with a suspected LVO. JBS-LVO consists of an algorithm and mobile application software module.

The JBS-LVO Image Analysis Algorithm (LVO Detection Algorithm) is a locked, artificial intelligence (AI) software algorithm utilizing convolutional neural network (CNN) that analyzes CTA images of the brain for a suspected LVO. The LVO Detection Algorithm is hosted on the JLK-server and analyzes applicable CTA images of the brain that are acquired on CT scanners and are automatically transmitted to the JLK-server. Upon detection of a suspected LVO, the LVO notification module sends a notification of the suspected finding.

The JBS-LVO notification functionality enable medical professionals and clinicians to preview compressed and informational images through via mobile application notification. Image viewing through the mobile application interface is for informational purposes only and is not for diagnostic use.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

JBS-LVO is a notification-only, parallel workflow tool for use by hospital networks and trained clinicians to identify and communicate images of specific patients to a specialist, independent of standard of care workflow.

JBS-LVO uses an artificial intelligence algorithm to analyze images for findings suggestive of a pre-specified clinical condition and to notify an appropriate medical specialist of these findings in parallel to standard of care image interpretation. Identification of suspected positive findings is not for diagnostic use beyond notification. Specifically, the device analyzes CT angiogram images of the brain acquired in the acute setting and sends notifications to a neurovascular specialist that a suspected large vessel occlusion has been identified and recommends a review of those images. Images can be previewed through a mobile application. JBS-LVO is intended to analyze terminal ICA and MCA-M1 vessels for LVOs.

Images that are previewed through the mobile application are compressed and for informational purposes only. They are not intended for diagnostic use beyond notification. The JBS-LVO device does not alter the original medical image. 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 physician before making care-related decisions or requests. JBS-LVO 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 a diagnosis.
Limitations: The device does not process scans containing metallic artifacts.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Viz LVO and JBS-LVO are both designed to analyze images for findings suggestive of a pre-specified clinical condition and to notify an appropriate medical specialist of these findings in parallel to standard of care image interpretation. Since both devices are equally intended for use as a tool for assisting study triage within existing patient pathways and they do not replace any part of the current standard of care, there is no question about the effectiveness and safety of JBS-LVO compared to Viz LVO.

Technological Comparison

21 CFR 807.92(a)(6)

Both the subject and predicate devices utilize artificial intelligence and machine learning (AI/ML) algorithms to detect suspected large vessel occlusions (LVOs) on CTA imaging of the brain in the same regions of the large vessels. Moreover, the software algorithm for the subject device is hosted on the similar architecture, automatically receives imaging in the same DICOM format, and uses similar mechanisms as the predicate device to identify applicable imaging for analysis. The outputs of the subject and predicate devices are the same; both devices identify suspected LVOs and send notifications of suspected LVO findings from the same server.

The subject and predicate devices integrate the same mobile software functions and outputs, presented through the same mobile application. Users can conveniently receive notifications for patients with suspected LVOs, view a unique list of patients with a suspected LVO (as determined by the LVO Detection Algorithm), and examine the non-diagnostic CT scan of the patient through the JBS-LVO mobile application. The imaging viewing of CTA scans analyzed by the subject and predicate devices are subject to the same limitations, which means they are solely for informational purposes (for prioritization review only, i.e., triage and notification) and are not intended for diagnostic use.

Where the subject and predicate device differ is that the subject device incorporates an advanced "Critical Pathway" (CP) feature within the JBS-LVO software system that enhances the management of clinical pathways for patient treatment. This feature is integrated into the mobile application interface, providing users with real-time access to detailed patient care steps and facilitating effective communication among medical staff. Unlike the predicate device, the subject device includes functionalities such as real-time updates, activity logs, and push notifications that are not present in the predicate device's interface. These enhancements in the subject device ensure that all parties

involved in patient care are consistently informed and coordinated, enhancing patient outcomes. Moreover, the inclusion of these advanced features does not introduce new safety or efficacy concerns, as confirmed by software testing which verified that the CP functionalities operateas expected. This integration of comprehensive care management tools into the user interface thus represents a significant advancement over the predicate device, promoting greater transparency and efficiency in patient care management. These differences do not raise any new or different questions of safety and efficacy. As such, the JBS-LVO is considered substantially equivalent to Viz LVO.

In conclusion, JBS-LVO does not raise any new or different questions of safety or effectiveness compared to the predicate device Viz LVO (K223042). Both devices are radiological computer-aided triage and notification software applications for use with CTA input. Hence, it is substantially equivalent to the predicate device.

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 JBS-LVO system. This performance validation testing demonstrated that the JBS-LVO 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, Inc. performed a standalone performance in accordance with the §892.2080 special controls to show acceptance of the clinical performance of the JBS-LVO 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. Performance testing is intended to inform users about the algorithm's accuracy. As a result, we achieved the desired performance results, demonstrating that JBS-LVO is as safe and effective as a predicate device.

A retrospective study has been conducted to assess the sensitivity and the standalone performance of the image analysis algorithm and notification functionality of Triage LVO. Specifically, the study evaluated the Triage LVO image analysis in terms of sensitivity and specificity with respect to ground truth, as established by US board-certified neuro-radiologists, in detecting large vessel occlusion (LVO) in the brain.

The primary endpoints, sensitivity and specificity, both exceeded 80%. Specifically, the sensitivity was 91.8% with a 95% confidence interval (Cl) of 85.8% to 95.8%. The specificity was 92.8% with a 95% Cl of 87.2% to 96.5%. The area under the curve (AUC) was 95.6% with a 95% Cl of 93.0% to 98.1 %.

The secondary endpoint involves an analysis of time-to-notification from CTA to notification for LVO-positive cases. The total CTA-to-notification time for the JBS-LVO system ranged from 2.32 to 3.29 minutes, with a mean time of 2.95 minutes (95% Cl: 2.89 - 3.02). This performance is comparable to the Reference device, Rapid LVO (K221248), which reported a mean time of 3.18 minutes (95% Cl: 3.11 - 3.25). JBS-LVO successfully meets the target time-to-notification of ≤ 3.5 minutes set by the Reference device.

Additionally, the time from CTA to notification using the JBS-LVO system successfully met the target goal.

In conclusion, JBS-LVO, which has the same intended use and exhibits substantially equivalent technological, safety, and performance characteristics, is comparable to the legally marketed predicate device, Viz LVO (K223042). Therefore, JBS-LVO is substantially equivalent to the selected predicate device and raises no questions regarding safety or effectiveness.