



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

March 3, 2025

Re: K243611

Trade/Device Name: Jlk-SDH
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer aided triage and notification software
Regulatory Class: Class II
Product Code: QAS
Dated: February 3, 2025
Received: February 3, 2025

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,

A handwritten signature in black ink that reads "Jessica Lamb". The signature is written in a cursive style. Behind the signature, there is a large, light blue, semi-transparent watermark of the letters "FDA".

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

Submission Number (if known)

K243611

Device Name

JLK-SDH

Indications for Use (Describe)

JLK-SDH is a notification-only, parallel workflow tool that is intended to assist trained radiologists to identify and communicate images of specific patients to a specialist, independent of the standard of care workflow.

JLK-SDH uses an artificial intelligence algorithm to analyze images for findings suggestive of a prespecified clinical condition and to notify an appropriate user of these findings in parallel to 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 for subdural hemorrhage (SDH) and sends notifications to a clinician that a suspected SDH has been identified and recommends a review of those images. Images can be previewed and compressed through PACS and mobile applications.

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.

JLK-SDH 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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510(k) SUMMARY
JLK, Inc.'s JLK-SDH
K243611

K243611

Applicant Name: JLK, Inc.
JLK Tower, 5, Teheran-ro 33-gil, Gangnam-gu,
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Date Prepared: January 31, 2025

Device Name and Classification

- Name of Device: JLK-SDH
- 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 SDH	K220439	QAS

Device Description

JLK-SDH is a radiological computer-assisted triage and notification (CADt) software package compliant with the DICOM standard. The device functions as a Non-Contrast Computed Tomography (NCCT) processing module, providing triage and notification prioritization for suspected hemispheric subdural hemorrhage (SDH). It serves as a notification-only, parallel workflow tool for hospital networks and trained clinicians. The device helps to identify and communicate specific patient images to trained radiologists, independent of the standard of care workflow. Utilizing an artificial intelligence algorithm, the system automatically receives and analyzes NCCT studies for image features indicating the presence of SDH and sends a notification to alert a radiologist of the case.

This algorithm, hosted on JLK servers, is designed to analyze non-contrast CT images of the head acquired on CT scanners and forwarded to JLK servers. The mobile software module



that enables user to receive and toggle notifications for suspected subdural hemorrhages identified by the JLK-SDH 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 images used to train the algorithm were sourced from datasets that included equipment from various manufacturers, such as GE, Siemens, Philips, and Toshiba. The training dataset utilized to develop the convolutional neural network (CNN) included 29,524 non-contrast CT (NCCT) scans that had been obtained in patients with and without intracranial hemorrhage. In particular, 3,330 patients had SDH, 11,732 had different kinds of intracranial hemorrhage (Intraparenchymal Hematoma (IPH), Intraventricular Hemorrhage (IVH), Subarachnoid Hemorrhage (SAH) or Epidural Hematoma (EDH)), and 14,462 patients did not have any intracranial hemorrhage. The datasets were comprised from a variety of institutions across separate geographic locations (the USA, Brazil, and South Korea), including Stanford University, Universidale Federal de Sao Paulo, Thomas Jefferson University Hospital, Seoul St. Mary's Hospital, and six other institutions to ensure its robustness and applicability. 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.

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-SDH 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-SDH is a notification-only, parallel workflow tool that is intended to assist trained radiologists to identify and communicate images of specific patients to a specialist, independent of the standard of care workflow.

JLK-SDH uses an artificial intelligence algorithm to analyze images for findings suggestive of a prespecified clinical condition and to notify an appropriate user of these findings in parallel to 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 for subdural hemorrhage (SDH) and sends notifications to a clinician that a suspected SDH has been identified and recommends a review of those images. Images that are previewed through mobile applications may be compressed only for notification.

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.

JLK-SDH 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 subdural hemorrhage (SDH) on non-contrast CT imaging of the head. JLK-SDH 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 SDH. Users can view a unique list of patients with suspected SDH 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 radiologist 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 SDH and send notifications of suspected SDH findings from the same server.

The subject and predicate device differ in the recipients of the notifications they send. While the predicate device, Viz SDH, sends notifications to neurovascular or neurosurgical specialists for time-sensitive cases with suspected findings, the subject device sends notifications to the radiologists. The radiologists then contact the appropriate specialist for further consultation per US standard-of-care workflow (e.g., neurovascular or neurosurgical specialist, or any other clinician capable of treating SDH patients). Yet, there is a clinical benefit in the subject workflow, similar to alerting a neurovascular/neurosurgical specialist of an SDH. In the United States, there is typically a designated "duty radiologist" and an "on-call neurosurgeon" who remains on standby at home and is ready to report to the hospital for emergency surgical procedures as required. Accordingly, this difference in notified user does not impact nor alter the US hospital workflow, as notifying a radiologist of suspected SDH functionally serves the same clinical utility as notifying a neurovascular or neurosurgery specialist within a given healthcare facility without raising any new or different questions of safety or effectiveness.

The JLK-SDH is as safe and effective as the predicate device Viz SDH (K220439). JLK-SDH has the same intended use and similar indications, technological characteristics, principles of operation, and performance characteristics as the legally marketed predicate device. Any differences in indications do not alter the intended diagnostic use of the device and do not affect its safety and effectiveness when used as labeled as discussed above. In addition, the technological differences between JLK-SDH and its predicate device do not raise any new questions of safety or effectiveness. Performance data demonstrates that JLK-SDH is as safe and effective as the predicate device, the previously cleared Viz SDH. Thus, JLK-SDH is substantially equivalent.

	Subject Device	Predicate Device
Device Name	JLK-SDH	Viz SDH
510(k) Number	K243611	K220439
Regulation Number	21 C.F.R. § 892.2080	21 C.F.R. § 892.2080
Product Code	QAS	QAS
Intended User	Radiologist	Neurovascular Specialist
Anatomical Region	Head	Head
Region of Interest	Hemispheric Subdural Hemorrhage	Hemispheric Subdural Hemorrhage
Indicated Imaging Modality	Non-contrast CT (NCCT)	Non-contrast CT (NCCT)
Alteration of Original Image Database	No	No
Diagnostic Application	Notification-only	Notification-only
Algorithm Implementation	Artificial Intelligence / Machine Learning	Artificial Intelligence / Machine Learning.
Results of Image Analysis	Internal, no image marking	Internal, no image marking
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.
Relationship to standard of care workflow	In Parallel / Concurrently	In Parallel / Concurrently
Compatibility with the environment and other devices	DICOM Compatible	DICOM Compatible
Technical Implementation	Artificial intelligence algorithm with database of images	Artificial intelligence algorithm with database of images
Preview Images	Initial assessment; non-diagnostic purposes Presentation of preview of the study for initial informational purposes	Initial assessment; non-diagnostic purposes Presentation of preview of the study for initial informational purposes
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	0.19 ±0.05 minutes	1.15±0.57 minutes

Performance Data

JLK, Inc. conducted extensive performance validation testing and software verification of the JLK-SDH system. This performance validation testing demonstrated that the JLK-SDH 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,

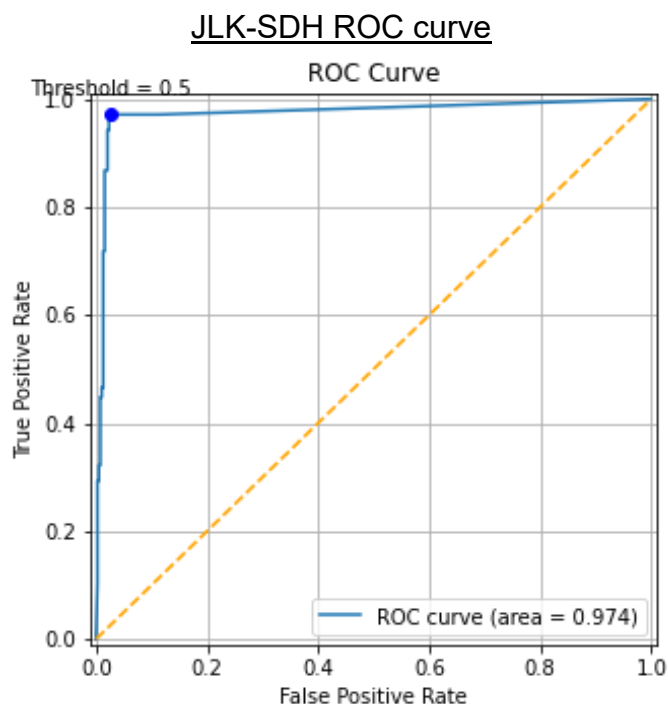
“Content of Premarket Submissions for Device Software Functions,” June 14, 2023.

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-SDH 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 subdural hemorrhage (SDH). Specifically, the study evaluated the Triage SDH image analysis in terms of sensitivity and specificity with respect to ground truth (as established by US board-certified neuro-radiologists) in detecting SDH in the head.

560 NCCT scans were obtained from various regions in the U.S. The analysis included 174 SDH positive and 386 SDH negative cases. Note that there were 28 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. We also considered variability among CT scanners, including those from Siemens, GE Medical Systems, Philips, Toshiba/Canon. 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 97.1%, with a 95% confidence interval (CI) of 94.4% to 99.4%. The specificity was 97.4%, with a 95% CI of 95.8% to 99.0%. The area under the curve (AUC) was 0.974 with a 95% CI of 0.958 to 0.989.



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 States (i.e. Clinical Site)			
Clinical Site	N	Sensitivity [95% CI]	Specificity [95% CI]
Region 001	422	0.97 [0.93, 0.99]	0.99 [0.98, 1.00]
Region 002	138	0.98 [0.94, 1.00]	0.9 [0.83, 0.96]

Region 001: South – North Carolina, Texas, Florida, Georgia

Region 002: Northeast – New York / Midwest – Missouri, Iowa, Wisconsin, Illinois, Ohio

Performance Metrics Overview for Patients Categorized by Age			
Age Range (Years)	N	Sensitivity [95% CI]	Specificity [95% CI]
<50	84	0.94 [0.80, 1.00]	0.99 [0.95, 1.00]
50-70	220	0.96 [0.89, 1.00]	0.98 [0.95, 0.99]
70<	256	0.98 [0.95, 1.00]	0.97 [0.93, 0.99]

Performance Metrics Overview for Patients Categorized by Gender			
Gender	N	Sensitivity [95% CI]	Specificity [95% CI]
Male	283	0.99 [0.97, 1.00]	0.96 [0.93, 0.98]
Female	277	0.95 [0.89, 0.99]	0.99 [0.97, 1.00]

Performance Metrics Overview for Patients Categorized by Race-Ethnicity			
Race-Ethnicity	N	Sensitivity [95% CI]	Specificity [95% CI]
Non-Hispanic White	424	0.97 [0.93, 0.99]	0.99 [0.97, 1.00]
Hispanic or Latino	51	1.0 [1.00, 1.00]	0.97 [0.89, 1.00]
Black or African American	67	0.96 [0.86, 1.00]	0.9 [0.81, 0.98]
Asian & Pacific Islander	9	1.0 [1.00, 1.00]	1.0 [0.00, 1.00]
Unknown / Refused	9	-	0.89 [0.67, 1.00]

Performance Metrics Overview for Patients Categorized by Scanner Manufacturer			
Manufacturer	N	Sensitivity [95% CI]	Specificity [95% CI]
General Electric	124	0.98 [0.93, 1.00]	0.89 [0.82, 0.96]
Siemens	340	0.95 [0.90, 0.99]	0.99 [0.98, 1.00]
Philips	70	1.0 [1.00, 1.00]	1.0 [1.00, 1.00]
Toshiba / Canon	26	1.0 [1.00, 1.00]	1.0 [1.00, 1.00]

Performance Metrics Overview for Patients Categorized by SDH Type		
SDH type	N	Sensitivity [95% CI]
Acute	96	0.95 [0.90, 0.99]
Chronic	25	1.0 [1.00, 1.00]
Both (Acute & Chronic)	53	1.0 [1.00, 1.00]

Performance Metrics Overview for Patients Categorized by SDH with Other Hemorrhage		
SDH and other Hemorrhage	N	Sensitivity [95% CI]
Subdural Hemorrhage Only	95	0.99 [0.97, 1.00]
Subdural Hemorrhage and Other Hemorrhage Present	79	0.95 [0.90, 0.99]

Performance Metrics Overview for Patients Categorized by SDH Location		
SDH Location	N	Sensitivity [95% CI]
Convexity	84	0.96 [0.92, 1.00]
Falx	12	0.83 [0.58, 1.00]
Tentorium	2	1.0 [1.00, 1.00]
Multi	76	1.0 [1.00, 1.00]

Performance Metrics Overview for Patients Categorized by Slice Thickness			
Slice Thickness	N	Sensitivity [95% CI]	Specificity [95% CI]
Slice thickness<2.5mm	1	-	1.0 [1.00, 1.00]
2.5mm≤Slice thickness <3.5mm	73	1.0 [1.00, 1.00]	0.94 [0.88, 0.99]
3.5mm≤Slice thickness ≤5mm	485	0.97 [0.94, 0.99]	0.98 [0.96, 0.99]
Slice thickness>5mm	1	1.0 [1.00, 1.00]	-

Performance Metrics Overview for Patients Categorized by SDH Thickness		
SDH Thickness	N	Sensitivity [95% CI]
Thickness < 3mm	15	0.67 [0.40, 0.87]
3mm ≤ Thickness < 6mm	36	1.0 [1.00, 1.00]
6mm ≤ Thickness < 10mm	45	1.0 [1.00, 1.00]
Thickness ≥ 10mm	78	1.0 [1.00, 1.00]

Performance Metrics Overview for Patients Categorized by SDH Volume		
Volume (mL)	N	Sensitivity [95% CI]
Volume < 1	42	0.88 [0.79, 0.98]
1 ≤ Volume < 5	51	1.0 [1.00, 1.00]
5 ≤ Volume < 10	16	1.0 [1.00, 1.00]
Volume ≥ 10	65	1.0 [1.00, 1.00]

Performance Metrics Overview for Patients Categorized by Metal Artifacts			
Metallic artifact	N	Sensitivity [95% CI]	Specificity [95% CI]
Metallic artifact (+)	122	1.0 [1.00, 1.00]	0.91 [0.85, 0.97]

Metallic artifact (-)	438	0.96 [0.93, 0.99]	0.99 [0.98, 1.00]
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A secondary endpoint of time-to-notification from non-contrast CT scans to notification for SDH-positive cases was also evaluated. The JLK-SDH system for SDH-positive cases demonstrated efficient triage with a total NCCT-to-notification time ranging from an average of 11.49 ± 3.04 seconds (0.19 ± 0.05 minutes), which successfully meets the target of 69.1 ± 34.3 seconds (1.15 ± 0.57 minutes) established by the predicate device, Viz SDH (K220439). These results affirm that the JLK-SDH system meets the time-to-notification goal, underscoring its effectiveness in timely triage and notification.

Conclusions

In conclusion, JLK-SDH, which has the same intended use and exhibits substantially equivalent technological, safety, and performance characteristics, is comparable to the legally marketed predicate device, Viz SDH (K220439). Therefore, JLK-SDH is substantially equivalent to the selected predicate device and raises no questions regarding safety or effectiveness.