SK Inc.
% Hannah Taggart
Regulatory Associate
Empirical Technologies
4628 Northpark Drive
Colorado Springs, Colorado 80918

July 1, 2024

Re: K240353
Trade/Device Name: Hyper Insight - ICH
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological Computer Aided Triage And Notification Software
Regulatory Class: Class II
Product Code: QAS
Dated: May 30, 2024
Received: May 30, 2024

Dear Hannah Taggart:

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.

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

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
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.

510(k) Number *(if known)*
K240353

Device Name
Hyper Insight - ICH

Indications for Use *(Describe)*
Hyper Insight - ICH is a notification-only workflow tool for trained clinicians to identify patients' brain CT images and share them with medical specialists in parallel with standard patient care workflow. Hyper Insight - ICH uses deep learning-based Al algorithms to analyze images to find suspected intracranial hemorrhage and notifies and shares the findings to medical specialists. Identification of images with suspected intracranial hemorrhage is for notification purposes only, not diagnostic purposes.
In particular, this medical device analyzes non-contrast brain CT images, and if a suspected intracranial hemorrhage is identified, it sends a notification to medical specialists, who are advised to review these images. Images may be previewed through the mobile app but are for informational purposes only and are not intended to be used for diagnostic purposes other than notifications and previews. The medical specialist who received the notification is responsible for reading the image in a diagnostic viewer.
Hyper Insight - ICH is limited to the purpose of analysis of image data and should not be used as a substitute for a full patient assessment or relied upon to make or confirm a 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.

K240353 510(K) SUMMARY

Submitter's Name:	SK Inc.
Submitter's Address:	SK U-Tower, 9 Seongnam-daero, Bundang-gu, Seongnam-si, Gyeonggi-do, 13558 Republic of Korea
Submitter's Telephone:	+82-2-6400-0114
Contact Person:	Hannah Taggart, MS Empirical Technologies 1-719-457-1152 htaggart@empiricaltech.com
Date Summary was Prepared:	June 25, 2024
Trade or Proprietary Name:	Hyper Insight - ICH
Device Classification Name:	Radiological Computer-Assisted Triage And Notification Software
Classification & Regulation #:	Class II per 21 CFR §892.2080
Product Code:	QAS
Classification Panel:	Radiology

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

Hyper Insight - ICH is software as a medical device (SaMD) that detects intracranial hemorrhage (ICH) condition by analyzing non-contrast CT images. The software needs to be integrated with a third-party worklist application to receive analysis requests and the corresponding DICOM images and return the ICH findings (whether suspected ICH is found) to the worklist to alert the radiologists.

For ICH patients, immediate emergency diagnosis and treatment is critical for saving their lives and later recovery. Thus, it is very important to triage and identify ICH patients in a speedy manner to prioritize their treatment. Computed tomography (CT) is a non-invasive and effective diagnosis imaging approach to detect ICH. Acute Intracranial hemorrhage can be recognized on non-contrast CT scans since blood has higher density (Hounsfield unit, HU) than other brain tissues but lower than that of bones. Radiologists can identify ICH and determine the location and severity of any such bleeding from the intensity patterns presented in the images.

To help radiologists triage and prioritize reading of images for patients with ICH, Hyper Insight - ICH uses deep learning methods to automatically detect acute ICH in non-contrast head CT scans.

The software analyzes the input image and returns a binary prediction as to whether the exam suggests the presence of acute ICH. The Hyper Insight-ICH device is for notification purposes only and should be not used for final diagnosis.

INDICATIONS FOR USE

Hyper Insight - ICH is a notification-only workflow tool for trained clinicians to identify patients' brain CT images and share them with medical specialists in parallel with standard patient care workflow. Hyper Insight - ICH uses deep learning-based AI algorithms to analyze images to find suspected intracranial hemorrhage and notifies and shares the findings to medical specialists. Identification of images with suspected intracranial hemorrhage is for notification purposes only, not diagnostic purposes.

In particular, this medical device analyzes non-contrast brain CT images, and if a suspected intracranial hemorrhage is identified, it sends a notification to medical specialists, who are advised to review these images. Images may be previewed through the mobile app but are for informational purposes only and are not intended to be used for diagnostic purposes other than notifications and previews. The medical specialist who received the notification is responsible for reading the image in a diagnostic viewer.

Hyper Insight - ICH is limited to the purpose of analysis of image data and should not be used as a substitute for

a full patient assessment or relied upon to make or confirm a diagnosis.

TECHNOLOGICAL CHARACTERISTICS

The predicates included in this submission were selected based on the best practices described in the FDA Draft Guidance document *Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission*. The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are identical between the subject and predicates:

- Indications for Use
- Intended End User
- Input/Output of Software
- Performance Data

510k Number	Trade or Proprietary or Model Name	Manufacturer	Product Code	Predicate Type
K193658	Viz ICH	Viz.ai, Inc.	QAS	Primary

Predicate Device Comparison

	Subject Name (Subject Device)	Viz.ai, Inc. Viz ICH (K193658)
Indications for Use	Hyper Insight - ICH is a notification-only workflow tool for trained clinicians to identify patients' brain CT images and share them with medical specialists in parallel with standard patient care workflow. Hyper Insight - ICH uses deep learning-based AI algorithms to analyze images to find suspected intracranial hemorrhage and notifies and shares the findings to medical specialists. Identification of images with suspected intracranial hemorrhage is for notification purposes only, not diagnostic purposes. In particular, this medical device analyzes non-contrast brain CT images, and if a suspected intracranial hemorrhage is identified, it sends a notification to medical specialists, who are advised to review these images. Images may be previewed through the mobile app but are for informational purposes only and are not intended to be used for diagnostic purposes other than notifications and previews. The medical specialist who received the notification is responsible for reading the image in a diagnostic viewer. Hyper Insight - ICH is limited to the purpose of analysis of image data and should not be used as a substitute for a full patient assessment or relied upon to make or confirm a diagnosis.	Viz ICH 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. Viz ICH uses an artificial intelligence algorithm to analyze images for findings suggestive of a prespecified clinical condition and to notify an appropriate medical specialist 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 brain acquired in the acute setting and sends notifications to a neurovascular or neurosurgical specialist that a suspected intracranial hemorrhage has been identified and recommends review of those images. Images can be previewed through a mobile application. Images that are previewed through the mobile application may be compressed and are for informational purposes only and not intended for diagnostic use beyond 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. Viz ICH is limited to analysis of imaging data and should not be used in-lieu of full patient evaluation or relied upon to make or confirm diagnosis. Viz ICH is contraindicated for analyzing non-contrast CT scans that are acquired on scanners from manufacturers other than General Electric (GE) or its subsidiaries (i.e. GE Healthcare). This contraindication applies to NCCT scans that conform to all applicable Patient Inclusion Criteria, are of adequate technical image quality, and would otherwise be expected to be analyzed by the device for a suspected ICH.
Product Code	QAS	QAS
Environment of use	Clinical/Hospital Environment	Clinical/Hospital Environment
Intended Clinical End User	Radiologist, emergency medicine physicians, neurosurgeons, neurologist	Radiologist, emergency medicine physicians, neurosurgeons, neurologist
Anatomical Region	Head	Head
Clinical Condition	Acute Intercranial Hemorrhage (ICH)	Intercranial Hemorrhage (ICH)

	Subject Name (Subject Device)	Viz.ai, Inc. Viz ICH (K193658)
Independent of standard of care workflow	Yes, No cases are removed from worklist	Yes
AI Used	Yes	Yes
Input Image Modality	Non-Contrast Head CT	Non-Contrast Head CT
Alteration of Image	No	No
DICOM Compatible	Yes	Yes
Transfer, store, and process DICOM images	Yes	Yes
Data Acquisition	Acquires medical image data from DICOM compliant imaging devices and modalities.	Acquires medical image data from DICOM compliant imaging devices and modalities.
Results of Image Analysis	Internal, no image marking	Internal, no image marking
Preview Images	Initial assessment; non-diagnostic	Initial assessment; non-diagnostic
View DICOM Data	DICOM Information about the patient, study and current image.	DICOM Information about the patient, study and current image.
Image viewing and manipulation (window,pan,zoom)	Yes	Yes
Output	AI findings (Suspected ICH or Case Processed)	Suspected ICH (Yes or No)
Clinical SoC Workflow	In parallel to	In parallel to
Results Receiver	PACS/Workstation	PACS/Workstation

Overall Performance Data Comparison

Performance	Subject Device	K193658
Sensitivity (%) 95% Confidence Interval	95.45 [91.55, 97.90]	93 [87, 97]
Specificity (%) 95% Confidence Interval	98.47 [95.59, 99.68]	90 [84, 94]
AUC of ROC	0.9864 [0.9738, 0.9989]	0.96
Average time to alerting a specialist	16.39±5.46 seconds	0.49±0.15 minutes

Age Subgroup Performance Data Comparison

Age Range (years)	Subject Device		K193658	
	Sensitivity [95 Cl]	Specificity [95% Cl]	Sensitivity [95 Cl]	Specificity [95% Cl]
<50	95.35 [84.19, 99.43]	96.94 [91.31, 99.36]	0.89 [0.52, 1.0]	0.95 [0.76, 1.0]
50 - 70	97.92 [88.93, 99.95]	100.00 [94.04, 100.00]	0.92 [0.82, 0.97]	0.9 [0.8, 0.96]
>70	94.39 [88.19, 97.91]	100.00 [90.75, 100.00]	0.94 [0.84, 0.99]	0.88 [0.76, 0.95]

Gender Subgroup Performance Data Comparison

Gender	Subject Device		K193658	
	Sensitivity [95% Cl]	Specificity [95% Cl]	Sensitivity [95% Cl]	Specificity [95% Cl]
Male	97.25 [92.17, 99.43]	100.00 [95.55, 100.00]	0.9 [0.8, 0.96]	0.9 [0.8, 0.96]
Female	93.26 [85.90, 97.49]	97.39 [92.57, 99.46]	0.95 [0.86, 0.99]	0.89 [0.8, 0.95]

ICH Subtype Performance Data Comparison

ICH Subtype	Subject Device	K193658
	Sensitivity [95% CI]	Sensitivity [95% CI]
Intraparenchymal Hemorrhage (IPH)	97.30 [90.58, 99.67]	0.98 [0.91, 1.0]
Intraventricular Hemorrhage (IVH)	97.67 [87.71, 99.94]	1.00 [0.74, 1.0]
Subarachnoid Hemorrhage (SAH)	97.65 [91.76, 99.71]	0.60 [0.26, 0.88]
Subdural Hemorrhage (SDH)	94.69 [88.80, 98.03]	0.85 [0.62, 0.97]
Extradural Hemorrhage (EDH)	100.00 [80.49, 100.00]	N/A
SDH or EDH	97.30 [90.58, 99.67]	0.85 [0.62, 0.97]

Slice Thickness Subgroup Performance Data Comparison

Slice Thickness	Subject Device		K193658	
	Sensitivity [95% CI]	Specificity [95% CI]	Sensitivity [95% CI]	Specificity [95% CI]
2.5mm <= Slice Thickness < 3.5mm	96.67 [88.47, 99.59]	94.00 [83.45, 98.75]	0.93 [0.85, 0.98]	0.92 [0.83, 0.97]
3.5mm <= Slice Thickness < = 5.0mm	94.78 [89.53, 97.87]	100.00 [97.45, 100.00]	0.92 [0.81, 0.98]	0.88 [0.77, 0.95]

PERFORMANCE DATA

SK Inc. conducted a retrospective study to evaluate the efficacy of radiological computer aided triage and notification software (CADt), which supports medical specialist to promptly diagnose and treat patients with suspected intracranial hemorrhage by providing notification, when analyzed as a patient with suspected intracranial hemorrhage. To this study, the clinical sensitivity and specificity of the investigational medical device 'Hyper Insight-ICH' was evaluated against the reading results of intracranial hemorrhage from brain CT images by the Reference Standard Establishment Committee. The results of this non-clinical testing show that the strength of the Hyper Insight-ICH is sufficient for its intended use and is substantially equivalent to legally marketed predicate device.

394 brain Computed Tomography images were obtained from 13 clinical sites in the U.S. There were approximately equal numbers of 'yes' or 'no' analysis results (198 with intracranial hemorrhage and 196 without intracranial hemorrhage). Sensitivity and specificity were calculated in the image database, comparing the Viz ICH's output to ground truth as established by trained neuro-radiologists. Sensitivity and specificity were 95.45% (95% CI) and 98.47% (95% CI), respectively. Because the lower bound of each confidence interval exceeded 80%, the study met the pre-specified performance goals of 80% for sensitivity and specificity.

In addition, the area under the receiver operating characteristic curve (AUC) was 0.9864 demonstrating the

clinical utility and potential benefits of the Hyper Insight - ICH based on the imaging study results.

In the study, the average time to analyzing the brain CT image and notify the result of the intracranial hemorrhage identification to the mobile (DICOM VIEWER) was analyzed was 16.39 ± 5.46 seconds (0.27 ± 0.091 minutes), which is lower than the average time to notification seen in the predicate device of 0.49 ± 0.15 minutes. This data will allow medical personnel to quickly and accurately identify patients suspected of intracranial hemorrhage through notifications and determine priority triage, providing them an opportunity to participate early in the clinical workflow.

	Subject Device	K193658
Average time to notification	16.39 ± 5.46 seconds (0.27 ± 0.091 minutes)	0.49 ± 0.15 minutes

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

Performance Stratified by Clinical Site		
Clinical Site	Sensitivity [95% Cl]	Specificity [95% Cl]
Clinical Site 1	100.00 [59.04, 100.00]	100.00 [59.04, 100.00]
Clinical Site 2	92.86 [66.13, 99.82]	50.00 [1.26, 98.74]
Clinical Site 3	100.00 [2.50, 100.00]	- [-, -]
Clinical Site 4	100.00 [15.81, 100.00]	90.00 [55.50, 99.75]
Clinical Site 5	100.00 [59.04, 100.00]	94.12 [71.31, 99.85]
Clinical Site 6	100.00 [2.50, 100.00]	- [-, -]
Clinical Site 7	100.00 [47.82, 100.00)	100.00 [15.81, 100.00]
Clinical Site 8	100.00 [2.50, 100.00]	100.00 [2.50, 100.00]
Clinical Site 9	100.00 [69.15, 100.00]	100.00 [59.04, 100.00]
Clinical Site 10	83.33 [35.88, 99.58]	100.00 [39.76, 100.00]
Clinical Site 11	92.59 [75.71, 99.09]	100.00 [94.72, 100.00]
Clinical Site 12	92.00 [80.77, 97.78]	100.00 [92.75, 100.00]
Clinical Site 13	98.51 [91.96, 99.96]	100.00 [88.06, 100.00]

Performance Stratified by Age		
Age Range (ye ars)	Sensitivity [95% Cl]	Specificity [95% Cl]
≤50	95.35 [84.19, 99.43]	96.94 [91.31, 99.36]
50 - 70	97.92 [88.93, 99.95]	100.00 [94.04, 100.00]
≥70	94.39 [88.19, 97.91]	100.00 [90.75, 100.00]

Performance Stratified by Gender		
Gender	Sensitivity [95% Cl]	Specificity [95% Cl]
Male	97.25 [92.17, 99.43]	100.00 [95.55, 100.00]
Female	93.26 [85.90, 97.49]	97.39 [92.57, 99.46]

Performance Stratified by Race		
Race	Sensitivity [95% Cl]	Specificity [95% Cl]
American Indian or Alaskan Native	100.00 [2.50, 100.00]	- [-, -]
Asian	100.00 [59.04, 100.00]	100.00 [29.24, 100.00]
Black or African American	100.00 [85.18, 100.00]	100.00 [90.00, 100.00]
Native Hawaiian or Other Pacific Islander	100.00 [15.81, 100.00]	- [-, -]
White	95.21 [90.37, 98.05]	97.79 [93.69, 99.54]
Two or more races	- [-, -]	- [-, -]
Unknown	89.47 [66.86, 98.70]	100.00 [84.56, 100.00]

Performance Stratified by ICH Subtype	
ICH Subtype	Sensitivity [95% CI]
Intraparenchymal Hemorrhage (IPH)	97.30 [90.58, 99.67]
Intraventricular Hemorrhage (IVH)	97.67 [87.71, 99.94]
Subarachnoid Hemorrhage (SAH)	97.65 [91.76, 99.71]
Subdural Hemorrhage (SDH)	94.69 [88.80, 98.03]
Epidural Hemorrhage (EDH)	100.00 [80.49, 100.00]

Performance Stratified by Slice Thickness		
Slice Thickness	Sensitivity [95% Cl]	Specificity [95% Cl]
0.5 mm ≤ slice thickness < 2.5 mm	100.00 [39.76, 100.00]	100.00 [29.24, 100.00]
2.5 mm ≤ slice thickness < 3.5 mm	96.67 [88.47, 99.59]	94.00 [83.45, 98.75]
3.5 mm ≤ slice thickness ≤ 5.0 mm	94.78 [89.53, 97.87]	100.00 [97.45, 100.00]

Performance Stratified by CT scanner's manufacturer		
CT scanner's manufacturer	Sensitivity [95% Cl]	Specificity [95% Cl]
Canon Medical Systems	100.00 [66.37, 100.00]	- [-, -]
GE MEDICAL SYSTEMS	96.77 [83.30, 99.92]	90.91 [70.84, 98.88]
Philips	92.50 [79.61, 98.43]	98.88 [93.90, 99.97]

PNMS	- [-, -]	100.00 [2.50, 100.00]
SIEMENS	93.44 [84.05, 98.18]	100.00 [93.62, 100.00]
TOSHIBA	98.25 [90.61, 99.96]	100.00 [87.66, 100.00]

Performance Stratified by ICH Volume	
Minimal Volume Threshold (mL)	Sensitivity above Threshold [95% Cl]
<1	90.00 [81.24, 95.58]
1≤ ICH volume < 5	98.13 [93.41, 99.77]
5≤ ICH volume < 10	97.37 [86.19, 99.93]
10≥	100.00 [96.61, 100.00]

CONCLUSION

Hyper Insight-ICH is as safe and effective as the predicate, Viz ICH (K193658), in that it has the same indications for use and minor technological differences compared to the predicate. Performance data demonstrate that Hyper Insight-ICH does not raise any new issues regarding safety or efficacy when compared to its predicate device. Thus, Hyper Insight-ICH is substantially equivalent to its predicate device.