Viz.ai, Inc.
Vi Ma
Regulatory Affairs Specialist
201 Mission St, 12th Floor,
SAN FRANCISCO CA 94105 USA

July 25, 2022

Re: K220439
Trade/Device Name: Viz 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 15, 2022
Received: February 16, 2022

Dear Vi Ma:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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
Imaging Software Team
DHT 8B: 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)*

K220439

Device Name

Viz SDH

Indications for Use *(Describe)*

Viz SDH 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 SDH 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 head for subdural hemorrhage and sends notifications to a neurovascular or neurosurgical specialist that a suspected subdural 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 SDH 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.

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
Viz.ai, Inc.'s Viz SDH

Applicant Name: Viz.ai, Inc.
201 Mission St, 12th Floor
San Francisco, CA 94105

Contact Person: Vi Ma
Regulatory Affairs Specialist
201 Mission Street, 12th Floor
San Francisco, CA 94105
Tel. (415) 663-6130
vi.ma@viz.ai

Date Prepared: June 23, 2022

Device Name and Classification

Name of Device: Viz 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	Device Name	Application No.
Viz.ai, Inc.	Viz ICH	K210209

Device Description

Viz SDH is a software-only, parallel workflow tool for use by hospital networks and trained clinicians to identify and communicate images of specific patients to an appropriate specialist, such as a neurovascular specialist or neurosurgeon, independent of the standard of care workflow. The system automatically receives and analyses non-contrast CT (NCCT) studies of patients for image features that indicate the presence of a subdural hemorrhage (SDH) using an artificial intelligence algorithm, and upon detection of a suspected SDH, sends a notification so as to alert a specialist clinician of the case.

Viz SDH is a combination of software modules that consists of an image analysis software algorithm and mobile application software module. The Viz SDH image analysis software algorithm is an artificial intelligence machine learning (AI/ML) software algorithm that analyzes non-contrast CT images of the head for a subdural hemorrhage. The Viz SDH Image Analysis Algorithm is hosted on Viz.ai's servers and analyzes applicable stroke-protocoled NCCT

images of the head that are acquired on CT scanners and are forwarded to Viz.ai servers. Upon detection of a suspected subdural hemorrhage, the Viz SDH Image Analysis Algorithm sends a notification of the suspected finding.

Viz SDH includes a mobile software module that enables the end user to receive and toggle notifications for suspected subdural hemorrhages identified by the Viz SDH Image Analysis Algorithm. The Viz SDH mobile notification software module is implemented into Viz.ai's non-diagnostic DICOM image viewer, Viz VIEW, which displays CT scans that are sent to Viz.ai's servers. When the Viz SDH mobile notification software module is enabled for a user, the user can receive and toggle the notifications for patients with a suspected subdural hemorrhage, view a unique patient list of patients with a suspected subdural hemorrhage, and view the non-diagnostic CT scan of the patient through the Viz VIEW mobile application. Image viewing through the mobile application interface is for non-diagnostic purposes only.

Intended Use / Indications for Use

Viz SDH 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 SDH 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 head for subdural hemorrhage and sends notifications to a neurovascular or neurosurgical specialist that a suspected subdural 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 SDH 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.

Summary of Technological Characteristics

The subject device, Viz SDH, is substantially equivalent to the predicate device, the Viz ICH device (K210209). In comparing the technological characteristics, both the subject and predicate devices use an artificial intelligence algorithm and mobile notification software to identify and notify specialists of patients with a suspected hemorrhage. Where the subject and predicate differ is that the software algorithm for the subject device is designed to detect subdural hemorrhages, while the predicate device detects a variety of intracranial hemorrhages, including subdural hemorrhages.

Both the subject and the predicate devices include mobile application software that allows a user to receive push notifications for patients identified with a suspected hemorrhage by their respective software algorithms. Both devices interface with a non-diagnostic mobile DICOM

image viewer to allow the specialist user to preview non-diagnostic images and view patient details associated with a series.

When used with the Viz VIEW mobile application software, the Viz SDH mobile notification software module is subject to the same non-diagnostic viewing limitations as the predicate and has the same non-diagnostic warning on the image viewing screen as the predicate.

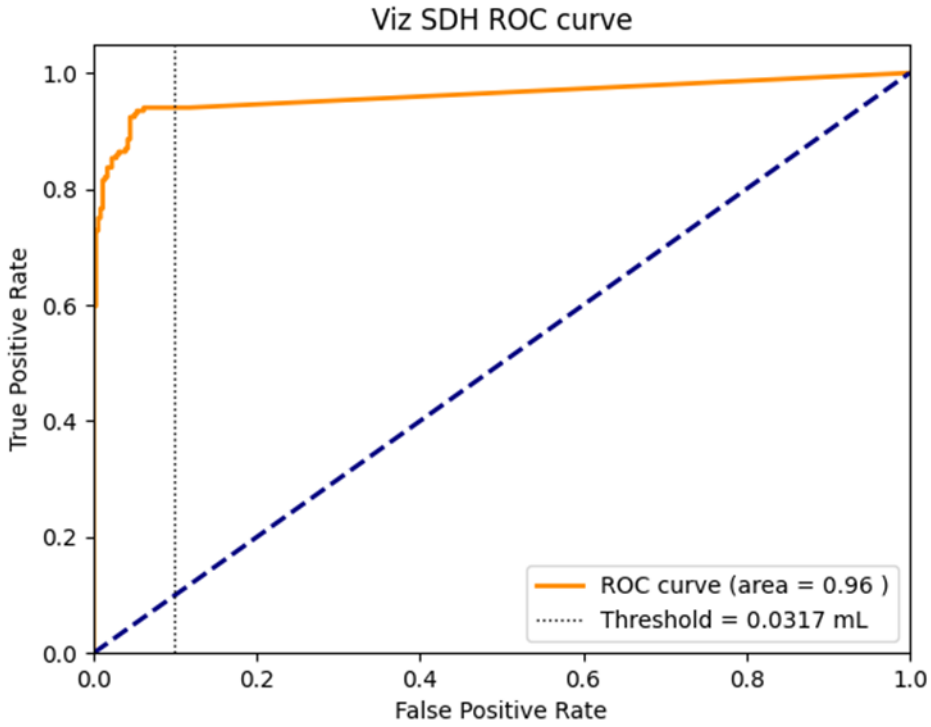
	Subject Device	**Predicate Device**
	Viz SDH	**Viz ICH**
Application No.	K220439	K210209
Product Code	QAS	QAS
Regulation No.	21 C.F.R. § 892.2080	21 C.F.R. § 892.2080
Anatomical Region	Head	Head
Diagnostic Application	Notification-only	Notification-only
Notification/ Prioritization	Yes	Yes
Intended User	Neurovascular or Neurosurgical Specialist	Neurovascular or Neurosurgical Specialist
DICOM Compatible	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.
Supported Imaging Modality	Computed Tomography, non-contrast (NCCT)	Computed Tomography, non-contrast (NCCT)
Alteration of Original Image	No	No
Results of Image Analysis	Internal, no image marking	Internal, no image marking
Preview Images	Initial assessment; non-diagnostic purposes	Initial assessment; non-diagnostic purposes
View DICOM Data	DICOM Information about the patient, study and current image.	DICOM Information about the patient, study and current image.
Time to Notification	1.15±0.57 minutes	1.15±0.83 minutes

Performance Data

542 Non-contrast Computed Tomography (NCCT) scans (studies) were obtained from three clinical sites in the U.S. There were approximately twice the number of negative than positive cases (66.1% images without SDH and 33.9.% with SDH, respectively) included in the analysis.

Sensitivity and specificity were calculated in the image database, comparing the Viz SDH's output to ground truth as established by trained neuro-radiologists. Sensitivity and specificity were 94% (90% - 97%) and 92% (89% - 95%), 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 0.96, demonstrating the clinical utility and potential benefits of the classifier based on the imaging study results.



In addition, the time to notification for SDH was compared to the time to notification for predicate device, Viz ICH. The Viz ICH time to notification was compared to the standard of care and was clinically meaningful from the perspective of effective triage (i.e., showing a reduction in the time to notification when compared to the standard of care).

Since SDH is a specific type of intracranial hemorrhage, a comparison of the Viz SDH time to notification with respect to the predicate device, Viz ICH (which was shown to support effective triage for hemorrhage) provides a comparable insight in the ability of Viz SDH to provide effective triage.

In the study, the average time to alerting a specialist was 69.1±34.3 sec (1.15±0.57 minutes), which is comparable to the average time to notification seen in the Viz ICH of 1.15±0.83 minutes. This data generally demonstrated that specialists could become involved in the clinical workflow early with notifications from the Viz SDH software.

Stratification of Device Performance

Device Performance by Clinical Site		
Clinical Site	**Sensitivity [95% CI]**	**Specificity [95% CI]**
Site 001	0.93 [0.83, 0.98]	0.91 [0.86, 0.95]
Site 002	0.93[0.81,0.99]	0.95[0.87,0.99]
Site 003	0.95 [0.89, 0.99]	0.92 [0.85, 0.96]

Device Performance by Age		
Age Range (Years)	**Sensitivity [95% CI]**	**Specificity [95% CI]**
<50	1.0 [0.54, 1.0]	0.95 [0.84, 0.99]
50-70	1.0 [0.88, 1.0]	0.92 [0.82, 0.97]
70<	0.91 [0.82, 0.96]	0.91 [0.81, 0.97]

Device Performance by Gender		
Gender (Years)	**Sensitivity [95% CI]**	**Specificity [95% CI]**
Male	0.97 [0.92, 0.99]	0.9 [0.84, 0.94]
Female	0.9 [0.80, 0.96]	0.94 [0.90, 0.97]

Device Performance by Presence of Subdural Hemorrhage and Other Hemorrhage		
Hemorrhage Subtypes	**Sensitivity [95% CI]**	**Specificity [95% CI]**
Subdural hemorrhage only	0.93 ['0.88', '0.97']	-
Subdural hemorrhage and other hemorrhage present	0.97 ['0.86', '1.00']	-
Other, non-subdural hemorrhage present	-	1.0 ['0.40', '1.00']

Device Performance by Slice Thickness		
Slice Thickness	**Sensitivity [95% CI]**	**Specificity [95% CI]**
2.5mm ≤ Slice Thickness < 3.5mm	0.95 [0.89, 0.98]	0.93 [0.88, 0.96]
3.5mm ≤ Slice Thickness ≤ 5.0mm	0.93 [0.83, 0.98]	0.91 [0.86, 0.95]

Device Performance by SDH Thickness	
Thickness	**Sensitivity [95% CI]**
3mm ≤ Thickness < 6mm	0.81 [0.58, 0.95]
6mm ≤ Thickness < 10mm	0.91 [0.8, 0.98]
Thickness > 10mm	0.97 [0.93, 0.99]

Device Performance by SDH Type	
SDH Type	**Sensitivity [95% CI]**

Acute	0.92 [0.85, 0.97]
Non-Acute (Chronic)	0.93 [0.82, 0.99]
Both (Acute and Chronic)	0.98 [0.88, 1.00]

Device Performance by SDH Location	
SDH Location	**Sensitivity [95% CI]**
Tentorial	1.0 CI: [0.79, 1.00]
Falcine	0.87 CI: [0.69, 0.96]
Posterior Fossa	0.33 CI: ['0.01', '0.91']

Device Performance by Scanner Manufacturer		
Manufacturer	**Sensitivity [95% CI]**	**Specificity [95% CI]**
General Electric	0.92 [0.84, 0.97]	0.92 [0.87, 0.95]
Siemens	0.94 [0.83, 0.99]	0.94 [0.87, 0.98]
Toshiba	0.98 [0.89, 1.0]	0.92 [0.81, 0.97]

Device Performance by Scanner Manufacturer/Model			
Manufacturer	**Model**	**Sensitivity [95% CI]**	**Specificity [95% CI]**
GE Medical Systems	BRIGHTSPEED	1.0 [0.63, 1.0]	0.82 [0.57, 0.96]
	RIGHTSPEED S	1.0 [0.29, 1.0]	1.0 [0.29, 1.0]
	DISCOVERY 610	1.0 [0.69, 1]	0.94 [0.70, 1]
	DISCOVERY CT750 HD	0.85 [0.65, 0.96]	0.93 [0.88, 0.97]
	LIGHTSPEED VCT	1.0 [0.48, 1.0]	0.5 [0.01, 0.99]
	LIGHTSPEED16	1.0 ['0.03', '1.00']	0.5 ['0.01', '0.99']
	OPTIMA CT540	1.0 ['0.03', '1.00']	N/A
	OPTIMA CT660	1.0 ['0.03', '1.00']	1.0 ['0.03', '1.00']
	REVOLUTION CT	1.0 ['0.74', '1.00']	0.67 ['0.09', '0.99']
	REVOLUTION EVO	0.86 ['0.65', '0.97']	0.94 ['0.81', '0.99']
Siemens	EMOTION 16	N/A	1.0 [0.03, 1.0]
	PERSPECTIVE	0.94['0.74', '1.00']	0.93 ['0.77', '0.99']
	SENSATION 64	1.0 [0.03, 1.0]	N/A
	SOMATOM DEFINITION AS	1.0 ['0.29', '1.00']	1.0 ['0.59', '1.00']
	SOMATOM DEFINITION AS+	0.89 ['0.67', '0.99']	0.95 ['0.83', '0.99']
	SOMATOM DEFINITION FLASH	1.0 ['0.16', '1.00']	N/A
	SOMATOM GO.ALL	1.0 ['0.29', '1.00']	0.88 ['0.47', '1.00']
	SOMATOM PERSPECTIVE	1.0 [0.03, 1.0]	N/A
Toshiba	AQUILION	1.0 ['0.84', '1.00']	0.95 ['0.76', '1.00']

Device Performance by Scanner Manufacturer/Model			
Manufacturer	**Model**	**Sensitivity [95% CI]**	**Specificity [95% CI]**
	AQUILION ONE	1.0 ['0.54', '1.00']	1.0 ['0.63', '1.00']
	AQUILION PRIME	0.95 ['0.75', '1.00']	0.87 ['0.69', '0.96']

Device Performance by Subdural Hemorrhage Volume	
Volume (mL)	**Sensitivity [95% CI]**
Volume <1	0.33 [0.04, 0.78]
1<= Volume < 5	0.85 [0.65, 0.96]
5 <= Volume < 10	1.0 [0.75, 1.0]
Volume >= 10	0.98 [0.94, 1.0]

Device Performance by Scanner Reconstruction Method			
Manufacturer	**Reconstruction Method**	**Sensitivity [95% CI]**	**Specificity [95% CI]**
GE Medical Systems	SOFT	0.79 ['0.49', '0.95']	1.0 ['0.79', '1.00']
	STANDARD	0.94 ['0.85', '0.98']	0.91 ['0.86', '0.95']
	STND#	1.0 ['0.66', '1.00']	0.67 ['0.09', '0.99']
Siemens	H30s	1.0 ['0.40', '1.00']	1.0 ['0.40', '1.00']
	['Hc40f', '2']	1.0 ['0.29', '1.00']	0.88 ['0.47', '1.00']
	['J30s', '2']	0.92 ['0.79', '0.98']	0.94 ['0.86', '0.98']
Toshiba	FC26	0.96 ['0.81', '1.00']	0.9 ['0.76', '0.97']
	FC68	1.0 ['0.82', '1.00']	0.95 ['0.75', '1.00']

Conclusions

Viz SDH is as safe and effective as the predicate device. Viz SDH has essentially the same intended use and similar indications, technological characteristics, and principles of operation as its predicate device. The 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. In addition, the technological differences between Viz SDH and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that Viz SDH is as safe and effective as the predicate device, the previously cleared Viz ICH software (K210209). Thus, Viz SDH is substantially equivalent.