Viz.ai, Inc.   March 18, 2020
℅ Mr. Gregory Ramina
Director of Regulatory Affairs
555 De Haro St., Suite 400
SAN FRANCISCO CA 94107

Re: K193658
    Trade/Device Name: Viz ICH
    Regulation Number: 21 CFR 892.2080
    Regulation Name: Radiological computer aided triage and notification software
    Regulatory Class: Class II
    Product Code: QAS
    Dated: March 2, 2020
    Received: March 2, 2020

Dear Mr. Ramina:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
    and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number *(if known)*

K193658

Device Name

Viz ICH

Indications for Use *(Describe)*

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.

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) SUMMARY

Viz.ai, Inc.'s Viz ICH K193658

Applicant Name: Viz.ai, Inc.
555 De Haro St Suite 400
San Francisco, CA 94107

Contact Person: Gregory Ramina
Director of Regulatory Affairs
555 De Haro St Suite 400
San Francisco, CA 94107
Tel. (415) 663-6130
Greg@viz.ai

Date Prepared: March 6, 2020

Device Name and Classification

Name of Device: Viz ICH

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 Devices

Manufacturer	Device Name	Application No.
Viz.ai, Inc. (Primary)	ContaCT	DEN170073
Aidoc Medical, Ltd.	BriefCase	K180647

Device Description

Viz ICH 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 analyzes non-contrast CT (NCCT) studies of patients for image features that indicate the presence of an intracranial hemorrhage (ICH) using an artificial intelligence algorithm, and upon detection of a suspected ICH, sends a notification so as to alert a specialist clinician of the case.

Viz ICH consists of backend and mobile application component software. The Backend software includes a DICOM router and backend server. The DICOM router transmits NCCT images of the head acquired on a local healthcare network to the Backend Server. The Backend Server receives, stores, processes and serves received NCCT scans. The Backend Server also includes an artificial intelligence algorithm that analyzes the received NCCT images for image characteristics that indicate an intracranial haemorrhage (ICH) and, upon detection, sends a notification of the suspected finding to pre-determined specialists.

The Viz ICH Mobile Application software receives notifications generated by the Backend of suspected image findings and allows the notification recipient to view the analyzed NCCT images through a non-diagnostic viewer, as well as patient information that was embedded in the image metadata. Image viewing through the mobile application is for informational purposes only and is not intended for diagnostic use.

Intended Use / Indications for Use

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.

Summary of Technological Characteristics

Viz ICH and its primary predicate, ContaCT (DEN170073), use the same process of automatic data identification and transfer to send images from the local hospital network to a

remote server for image processing and analysis, i.e., via a DICOM router that automatically identifies relevant images on a local IT Network and transfers them to a Backend Server using a DICOM compliant communication protocol.

Both Viz ICH and the ContaCT device have Backend Server software that can receive, store, process, and serve images that are forwarded from a DICOM router. The Backend Server software for each device has the same additional software functionality that interacts with the image management architecture, including a notifier module.

Where Viz ICH and the primary predicate differ, namely the specific condition and image modality analyzed by each device's algorithm, Viz ICH is similar to the secondary predicate, BriefCase (K180647), in that both software algorithms are designed to detect the same condition, intracranial haemorrhage (ICH), in non-contrast Computed Tomography images (NCCTs) of the head. Like the secondary predicate, BriefCase, the Viz ICH algorithm does not externalize any internal segmentation, analysis, or intermediate outputs used in determining if an ICH is present in the NCCT, nor does either algorithm mark the analyzed NCCT image.

Both Viz ICH and the ContaCT predicate support a mobile application that allows a user to receive push notifications, preview related images, and view patient details associated with a series. The Viz ICH mobile application is subject to the same non-diagnostic viewing limitations as the ContaCT predicate and has the same non-diagnostic warning on the image viewing screen as the predicate. Furthermore, the mobile application for Viz ICH and the ContaCT predicate can perform the same image viewing functions (window, pan, level, zoom, scroll through a cine).

|	Viz ICH	ContaCT (DEN170073)	BriefCase (K180647)
Technological Characteristics			
DICOM Compatible	Yes	Yes	Yes
Transfer, store, and process DICOM images	Yes	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.	Acquires medical image data from DICOM compliant imaging devices and modalities.
Image Analysis			
Supported Imaging Modality	Computed Tomography, non-contrast (NCCT)	Computed Tomography, contrast-enhanced (CTA)	Computed Tomography, non-contrast (NCCT)
Alteration of Original Image	No	No	No
Results of Image Analysis	Internal, no image marking	Internal, no image marking	Internal, no image marking
Image Viewing Functionality			
Preview Images	Initial assessment; non-diagnostic purposes	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.	DICOM Information about the patient, study and current image.
Image viewing	Yes	Yes	Yes

and manipulation (window, pan, level, zoom)			

Performance Data

Viz.ai conducted a retrospective study to assess the standalone performance of the image analysis algorithm and notification functionality of Viz ICH. The study evaluated the Viz ICH image analysis algorithm in terms of sensitivity and specificity with respect to a ground truth, as established by trained neuro-radiologists, in the detection of intracranial hemorrhage (ICH) in the brain. In addition, the study reported and compared the time to notification for the Viz ICH device with respect to the time to notification for the standard of care as established from available radiological reports.

261 non-contrast Computed Tomography (NCCT) scans (studies) were obtained from two clinical sites in the U.S. There were approximately equal numbers of positive and negative cases (47% of images with ICH and 53% without ICH, respectively) included in the analysis. 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 93% (87%-97%) and 90% (84%-94%), 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.

Viz ICH ROC curve
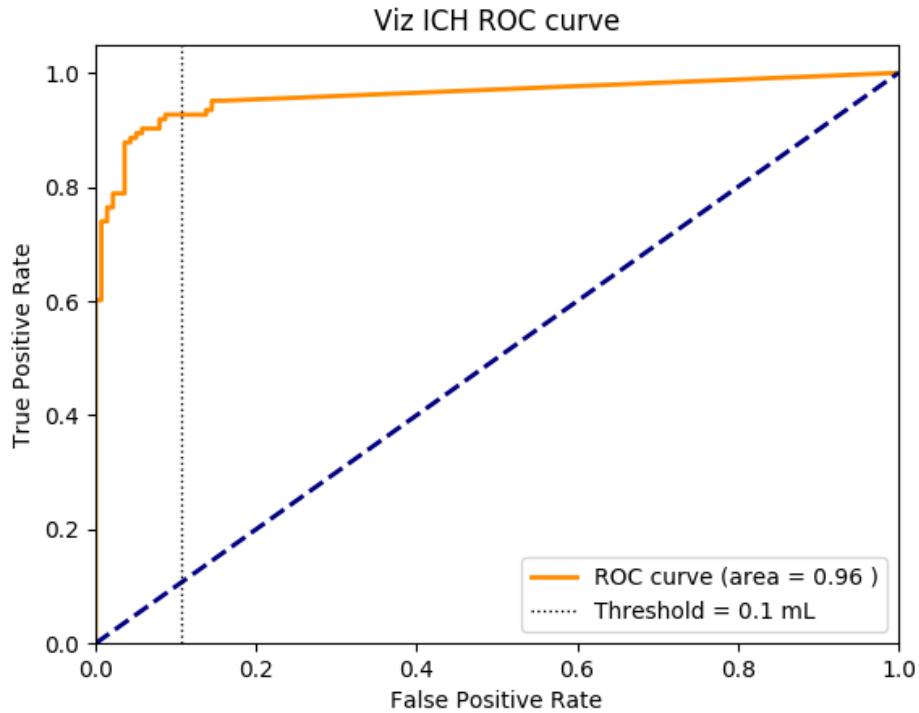
In the study, the average time to alerting a specialist was 0.49±0.15 minutes, which is substantially lower than the average time to notification seen in the Standard of Care of 38.2±84.3 minutes. This data generally demonstrates that specialists have the opportunity to become involved in the clinical workflow early with notifications from the Viz ICH software.

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% CI]	Specificity [95% CI]
Erlanger	0.93 [0.85, 0.98]	0.92 [0.84, 0.97]
Mt. Sinai	0.92 [0.8, 0.98]	0.86 [0.75, 0.94]

Performance Stratified by Age		
Age Range (years)	Sensitivity [95% CI]	Specificity [95% CI]
<50	0.89 [0.52, 1.0]	0.95 [0.76, 1.0]
50 - 70	0.92 [0.82, 0.97]	0.9 [0.8, 0.96]
>70	0.94 [0.84, 0.99]	0.88 [0.76, 0.95]

Performance Stratified by Gender		
Gender	Sensitivity [95% CI]	Specificity [95% CI]
Male	0.9 [0.8, 0.96]	0.9 [0.8, 0.96]
Female	0.95 [0.86, 0.99]	0.89 [0.8, 0.95]

Performance Stratified by ICH Subtype	
ICH Subtype	Sensitivity [95% CI]
Intraparenchymal Hemorrhage (IPH)	0.98 [0.91, 1.0]
Intraventricular Hemorrhage (IVH)	1.00 [0.74, 1.0]
Subarachnoid Hemorrhage (SAH)	0.60 [0.26, 0.88]
Subdural Hemorrhage (SDH)	0.85 [0.62, 0.97]
Extradural Hemorrhage (EDH)	N/A
SDH or EDH	0.85 [0.62, 0.97]

Performance Stratified by Slice Thickness		
Slice Thickness	Sensitivity	Specificity
2.5mm <= Slice Thickness < 3.5mm	0.93 [0.85, 0.98]	0.92 [0.83, 0.97]
3.5mm <= Slice Thickness <= 5.0mm	0.92 [0.81, 0.98]	0.88 [0.77, 0.95]

Performance Stratified by ICH Volume		
Minimal Volume Threshold (mL)	Sensitivity above Threshold [95% CI]	Sensitivity below/equal Threshold [95% CI]
1	0.95 [0.89, 0.98]	0.73 [0.39, 0.94]
5	0.97 [0.91, 0.99]	0.81 [0.64, 0.93]
10	0.99 [0.93, 1.0]	0.84 [0.7, 0.93]

Conclusions

Viz ICH is as safe and effective as the primary predicate, ContaCT (DEN170073), in that it has the same intended use and similar indications, technological characteristics and principles of operation. Where minor differences in indications exist between both devices, Viz ICH is similar to the secondary predicate device, BriefCase (K180647), which uses an artificial intelligence algorithm to detect and notify specified clinicians of an intracranial haemorrhage (ICH) in NCCT scans of the head. The minor differences in indications between ContaCT and Viz ICH do not alter the intended diagnostic use of the device and do not affect its safety and effectiveness. In addition, the minor technological differences between the Viz ICH and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that Viz ICH can identify an ICH per the same primary

performance goals, in terms of sensitivity and specificity, as the BriefCase predicate and is as safe and effective as the predicate devices. Thus, Viz ICH is substantially equivalent to its predicate devices.