Viz.ai, Inc.
℅ Gregory Ramina
Director of Regulatory Affairs
201 Mission Street
12th Floor
SAN FRANCISCO CA 94105

October 21, 2022

Re: K223042
Trade/Device Name: Viz LVO
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer aided triage and notification software
Regulatory Class: Class II
Product Code: QAS
Dated: September 28, 2022
Received: September 29, 2022

Dear Gregory 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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT 8B: Division of Radiological Imaging
Devices and Electronic Products
OHT 8: 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)

K223042

Device Name

Viz LVO

Indications for Use (Describe)

Viz 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.

Viz 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 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 review of those images. Images can be previewed through a mobile application. Viz LVO is intended to analyze terminal ICA and MCA-M1 vessels for LVOs.

Images that are previewed through the mobile application are 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 LVO 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY K223042

Viz.ai, Inc.'s Viz LVO

Applicant Name: Viz.ai, Inc.
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San Francisco, CA 94105

Contact Person: Gregory Ramina
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Greg@viz.ai

Date Prepared: September 28, 2022

Device Name and Classification

Name of Device: Viz LVO

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.	ContaCT	DEN170073

Purpose of Special 510(k)

Viz LVO is a modification to the predicate device, ContaCT. This Special 510(k) was submitted for changes to the Viz LVO indications for use which provide additional information regarding the intended regions analyzed by the Viz LVO device.

Intended Use / Indications for Use

Viz 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.

Viz 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 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 review of those images. Images can be previewed through a mobile application. Viz LVO is intended to analyze terminal ICA and MCA-M1 vessels for LVOs.

Images that are previewed through the mobile application are 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 LVO 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.

Device Description

Viz LVO is a notification-only, parallel workflow tool for use by hospital networks and trained clinicians to analyze images for findings suggestive of a suspected large vessel occlusion and to notify an appropriate medical specialist of these findings in parallel to standard of care image interpretation. Viz LVO was previously granted a de-novo as ContaCT (DEN170073); following the granting of the de-novo the device name was changed to Viz LVO.

Viz LVO is a combination of software modules that allow for detection and notification of patients with a suspected large vessel occlusion. Viz LVO consists of an algorithm and mobile application software module.

The Viz LVO Image Analysis Algorithm (LVO Detection Algorithm) is a locked, artificial intelligence machine learning (AI/ML) software algorithm that analyzes CTA images of the head for a suspected large vessel occlusion (LVO). The LVO Detection Algorithm is hosted on Viz.ai's Backend Server and analyzes applicable stroke-protocoled CTA images of the head that are acquired on CT scanners and are forwarded to Viz.ai's Backend Server. Upon detection of a suspected LVO, the LVO Detection Algorithm sends a notification of the suspected finding.

The Viz LVO Mobile Notification Software is a software module that enables the end user to receive and toggle notifications for suspected large vessel occlusions identified by the LVO Detection Algorithm. The LVO Mobile Notification Software module is implemented into Viz.ai's generic non-diagnostic DICOM image viewer, Viz VIEW (formerly referred to as the Imaging Viewing Software in

the previous submission, DEN170073), which displays CT scans that are sent to Viz.ai's Backend Server. When the Viz LVO Mobile Notification Software module is enabled for a user, the user can receive and toggle the notifications for patients with a suspected LVO, view a unique list of patients with a suspected LVO (as determined by the LVO Detection Algorithm), 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 informational purposes only and is not for diagnostic use.

Technological Characteristics

Both the subject and predicate device use the same artificial intelligence, machine learning (AI/ML) software algorithm to identify suspected large vessel occlusions (LVOs) on stroke-protocoled CTA imaging of head in the same regions of the large vessels. Additionally, the software algorithm for the subject device is hosted on the same architecture, automatically receives imaging in the same DICOM format, and uses the same mechanisms to identify applicable imaging for analysis as the predicate device. The outputs of the subject and predicate device are the same, i.e., both devices identify suspected large vessel occlusions (LVOs) and both devices send notifications for suspected LVO findings from the same server.

Both the subject and predicate device include the same mobile software functions and outputs which are presented through the same mobile application. The user can receive and toggle the notifications for patients with a suspected LVO, view a unique list of patients with a suspected LVO (as determined by the LVO Detection Algorithm), and view the non-diagnostic CT scan of the patient through the Viz VIEW mobile application. In addition, imaging viewing of CTA scans analyzed by the subject and predicate device are subject to the same limitations, that is they are limited to informational purposes (for prioritization review only) and are not for diagnostic use.

Where the subject and predicate device differ is that the subject device includes additional information which are embedded into the mobile application interface that inform the user of the limitations of the Viz LVO algorithm. These additional mechanisms implemented in the mobile application to communicate limitations of the subject device are not incorporated into the mobile application interface for the predicate device. Providing additional mechanisms through the user interface to inform the device user of the limitations of the subject device through the user interface provide additional means of promoting information for transparency regarding the limitations of the device. Furthermore, these same limitations are applicable to the predicate device. Supportive software testing demonstrated that the additional information is displayed through the mobile application interface as expected. Thus, the additional information provided through the user interface for the user does not raise any new or different questions of safety or efficacy.

Performance Data and Software Testing

Performance data was not included as part of part of the premarket notification. Supporting software verification and validation (V&V) testing were provided to demonstrate implementation of the device changes.

Substantial Equivalence

The Viz LVO device has the same intended use, and has very similar indications, technological characteristics, and principles of operation as its predicate. Although there are minor differences between Viz LVO and the predicate device such as the device indications and the presentation of device limitations and device information available through the mobile application interface, those differences do not raise new questions of safety or efficacy. Thus, the Viz LVO device is substantially equivalent.

Table 1: Substantial Equivalence Table Comparing Subject and Predicate Devices

	Subject Device	**Predicate Device**
	Viz LVO	**ContaCT**
Application No.	KXXXXXX	DEN170073
Product Code	QAS	QAS
Regulation No.	21 C.F.R. § 892.2080	21 C.F.R. § 892.2080
Intended Use / Indications for Use	Viz 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. Viz 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 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 review of those images. Images can be previewed through a mobile application. Viz LVO is intended to analyze terminal ICA and MCA-M1 vessels for LVOs. Images that are previewed through the mobile application are 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 LVO 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.	ContaCT 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. ContaCT 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 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 review of those images. Images can be previewed through a mobile application. Images that are previewed through the mobile application are 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. ContaCT 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.
Anatomical Region	Head	Head

	Subject Device	Predicate Device
Diagnostic Application	Notification-only	Notification-only
Notification/ Prioritization	Yes	Yes
Intended User	Neurovascular Specialist	Neurovascular 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 Angiography (CTA)	Computed Tomography Angiography (CTA)
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.