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

February 18, 2022

Re: K213319
Trade/Device Name: Viz ANEURYSM, Viz ANX
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer aided triage and notification software
Regulatory Class: Class II
Product Code: QFM
Dated: January 18, 2022
Received: January 19, 2022

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,

Jessica Lamb
Assistant 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

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)*

K213319

Device Name

Viz ANEURYSM, Viz ANX

Indications for Use *(Describe)*

Viz ANEURYSM (Viz ANX) is a radiological computer-assisted triage and notification software device for analysis of CT images of the head. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and prioritizing studies with suspected aneurysms during routine patient care.

Viz ANEURYSM uses an artificial intelligence algorithm to analyze images and highlight studies with suspected aneurysms in a standalone application for study list prioritization or triage in parallel to ongoing standard of care. The device generates compressed preview images that are meant for informational purposes only and not intended for diagnostic use. The device does not alter the original medical image and is not intended to be used as a diagnostic device.

Analyzed images are available for review through the standalone application. When viewed through the standalone application the images are for informational purposes only and not for diagnostic use. The results of Viz ANEURYSM, in conjunction with other clinical information and professional judgment, are to be used to assist with triage/prioritization of medical images. Radiologists who read the original medical images are responsible for the diagnostic decision. Viz ANEURYSM 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 ANEURYSM is limited to detecting aneurysms at least 4mm in diameter.

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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K213319

510(k) SUMMARY

Viz.ai, Inc.'s Viz ANEURYSM (Viz ANX)

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

Contact Person: Gregory Ramina
Director of Regulatory Affairs
201 Mission St, 12th Floor
San Francisco, CA 94105
Tel. (415) 663-6130
Greg@viz.ai

Date Prepared: January 11, 2022

Device Name and Classification

Name of Device: Viz ANEURYSM, Viz ANX

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: QFM

Predicate Device

Manufacturer	Device Name	Application No.
Shanghai United Imaging Intelligence Co., Ltd.	uAI EasyTriage-Rib	K193271

Device Description

Viz ANEURYSM (Viz ANX) is a radiological computer-assisted triage and notification software device for analysis of CTA images of the head. The software automatically receives and analyzes CT angiogram (CTA) imaging of the head for image features that indicate the presence of an aneurysm using an artificial intelligence algorithm, and prioritizes patient imaging in a standalone application for workflow triage and review by a radiologist in parallel to standard of care image interpretation.

Viz ANEURYSM is a combination of software modules that consists of an image analysis software algorithm and mobile application software module. The Viz ANEURYSM Image Analysis Algorithm is an artificial intelligence machine learning (AI/ML) software algorithm that analyzes CTA images of the head for an aneurysm. Images acquired during patient care are forwarded to Viz.ai's Backend server where they are analyzed by the Viz ANEURYSM artificial intelligence algorithm for an aneurysm.

Viz ANEURYSM includes a mobile software module that enables the end user to view cases identified by the Viz ANEURYSM algorithm to contain a suspected aneurysm. The Viz ANEURYSM mobile software module is implemented into Viz.ai's generic non-diagnostic DICOM image mobile viewing application, Viz VIEW, which displays CTA scans that are sent to the Backend server. When the Viz ANEURYSM mobile software module is enabled, studies determined by the algorithm to contain a suspected aneurysm are highlighted in the standalone mobile application for study list prioritization or triage in parallel to ongoing standard of care. The user can also view compressed preview images and a non-diagnostic preview of the analyzed CTA scan of the patient through the mobile application.

The preview images and additional patient imaging available through the standalone mobile application are meant for informational purposes only and not intended for diagnostic use. The results of Viz ANEURYSM, in conjunction with other clinical information and professional judgment, are to be used to assist with triage/prioritization of medical images. Radiologists who read the original medical images are responsible for the diagnostic decision.

Intended Use / Indications for Use

Viz ANEURYSM (Viz ANX) is a radiological computer-assisted triage and notification software device for analysis of CT images of the head. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and prioritizing studies with suspected aneurysms during routine patient care.

Viz ANEURYSM uses an artificial intelligence algorithm to analyze images and highlight studies with suspected aneurysms in a standalone application for study list prioritization or triage in parallel to ongoing standard of care. The device generates compressed preview images that are meant for informational purposes only and not intended for diagnostic use. The device does not alter the original medical image and is not intended to be used as a diagnostic device.

Analyzed images are available for review through the standalone application. When viewed through the standalone application the images are for informational purposes only and not for diagnostic use. The results of Viz ANEURYSM, in conjunction with other clinical information and professional judgment, are to be used to assist with triage/prioritization of medical images. Radiologists who read the original medical images are responsible for the diagnostic decision. Viz ANEURYSM 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 ANEURYSM is limited to detecting aneurysms at least 4mm in diameter.

Summary of Technological Characteristics

The subject device, Viz ANEURYSM, is substantially equivalent to the predicate device, uAI EasyTriage-Rib (K193271). In comparing the technological characteristics, both the subject and predicate devices use an artificial intelligence algorithm to identify clinical findings in CT imaging. Where the subject and predicate differ is that the software algorithm for the subject device identifies suspected aneurysm findings in CTA imaging of the head whereas the predicate device's algorithm identifies rib fractures in CT imaging of the chest.

Both the subject and the predicate devices provide findings through standalone software applications that allow the user to view preview images and patients identified with a suspected finding by their respective software algorithms in parallel to the standard of care. Both devices produce preview images and neither device removes images from a reading queue. Where the subject device and predicate device differ is that the subject device identifies patients for prioritization through a standalone mobile application whereas the predicate device provides prioritization on a standalone application on the radiologist workstation. The differences in standalone applications do not raise different or new questions of safety or effectiveness because the subject device's standalone mobile application includes a non-diagnostic warning to inform the user of the viewing limitations and both standalone applications are intended to facilitate the preemptive review of the case by the radiologists who can then turn to PACS to review the original medical images.

Both devices have the same technical and clinical limitations, namely, both are limited to analysis of imaging data and are intended to be used in conjunction with other clinical information and professional judgment to assist in performing triage and prioritization and not as the sole-basis for decision making.

	Subject Device	**Predicate Device**
	Viz ANEURYSM	**uAI EasyTriage-Rib**
Application No.	K213319	K193271
Product Code	QFM	QFM
Regulation No.	21 C.F.R. § 892.2080	21 C.F.R. § 892.2080
Intended Use / Indications for Use	Viz ANEURYSM (Viz ANX) is a radiological computer-assisted triage and notification software device for analysis of CT images of the head. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and prioritizing studies with suspected aneurysms during routine patient care.	uAI EasyTriage-Rib is a radiological computer-assisted triage and notification software device for analysis of CT chest images. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and prioritizing trauma studies with suspected positive findings of multiple (3 or more) acute rib fracture(s).

	Subject Device	Predicate Device
	Viz ANEURYSM uses an artificial intelligence algorithm to analyze images and highlight studies with suspected aneurysms in a standalone application for study list prioritization or triage in parallel to ongoing standard of care. The device generates compressed preview images that are meant for informational purposes only and not intended for diagnostic use. The device does not alter the original medical image and is not intended to be used as a diagnostic device. Analyzed images are available for review through the standalone application. When viewed through the standalone application the images are for informational purposes only and not for diagnostic use. The results of Viz ANEURYSM, in conjunction with other clinical information and professional judgment, are to be used to assist with triage/prioritization of medical images. Radiologists who read the original medical images are responsible for the diagnostic decision. Viz ANEURYSM 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 ANEURYSM is limited to detecting aneurysms at least 4mm in diameter.	uAI EasyTriage-Rib uses an artificial intelligence algorithm to analyze images and highlight studies with suspected multiple (3 or more) acute rib fracture(s) in a standalone application for study list prioritization or triage in parallel to ongoing standard of care. The user is presented with notifications of cases with suspected findings. Notifications include compressed preview images that are meant for informational purposes only and not intended for diagnostic use beyond notification. The device does not alter the original medical image and is not intended to be used as a diagnostic device. The results of uAI EasyTriage-Rib, in conjunction with other clinical information and professional judgment, are to be used to assist with triage/prioritization of medical images. Notified radiologists who read the original medical images are responsible for the diagnostic decision.
Anatomical Region	Head	Chest
Independent Standard of Care Workflow	Yes	Yes
Notification/ Prioritization	Yes	Yes
Identify patients with pre-specified clinical condition	Yes	Yes
Clinical Condition	Aneurysm	Multiple (3 or more) acute rib fractures.
Intended User	Radiologist	Radiologist
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.

	Subject Device	Predicate Device
Supported Imaging Modality	Computed Tomography Angiography (CTA)	Computed Tomography (CT)
Alteration of Original Image	No	No
Artificial Intelligence Algorithm	Yes	Yes
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.
Results Returned in Standalone Application	Yes	Yes

Performance Data

315 scans were used in the analysis to assess the device performance in the detection of aneurysms at least 4mm in diameter. Of the 315 scans included in the analysis, 67 scans were positive (21.3%) and 248 scans were negative (78.7%).

Sensitivity and specificity were calculated in the image database, comparing the Viz ANEURYSM's output to ground truth as established by trained neuro-radiologists. Sensitivity and specificity were 93% (83% - 98%) and 89% (85% - 93%), 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.

Table 1: Primary Endpoint Results

	Point Estimate [95% CI]
Sensitivity (Positives = 67)	0.93 [0.83, 0.98]
Specificity (Negatives = 248)	0.89 [0.85, 0.93]

In addition, the area under the receiver operating characteristic curve (AUC) was 0.967 (95% CI: 0.936 - 0.997), demonstrating the clinical utility and potential benefits of the classifier based on the imaging study results.

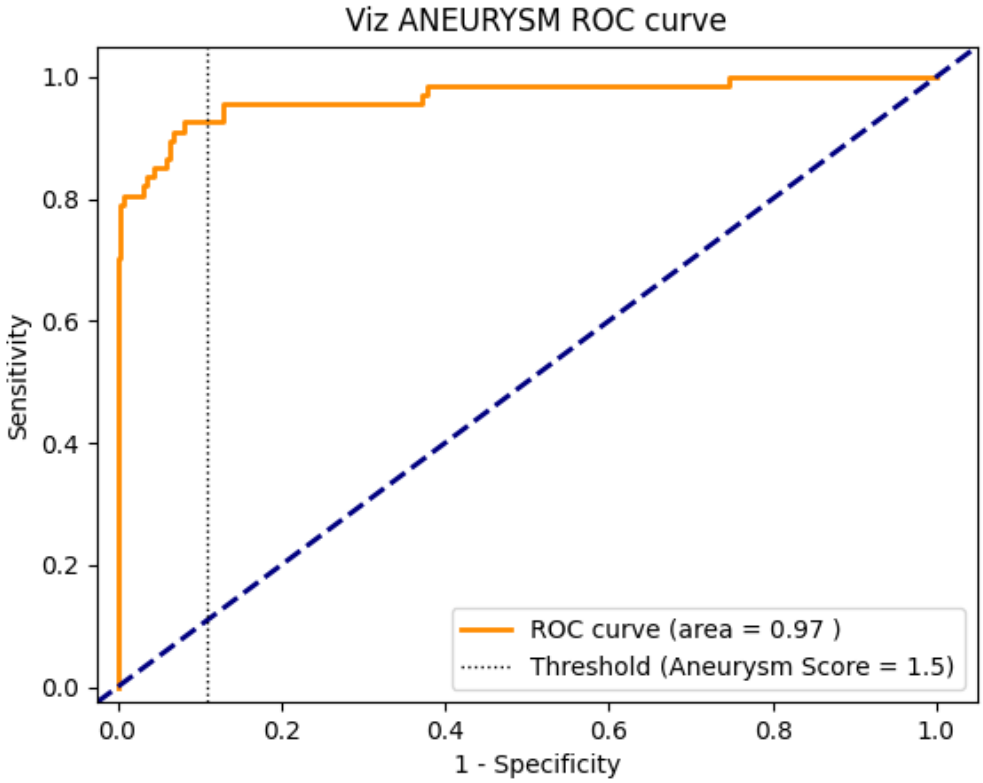

Figure 1: Viz ANEURYSM ROC curve with an AUC of .97

In the study, for true positive cases where the standard of care time-to-notification was available, the Viz ANEURYSM time-to-notification was faster than the standard of care time-to-notification for all 20 cases used in the time analysis (time differences ranged from 6.6 to 174.5 minutes). The average time to notification of the device was 219.8 seconds (3.67 minutes) on average, with a median of 203.44 seconds (3.39 minutes). This was faster than the Standard of Care time-to-notification which showed an average duration of 2613.0 seconds (43.6 minutes), with a median of 1620.0 seconds (27.0 minutes). This data generally demonstrates that radiologists have the opportunity to be made aware of cases for workflow prioritization and triage in a timely manner from the Viz ANEURYSM software.

Stratification of Device Performance

In addition, a secondary analysis reported the device performance when stratified into subgroups:

Table 2: Device Performance per Clinical Site

Clinical Site	Sensitivity [95% CI]	Specificity [95% CI]
Site 001	0.91 [0.76, 0.98]	0.87 [0.80, 0.92]
Site 002	0.94 [0.80, 0.99]	0.92 [0.85, 0.96]

Table 3: Device Performance per Age

Age Range (Years)	Sensitivity [95% CI]	Specificity [95% CI]
<50	0.91 [0.59, 1.0]	0.88 [0.75, 0.95]
50-70	0.93 [0.77, 0.99]	0.90 [0.83, 0.95]
70<	0.93 [0.76, 0.99]	0.89 [0.80, 0.94]

Table 4: Device Performance per Sex

Sex	Sensitivity [95% CI]	Specificity [95% CI]
Male	0.95 [0.77, 1.0]	0.92 [0.85, 0.96]
Female	0.91 [0.79, 0.98]	0.87 [0.80, 0.92]

Table 5: Device Performance by Aneurysm Diameter

Maximum Aneurysm Diameter	Sensitivity [95% CI]
$4 \leq d < 7$ mm	0.93 [0.82, 0.99]
$7 \leq d < 13$ mm	0.88 [0.64, 0.99]
$13 \leq d < 25$ mm	1.0 [0.40, 1.0]
$d \geq 25$ mm	-

Table 6: Device Performance by Saccular Aneurysm Location

Saccular Aneurysm Location	Sensitivity [95% CI]
AComm (including Acomm/ACA junction)	1.0 [0.63, 1.0]
Basilar Artery Tip	1.0 [0.48, 1.0]
Bifurcation of the M2 segments of the MCA	1.0 [0.78, 1.0]
PComm (including PComm/PCA junction)	0.91 [0.59, 1.0]
ICA or MCA-M1 segment (including ICA/ACA junction)	0.82 [0.60, 0.95]
Other	1.0 [0.54, 1.0]

Table 7: Device Performance by Slice Thickness

Slice Thickness	Sensitivity [95% CI]	Specificity [95% CI]
0.5mm ≤ Slice Thickness <0.625mm	0.93 [0.83, 0.98]	0.89 [0.84, 0.93]
0.625mm ≤ Slice Thickness ≤ 1.0mm	0.89 [0.52, 1.0]	0.92 [0.75, 0.99]

Table 8: Device Performance by Scanner Manufacturer

Manufacturer	Sensitivity [95% CI]	Specificity [95% CI]
General Electric	0.91 [0.78, 0.97]	0.89 [0.83, 0.93]
Siemens	1.0 [0.77, 1.0]	0.87 [0.74, 0.95]
Toshiba	0.89 [0.52, 1.0]	0.93 [0.76, 0.99]

Table 9: Device Performance by CT Scanner (Manufacturer/Model)

Manufacturer	Model	Sensitivity [95% CI]	Specificity [95% CI]
GE Medical Systems	LightSpeed VCT	0.86 [0.65, 0.97]	0.88 [0.80, 0.93]
	Optima CT660	1.0 [0.16, 1.0]	0.89 [0.52, 1.0]
	Revolution EVO	1.0 [0.16, 1]	1.0 [0.40, 1]
	Revolution HD	1.0 [0.40, 1.0]	0.96 [0.79, 1.0]
	BrightSpeed	0.93 [0.66, 1.0]	0.87 [0.70, 0.96]
Siemens	Sensation 64	N/A	1.0 [0.03, 1.0]
	SOMATOM Definition AS+	1.0 [0.66, 1]	1.0 [0.81, 1.0]
	SOMATOM Edge Plus	N/A	0.5 [0.16, 0.84]
	SOMATOM Perspective	1.0 [0.48, 1.0]	0.89. [0.67, 0.99]
Toshiba	Aquilion PRIME	1.0 [0.40, 1.0]	0.92 [0.62, 1.0]
	Aquilion	0.8 [0.28, 0.99]	0.94 [0.70, 1.0]

Table 10: Device Performance by Scanner Row Detectors

Detector Rows	Sensitivity [95% CI]	Specificity [95% CI]
16	0.93 [0.66, 1.0]	0.87 [0.70, 0.96]
32	N/A	1.0 [0.03, 1.0]
64	0.92 [0.80, 0.98]	0.89 [0.84, 0.93]
80	1.0 [0.40, 1.0]	0.92 [0.62, 1.0]

Conclusions

Viz ANEURYSM is as safe and effective as the predicate device. The subject device and the predicate have the same intended use and similar indications, technological characteristics, and principles of operation. The subject device differs in that it detects and identifies a different suspected finding in CTA imaging of the head and provides findings through a different standalone application for review. These differences do not present new or different questions of safety or effectiveness with respect to the predicate device. Viz.ai has provided supportive clinical data and software testing which demonstrates that the subject device can perform effective detection and timely identification of patients with a suspected aneurysm. Thus, Viz ANEURYSM is substantially equivalent to the predicate.