Viz. ai, Inc.
℅ Pooja Shah
Regulatory Affairs Specialist
201 Mission St., 12th Floor
SAN FRANCISCO CA 94105

March 17, 2023

Re: K223443
Trade/Device Name: Viz AAA
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer aided triage and notification software
Regulatory Class: Class II
Product Code: QFM
Dated: February 10, 2023
Received: February 10, 2023

Dear Pooja Shah:

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
DHT8B: Division of 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)*

K223443

Device Name

Viz AAA

Indications for Use *(Describe)*

Viz AAA is a radiological computer-assisted triage and notification software device for analysis of CTA images of the abdomen. The device is intended to assist hospital networks and vascular or endovascular specialists in workflow triage by flagging and prioritizing studies with suspected abdominal aortic aneurysms during routine patient care.

Viz AAA uses an artificial intelligence algorithm to analyze images and highlight studies with suspected abdominal aortic 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 AAA, in conjunction with other clinical information and professional judgment, are to be used to assist with triage/prioritization of medical images. Vascular or endovascular specialists who read the original medical images are responsible for the diagnostic decision. Viz AAA 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 AAA is limited to detecting aneurysms at least 3 cm in diameter. Viz AAA is intended to identify infra-renal, fusiform abdominal aortic aneurysms.

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.

K223443

510(k) SUMMARY

Viz.ai, Inc.'s Viz AAA

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

Contact Person: Pooja Shah
Regulatory Affairs Specialist
201 Mission St, 12th Floor
San Francisco, CA 94105
Tel. (415) 663 - 6130
pooja.shah@viz.ai

Date Prepared: March 3, 2023

Device Name and Classification

Name of Device: Viz AAA

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(s)

Manufacturer	Device Name	Application No.
Viz.ai, Inc.	Viz ANEURYSM, Viz ANX	K213319

Device Description

Viz AAA is a radiological computer-assisted triage and notification software device for analysis of CTA images of the abdomen. The software automatically receives and analyzes CT angiogram (CTA) imaging of the abdomen for the presence of an aortic aneurysm using an artificial intelligence algorithm and highlights suspect patient imaging in a standalone application for study list prioritization or triage by vascular or endovascular specialists in parallel to standard of care image interpretation.

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

Viz AAA includes a mobile software module that enables the end user to view cases identified by the Viz AAA algorithm to contain a suspected abdominal aortic aneurysm. The Viz AAA 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 AAA Mobile Software module is enabled, studies determined by the algorithm to contain a suspected abdominal aortic 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 AAA, in conjunction with other clinical information and professional judgment, are to be used to assist with triage/prioritization of medical images. Vascular or endovascular specialists who read the original medical images are responsible for the diagnostic decision.

Intended Use / Indications for Use

Viz AAA is a radiological computer-assisted triage and notification software device for analysis of CTA images of the abdomen. The device is intended to assist hospital networks and vascular or endovascular specialists in workflow triage by flagging and prioritizing studies with suspected abdominal aortic aneurysms during routine patient care.

Viz AAA uses an artificial intelligence algorithm to analyze images and highlight studies with suspected abdominal aortic 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 AAA, in conjunction with other clinical information and professional judgment, are to be used to assist with triage/prioritization of medical images. Vascular or endovascular specialists who read the original medical images are responsible for the diagnostic decision. Viz AAA 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 AAA is limited to detecting aneurysms at least 3 cm in diameter. Viz AAA is intended to identify infra-renal, fusiform abdominal aortic aneurysms.

Summary of Technological Characteristics

The subject device, Viz AAA, is substantially equivalent to the predicate device, Viz ANEURYSM (Viz ANX) (K213319). In comparing the technological characteristics, both the subject and predicate devices use an artificial intelligence algorithm and mobile software module to identify and highlight suspected clinical findings in a standalone application for study list prioritization. Where the subject and predicate differ is that the software algorithm for the subject device identifies suspected aortic aneurysm findings in CTA imaging of the abdomen whereas the predicate device's algorithm identifies suspected aneurysms in CTA imaging of the head.

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 which can be viewed through a mobile application, and neither device removes patient imaging from a reading queue. Where the devices differ is that the subject device uses a different visual than the predicate to notify users of suspected findings specific to abdominal aortic aneurysms in patient imaging. The visual used to notify the user of the different clinical finding by the subject device does not raise new or different questions of safety and effectiveness as they are displayed to the user through the user interface using the same conventions.

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 AAA	**Viz ANEURYSM (Viz ANX)**
Application No.	K223443	K213319
Product Code	QFM	QFM
Regulation No.	21 C.F.R. § 892.2080	21 C.F.R. § 892.2080
Intended Use/ Indications for Use	Viz AAA is a radiological computer-assisted triage and notification software device for analysis of CTA images of the abdomen. The device is intended to assist hospital networks and vascular or endovascular specialists in workflow triage by flagging and prioritizing studies with suspected abdominal aortic aneurysms during routine patient care. Viz AAA uses an artificial intelligence algorithm to analyze images and highlight studies with suspected abdominal aortic 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 AAA, in conjunction with other clinical information and professional judgment, are to be used to assist with triage/prioritization of medical images. Vascular or endovascular specialists who read the original medical images are responsible for	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.

	the diagnostic decision. Viz AAA 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 AAA is limited to detecting aneurysms at least 3 cm in diameter. Viz AAA is intended to identify infra-renal, fusiform abdominal aortic aneurysms.	Viz ANEURYSM is limited to detecting aneurysms at least 4mm in diameter.
Anatomical Region	Abdomen	Head
Diagnostic Application	Notification-only, highlighting for prioritization and review.	Notification-only, highlighting for prioritization and review.
Notification/ Prioritization	Yes	Yes
Intended User	Vascular or Endovascular Specialists	Radiologists
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
Results returned in Standalone Application	Yes	Yes

Performance Data

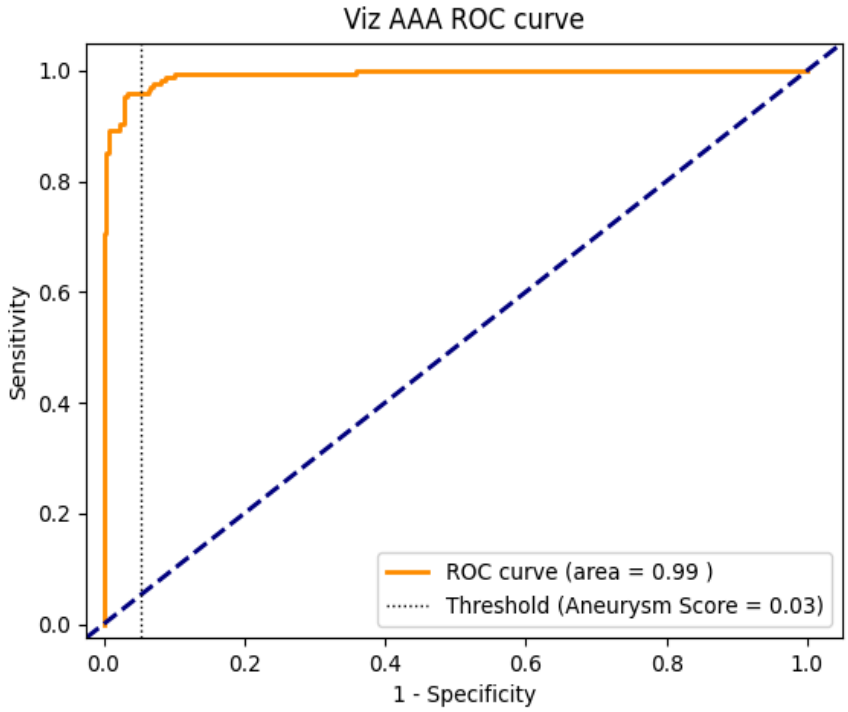
466 CTA scans were obtained from the two clinical sites in the U.S. There were approximately twice the number of negative than positive cases, 299 (64.16%) without abdominal aortic aneurysm, and 167 (35.84%) scans with an abdominal aortic aneurysm included in the analysis.

Sensitivity and specificity were calculated for the image database, comparing Viz AAA's output to ground truth as established by trained radiologists with fellowship in vascular radiology. Sensitivity and specificity were reported to be 96% [0.92, 0.98] and 95% [0.92, 0.97], 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: Device Sensitivity and Specificity

	Performance (95% C.I.)
Sensitivity (N=167)	96% [0.92, 0.98]
Specificity (N=299)	95% [0.92, 0.97]

The area under the receiver operating characteristic curve (AUC) was reported as 0.99 [0.98 – 1.00], demonstrating the clinical utility and potential benefits of the classifier based on the imaging study results. Because the point estimate of the AUC was greater than 0.95, the study exceeded the secondary performance goal for device AUC.



Stratification of Device Performance

In addition, a secondary analysis reported the device performance when stratified into subgroups by patient demographics, disease characteristics, and technical factors:

Table 2: Performance Stratified by Health Care System (Clinical Site)

Device Performance by Health Care System		
Health Care System (Clinical Site)	**Sensitivity [95% CI]**	**Specificity [95% CI]**
Site 001	0.94 [0.85, 0.98]	0.96 [0.92, 0.99]
Site 002	0.97 [0.92, 0.99]	0.94 [0.89, 0.98]

Table 3: Performance Stratified by Age

Device performance by Patient Age		
Age Group (years)	**Sensitivity [95% CI]**	**Specificity [95% CI]**
< 50	N/A	1 [0.90, 1.00]
50 - 70	0.95 [0.83, 0.99]	0.96 [0.91, 0.99]
>=70	0.96 [0.91. 0.99]	0.94 [0.88, 0.97]

Table 4: Performance Stratified by Sex

Device Performance by Patient Sex		
Sex	**Sensitivity [95% CI]**	**Specificity [95% CI]**
Male	0.96 [0.91, 0.99]	0.95 [0.90, 0.98]
Female	0.94 [0.80, 0.99]	0.96 [0.91, 0.99]

Table 5: Performance Stratified by Abdominal Aortic Aneurysm Location

Device Performance by Aneurysm Location	
Location	**Sensitivity [95% CI]**
Infra-renal	0.97 [0.93, 0.99]

Table 6: Performance Stratified by Abdominal Aortic Aneurysm Diameter

Device Performance by Aneurysm Diameter	
Diameter Range (mm)	**Sensitivity [95% CI]**
3.0 – 3.9	0.91 [0.80, 0.97]
4.0 – 4.9	0.98 [0.91, 1.00]
5.0 – 5.3	1.00 [0.78, 1.00]
>= 5.4	0.97 [0.87, 1.00]

Table 7: Performance Stratified by Aneurysm Type

Device Performance by Aneurysm Type	
Type	**Sensitivity [95% CI]**
Fusiform	0.97 [0.94, 0.99]

Table 8: Performance Stratified by CT Scanner Manufacturer

Device Performance by Manufacturer		
Manufacturer	**Sensitivity [95% CI]**	**Specificity [95% CI]**
GE MEDICAL SYSTEMS	0.94 [0.84, 0.98]	0.95 [0.89, 0.98]
SIEMENS	0.97 [0.91, 0.99]	0.96 [0.92, 0.98]
TOSHIBA	1.00 [0.63, 1.00]	0.88 [0.64, 0.99]

Table 9: Performance Stratified by CT Scanner Manufacturer and Model

Device Performance by Manufacturer and Model			
Manufacturer	**Model**	**Sensitivity [95% CI]**	**Specificity [95% CI]**
GE MEDICAL SYSTEMS	Discovery 610	0.85 [0.65, 0.96]	0.97 [0.88, 1.00]
	InteleViewer	1.00 [0.29, 1.00]	1.00 [0.29, 1.00]
	LightSpeed Pro 32	1.00 [0.4,0 1.00]	0.91 [0.59, 1.00]
	Optima CT660	1.00 [0.4,0 1.00]	1.00 [0.59, 1.00]
	Revolution EVO	1.00 [0.80, 1.00]	0.90 [0.70, 0.99]
	Revolution Maxima	1.00 [0.4,0 1.00]	1.00 [0.16, 1.00]
	Model N/A	1 [0.40, 1.00]	N/A
Siemens	InteleViewer	1.00 [0.48, 1.00]	1.00 [0.54, 1.00]
	Perspective	0.83 [0.36, 1.00]	0.83 [0.52, 0.98]
	SOMATOM Definition AS	1.00 [0.92, 1.00]	0.98 [0.93, 1.00]
	SOMATOM Definition Flash	0.95 [0.75, 1.00]	0.97 [0.86, 1.00]
	SOMATOM Perspective	1.00 [0.74, 1.00]	0.80 [0.44, 0.97]
	Sensation 40	0.80 [0.28, 0.99]	1.0 [0.29, 1.00]
	Sensation 64	N/A	1.0 [0.29, 1.00]
	Model N/A	1 [0.40. 1.00]	1 [0.03, 1.00]

Device Performance by Manufacturer and Model			
Manufacturer	**Model**	**Sensitivity [95% CI]**	**Specificity [95% CI]**
Toshiba	Aquilion ONE	1.00 [0.63, 1.00]	0.88 [0.64, 0.99]

Table 10: Performance by CT Scanner Row Detectors

Device Performance by Scanner Detector Rows		
Detector Rows	**Sensitivity [95% CI]**	**Specificity [95% CI]**
<=24	0.8 [0.28, 0.99]	1.00 [0.40, 1.00]
32	0.99 0.94, 1.00]	0.96 [0.91, 0.98]
64	0.93 [0.84, 0.98]	0.96 [0.90, 0.99]
80	1.00 [0.63, 1.00]	0.88 [0.64, 0.99]
Unknown Rows	1 [0.03, 1.00]	1 [0.16, 1.00]

Table 11: Performance by Slice Thickness

Device Performance by Slice Thickness		
Slice Thickness	**Sensitivity [95% CI]**	**Specificity [95% CI]**
Slice thickness <= 2.0	0.95 [0.83, 0.99]	0.94 [0.85, 0.98]
2.0 < Slice thickness <= 2.5	0.94 [0.85, 0.98]	0.95 [0.89, 0.98]
Slice thickness > 2.5	0.98 [0.91, 1.00]	0.96 [0.91, 0.99]

Table 12: Performance by Imaging Protocol

Type	Sensitivity [95% CI]	Specificity [95% CI]
Abdomen	1.00 [0.85, 1.00]	0.93 [076, 0.99]
Abdomen-Pelvis	0.99 [0.92, 1.00]	0.96 [0.92, 0.99]
Chest-Abdomen	0.94 [0.71, 1.00]	0.94 [0.80, 0.99]
Chest-Abdomen-Pelvis	0.9 [0.55, 1.00]	0.98 [0.88. 100]
Undetermined	0.92 [0.81, 0.98]	0.94 [0.84, 0.99]

Table 13: Performance by Presence of Metal Artifact

Presence of Metal Artifact	Sensitivity (95% C.I.)	Specificity (95% C.I.)
No metallic artifact	0.98 [0.93, 1.00]	0.94 [0.89, 0.97]
Metal is present, not obscuring the aorta	0.95 [0.87, 0.99]	0.98 [0.94, 1.00]
Metal is present obscuring the aorta	0.67 [0.22, 0.96]	0.93 [0.66, 1.00]

Conclusions

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 identifies a different suspected finding in CTA imaging of the abdomen and has a unique mobile module for suspected abdominal aortic aneurysm findings. 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 identification and notification of patients with a suspected abdominal aortic aneurysm for worklist prioritization. Thus, Viz AAA is substantially equivalent to the predicate.