



June 10, 2025

Viz.ai, Inc.
Gregory Ramina
Regulatory Affairs Director
5000 Center Green Way
Cary, North Carolina 27513

Re: K250354

Trade/Device Name: Viz Subdural+, Viz SUBDURAL PLUS
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: May 5, 2025
Received: May 5, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

A handwritten signature in black ink that reads "Jessica Lamb". The signature is written in a cursive style. A large, light blue "FDA" watermark is visible in the background behind the signature.

Jessica Lamb, Ph.D.
Assistant Director
DHT8B: 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

Indications for Use

Submission Number (if known)

K250354

Device Name

Viz Subdural+, Viz SUBDURAL PLUS

Indications for Use (Describe)

The Viz Subdural+ (Subdural Plus) device is intended for automatic labeling, visualization and quantification of collections in the subdural space from a set of Non-Contrast Head CT (NCCT) images. The software is intended to automate the current manual process of identifying, labeling and quantifying the volume of collections in the subdural space identified on NCCT images. Viz Subdural + provides volumes from NCCT images acquired at a single time point. The Viz Subdural+ software is intended for labeling subdural collections and reporting the grayscale value of the collection, widest width of the subdural collection, and midline shift. The device output should be reviewed along with the patient's original images by a physician qualified to interpret brain CT images.

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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K250354

510(k) Summary

Viz Subdural+

Applicant Name: Viz.ai, Inc.
5000 Center Green Way
Cary NC, 27513

Contact Person: Gregory Ramina
Regulatory Affairs Director
5000 Center Green Way
Cary NC, 27513
Tel. (415) 663-6130
Greg@viz.ai

Date Prepared: May 1, 2025

Device Name and Classification

Name of Device: Viz Subdural+, Viz SUBDURAL PLUS

Common or Usual Name: Automated Radiological Image Processing Software

Classification Panel: Radiology

Regulation No: 21 C.F.R. § 892.2050

Regulatory Class: Class II

Product Code: QIH

Predicate Device(s)

Manufacturer	Device Name	Application No.
Viz.ai, Inc.	Viz HDS	K232363

Device Description

Viz Subdural+ is a software-only device that uses a locked artificial intelligence machine learning (AI/ML) algorithm to process and analyze non-contrast CT (NCCT) scans of the head to automatically measure the collections in the subdural region in the brain and midline shift.

The device output provides visual overlays of automatically measured subdural collections where the overlay opacity (intensity) corresponds to the grayscale value of the collection within the native



NCCT, and reports the total volume and widest width of the subdural collections. The device also automates and reports the measure of midline shift.

The results of the automated measurement are provided in a summary series and segmentation series in DICOM format. The summary series consists of a summary table of subdural collections, snapshot of each collection and a midline shift measurement. The first slice of the Subdural+ summary series summarizes the measurement results of each subdural collection (volume and widest width), total volume and midline shift in tabular format. The summary series also contains a snapshot of each subdural collection and a snapshot of the midline shift measurement. The segmentation series shows an RGB overlay where a subdural collection is identified by a colored overlay with the color intensity corresponding to the HU values of the original image on each slice of the input series of the segmented region. On slices with an overlay representing a measured subdural collection, the volume of the subdural collection is provided. The midline shift is overlaid and provided on the slice where the midline shift is measured.

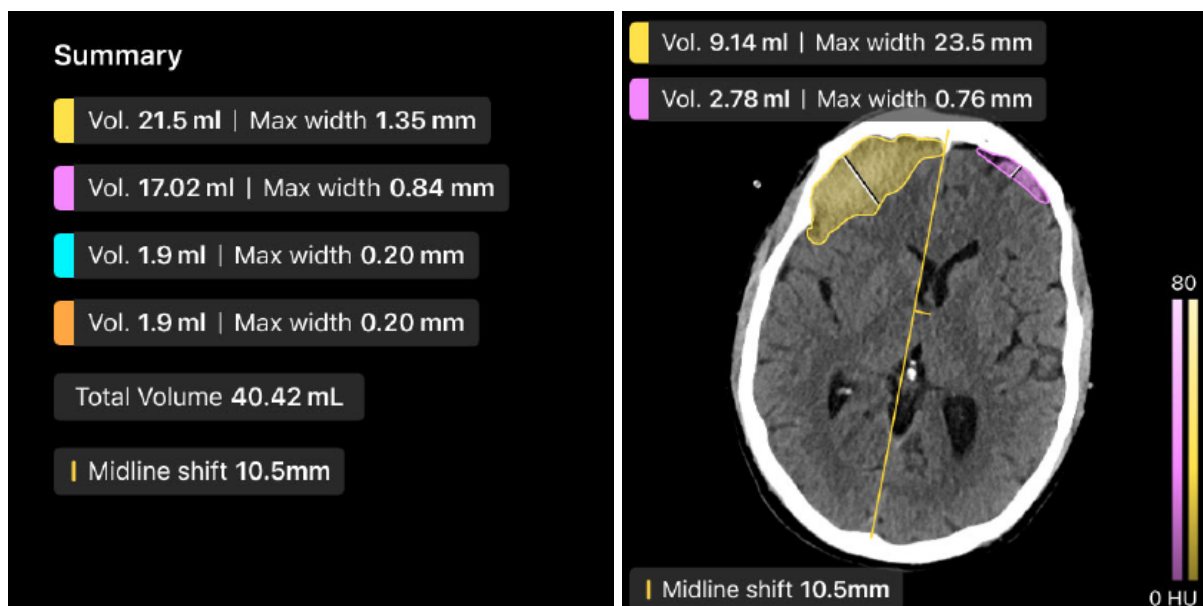


Figure 1. Examples of the summary table from the summary series output (left) and a slice from the segmentation series output (right). The summary series would include an additional summary image (snapshot) of each collection in the table and a summary image of the midline shift. The color overlay gradient in the slice from the segmentation series output corresponds to the Hounsfield Unit (HU) of each corresponding pixel in the NCCT.

Images are automatically forwarded from the Healthcare Facility and sent to Viz.ai's Backend Server after acquisition at the CT scanner. Viz Subdural+ is hosted on Viz.ai's Backend Server and automatically analyzes applicable NCCT scans that are acquired on CT scanners and are forwarded to Viz.ai's Backend Server. The results of the analysis are exported in DICOM format and are sent to a DICOM destination (e.g., PACS) where they are available for review by radiologists, neurologists, neuro-surgeons, interventional neuroradiologists, or other appropriately trained professionals to



assist in the measurement of subdural collection volume, widest subdural collection width and midline shift.

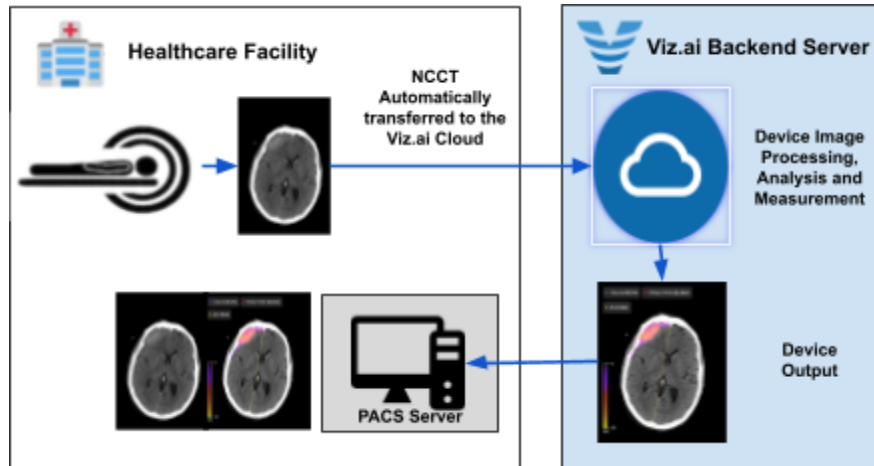


Figure 2. Data flow diagram for Viz Subdural+.

Intended Use and Indications for Use

The Viz Subdural+ (Subdural Plus) device is intended for automatic labeling, visualization and quantification of collections in the subdural space from a set of Non-Contrast Head CT (NCCT) images. The software is intended to automate the current manual process of identifying, labeling and quantifying the volume of collections in the subdural space identified on NCCT images. Viz Subdural+ provides volumes from NCCT images acquired at a single time point.

The Viz Subdural+ software is intended for labeling subdural collections and reporting the grayscale value of the collection, widest width of the subdural collection, and midline shift. The device output should be reviewed along with the patient's original images by a physician qualified to interpret brain CT images.

Summary of Technological Characteristics

The subject device, Viz Subdural+, is substantially equivalent to the predicate device, Viz HDS (K232363). In comparing the technological characteristics, both the subject and predicate devices use an artificial intelligence algorithm to identify, label and quantify measured quantities in NCCT imaging of the head from images acquired at a single time point. Both the subject and predicate devices use software algorithms that incorporate artificial-intelligence to perform as intended. Both devices' algorithms automatically receive, assess the applicability of received input imaging, and automatically process and measure supported imaging. Both devices' algorithms use similar pipelines with similar steps to measure their indicated structures and both devices' algorithms use deep-learning convolutional neural networks with similar architectures. Both devices provide their outputs in DICOM format and return the results to a pre-configured destination (e.g., a PACS server) for the user to view the device outputs.



While both devices provide an automated measurement of midline shift, the subject device's algorithm is different from the predicate device's algorithm and is designed and indicated for automatically labeling and quantifying subdural collections (subdural collection volume and widest width) whereas the predicate device's algorithm is indicated and designed for automatically labeling and measuring the volume of intracranial hyperdensities and lateral ventricles. Performance testing demonstrated that Viz Subdural+ has acceptable subdural collection volume and collection width measurement performance. Additionally, the Viz Subdural+ algorithm can measure midline shift within the same performance limits (MAE < 2mm) as the predicate device. Thus, any differences in the subject device's algorithm or the different structures measured by the Viz Subdural+ algorithm do not raise any new or different questions of safety and efficacy.

Both devices provide summary and segmentation series outputs. Both device outputs include overlays of the segmentation on the measured NCCT which forms the basis of the reported volume measurements. The subject device's overlay output differs from the predicate in that the subject device's overlay color intensity at each pixel corresponds to the HU values of the segmented pixels representing subdural collection in the original NCCT whereas the overlays of the predicate device are a single color used solely to differentiate between hyperdensities. This difference does not raise any new or different questions of safety and efficacy regarding the segmentation overlay as the information provided by the color intensity represents standardized HU information which the user can retrieve by looking at the original NCCT.

Substantial Equivalence Table		
	Predicate Device	Subject Device
	Viz HDS	Viz Subdural+
Application No.	K232363	K250354
Product Code	QIH	QIH
Regulation No.	21 C.F.R. § 892.2050	21 C.F.R. § 892.2050



Intended Use / Indications for Use	The Viz HDS device is intended for automatic labeling, visualization, and quantification of segmentable brain structures from a set of Non-Contrast CT (NCCT) head scans. The software is intended to automate the current manual process of identifying, labeling, and quantifying the volume of segmentable brain structures identified on NCCT images. Viz HDS provides volumes from NCCT scans acquired at a single time point. The Viz HDS software is indicated for use in the analysis of the following structures: Intracranial Hyperdensities, Lateral Ventricles and Midline Shift. The device output should be reviewed along with patient's original images by a physician.	The Viz Subdural+ (Subdural Plus) device is intended for automatic labeling, visualization and quantification of collections in the subdural space from a set of Non-Contrast Head CT (NCCT) images. The software is intended to automate the current manual process of identifying, labeling and quantifying the volume of collections in the subdural space identified on NCCT images. Viz Subdural+ provides volumes from NCCT images acquired at a single time point. The Viz Subdural+ software is intended for labeling subdural collections and reporting the grayscale value of the collection, widest width of the subdural collection, and midline shift. The device output should be reviewed along with the patient's original images by a physician qualified to interpret brain CT images.
Anatomical Region	Head	Head
Independent Standard of Care Workflow	Yes	Yes
Input images	Non-contrast CT from a single time point	Non-contrast CT from a single time point
Measured Structures / Conditions	Intracranial hyperdensities, lateral ventricles and midline shift	Subdural collections and midline shift
Measurands	Intracranial hyperdensities volume; lateral ventricles volume; midline shift	Subdural collections volume; Subdural collections widest width; midline shift
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	Non-contrast CT (NCCT)	Non-contrast CT (NCCT)
Alteration of Original Image	No	No
Artificial Intelligence Algorithm	Yes	Yes
Output	Multiple electronic reports with measurements quantifying brain structures and midline shift; annotated DICOM Images.	Multiple electronic reports with measurements quantifying subdural collections and midline shift; annotated DICOM Images.

Performance Data

A retrospective study was conducted to assess the standalone performance of the image analysis algorithm for Viz Subdural+ as compared to a ground truth established by trained neuroradiologists in segmenting, labeling and quantifying subdural collections, maximal subdural collection width (thickness) and midline shift. Subdural collection measurement performance (volume and thickness) and midline shift were assessed on datasets with 203 and 151 cases, respectively. Each dataset was obtained from two clinical sites. Imaging within each dataset were from patients that received an NCCT imaging assessment after presenting to one of the participating sites.

Metric	Mean Absolute Error (MAE)			DICE Score
	Mean (95% Confidence Interval)	Standard Deviation	Median (10th - 90th Percentile)	Mean (95% Confidence Interval)
Subdural Collection Volume (N=203)	7.53 (5.60, 9.45)	13.91	2.70 (0.0 - 22.22)	73% (68% - 77%)
Subdural Collection Maximum (Widest) Thickness (N=203)	1.77 (1.24, 2.30)	3.84	0.43 (0.0 - 5.37)	N/A
Midline Shift (N=151)	1.1 (0.94, 1.27)	1.03	0.8 (0.17 - 2.37)	N/A

The results of the retrospective study demonstrated the device passed the primary endpoints for the study in terms of mean absolute error (MAE).



Additional stratification of the device performance as measured by MAE was provided by different patient demographic, technical and radiographic findings to demonstrate generalizability of the device within the intended population. Device results for subdural collection volume, widest width and midline shift were also compared to the truther consensus by Bland-Altman plots and linear regression analysis.

Conclusions

Viz Subdural+ 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. Differences in the types of structures labeled and quantified by each device, and the information provided in the device's respective outputs do not raise any new or different questions of safety and efficacy. Viz.ai has provided supportive clinical data and software testing which demonstrates that the subject device can perform effective labeling, visualization and quantification of subdural collection volume, widest subdural collection width and midline shift. Thus, Viz Subdural+ is substantially equivalent to the predicate.