Viz.ai, Inc.
Pooja Shah
Regulatory Affairs Specialist
5000 Center Green Way
Cary, NC 27513

February 5, 2024

Re: K232363
Trade/Device Name: Viz HDS, Viz Volume Plus, Viz ICH+
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: January 10, 2024
Received: January 10, 2024

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 (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.

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,

Jessica Lamb
Assistant Director
Imaging Software Team
DHT8B: Division of Radiologic 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)*
K232363

Device Name

Viz HDS, Viz Volume Plus, Viz ICH+

Indications for Use *(Describe)*

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.

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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510(k) SUMMARY

Viz.ai, Inc.'s Viz HDS

Applicant Name: Viz.ai, Inc.

5000 Center Green Way,

Cary, NC 27513

Contact Person: Pooja Shah

Regulatory Affairs Specialist

5000 Center Green Way,

Cary, NC 27513

Tel. (669)288-4344

pooja.shah@viz.ai

Date Prepared: January 30, 2024

Device Name and Classification:

Name of Device: Viz HDS, Viz Volume Plus, Viz ICH+

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 Devices

Manufacturer	Device Name	Application No.
Qure.ai technologies	qER-Quant	K211222

Device Description

Viz HDS is a software-only device that uses a locked artificial intelligence machine learning (AI/ML) algorithm to processes non-contrast head CT scans to outline intracranial hyperdensity areas, lateral ventricles (right and left), midline shift, and then quantify the volume of intracranial hyperdensity(ies), volume of lateral ventricles, lateral ventricle asymmetry ratio and distance of midline shift.

Viz HDS analyzes the head NCCT series in DICOM format and produces a summary series and a segmentation series in DICOM format. The summary series is a two-slice output: a single slice from the NCCT series with segmented areas overlaid on it, and a summary table providing the calculated measurements. The segmentation series shows an RGB overlay, on each slice of the input series, of the lateral ventricles and hyperdensity(ies) segmentation masks and a midline shift. For slices including hyperdensity/hyperdensities or ventricle/ventricles, its volume would be mentioned in a color legend that is also overlaid on the slice. The colors are only for visual differentiation between the segmented regions, the colors don't have a meaning on their own. The device output is exported in DICOM format, which is sent to a pre-configured PACS destination together with the original NCCT series for review by a physician to aid in the assessment of measuring intracranial hyperdensity(ies), lateral ventricles, and midline shift.

Workflow:

Viz HDS is hosted in Viz.ai's cloud server. For customers that have Viz HDS enabled, when they send NCCT head scans to the server, the scans are directed to the HDS processor for analysis. At the end of the processing the results series are created and sent back to the customer's site to a DICOM node (e.g. PACS) defined for that customer.

Workflow Diagram:

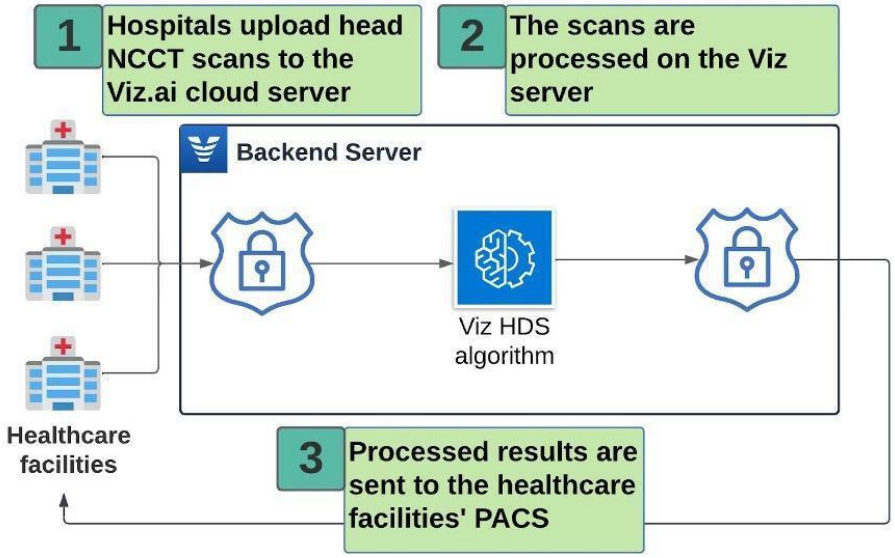

Figure 1. Workflow diagram of Viz HDS

Segmentation and Summary Series:

Following are two examples for the output series generated by the Viz HDS device. Figure 1 shows a sample image from the Segmentation series and next to it the original slice from the head NCCT series (without the overlay and legend). Figure 2 shows an example of the summary slice and next to it the summary table image that is part of the summary series.

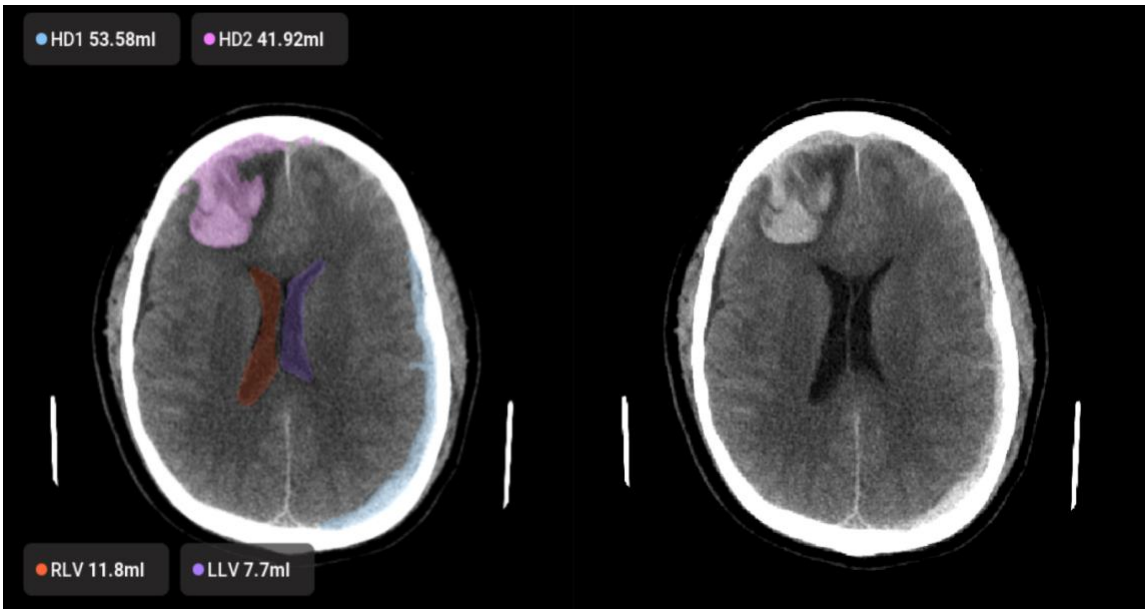

Figure 2. Left image: A sample image from the Segmentation series showing overlays of the identified hyperdensities and lateral ventricles segmentation provided by the Viz HDS device, legend contains the HDS volume measurements, sorted from high to low volume, and the lateral ventricles volume measurements. Right image: the corresponding image from the original head NCCT series.

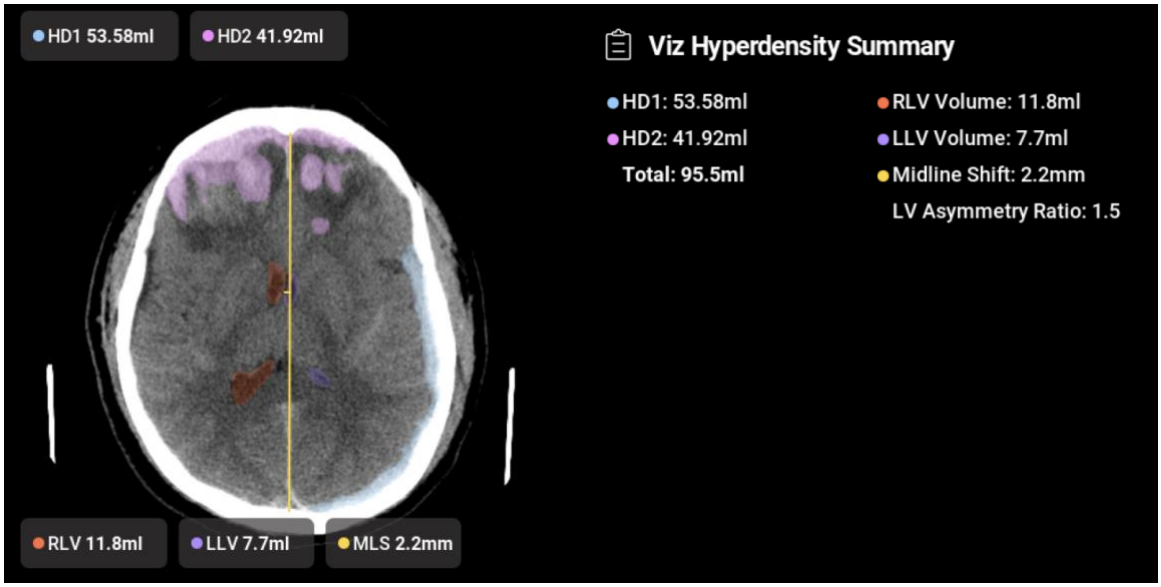

Figure 3. Left image: An example of a single slice summary image showing as overlays the identified hyperdensity, lateral ventricles and midline shift segmentation provided by the Viz HDS device. The legend contains the hyperdensities volume measurements (mL), sorted from high to low volume, the right and left lateral ventricles volume measurements (mL) and the midline shift value (mm). Right image: An example of the summary table image in the Summary series generated by the Viz HDS device. The table shows all of the

identified hyperdensities, the right and left lateral ventricles, their asymmetry ratio and midline shift that was measured by the algorithm in the original NCCT series.

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.

Summary of Technological Characteristics

The subject device, Viz HDS, is substantially equivalent to the predicate device, qER-Quant (K211222). In comparing the technological characteristics, both the subject and predicate devices use an artificial intelligence algorithm to identify, label and quantify clinical findings in NCCT imaging. Where the subject and predicate device differ is that the software algorithm for the subject device provides volumes from NCCT scans acquired at single time point whereas, predicate device provides volumes from NCCT images acquired at a single time point and provides comparative analysis for two or more images that were acquired on the same scanner with the same acquisition protocol for the same individual at multiple time points.

Both the subject device and the predicate device provide findings through back to PACS to hospital's server that allow user to preview images and patients identified, labeled and quantified with segmentable brain structure to automate the manual process of measurement. Both the devices have DICOM annotated series image and summary report as an output. Where the subject and predicate device differ is that the subject device have RGB overlay as the output for abnormal hyperdensities whereas the predicate device represent hyperdensities is a singular color. This difference does not raise any safety or efficacy question as the colors are only for visual differentiation between the segmented regions, the colors don't have a meaning on their own.

Both the subject and predicate device use a deep-learning algorithm that analyzes NCCT images for identifying, labeling and quantifying volume of segmentable brain structures. Both the devices are intended to be used as aid to physicians for identifying, labeling and quantifying segmentable brain structures on NCCT images. Because of the similarities regarding the type of algorithms, the type of imaging data processed by the devices, the intended use of the devices, and the outputs of the image analysis, the difference in the output visual does not raise new or different questions regarding safety or efficacy.

	Predicate Device	Subject Device
	qER-Quant	Viz HDS
Application No.	K211222	K232363
Product Code	QIH	QIH
Regulation No.	21 C.F.R. § 892.2050	21 C.F.R. § 892.2050
Intended Use / Indications for Use	The qER-Quant device is intended for automatic labeling, visualization and quantification of segmentable brain structures 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 segmentable brain structures identified on NCCT images. qER-Quant provides volumes from NCCT images acquired at a single time point and provides a table with comparative analysis for two or more images that were acquired on the same scanner with the same image acquisition protocol for the same individual at multiple time points. The qER-Quant software is indicated for use in the analysis of the following structures: Abnormal Intracranial Hyperdensities, Lateral Ventricles and Midline Shift.	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.
Anatomical Region	Head	Head
Independent Standard of Care Workflow	Yes	Yes

Input images	Non-contrast CT from a single or multiple time points	Non-contrast CT from a single time point
Clinical Condition	Intracranial hyperdensities, lateral ventricles and midline shift	Intracranial hyperdensities, lateral ventricles and 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 volumetric information of brain structures and midline shift AND Annotated DICOM Images	Multiple electronic reports with volumetric information of brain structures and midline shift AND Annotated DICOM Images

Performance Data

Clinical testing was performed as a study comparing the Viz HDS's output to the ground truth as established by trained radiologists. The study demonstrated that the MAE (Mean absolute error) for hyperdensities total volume, right lateral ventricle volume, left lateral ventricle volume, and midline shift distance upper 95% CI bounds were less than 7.5 mL, 3 mL, 3 mL, and 2 mm, respectively between the algorithm and the established ground truth, which was aligned with the performance goal.

Additionally, DICE score was calculated to describe the degree of agreement between the measurements by the Viz HDS algorithm in comparison to the measurements that were obtained manually. The study demonstrated that the DICE score for hyperdenity(ies) and both lateral ventricles lower CI bound was greater than 70%, which was aligned with the performance goal.

Stratification of device performance was divided by clinical site, gender, age, slice thickness, scanner manufacturer,model, scanning parameters and size of estimated quantity.

Conclusions

Viz HDS 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 provides a report acquired at a single time point whereas, predicate device provides a report acquired at a single time point and provides comparative analysis. Both subject and predicate provide findings through back to PACS destination of hospital. 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 labeling, visualization and quantification of intracranial hyperdensities, lateral ventricles and midline shift. Thus, Viz HDS is substantially equivalent to the predicate.