



Qure.ai Technologies  
Rajesh Sukhija  
Regulatory Affairs Associate  
6th Floor, Wing E, Times Square, Andheri- Kurla Road, Marol,  
Andheri  
Mumbai, Maharashtra 400059  
India

September 8, 2025

Re: K251610  
Trade/Device Name: qER-CTA (v1.0)  
Regulation Number: 21 CFR 892.2080  
Regulation Name: Radiological Computer Aided Triage And Notification Software  
Regulatory Class: Class II  
Product Code: QAS  
Dated: July 31, 2025  
Received: August 1, 2025

Dear Rajesh Sukhija:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



Jessica Lamb, Ph D  
Assistant Director  
Imaging Software Team  
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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K251610

?

Please provide the device trade name(s).

?

qER-CTA (v1.0)

Please provide your Indications for Use below.

?

qER-CTA 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 the standard of care workflow. qER-CTA uses a deep learning algorithm to analyze images for findings suggestive of a pre-specified clinical condition and to notify an appropriate medical specialist in parallel to standard of care image interpretation. Identification of suspected findings is not for diagnostic use beyond notification. Specifically, the device analyses 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, recommending review of those images. Images can be previewed through a mobile application. qER-CTA is intended to analyze the internal carotid artery (ICA) and M1 segment of the middle cerebral artery (MCA) for LVOs on CTA scans of adults ( $\geq 22$  years of age). Images previewed through the mobile application are compressed and for informational purposes only, not intended for diagnostic use beyond notification. Notified clinicians are responsible for viewing non-compressed images on a diagnostic viewer, conducting appropriate patient evaluation, and engaging in relevant discussions with the treating physician before making care-related decisions or requests. qER-CTA is limited to the analysis of imaging data and should not be used as a substitute for full patient evaluation or relied upon to make or confirm a diagnosis.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)  
☐ Over-The-Counter Use (21 CFR 801 Subpart C)

?

**510(k) SUMMARY****qER-CTA****1 SUBMITTER**

Qure.ai Technologies Pvt. Ltd.  
6th Floor, Wing E, Times Square,  
Andheri-Kurla Road, Marol, Andheri (East),  
Mumbai - 400059, Maharashtra  
Phone: +91-7015256339  
**Primary Contact Person:** Rajesh, Regulatory Affairs Associate  
**Secondary Contact Person:** Bunty Kundnani, Chief Regulatory Affairs Officer

**Date Prepared:**

**2 SUBJECT DEVICE**

|                             |                                                                 |
|-----------------------------|-----------------------------------------------------------------|
| <b>Name of Device:</b>      | qER-CTA (v1.0)                                                  |
| <b>Classification Name:</b> | Radiological computer-assisted triage and notification software |
| <b>Regulatory Class:</b>    | Class II                                                        |
| <b>Regulation Number:</b>   | 21 CFR 892.2080                                                 |
| <b>Product Code:</b>        | QAS                                                             |

**3 PREDICATE DEVICES**

|                           |                 |
|---------------------------|-----------------|
| <b>Name of Device:</b>    | Viz LVO         |
| <b>Manufacturer:</b>      | Viz.ai, Inc.    |
| <b>510(k) Number:</b>     | K223042         |
| <b>Regulatory Class:</b>  | Class II        |
| <b>Regulation Number:</b> | 21 CFR 892.2080 |
| <b>Product Code</b>       | QAS             |

**4 INTENDED USE / INDICATIONS FOR USE:**

qER-CTA 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 the standard of care workflow. qER-CTA uses a deep learning algorithm to analyze images for findings suggestive of a pre-specified clinical condition and to notify an appropriate medical specialist in parallel to standard of care image interpretation. Identification of suspected findings is not for diagnostic use beyond notification. Specifically, the device analyses 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, recommending review of those images. Images can be previewed through a mobile application. qER-CTA is intended to analyze the internal carotid artery (ICA) and M1 segment of the middle cerebral artery (MCA) for LVOs on CTA scans of adults ( $\geq 22$  years of age). Images previewed through the mobile application are compressed and for informational purposes only, not intended for diagnostic use beyond notification. Notified clinicians are responsible for viewing non-compressed images on a diagnostic viewer, conducting appropriate patient evaluation, and engaging in relevant

discussions with the treating physician before making care-related decisions or requests. qER-CTA is limited to the analysis of imaging data and should not be used as a substitute for full patient evaluation or relied upon to make or confirm a diagnosis.

## **5 DEVICE DESCRIPTION**

qER-CTA is a radiological computer-aided triage and notification (CADt) software designed to assist trained clinicians and radiologists in analyzing and triaging head CTA scans for suspected LVO (Large Vessel Occlusion) in the anterior circulation.

The software uses a deep learning algorithm to analyze CTA images and provide a case-level output available in the PACS or workstation for worklist prioritization or triage. It does not alter the original image, change the worklist order, or send proactive alerts directly to the end user. Instead, the end user can sort the worklist based on the passive notification flag. Images can be previewed through a mobile application also. There are two alternatives' users can choose from engaging with qER-CTA.

1. For de-identified CTA scans, they are sent to qER-CTA via transmission functions built within the user's PACS or workstation. Results are pushed back to the user's PACS or other user-specified radiology software database once the processing is complete.
2. For the client system that does not have de-identification and re-identification capabilities, qER-CTA interacts with on-premises gateway rather than directly with the PACS.

qER-CTA is not intended to direct attention to specific portions of the image, rule out target conditions, or be used as a standalone tool for clinical decision-making. It operates as a parallel workflow tool, independent of the standard of care, to assist in identifying and communicating suspected LVO cases to appropriate medical specialists for further review. Images previewed through the mobile application are compressed and are for informational purposes only.

## 6 COMPARISON WITH PREDICATE DEVICE

**Table 1 Comparison between qER-CTA and the Predicate Device**

|                                    | Primary Predicate Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Subject Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Device Name                        | Viz LVO                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | qER-CTA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 510(k) Number                      | K223042                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | K251610                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Device Class                       | Class II                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Class II                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Device Classification Name         | Radiological computer aided triage and notification software                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Radiological computer aided triage and notification software                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Regulation Number                  | 21 CFR 892.2080                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 21 CFR 892.2080                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Product Code                       | QAS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | QAS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Manufacturer                       | Viz.ai, Inc.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Qure.ai Technologies Pvt. Ltd.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Intended use / Indications for Use | Viz LVO is a notification-only, parallel workflow tool designed for use by hospital networks and trained clinicians to identify and communicate images of specific patients to a specialist, independent of the 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. The identification of suspected findings is intended solely for notification purposes and not for diagnostic use beyond this notification. Specifically, the device analyzes CT angiogram images of the brain acquired in acute settings and sends notifications to a neurovascular specialist when a suspected large vessel occlusion (LVO) has been identified. It also recommends a review of those images. Images can be previewed through a mobile application. Viz LVO is intended to analyze the terminal ICA and MCA-M1 vessels for LVOs. Images previewed through the mobile application are | qER-CTA 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 the standard of care workflow. qER-CTA uses a deep learning algorithm to analyse images for findings suggestive of a pre-specified clinical condition and to notify an appropriate medical specialist in parallel to standard of care image interpretation. Identification of suspected findings is not for diagnostic use beyond notification. Specifically, the device analyses 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, recommending review of those images. Images can be previewed through a mobile application. qER-CTA is intended to analyse the internal carotid artery (ICA) and M1 segment of the middle cerebral artery (MCA) for LVOs on CTA scans of adults ( $\geq 22$ years of age). Images previewed through the mobile application are compressed and for informational |

|                                                         | Primary Predicate Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Subject Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|---------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Device Name                                             | Viz LVO                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | qER-CTA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|                                                         | compressed and are for informational purposes only. They are 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 discussions with the treating physician before making care-related decisions or requests. Viz LVO is limited to the analysis of imaging data and should not be used in lieu of a full patient evaluation or relied upon to make or confirm a diagnosis. | purposes only, not intended for diagnostic use beyond notification. Notified clinicians are responsible for viewing non-compressed images on a diagnostic viewer, conducting appropriate patient evaluation, and engaging in relevant discussions with the treating physician before making care-related decisions or requests. qER-CTA is limited to the analysis of imaging data and should not be used as a substitute for full patient evaluation or relied upon to make or confirm a diagnosis. |
| Intended User                                           | Neurovascular specialists, such as vascular neurologists, neuro-interventional specialists, or users with similar training who have been pre-authorized by their Healthcare Organization or Facility.                                                                                                                                                                                                                                                                                                                              | Neurologists, neuroradiologists, radiologists, neuro-interventional specialist, and/or other emergency department physicians.                                                                                                                                                                                                                                                                                                                                                                        |
| Modality                                                | Head Computed Tomography Angiography (CTA)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Head Computed Tomography Angiography (CTA)                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Target clinical conditions                              | Large Vessel Occlusion                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Large Vessel Occlusion                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Algorithm for pre-specified critical findings detection | Image processing algorithms for large vessel occlusion                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Image processing algorithms for large vessel occlusion                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Input format                                            | DICOM                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | DICOM                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Performance level – accuracy of classification          | <p>Sensitivity: 87.8% (95% CI: 81.2% - 92.5%)</p> <p>Specificity: 89.6% ( 95% CI: 83.7% - 93.9%)</p> <p>AUC: 0.91</p>                                                                                                                                                                                                                                                                                                                                                                                                              | <p>Sensitivity: 91.35% (95% CI: 87.54%-94.07%)</p> <p>Specificity: 91.86% (95% CI: 88.18% -94.47%)</p> <p>AUC: 0.959</p>                                                                                                                                                                                                                                                                                                                                                                             |

|                           | Primary Predicate Device | Subject Device      |
|---------------------------|--------------------------|---------------------|
| Device Name               | Viz LVO                  | qER-CTA             |
| Mean Time to Notification | 7.32 [5.51, 9.13]        | 6.36 [ 6.06, 6.66 ] |

## 7 TESTING

### Software:

Software verification and validation testing was executed, and documentation was provided as recommended by FDA's Guidance for the Content of Premarket Submission for Device Software Functions (June 2023). During all verification and validation tests carried out for the qER-CTA software, which included evaluating both the algorithmic functionality and the overall performance of the software and its components, qER-CTA functioned as designed and successfully met the anticipated performance criteria.

Verification, validation, and testing activities were conducted to establish the performance, functionality, and reliability characteristics of the device. Unit Test, Integration Test, Regression Test and User Acceptance test were carried out to account towards the device's performance non-clinically. Functional testing is done to assess functional requirements of the product. The device passed all the tests based on determined acceptance criteria. Standards Regulatory references Used are ISO 13485: 2016 and IEC 62304:2006+A1:2015.

### Clinical Performance Testing:

Performance of the qER-CTA device in classification of large vessel occlusion was assessed using the standalone study. The target sample size for the study, including confounders was 584 head CTA scans (LVO = 289; non-LVO = 295), Three U.S. board certified neuroradiologists with at least 10 years of experience did the ground truthing. The device showed good performance and met the predefined success criteria when evaluated against the ground truth (reference standard). The study results also indicated that the outputs of the device are accurate and uniform across a wide range of potential sources of measurement error.

**Table 2 Standalone Performance Testing Results for qER-CTA**

| Abnormality            | AUC (95% CI)          | Sensitivity (95% CI), TP/P | Specificity (95% CI), TN/N |
|------------------------|-----------------------|----------------------------|----------------------------|
| Large Vessel Occlusion | 0.959 (0.943 – 0.975) | 91.35% (87.54%-94.07%)     | 91.86% (88.18% - 94.47%)   |

### Time to Notification

| qER-CTA<br>(N = 584) | Time to Notification of Specialist for LVO cases (mins) |
|----------------------|---------------------------------------------------------|
| Mean                 | 6.36 (6.06-6.66)                                        |
| SD                   | 3.68                                                    |
| Median               | 6.89                                                    |

## 8 CONCLUSION

The comparison in **Table 1** as well as the software & performance testing presented above demonstrate that the qER-CTA device is substantially equivalent to the predicate device. Both the subject and predicate device are medical image analyzers intended to read head CTA scans to classify user identified large vessel occlusion. The algorithms function similarly and with the same purpose of classification of large vessel occlusion. The new device does not introduce fundamentally new scientific technology, and the clinical tests demonstrate that the device is safe and effective.

The qER-CTA is a software only device with similar indications, technological characteristics, and principles of operation as the predicate devices. The comparison of intended purpose, technological characteristics and performance demonstrates that the qER-CTA device performs as intended and can be considered as substantially equivalent to the predicate device, Viz LVO (K223042).