



June 18, 2026

GuideAI
% J. David Giese
Partner
Innolitics, LLC
1101 W. 34th St. #550
Austin, TX 78705

Re: K260729
Trade/Device Name: Vascular Assist Occlusion Triage (VAOT)
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological Computer Aided Triage And Notification Software
Regulatory Class: Class II
Product Code: QAS
Dated: May 22, 2026
Received: May 22, 2026

Dear J. David Giese :

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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. Behind the signature, there is a faint, light blue watermark of the letters "FDA".

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.

K260729

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Please provide the device trade name(s).

?

Vascular Assist Occlusion Triage (VAOT) (v1.0)

Please provide your Indications for Use below.

?

VAOT is radiological computer-aided triage and notification software indicated for use in the analysis of CTA studies of adult patients. The device is intended to assist hospital networks and trained medical specialists in workflow prioritization by identifying studies with imaging patterns consistent with possible total arterial occlusion within the aorta, common iliac, external iliac, common femoral, superficial femoral, and popliteal arteries.

VAOT analyzes CTA images in parallel with the on-going standard-of-care interpretation workflow. When predefined criteria are met, VAOT generates a notification to alert the user that the case may warrant prioritization.

Notifications may include compressed preview images provided for informational purposes only and are not intended for diagnostic use.

The results of VAOT are not intended for primary diagnosis, screening, disease detection, or patient management decisions. The interpreting clinician remains responsible for viewing the full imaging study according to standard clinical practice.

VAOT does not detect, localize, characterize, measure, or diagnose vascular disease and does not alter the original medical images.

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

Prescription Use ([21 CFR 801 Subpart D](#))

Over-The-Counter Use ([21 CFR 801 Subpart C](#))

?

Please select the age group(s) for which the device(s) is to be used.

Neonates/Newborns (Birth to < 29 days old)

Infants (29 days old to < 2 years old)

Children (2 years old to < 12 years old)

Adolescents (12 years old to < 22 years old)

Adults (22 years old and greater)

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510(k) Summary

1. ADMINISTRATIVE INFORMATION

Parameter	Value
Company Name	GuideAI Health, Inc.
Address	GuideAI Health, Inc. 45 Temple Street Unit 106 Boston, MA 02114
Phone Number	(857) 276-8823
Fax Number	N/A
Company Representative	Raj Shah MD, MBA, CEO
Email	rajshah@guideaihealth.com
Primary Correspondent	J. David Giese, Partner
Primary Correspondent Email	jdgiese@innolitics.com
Date Summary Prepared	February 24, 2026

2. SUBJECT DEVICE INFORMATION

Parameter	Value
Trade Name	Vascular Assist Occlusion Triage (VAOT) v1.0
Common Name	Radiological computer aided triage and notification software
Product Code	QAS
Regulation Number	21 CFR §892.2080
Class	Class II
Panel	Radiology

3. PREDICATE DEVICE INFORMATION

Parameter	Value
Predicate Device Name	Briefcase LVO Triage
Predicate Device K Number	K220709
Product Code	QAS
Regulation Number	21 CFR §892.2080
Class	Class II
Panel	Radiology

4. DEVICE DESCRIPTION

VAOT is radiological computer-assisted triage and notification software indicated for use in the analysis of CTA studies of adult patients. The software uses machine-learning techniques to automatically analyze CTA studies and to alert the PACS/RIS workstation once images with features suggestive of arterial occlusion are identified.

Using VAOT, a radiologist is able to review studies with features suggestive of arterial occlusion earlier than in the standard of care workflow.

CTA studies are captured by a CT imaging system and deposited on the PACS. The Gateway instance, a component of VAOT that runs acting as a PACS listener, receives a copy of the CTA DICOM study, checks the DICOM meta data to confirm it can be processed, de-identifies it, and securely transmits it to the VAOT cloud for processing.

The VAOT cloud receives the DICOM image(s) and determines whether a possible occlusion should be flagged using an image-processing pipeline consisting of several deep neural networks. If one or more possible occlusions are flagged, then an axial slice from the original study is selected as a “preview image” for the radiologist, and is sent back to the Gateway instance.

The Gateway instance re-associates the preview image with the patient, embeds it into a DICOM Secondary Capture, and routes it to the DICOM Destination (e.g., the PACS).

The PACS receives the DICOM Secondary Capture containing the preview image and associates it with the original study. The PACS can then use the Secondary Capture to notify radiologists of the suspected occlusion.

In summary, the VAOT device is intended to enable a passive notification through the PACS to the radiologist indicating the existence of a case that may potentially benefit from that radiologist's prioritization. The device aims to aid in prioritization and triage of radiological medical images only.

5. INTENDED USE / INDICATIONS FOR USE

VAOT is radiological computer-aided triage and notification software indicated for use in the analysis of CTA studies of adult patients. The device is intended to assist hospital networks and trained medical specialists in workflow prioritization by identifying studies with imaging patterns consistent with possible total arterial occlusion within the aorta, common iliac, external iliac, common femoral, superficial femoral, and popliteal arteries.

VAOT analyzes CTA images in parallel with the on-going standard-of-care interpretation workflow. When predefined criteria are met, VAOT generates a notification to alert the user that the case may warrant prioritization.

Notifications may include compressed preview images provided for informational purposes only and are not intended for diagnostic use.

The results of VAOT are not intended for primary diagnosis, screening, disease detection, or patient management decisions. The interpreting clinician remains responsible for viewing the full imaging study according to standard clinical practice.

VAOT does not detect, localize, characterize, measure, or diagnose vascular disease and does not alter the original medical images.

6. CONTRAINDICATIONS FOR USE

The VAOT device was not tested on pediatric patients.

7. SUBSTANTIAL EQUIVALENCE DISCUSSION

The subject device, VascularAssist Occlusion Triage (VAOT), and the predicate device, Aidoc BriefCase LVO Triage (K220709), share the same intended use as radiological computer-aided triage and notification software under 21 CFR §892.2080 (product code QAS). Both are Class II, notification-only tools that analyze CTA studies in adult patients using deep-learning algorithms and generate alerts to assist hospital networks and trained clinicians with workflow prioritization. Both devices operate entirely in parallel with the standard-of-care interpretation workflow: neither removes cases from the reading queue, alters original DICOM images, directs attention to specific locations in the diagnostic images, nor provides primary diagnostic output. Notifications, which may include compressed preview images for informational purposes only, are explicitly not intended for diagnostic use. The difference between the two devices lies

in the vascular territory evaluated—intracranial vessels for the predicate versus lower-extremity arteries (aorta through popliteal) for the subject device—which represents a difference in indications for use within the same clinical purpose of rapid identification and prioritization of suspected acute vascular occlusion, rather than a new intended use.

The subject and predicate devices share nearly identical technological characteristics. Both are software packages that:

- Utilize artificial intelligence and deep learning algorithms to analyze DICOM CTA images.
- Receive images from DICOM-compliant imaging devices (CT scanners) or PACS.
- Process images automatically to detect specific findings.
- Notify clinicians of suspected findings to facilitate triage.
- Provide compressed preview images for informational purposes only, which are not intended for diagnostic use.
- Do not alter the original medical images or remove cases from the standard worklist.

The devices differ in the anatomical region and specific pathology targeted:

- The **Predicate Device** is indicated for the analysis of Head CTA images to detect Large Vessel Occlusions (LVO) and Medium Vessel Occlusions (MeVO) associated with stroke.
- The **Subject Device** is indicated for the analysis of CTA images of the lower extremities to detect total arterial occlusions in the aorta, common iliac, external iliac, common femoral, superficial femoral, and popliteal arteries.

The primary difference between the subject and predicate devices is the anatomical location of the suspected findings (Lower Extremities vs. Head). This difference requires the subject device's AI algorithms to be trained on a different dataset specific to lower extremity vasculature. However, this difference does not raise new questions of safety and effectiveness.

Both devices serve the same triage function within their respective clinical contexts. The risks—false positives (unnecessary prioritization) or false negatives (standard of care review applies)—remain similar. Neither device replaces the radiologist's interpretation, and both rely on the clinician to view the full original study for diagnosis. Standalone performance testing, along with verification and validation, demonstrates that the subject device performs as intended for its specific anatomical region.

A table comparing the key features of the subject and the primary predicate devices is provided below.

Parameter	VAOT Subject Device	Briefcase LVO Triage (K220709) Predicate Device	Discussion
Product Code	QAS	QAS	Same

Parameter	VAOT Subject Device	Briefcase LVO Triage (K220709) Predicate Device	Discussion
Regulation	21 CFR §892.2080	21 CFR §892.2080	Same
Intended Use	Radiological computer aided triage and notification	Radiological computer aided triage and notification	Same
Indications for Use	<p>VAOT is radiological computer-aided triage and notification software indicated for use in the analysis of CTA studies of adult patients. The device is intended to assist hospital networks and trained medical specialists in workflow prioritization by identifying studies with imaging patterns consistent with possible total arterial occlusion within the aorta, common iliac, external iliac, common femoral, superficial femoral, and popliteal arteries.</p> <p>VAOT analyzes CTA images in parallel with the on-going standard-of-care interpretation workflow. When predefined criteria are met, VAOT generates a notification to alert the user that the case may warrant prioritization. Notifications may include compressed preview images provided for informational purposes only and are not intended for diagnostic use.</p> <p>The results of VAOT are not intended for primary diagnosis, screening, disease detect, or patient management decisions. The interpreting</p>	<p>BriefCase is a radiological computer aided triage and notification software indicated for use in the analysis of head CTA images in adults or transitional adolescents aged 18 and older. The device is intended to assist hospital networks and appropriately trained medical specialists in workflow triage by flagging and communication of suspected positive findings of complete Large Vessel Occlusion (LVO) - MCA-M1, PCA-P1, ACA-A1, ICA, Basilar; and Medium Vessel Occlusions (MeVO) - MCA-M2, MCA-proximal M3, PCA-P2, PCA-proximal P3, ACA-A2, ACA-proximal A3, and Vertebral-V4.</p> <p>BriefCase uses an artificial intelligence algorithm to analyze images and highlight cases with detected findings on a standalone desktop application in parallel to the ongoing standard of care image interpretation. The user is presented with notification for cases with suspected findings. Notifications include compressed preview images that are meant for informational purposes only and not intended for diagnostic use beyond notification. The device does not alter the original medical image and is not intended to be used as a diagnostic device.</p>	<p>Both devices are radiological computer-aided triage and notification software that analyze CTA images in parallel with the standard-of-care interpretation workflow and provide notification with compressed preview images intended for informational use only. Each device is intended to assist appropriately trained clinical users with workflow prioritization by flagging studies with imaging patterns consistent with suspected vascular occlusion in its indicated anatomy.</p>

Parameter	VAOT Subject Device	Briefcase LVO Triage (K220709) Predicate Device	Discussion
	<p>clinician remains responsible for viewing the full imaging study according to standard clinical practice.</p> <p>VAOT does not detect, localize, characterize, measure, or diagnose vascular disease and does not alter the original medical images.</p>	<p>The results of BriefCase are intended to be used in conjunction with other patient information and based on their professional judgment, to assist with triage/prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care.</p>	
User Population	Hospital networks and appropriately trained medical specialists	Hospital networks and appropriately trained medical specialists	Same
Anatomical Site	Lower Extremities	Head	The devices are indicated for different anatomical sites.
Disease/Condition	Suspected Peripheral Arterial Occlusion	Suspected Stroke/LVO	Both devices attempt to identify occlusions to the large vessels in their indicated anatomical sites.
Input Data	CTA	CTA	Same
Data Acquisition	Acquires medical image data from DICOM-compliant imaging devices and modalities	Acquires medical image data from DICOM-compliant imaging devices and modalities	Same
Preview Images	Preview images provided for informational purposes only and not intended for diagnostic use beyond notification.	Preview images provided for informational purposes only and not intended for diagnostic use beyond notification.	Same
Algorithm	Artificial intelligence algorithm with database of images	Artificial intelligence algorithm with database of images	Same
Patient Population	Adult	Adult	Same

Parameter	VAOT Subject Device	Briefcase LVO Triage (K220709) Predicate Device	Discussion
Images format	DICOM	DICOM	Same
Notification only, parallel workflow tool	Yes	Yes	Same
Notification delivery	Using DICOM Secondary Captures	Using a Standalone Desktop Application	Both devices provide notifications to support workflow prioritization; however, the mechanisms differ (DICOM secondary captures versus a standalone desktop application). Despite different delivery approaches, both present compressed preview images for informational purposes to facilitate timely user awareness.
Interference with standard workflow	No. No cases are removed from Worklist or deprioritized.	No. No cases are removed from Worklist or deprioritized	Same

8. PERFORMANCE TESTING

8.1. Pivotal Study Summary

GuideAI conducted a retrospective, blinded, multicenter study with the VAOT software to evaluate the software’s performance in identifying peripheral arterial occlusions in 317 cases from US-based clinical sites. The study compared the software’s performance to the ground truth, as determined by 3 expert US board certified Radiologists, using majority voting. The cases collected for the pivotal dataset were all distinct from the cases used to train the algorithm.

The study included 317 cases (165 positive for occlusion, 152 negative). The dataset included cases from multiple scanner manufacturers and covered a broad range of patient ages. The gender distribution was 180 Male and 137 Female. The study sample was enriched for cases with aortic occlusions.

8.2. Primary Endpoint

VAOT met the primary endpoints of sensitivity and specificity with an 80% performance goal. Sensitivity was 0.915 (95% CI: 0.862, 0.953) and specificity was 0.901 (95% CI: 0.842, 0.944).

8.3. Secondary Endpoint

VAOT met the secondary endpoint of time-to-notification less than 5 minutes.

The time-to-notification includes the time to get the DICOM exam, de-identify it, upload it to the cloud, analyze and send a notification on a positive suspect case back to the desktop application.

8.4. Clinical Subgroups and Confounders

Frequency Distribution of Manufacturer:

Manufacturer	N	%
GE MEDICAL SYSTEMS	192	60.6%
SIEMENS	73	23.0%
Philips	14	4.4%
Canon/Toshiba	37	11.7%
Other	1	0.3%
Total	317	100.0%

Clinical Subgroups And Confounders:

- Pathologies present in negative cases: Non-occlusive arterial disease (mimics); Post-operative and device confounders; Out-of-scope vessels/locations; Other vascular pathologies; Acquisition/technical quality issues.
- Vessel Occlusions: Aorta, Common Iliac, External Iliac, Common Femoral, Superficial Femoral, and Popliteal. The set was enriched with 21 positive vessel aortic occlusions cases.

8.5. Software Validation

Software verification and validation testing were conducted, and documentation was provided as recommended by 2023 FDA Guidance “Content of Premarket Submissions for Device Software Functions”.

The software verification and validation testing verified that the design requirements were successfully met. The Intended use and user needs were successfully validated.

8.6. Cybersecurity

GuideAI conducted a cybersecurity risk assessment and testing in accordance 2025 FDA Guidance “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions”.

9. CONCLUSIONS

VAOT shares the same intended use, technological characteristics, and principles of operation as the predicate device. The differences in anatomical indication are addressed through standalone performance testing. We believe the introduction of VAOT into the U.S. market should not raise any safety or efficacy concerns. The device demonstrates substantial equivalence to the predicate device.