



May 14, 2026

Aidoc Medical , Ltd.
Amalia Schreier
Chief Regulatory and Legal Officer
34 Hamasger St.
Tel Aviv, 6721119
Israel

Re: K261317

Trade/Device Name: BriefCase-Triage
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological Computer Aided Triage And Notification Software
Regulatory Class: Class II
Product Code: QAS
Dated: April 21, 2026
Received: April 21, 2026

Dear Amalia Schreier:

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. In the background, there is a large, light blue, semi-transparent watermark of the letters "FDA".

Jessica Lamb, Ph.D.

Assistant Director

DHT8B: Division of Radiological Imaging

Devices and Electronic Products

OHT8: Office of Radiological Health

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

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

K261317

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Please provide the device trade name(s).

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BriefCase-Triage

Please provide your Indications for Use below.

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BriefCase-Triage 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. BriefCase-Triage uses an artificial intelligence algorithm to analyze images and highlight cases with detected findings in parallel to the ongoing standard of care image interpretation. The user is presented with notifications 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. The results of BriefCase-Triage 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.

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](#))

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510(k) Summary**Aidoc Medical, Ltd.'s Briefcase-Triage****Submitter:**

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34 Hamasger St.
Tel-Aviv, Israel

Phone: +972-73-7946870

Contact Person: Amalia Schreier, LL.M

Date Prepared: April 21, 2026

Name of Device: Briefcase-Triage

Classification Name: Radiological computer-assisted triage and notification software device

Regulatory Class: Class II

Product Code: QAS

Primary Predicate Device: Briefcase for VO (K220709)

Reference Device: BriefCase-Triage CARE Multi-Triage CT for Pneumothorax; Pericardial effusion; Large aortic aneurysm; Shoulder fracture or dislocation (K253578)

Device Description

Briefcase-Triage is a radiological computer-assisted triage and notification software device.

The software is based on an algorithm programmed component and is intended to run on a linux-based server in a cloud environment.

The Briefcase-Triage receives filtered DICOM Images, and processes them chronologically by running the algorithms on each series to detect suspected cases. Following the AI processing, the output of the algorithm analysis is transferred to an image review software (desktop application). When a suspected case is detected, the user receives a pop-up notification and is presented with a compressed, low-quality, grayscale image that is captioned "not for diagnostic use, for prioritization only" which is displayed as a



preview function. This preview is meant for informational purposes only, does not contain any marking of the findings, and is not intended for primary diagnosis beyond notification.

Presenting the users with worklist prioritization facilitates efficient triage by prompting the user to assess the relevant original images in the PACS. Thus, the suspect case receives attention earlier than would have been the case in the standard of care practice alone.

The algorithm was trained during software development on images of the pathology. As is customary in the field of machine learning, deep learning algorithm development consisted of training on labeled (“tagged”) images. In that process, each image in the training dataset was tagged based on the presence of the critical finding.

Intended Use / Indications for Use

BriefCase-Triage 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.

BriefCase-Triage uses an artificial intelligence algorithm to analyze images and highlight cases with detected findings in parallel to the ongoing standard of care image interpretation. The user is presented with notifications 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. The results of BriefCase-Triage 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.

Summary of Technological Characteristics

The subject Briefcase-Triage for VO and the algorithm analysis module for the predicate Briefcase for VO (K220709) are identical and differ only with respect to the inclusion criteria (addition of mCTA images).

Both the predicate and subject devices are radiological computer-aided triage and notification software programs. Both devices are artificial intelligence, deep-learning algorithms incorporated in software components for use with DICOM compliant CT scanners, PACS, and radiology workstations.

Both devices are intended to aid in triage and prioritization of radiological images and utilize the same design of deep learning algorithm trained on medical images. Both devices are intended to provide the specialists with notifications and unannotated, compressed, low-quality, and grayscale preview images of suspect studies for the purpose of preemptive triage.

The subject and predicate Briefcase-Triage devices raise the same types of safety and effectiveness questions, namely, accurate triage of findings within the processed study. It is important to note that, like

the predicate, the subject device neither removes cases from the standard of care reading queue nor de-prioritized cases. Both devices operate in parallel with the standard of care, which remains the default option for all cases.

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

Table 1. Key Feature Comparison

	Subject Device Aidoc's Briefcase-Triage for VO	Predicate Device Aidoc's Briefcase for VO (K220709)
Intended Use / Indications for Use	BriefCase-Triage 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. BriefCase-Triage uses an artificial intelligence algorithm to analyze images and highlight cases with detected findings in parallel to the ongoing standard of care image interpretation. The user is presented with notifications 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. The	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. BriefCase uses an artificial intelligence algorithm to analyze images and highlight cases with detected findings in parallel to the ongoing standard of care image interpretation. The user is presented with notifications 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. The results of BriefCase are intended to be used in conjunction with other patient information and based on

	Subject Device Aidoc's Briefcase-Triage for VO	Predicate Device Aidoc's Briefcase for VO (K220709)
	results of BriefCase-Triage 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.	their professional judgment, to assist with triage/prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care.
User population	Hospital networks and appropriately trained medical specialists	Hospital networks and appropriately trained medical specialists
Anatomical region of interest	Head	Head
Data acquisition protocol	Head CTA/mCTA	Head CTA
Notification-only (/notification alerts), parallel workflow tool	Yes	Yes
Images format	DICOM	DICOM
Interference with	No. No cases are removed from desktop app or deprioritized	No. No cases are removed from desktop app or deprioritized

	Subject Device Aidoc's Briefcase-Triage for VO	Predicate Device Aidoc's Briefcase for VO (K220709)
standard workflow		
Inclusion/ Exclusion criteria for clinical performance testing	<u>Inclusion Criteria</u> • Head CTA or mCTA images . • Scans performed on adults/ transitional adults ≥ 18 years of age. • Slice thickness 0.5 mm – 1.25 mm. <u>Exclusion Criteria</u> • All studies that have an inadequate field of view.	<u>Inclusion Criteria</u> • Head CTA protocol with a 64-slice scanner or higher. • Scans performed on adults/ transitional adults ≥ 18 years of age. • Slice thickness 0.5 mm – 1.25 mm. <u>Exclusion Criteria</u> • All scans that are technically inadequate, including motion artifacts, severe metal artifacts, suboptimal bolus timing or an inadequate field of view.
Algorithm	Artificial intelligence algorithm with database of images.	Artificial intelligence algorithm with database of images.
Structure	- Integrated with image routing module via image communication platform (ICP) (image acquisition). - Algorithm module (image processing) - Integrated with desktop application for workflow integration (feed and non-diagnostic Image Viewer).	- AHS module (image acquisition); - ACS module (image processing); - Aidoc Desktop Application for workflow integration (Feed/Worklist (alternate names) and non-diagnostic Image Viewer).

Performance Data

Pivotal Study Summary

Aidoc conducted a retrospective, blinded, multicenter study is designed to evaluate the performance of the BriefCase Software Application for Vessel Occlusion (VO) triage when using mCTA acquisition protocols. The study assessed the software's accuracy in flagging suspected mCTA VO findings. BriefCase accuracy was determined by comparing its positive/negative determination to ground truth established by 2+1 expert, U.S. board-certified radiologist reviewers using majority voting.

The primary objective was to evaluate the accuracy of the BriefCase Software Algorithm in analysis and identification of Vessel Occlusion (VO) findings in head CT images exams using mCTA acquisition protocol. For this subset analysis, the sensitivity and specificity of BriefCase was estimated and reported to characterize performance within this population. Positive Predictive Value (PPV), Negative Predictive Value (NPV), Positive Likelihood Ratio (PLR), and Negative Likelihood Ratio (NLR) were also assessed.

Primary Endpoint

Sensitivity was 81.4% (95% CI: 71.6-89%) and Specificity was 85.5% (95% CI: 78-91.2%).

Since VO performance using mCTA protocol and overall VO performance are comparable and are both exceeding the 80% sensitivity and specificity thresholds, the primary endpoint was met.

Secondary Endpoint

NPV was 97.6% (95% CI: 96.4%-98.5%) and PPV was 38.4% (95% CI: 28.7%-49.1%).

PLR was 5.6 (95% CI: 3.6-8.7) and NLR was 0.22 (95% CI: 0.14-0.34).

Time-to-notification (In this case, flagged scan details input into the Aidoc worklist) analysis was calculated as 1.09 minutes (compared to 2.23 minutes, of the predicate).

Cybersecurity

Cybersecurity has been incorporated into the software development lifecycle in alignment with Section 524B of the FD&C Act and FDA cybersecurity guidance. Aidoc has implemented a risk-based approach to cybersecurity, including secure design practices, vulnerability assessments, a Software Bill of Materials (SBOM), and penetration testing. These efforts support the safety, effectiveness, and resilience of the software against cybersecurity threats.

Conclusions

The subject Briefcase-Triage for VO and the predicate Briefcase for VO (K220709) are intended to aid in prioritization and triage of radiological images for the indications for suspected positive findings of vessel occlusions. Both devices are software components consisting of the same deep learning AI algorithm that process images and produce analysis results, which are displayed to the user by a prioritization alert and a compressed, low-quality, grayscale, unannotated preview image. In both devices, the labeling clearly states that the devices are not for diagnostic use and instructs the user to further evaluate and diagnose based only on the original images in the local PACS.

Both devices operate in parallel to the standard of care workflow in the sense that they do not change the original image, do not provide any marking on the output preview, do not remove images from the standard of care FIFO queue and do not de-prioritize cases, thus not disturbing standard interpretation



of the images. Both devices notify the radiologist of time-sensitive critical cases within the range of several minutes, and thus contribute similarly to the standard of care workflow turnaround time reduction through preemptive triage.

The subject Briefcase-Triage device for VO is thus substantially equivalent to the primary predicate Briefcase for VO (K220709).