Aidoc Medical, Ltd.
℅ John Smith
Partner
Hogan Lovells US LLP
555 Thirteenth Street NW
Washington, District of Columbia 20004

January 27, 2026

Re: K251195
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: December 22, 2025
Received: December 22, 2025

Dear John Smith:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica Lamb, PhD
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K251195

Device Name
BriefCase-Triage

Indications for Use *(Describe)*

BriefCase-Triage is a radiological computer aided triage and notification software indicated for use in the analysis of contrast-enhanced CT images that include the brain, 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 cases of Brain Aneurysm (BA) findings that are 3.0 mm or larger.

BriefCase-Triage uses an artificial intelligence algorithm to analyze images and flag suspect cases in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for suspect cases. 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 professional judgment, to assist with triage/prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care.

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary
Aidoc Medical, Ltd.'s BriefCase-Triage
K251195

Submitter:

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Date Prepared: January 24, 2025

Name of Device:	BriefCase-Triage
Classification Name:	Radiological computer-assisted triage and notification software device
Regulatory Class:	Class II
Product Code:	QAS (21 C.F.R. 892.2080)
Primary Predicate Device:	BriefCase-Triage for BA (K213721)
Reference Device:	BriefCase-Triage for iPE (K250248) Rapid Aneurysm Triage and Notification (K230074) Viz ANEURYSM, Viz ANX (K213319)

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 manually labeled ("tagged") images. In that process, critical findings were tagged in all CTs in the training data set.

Intended Use / Indications for Use

BriefCase-Triage is a radiological computer aided triage and notification software indicated for use in the analysis of contrast-enhanced CT images that include the brain, 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 cases of Brain Aneurysm (BA) findings that are 3.0 mm or larger.

BriefCase-Triage uses an artificial intelligence algorithm to analyze images and flag suspect cases in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for suspect cases. 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 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 BA and the algorithm analysis module for the primary predicate BriefCase-Triage for BA (K213721) are identical in most aspects and differ mostly with respect to their algorithm performance. In addition, the SW architecture was changed to separate the image communication platform from the BriefCase-Triage SW. The subject device consists of only the algorithm analysis module which can be integrated with image communication platforms that meet the BriefCase-Triage input and output requirements.

Both the primary predicate and subject devices are radiological computer-aided triage and notification software programs. Both devices are artificial intelligence, deep-learning algorithms incorporated in software packages 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 BriefCase-Triage for BA**	**Predicate Device** **Aidoc BriefCase-Triage for BA (K213721)**
Intended Use / Indications for Use	BriefCase-Triage is a radiological computer aided triage and notification software indicated for use in the analysis of contrast-enhanced CT images that include the brain, 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 cases of Brain Aneurysm (BA) findings that are 3.0 mm or larger. BriefCase-Triage uses an artificial intelligence algorithm to analyze images and flag suspect cases in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for suspect cases. 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 professional judgment, to assist with triage/prioritization of medical images. Notified clinicians are	BriefCase is a radiological computer aided triage and notification software indicated for use in the analysis of head CT Angio (CTA) images. The device is intended to assist hospital networks and appropriately trained medical specialists in workflow triage by flagging and communication of suspected positive cases of Brain Aneurysm (BA) findings above 5 mm size. BriefCase uses an artificial intelligence algorithm to analyze images and flag suspect cases on a standalone desktop application in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for suspect cases. 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 professional judgment, to assist with triage/prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care.

	Subject Device **Aidoc BriefCase-Triage for BA**	**Predicate Device** **Aidoc BriefCase-Triage for BA (K213721)**
	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
Threshold BA Findings	Brain Aneurysm (BA) findings that are 3.0 mm size or larger	Brain Aneurysm (BA) findings above 5 mm size
Anatomical region of interest / Organ	Brain	Head
Data acquisition protocol	Contrast-enhanced CT images that include the brain	Computed tomography angiography (CTA) of the head
Notification-only (/notification alerts), parallel workflow tool	Yes	Yes
Images format	DICOM	DICOM
Interference with standard workflow	No. No cases are removed from desktop app or deprioritized	No. No cases are removed from desktop app or deprioritized

	Subject Device **Aidoc BriefCase-Triage for BA**	**Predicate Device** **Aidoc BriefCase-Triage for BA (K213721)**
Inclusion/ Exclusion criteria for clinical performance testing	Inclusion criteria ● Contrast-enhanced CT images that include the brain ● Scans performed on adults/transitional adults ≥ 18 years of age. ● Slice thickness; 0.5 mm – 2.5 mm axial slices. Exclusion Criteria ● All studies that have an inadequate field of view.	Inclusion criteria ● computed tomography angiography (CTA) of the head. ● Scans performed on adults/transitional adults ≥ 18 years of age. ● Scans performed on CT scanners with 64 or greater number of detectors. ● Slice thickness; 0.5 – 2.5 mm axial slices. Exclusion Criteria ● All scans that are technically inadequate, including motion artifacts, severe metal artifacts, or an inadequate field of view.
Additional Operating Points	3 Additional Operating Points	N/A
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 with the BriefCase-Triage software to evaluate the software's performance in identifying contrast-enhanced CT images that include the brain containing Brain

Aneurysm in 544cases from 6 US-based clinical sites, compared to the ground truth as determined by three senior board-certified radiologists. The cases collected for the pivotal dataset were all distinct in time or center from the cases used to train the algorithm. Test pivotal study data was sequestered from algorithm development activities, and use of the data is managed by appropriate Quality Management System procedures.

Primary endpoints were sensitivity and specificity with an 80% performance goal. Secondary endpoints were BriefCase-Triage time-to-notification compared to the predicate device. Positive Predictive Value (PPV), Negative Predictive Value (NPV), Positive Likelihood Ratio (PLR), and Negative Likelihood Ratio (NLR) were also assessed.

Primary Endpoint

For the primary endpoint, sensitivity was 87.8% (95% CI: 83.1%, 91.6%) and specificity was 91.6% (95% CI: 87.9%, 94.5%), meeting the study's primary endpoint.

Secondary Endpoint

In addition, the time-to-notification metric observed for the BriefCase-Triage software, when integrated with a compatible image communication platform, was compared to the equivalent metric of the predicate devices. The BriefCase-Triage 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.

The BriefCase-Triage time-to-notification was measured for all True Positive cases (i.e., identified as positive both by the reviewers as well as the BriefCase-Triage device) and is given in **Table 2** below. The Table also displays the same metric reported for the predicate BriefCase-Triage for BA.

The time-to-notification results obtained for the subject BriefCase-Triage device show comparability with the primary predicate with regard to time savings to the standard of care review. The BriefCase-Triage mean time-to-notification for the subject BA triage was 44.8 seconds (95% CI: 41.4-48.2). The time-to-notification for the predicate BA was 252 seconds (95% CI: 234-270).

Table 2. Time-to- notification comparison for BriefCase-Triage devices (Seconds)

Time -to-notification	Mean Estimate (seconds)	N	95% Lower CL	95% Upper CL	Median
Predicate K213721 Processing Time	252	103	234	270	252

Time -to-notification	Mean Estimate (seconds)	N	95% Lower CL	95% Upper CL	Median
BriefCase-Triage and Image Communication Platform Time-To-Notification	44.8	241	41.4	48.2	38.2

Thus, the reported similar time-to-notification data demonstrates that when using the subject BriefCase-Triage for BA the clinician may have the same benefit in time saving as with the predicate BriefCase-Triage for BA.

NPV was 98.9% (95% CI: 98.4%-99.2%) and PPV was 47.6% (95% CI: 38.4%-57.1%).
PLR was 10.5 (95% CI: 7.2-15.3) and NLR was 0.13 (95% CI: 0.1-0.19).

As can be seen in **Table 3** the mean age of patients whose scans were reviewed for BA was 61.9 years, with a standard deviation of 17.7 years. Gender distribution was 38.1% male, and 61.9% female (**Table 4**). Scanner distribution can also be found in **Table 5** below.

Table 3. Descriptive Statistics for Age

	Mean	Std	Min	Median	Max	N
Age (Years)	61.9	17.7	18	65	98	544

Table 4. Frequency Distribution of Gender *

Ground Truth Results	Gender				All	
	Female		Male			
	N	%	N	%	N	%
Positive	165	30.3%	81	14.9%	246	45.2%
Negative	172	31.6%	126	23.2%	298	54.8%
All	337	61.9%	207	38.1%	544	100.0%

Table 5. Frequency Distribution of Manufacturer

Manufacturer	N	%
GE MEDICAL SYSTEMS	243	44.7%
Philips	69	12.7%
SIEMENS	166	30.5%
TOSHIBA	66	12.1%
Total	544	100%

Table 6. Frequency Distribution of slice thickness

Thickness (mm)	N	%
0-1	355	65.3%
1-2.5	189	34.70%
Total	**544**	**100%**

Table 7. Frequency Distribution of protocol

Protocol	N	%
CT angiogram	270	49.6%
CT w/ contrast	274	50.4%
Total	**544**	**100%**

Clinical Subgroups and Confounders:

Pathologies present in negative cases: Inflammatory; Oncology; Trauma; Heart & vascular; Chronic Diseases, Fully Negative and None of the above.

Additional Operating Points:

In addition to the default operating point that was selected to maximize both sensitivity and specificity, three additional operating points were selected to enhance specificity gradually (with AOP3 chosen to maximize specificity) while meeting the 80% threshold for both sensitivity and specificity.

The performance results for the algorithm at the AOP1-AOP3 is shown below in **Table 8**:

Table 8. Additional Operating Points

Operating Points	Sensitivity % (95% CI)	Specificity % (95% CI)

AOP1	87.4% (95% CI: 82.6%-91.3%)	91.9% (95% CI: 88.3%-94.8%)
AOP2	87.0% (95% CI: 82.1%-90.9%)	92.6% (95% CI: 89.0%-95.3%)
AOP3	86.2% (95% CI: 81.2%-90.2%)	93.6% (95% CI: 90.2%-96.1%)

In summary, performance goals were achieved for the default and four additional operating points. Combined with the comparison results of time-to-notification metric with the predicate device, these data establish the achievement by the subject BriefCase-Triage of preemptive triage in the range of several minutes.

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 utilizes 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 BA and the predicate BriefCase-Triage for BA (K213721) are intended to aid in prioritization and triage of radiological images for the indications for suspected positive findings of incidental pulmonary embolism pathologies. Both devices are software packages consisting of deep learning AI algorithms 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 technological characteristics of both devices are identical with the exception of additional operating points and minor changes in inclusion and exclusion criteria. These differences do not raise new questions of substantial equivalence. The subject BriefCase-Triage device for BA is thus substantially equivalent to the primary predicate BriefCase-Triage for BA (K213721).