May 30, 2025

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

Re: K251406
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: May 6, 2025
Received: May 6, 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,

for

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251406

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 CT chest, abdomen, or chest/abdomen exams with contrast (CTA and CT with contrast) 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 Aortic Dissection (AD) pathology.

BriefCase-Triage 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 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.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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aidoc

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

Submitter:

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Phone: +972-73-7946870

Contact Person: Amalia Schreier, LL.M

Date Prepared: May 28, 2025

Name of Device: Briefcase-Triage

Classification Name: Radiological computer-assisted triage and notification software device (21 CFR 892.2080)

Regulatory Class: Class II

Product Code: QAS

Primary Predicate Device: Briefcase-Triage for AD (K222329)

Reference Device: BriefCase-Triage for RibFx (K243548)

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 CT chest, abdomen, or chest/abdomen exams with contrast (CTA and CT with contrast) 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 Aortic Dissection (AD) pathology.

BriefCase-Triage 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 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.

Summary of Technological Characteristics

The subject Briefcase-Triage for AD and the algorithm analysis module for the primary predicate Briefcase-Triage for AD (K222329) are identical in most aspects and differ mostly with respect to changes in algorithm training process and their algorithm performance.

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 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 Briefcase-Triage for AD**	**Predicate Device** **Aidoc Briefcase-Triage for AD (K222329)**
Intended Use / Indications for Use	BriefCase-Triage is a radiological computer aided triage and notification software indicated for use in the analysis of CT chest, abdomen, or chest/abdomen with contrast (CTA and CT with contrast) 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 Aortic Dissection (AD) pathology. BriefCase-Triage 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 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.	BriefCase is a radiological computer aided triage and notification software indicated for use in the analysis of CT exams with contrast (CTA and CT with contrast) that include the chest 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 Aortic Dissection (AD) pathology. 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 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 their professional judgment, to assist with triage/ prioritization.

	Subject Device **Aidoc Briefcase-Triage for AD**	**Predicate Device** **Aidoc Briefcase-Triage for AD (K222329)**
User population	Hospital networks and appropriately trained medical specialists	Hospital networks and appropriately trained medical specialists
Anatomical region of interest	Chest, abdomen and thoraco-abdominal	Chest, abdomen and thoraco-abdominal
Data acquisition protocol	CT chest, abdomen, or chest/abdomen exams with contrast (CTA and CT with contrast)	CT exams with contrast (CTA and CT with contrast) that include the chest
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 AD**	**Predicate Device** **Aidoc Briefcase-Triage for AD (K222329)**
Inclusion/ Exclusion criteria for clinical performance testing	<u>Inclusion Criteria</u> ● Scans performed on adults/transitional adolescents ≥ 18 years of age. ● CT chest, abdomen, or chest/abdomen exams with contrast (CTA and CT with contrast) ● Slice thickness 0.5 mm - 5.0 mm <u>Exclusion Criteria</u> ● All studies that have an inadequate field of view	<u>Inclusion Criteria</u> ● Scans performed on adults/transitional adolescents ≥ 18 years of age. ● CT exams with contrast (CTA and CT with contrast) that include the chest ● Slice thickness 0.5 mm - 5.0 mm <u>Exclusion Criteria</u> ● All studies that are technically inadequate, such as severe metal artifacts, or inadequate field of view.
Additional Operating Points	4 Additional Operating Points	2 Additional Operating Points
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 CT chest, abdomen, or chest/abdomen exams

with contrast (CTA and CT with contrast) in 509 cases from 5 US-based clinical sites. The study compared the software's performance 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, as was used for the most recent clearance (K222329). 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

Sensitivity was 92.7% (95% CI: 88.2%, 95.8%) and Specificity was 92.8% (95% CI: 89.2%, 95.4%). Because the lower bound of each 95% CI exceeded 80%, the study's primary endpoints were achieved.

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 AD.

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 AD triage was 10.7 seconds (95% CI: 10.5-10.9) . The time-to-notification for the predicate AD was 38.0 seconds (95% CI: 35.5-40.4).

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 K222329 Processing Time	38.0	499	35.5	40.4	31.1
Briefcase-Triage + Image Communication Platform Time-To-Notification	10.7	212	10.5	10.9	10.4

NPV was 99.8% (95% CI: 99.7%- 99.9%) and PPV was 24.7% (95% CI: 18.0%- 33.0%).
PLR was 12.8 (95% CI: 8.5- 19.2) and NLR was 0.08 (95% CI: 0.05- 0.13).

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

As can be seen in **Table 3** the mean age of patients whose scans were reviewed for AD was 60.1 years, with a standard deviation of 17.3 years. Gender distribution was 50.9% male, and 49.1% 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)	60.1	17.3	18	62	90	212

Table 4. Frequency Distribution of Gender

Ground Truth Results	Gender				All	
	Female		Male			
	N	%	N	%	N	%
Positive	73	14.3%	132	25.9%	205	40.3%
Negative	177	34.8%	127	25.0%	304	59.7%
All	250	49.1%	259	50.9%	509	100.0%

Table 5. Frequency Distribution of Manufacturer

Manufacturer	N	%
GE MEDICAL SYSTEMS	141	27.7%
Philips	112	22%
SIEMENS	174	34.2%
TOSHIBA	82	16.1%
Total	**509**	**100%**

Clinical Subgroups and Confounders:

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

Additional Operating Points:

In addition to the default operating point that was selected to maximize both sensitivity and specificity, four additional operating points (AOP) were selected to maximize specificity or sensitivity

while maintaining a lower bound 95% confidence interval of 80% for sensitivity and specificity respectively:

Table 6. Additional Operating Points

Operating Points	Sensitivity % (95% CI)	Specificity % (95% CI)
AOP1	95.6% (95% CI: 91.8%-98.0%)	88.2% (95% CI: 84.0%-91.6%)
AOP2	94.1% (95% CI: 90.0%-96.9%)	89.8% (95% CI: 85.8%-93.0%)
AOP3	89.3% (95% CI: 84.2%-93.2%)	94.7% (95% CI: 91.6%-97.0%)
AOP4	86.3% (95% CI: 80.9%-90.7%)	97.7% (95% CI: 95.3%-99.1%)

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.

Conclusions

The subject Briefcase-Triage for AD and the predicate Briefcase-Triage for AD (K222329) 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 components 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 subject Briefcase-Triage device for AD is thus substantially equivalent to the primary predicate Briefcase-Triage for AD (K222329).