



Aidoc Medical , Ltd.  
Amalia Schreier  
SVP of Regulation and Legal  
34 Hamasger St.  
Tel Aviv, 6721119  
Israel

March 26, 2026

Re: K253578

Trade/Device Name: BriefCase-Triage: CARE Multi-Triage CT for Pneumothorax; Pericardial effusion; Large aortic aneurysm; Shoulder fracture or dislocation device

Regulation Number: 21 CFR 892.2080

Regulation Name: Radiological Computer Aided Triage And Notification Software

Regulatory Class: Class II

Product Code: QAS

Dated: January 27, 2026

Received: January 27, 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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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](mailto: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 over a large, semi-transparent blue watermark of the FDA logo, which consists of the letters "FDA" in a stylized font.

Jessica Lamb  
Assistant Director  
Imaging Software  
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.

K253578

?

Please provide the device trade name(s).

?

BriefCase-Triage: CARE Multi-Triage CT for Pneumothorax; Pericardial effusion; Large aortic aneurysm; Shoulder fracture or dislocation device

Please provide your Indications for Use below.

?

BriefCase-Triage: CARE (Clinical AI Reasoning Engine) Multi-Triage CT for Pneumothorax; Pericardial effusion; Large aortic aneurysm; Shoulder fracture or dislocation device is a radiological computer aided triage and notification software indicated for use in the analysis of contrast and non-contrast CT images of the chest, abdomen, or chest/abdomen, 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 communicating suspected positive findings, per study, of:

Pneumothorax;  
Pericardial effusion;  
Large aortic aneurysm  
Shoulder Fracture or Dislocation

The device flags cases with at least one suspected finding to assist with triage/prioritization of medical images. The device will provide a flag for each suspected finding within this study. A preview image will be provided for each distinct suspected finding.

BriefCase-Triage uses a foundation model-based artificial intelligence (AI) system 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 for each suspected finding that are meant for informational purposes only and not intended for diagnostic use beyond notification. The device does not alter the original medical images 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

### BriefCase-Triage: CARE Multi-Triage CT for Pneumothorax; Pericardial effusion; Large aortic aneurysm; Shoulder fracture or dislocation device

<b>Submitter:</b>	Aidoc Medical, Ltd. 34 Hamasger St. Tel-Aviv, Israel, 6721119
<b>Phone:</b>	+972-73-7946870
<b>Contact Person:</b>	Amalia Schreier, LL.M, SVP Regulation and Legal
<b>Date Prepared:</b>	February 12, 2026
<b>Name of Device:</b>	BriefCase-Triage: CARE Multi-Triage CT for Pneumothorax; Pericardial effusion; Large aortic aneurysm; Shoulder fracture or dislocation device
<b>Classification Name:</b>	Radiological computer-assisted triage and notification software device
<b>Regulatory Class:</b>	Class II
<b>Product Code:</b>	QAS, QFM
<b>Predicate Device:</b>	Briefcase-Triage for AD (K251406)

### Device Description

BriefCase-Triage: CARE Multi-Triage CT for Pneumothorax; Pericardial effusion; Large aortic aneurysm; Shoulder fracture or dislocation device 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 device receives images that match meta-data criteria according to the BriefCase-Triage predefined set of parameters. Then, the BriefCase-Triage processes the series chronologically, identifying cases with suspected positive finding(s) and selecting key slice(s) for preview. BriefCase-Triage output consists of suspected positive flag/notification regarding the existence of each finding in the analyzed study. Each finding includes a Representative Key Slice. The Key Slice(s) may be presented to the users as compressed, low-quality, grayscale, preview images with the date and time imprinted. The previews are not annotated and are captioned with the disclaimer "Not for diagnostic use, for prioritization only" according to the device requirement from the Image Communication Platform (ICP).

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: CARE (Clinical AI Reasoning Engine) Multi-Triage CT for Pneumothorax; Pericardial effusion; Large aortic aneurysm; Shoulder fracture or dislocation device is a radiological computer aided triage and notification software indicated for use in the analysis of contrast and non-contrast CT images of the chest, abdomen, or chest/abdomen, 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 communicating suspected positive findings, per study, of:

1. Pneumothorax;
2. Pericardial effusion;
3. Large aortic aneurysm
4. Shoulder Fracture or Dislocation

The device flags cases with at least one suspected finding to assist with triage/prioritization of medical images. The device will provide a flag for each suspected finding within this study. A preview image will be provided for each distinct suspected finding.

BriefCase-Triage uses a foundation model-based artificial intelligence (AI) system 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 for each suspected finding that are meant for informational purposes only and not intended for diagnostic use beyond notification. The device does not alter the original medical images 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**

BriefCase-Triage: CARE Multi-Triage CT for Pneumothorax; Pericardial effusion; Large aortic aneurysm; Shoulder fracture or dislocation device is substantially equivalent to BriefCase-Triage for Aortic Dissection (AD) (K251406). As explained in more detail below, BriefCase-Triage device has the same intended use and similar indications for use, technological characteristics, and principles of operation as the previously cleared predicate BriefCase-Triage for AD (K251406). While the specific clinical indications differ, each indication remains independently time-sensitive. Additionally, both devices have modules fine tuned from a locked foundation model.

A substantial equivalence chart comparing the similarities and differences between the BriefCase-Triage and its predicate device is provided in **Table 1** below. The differences in the technological characteristics do not raise different questions of safety or effectiveness. Standalone testing demonstrates that the subject device is substantially equivalent to its predicate device.

Both the predicate and subject device 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 format CT images, 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 predicate devices is provided below.

**Table 1. Key Feature Comparison**

	<b>Subject Device</b> <b>Aidoc’s BriefCase-Triage: CARE Multi-Triage CT for Pneumothorax; Pericardial effusion; Large aortic aneurysm; Shoulder fracture or dislocation</b>	<b>Predicate Device</b> <b>Aidoc’s Briefcase-Triage for AD (K251406)</b>
Intended Use / Indications for Use	<p>BriefCase-Triage: CARE (Clinical AI Reasoning Engine) Multi-Triage CT for Pneumothorax; Pericardial effusion; Large aortic aneurysm; Shoulder fracture or dislocation device is a radiological computer aided triage and notification software indicated for use in the analysis of contrast and non-contrast CT images of the chest, abdomen, or chest/abdomen, 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 communicating suspected positive findings, per study, of:</p> <ol style="list-style-type: none"> <li>1. Pneumothorax;</li> <li>2. Pericardial effusion;</li> <li>3. Large aortic aneurysm</li> <li>4. Shoulder Fracture or Dislocation</li> </ol> <p>The device flags cases with at least one suspected finding to assist with triage/prioritization of medical images. The device will provide a flag for each suspected</p>	<p>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.</p> <p>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</p>

	<b>Subject Device</b> <b>Aidoc's BriefCase-Triage: CARE Multi-Triage CT for Pneumothorax; Pericardial effusion; Large aortic aneurysm; Shoulder fracture or dislocation</b>	<b>Predicate Device</b> <b>Aidoc's Briefcase-Triage for AD (K251406)</b>
	<p>finding within this study. A preview image will be provided for each distinct suspected finding.</p> <p>BriefCase-Triage uses a foundation model-based artificial intelligence (AI) system 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 for each suspected finding that are meant for informational purposes only and not intended for diagnostic use beyond notification. The device does not alter the original medical images and is not intended to be used as a diagnostic device.</p> <p>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.</p>	<p>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>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.</p>
User population	Hospital networks and appropriately trained medical specialists	Hospital networks and appropriately trained medical specialists
Clinical Indication	<ol style="list-style-type: none"> <li>1. Pneumothorax;</li> <li>2. Pericardial effusion;</li> <li>3. Large aortic aneurysm;</li> <li>4. Shoulder fracture or dislocation</li> </ol>	<ol style="list-style-type: none"> <li>1. Aortic Dissection</li> </ol>
Anatomic region of interest	Chest, abdomen, or chest/abdomen	Chest, abdomen, or chest/abdomen

	<b>Subject Device</b> <b>Aidoc's BriefCase-Triage: CARE Multi-Triage CT for Pneumothorax; Pericardial effusion; Large aortic aneurysm; Shoulder fracture or dislocation</b>	<b>Predicate Device</b> <b>Aidoc's Briefcase-Triage for AD (K251406)</b>
Data acquisition protocol	Contrast and non-contrast CT images	CTA and CT with contrast
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
Inclusion/Exclusion criteria for clinical performance testing	<p><u>Inclusion Criteria:</u></p> <ul style="list-style-type: none"> <li>● Patient population: CT scans performed on adults/transitional adults ≥ 18 years of age</li> <li>● Slice thickness: 0.5 mm - 5.0 mm axial</li> <li>● Contrast-enhanced and non-contrast CT images*</li> </ul> <p><u>Exclusion Criteria</u></p> <ul style="list-style-type: none"> <li>● All studies that have an inadequate field of view.</li> </ul> <p>*Contrast and non-contrast CT images of the chest, abdomen, or chest/abdomen as applicable to indication-specific inclusion criteria.</p>	<p><u>Inclusion Criteria</u></p> <ul style="list-style-type: none"> <li>● Scans performed on adults/transitional adolescents ≥ 18 years of age.</li> <li>● CT exams with contrast (CTA and CT with contrast) that include at least part of the aorta</li> <li>● Slice thickness 0.5 mm - 5.0 mm</li> </ul> <p><u>Exclusion Criteria</u></p> <ul style="list-style-type: none"> <li>● All studies that have an inadequate field of view.</li> </ul>

	<b>Subject Device</b> <b>Aidoc’s BriefCase-Triage: CARE Multi-Triage CT for Pneumothorax; Pericardial effusion; Large aortic aneurysm; Shoulder fracture or dislocation</b>	<b>Predicate Device</b> <b>Aidoc’s Briefcase-Triage for AD (K251406)</b>
Additional Operating Points	4 Additional Operating Points	4 Additional Operating Points
Algorithm	Multi-triage module, locked artificial intelligence algorithm fine tuned from a foundation model.	Single-triage module, locked, artificial intelligence algorithm fine tuned from a foundation model.
Structure	<ul style="list-style-type: none"> <li>- Integrated with image routing module via image communication platform (ICP) (image acquisition).</li> <li>- Algorithm module (image processing)</li> <li>- Integrated with desktop application for workflow integration (feed and non-diagnostic Image Viewer).</li> </ul>	<ul style="list-style-type: none"> <li>- Integrated with image routing module via image communication platform (ICP) (image acquisition).</li> <li>- Algorithm module (image processing)</li> <li>- Integrated with desktop application for workflow integration (feed and non-diagnostic Image Viewer).</li> </ul>

## Performance Data

### *Pivotal Study Summary*

Aidoc conducted a retrospective, blinded, multicenter study with the BriefCase-Triage: CARE Multi-Triage CT for Pneumothorax; Pericardial effusion; Large aortic aneurysm; Shoulder fracture or dislocation software to evaluate the standalone performance analysis individually for each of the 4 clinical indications supported by BriefCase-Triage. The standalone performance study evaluated the software’s performance in identifying contrast-enhanced and non-contrast CT images in cases from 6 US-based clinical sites, representing diverse geographic locations and site types.

Each of 4-clinical indications had a sample size of N = 280 each, with 772 unique scans included across device indications.

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. 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 pre-specified standalone performance goal (PG) of area under the curve (AUC) > 0.95 lower bound 95% confidence interval for the finding level receiver operating characteristic (ROC) curve. Secondary

endpoints were sensitivity, specificity and BriefCase 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.

#### AUC, Sensitivity and Specificity

AUC, Sensitivity and Specificity of 4-clinical indication exceeded the pre-specified performance goal (PG) of area under the curve (AUC) > 0.95 lower bound 95% confidence interval for the finding level receiver operating characteristic (ROC) curve and 80% for both sensitivity and specificity, as further detailed in **Table 2** below:

**Table 2. AUC, Sensitivity, Specificity**

Indication 1: Pneumothorax								
AUC		Sensitivity (Se)		Specificity (Sp)		Case Count		
AUC	95% CI	Se	95% CI	Sp	95% CI	Total	Positive	Negative
98.9	97.8-99.7	94.8%	89.5%-97.9%	95.9%	91.3%-98.5%	280	134	146
Indication 2: Pericardial effusion								
AUC		Sensitivity (Se)		Specificity (Sp)		Case Count		
AUC	95% CI	Se	95% CI	Sp	95% CI	Total	Positive	Negative
99.1	98.0-99.8	96.4%	91.7%-98.8%	96.5%	92.0%-98.8%	280	138	142
Indication 3: Large aortic aneurysm								
AUC		Sensitivity (Se)		Specificity (Sp)		Case Count		
AUC	95% CI	Se	95% CI	Sp	95% CI	Total	Positive	Negative
99.5	98.9-99.9	97.1%	92.7%-99.2%	97.2%	92.9%-99.2%	280	138	142
Indication 4: Shoulder fracture or dislocation								
AUC		Sensitivity (Se)		Specificity (Sp)		Case Count		
AUC	95% CI	Se	95% CI	Sp	95% CI	Total	Positive	Negative
99.9	99.7-100	97.8%	93.7%-99.5%	99.3%	96.2%-100.0%	280	136	144

#### Time to Notification

In addition, the time-to-notification metric observed for the BriefCase-Triage: CARE Multi-Triage CT for Pneumothorax; Pericardial effusion; Large aortic aneurysm; Shoulder fracture or dislocation software was compared to the equivalent metric of the predicate device. 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 result back to the desktop application.

The BriefCase-Triage: CARE Multi-Triage CT for Pneumothorax; Pericardial effusion; Large aortic aneurysm; Shoulder fracture or dislocation software 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 3** below. The Table also displays the same metric reported for the predicate Briefcase-Triage for AD.

The time-to-notification results obtained for the subject Briefcase-Triage device show comparability with the predicate with regard to time savings to the standard of care review. The BriefCase-Triage: CARE Multi-Triage CT for Pneumothorax; Pericardial effusion; Large aortic aneurysm; Shoulder fracture or dislocation mean time-to-notification for the subject device triage was 49.9 seconds (95% CI: 46.4-53.5). The time-to-notification for

the predicate Briefcase-Triage for AD was 10.7 seconds (95% CI: 10.5-10.9).

**Table 3. Time-to- notification comparison for Briefcase-Triage devices (Seconds)**

Time-to-notification	Mean Estimate (seconds)	N	95% Lower CL	95% Upper CL	Median	IQR
Predicate K251406 Processing Time	10.7	212	10.5	10.9	10.4	0.4
BriefCase-Triage and compatible image communication platform Time-to-notification	49.9	536	46.4	53.5	38.8	33.1

Thus, the reported similar time-to-notification data demonstrates that when using the subject BriefCase-Triage: CARE Multi-Triage CT for Pneumothorax; Pericardial effusion; Large aortic aneurysm; Shoulder fracture or dislocation the clinician may have the same benefit in time-to-notification as with the predicate Briefcase-Triage for AD.

**Table 4** presents the mean age of patients whose scans were reviewed for BriefCase-Triage, with the standard deviation. Gender distribution, Scanner distribution and slice thickness can also be found in **Tables 5-7** below.

**Table 4. Descriptive Statistics for Age**

Indication 1: Pneumothorax					
Age (Years)					
Mean	Std	Min	Median	Max	N
60.4	18.6	18	65	90	280
Indication 2: Pericardial effusion					
Age (Years)					
Mean	Std	Min	Median	Max	N
61.2	17.7	18	64	90	280
Indication 3: Large aortic aneurysm					
Age (Years)					
Mean	Std	Min	Median	Max	N
66.6	17.2	18	71	90	280
Indication 4: Shoulder fracture or dislocation					
Age (Years)					
Mean	Std	Min	Median	Max	N
61.5	17.3	18	65	90	280

Table 5. Descriptive Statistics for Gender

<b>Indication 1: Pneumothorax</b>						
*5 cases were unknown for gender, 4 positive and 1 negative						
<b>Gender</b>						
<b>Ground Truth Results</b>	<b>Female</b>		<b>Male</b>		<b>All</b>	
	N	%	N	%	N	%
Positive	47	17.1%	83	30.2%	130	47.3%
Negative	80	29.1%	65	23.6%	145	52.7%
All	127	46.2%	148	53.8%	275	100.0%
<b>Indication 2: Pericardial effusion</b>						
<b>Gender</b>						
<b>Ground Truth Results</b>	<b>Female</b>		<b>Male</b>		<b>All</b>	
	N	%	N	%	N	%
Positive	76	27.1%	62	22.1%	138	49.3%
Negative	80	28.6%	62	22.1%	142	50.7%
All	156	55.7%	124	44.3%	280	100.0%
<b>Indication 3: Large aortic aneurysm</b>						
<b>Gender</b>						
<b>Ground Truth Results</b>	<b>Female</b>		<b>Male</b>		<b>All</b>	
	N	%	N	%	N	%
Positive	42	15.0%	96	34.3%	138	49.3%
Negative	82	29.3%	60	21.4%	142	50.7%
All	124	44.3%	156	55.7%	280	100.0%
<b>Indication 4: Shoulder fracture or dislocation</b>						
*8 cases were unknown for gender, all positive						
<b>Gender</b>						
<b>Ground Truth Results</b>	<b>Female</b>		<b>Male</b>		<b>All</b>	
	N	%	N	%	N	%
Positive	48	17.6%	80	29.4%	128	47.1%
Negative	76	27.9%	68	25.0%	144	52.9%
All	124	45.6%	148	54.4%	272	100%

Table 6. Frequency Distribution of Manufacturer

<b>Indication 1: Pneumothorax</b>		
<b>Manufacturer</b>	<b>N</b>	<b>%</b>
GE MEDICAL SYSTEMS	80	28.6%
Philips	68	24.3%
SIEMENS	69	24.6%
TOSHIBA	63	22.5%
<b>Total</b>	<b>280</b>	<b>100%</b>
<b>Indication 2: Pericardial effusion</b>		
<b>Manufacturer</b>	<b>N</b>	<b>%</b>
GE MEDICAL SYSTEMS	100	35.70%

Philips	63	22.5%
SIEMENS	60	21.4%
TOSHIBA	57	20.4%
<b>Total</b>	280	100%
<b>Indication 3: Large aortic aneurysm</b>		
<b>Manufacturer</b>	<b>N</b>	<b>%</b>
GE MEDICAL SYSTEMS	95	33.90%
Philips	63	22.5%
SIEMENS	66	23.60%
TOSHIBA	56	20.0%
<b>Total</b>	280	100
<b>Indication 4: Shoulder fracture or dislocation</b>		
<b>Manufacturer</b>	<b>N</b>	<b>%</b>
GE MEDICAL SYSTEMS	92	32.9%
Philips	58	20.7%
SIEMENS	66	23.6%
TOSHIBA	64	22.9%
<b>Total</b>	280	100%

Table 7. Frequency Distribution of Slice Thickness

<b>Indication 1: Pneumothorax</b>		
<b>Slice Thickness (mm)</b>	<b>N</b>	<b>%</b>
0.5-1	67	23.9%
1-2.5	71	25.4%
2.5-5	142	50.7%
Total	280	100%
<b>Indication 2: Pericardial effusion</b>		
<b>Slice Thickness (mm)</b>	<b>N</b>	<b>%</b>
0.5-1	56	20.0%
1-2.5	91	32.5%
2.5-5	133	47.5%
Total	280	100%
<b>Indication 3: Large aortic aneurysm</b>		
<b>Slice Thickness (mm)</b>	<b>N</b>	<b>%</b>
0.5-1	63	22.5%
1-2.5	84	30.0%
2.5-5	133	47.5%
Total	280	100%
<b>Indication 4: Shoulder fracture or dislocation</b>		
<b>Slice Thickness (mm)</b>	<b>N</b>	<b>%</b>
0.5-1	85	30.4%
1-2.5	73	26.1%
2.5-5	122	43.6%
Total	280	100%

Clinical Subgroups and Confounders:

Pathologies present in negative cases: Inflammatory; Oncology; Heart and Vascular; Trauma; Chronic Disease; Fully Negative; and None of the above

Additional Operating Points

In addition to the default (balanced) operating point that was selected to maximize both sensitivity and specificity, a total of four additional operating points (AOP1-AOP4) were selected for each indication, allowing to enhance sensitivity or specificity while maintaining a lower bound 95% confidence interval of 80% for specificity and sensitivity (respectively) for each operating point. AOP1 corresponds to the highest sensitivity point estimate with acceptable specificity. AOP4 corresponds to the highest specificity point estimate with acceptable sensitivity. AOP2 and AOP3 represent operating points between the two, while maintaining acceptable performance.

**Table 8. Sensitivity, Specificity for AOP1-AOP4**

<b>Indication 1: Pneumothorax</b>			
<b>AOP1</b>			
<b>Sensitivity (Se)</b>		<b>Specificity (Sp)</b>	
<b>Se</b>	<b>95% CI</b>	<b>Sp</b>	<b>95% CI</b>
98.5%	94.7%-99.8%	89.0%	82.8%-93.6%
<b>AOP2</b>			
<b>Sensitivity (Se)</b>		<b>Specificity (Sp)</b>	
<b>Se</b>	<b>95% CI</b>	<b>Sp</b>	<b>95% CI</b>
97.8%	93.6%-99.5%	93.2%	87.8%-96.7%
<b>AOP3</b>			
<b>Sensitivity (Se)</b>		<b>Specificity (Sp)</b>	
<b>Se</b>	<b>95% CI</b>	<b>Sp</b>	<b>95% CI</b>
90.3%	84.0%-94.7%	97.3%	93.1%-99.2%
<b>AOP4</b>			
<b>Sensitivity (Se)</b>		<b>Specificity (Sp)</b>	
<b>Se</b>	<b>95% CI</b>	<b>Sp</b>	<b>95% CI</b>
88.8%	82.2%-93.6%	98.6%	95.1%-99.8%
<b>Indication 2: Pericardial effusion</b>			
<b>AOP1</b>			
<b>Sensitivity (Se)</b>		<b>Specificity (Sp)</b>	
<b>Se</b>	<b>95% CI</b>	<b>Sp</b>	<b>95% CI</b>
97.1%	92.7%-99.2%	89.4%	83.2%-94.0%
<b>AOP2</b>			
<b>Sensitivity (Se)</b>		<b>Specificity (Sp)</b>	
<b>Se</b>	<b>95% CI</b>	<b>Sp</b>	<b>95% CI</b>
95.7%	90.8%-98.4%	97.2%	92.9%-99.2%
<b>AOP3</b>			
<b>Sensitivity (Se)</b>		<b>Specificity (Sp)</b>	
<b>Se</b>	<b>95% CI</b>	<b>Sp</b>	<b>95% CI</b>
94.2%	88.9%-97.5%	99.3%	96.1%-100.0%
<b>AOP4</b>			
<b>Sensitivity (Se)</b>		<b>Specificity (Sp)</b>	
<b>Se</b>	<b>95% CI</b>	<b>Sp</b>	<b>95% CI</b>

91.3%	85.3%-95.4%	100.0%	97.4%-100.0%
<b>Indication 3: Large aortic aneurysm</b>			
<b>AOP1</b>			
<b>Sensitivity (Se)</b>		<b>Specificity (Sp)</b>	
<b>Se</b>	<b>95% CI</b>	<b>Sp</b>	<b>95% CI</b>
97.8%	93.8%-99.5%	92.3%	86.6%-96.1%
<b>AOP2</b>			
<b>Sensitivity (Se)</b>		<b>Specificity (Sp)</b>	
<b>Se</b>	<b>95% CI</b>	<b>Sp</b>	<b>95% CI</b>
96.4%	91.7%-98.8%	98.6%	95.0%-99.8%
<b>AOP3</b>			
<b>Sensitivity (Se)</b>		<b>Specificity (Sp)</b>	
<b>Se</b>	<b>95% CI</b>	<b>Sp</b>	<b>95% CI</b>
94.9%	89.8%-97.9%	99.3%	96.1%-100.0%
<b>AOP4</b>			
<b>Sensitivity (Se)</b>		<b>Specificity (Sp)</b>	
<b>Se</b>	<b>95% CI</b>	<b>Sp</b>	<b>95% CI</b>
87.7%	81.0%-92.7%	99.3%	96.1%-100.0%
<b>Indication 4: Shoulder fracture or dislocation</b>			
<b>AOP1</b>			
<b>Sensitivity (Se)</b>		<b>Specificity (Sp)</b>	
<b>Se</b>	<b>95% CI</b>	<b>Sp</b>	<b>95% CI</b>
100.0%	97.3%-100.0%	95.1%	90.2%-98.0%
<b>AOP2</b>			
<b>Sensitivity (Se)</b>		<b>Specificity (Sp)</b>	
<b>Se</b>	<b>95% CI</b>	<b>Sp</b>	<b>95% CI</b>
99.3%	96.0%-100.0%	95.8%	91.2%-98.5%
<b>AOP3</b>			
<b>Sensitivity (Se)</b>		<b>Specificity (Sp)</b>	
<b>Se</b>	<b>95% CI</b>	<b>Sp</b>	<b>95% CI</b>
92.6%	86.9%-96.4%	100.0%	97.5%-100.0%
<b>AOP4</b>			
<b>Sensitivity (Se)</b>		<b>Specificity (Sp)</b>	
<b>Se</b>	<b>95% CI</b>	<b>Sp</b>	<b>95% CI</b>
89.0%	82.5%-93.7%	100.0%	97.5%-100.0%

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 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: CARE Multi-Triage CT for Pneumothorax; Pericardial effusion; Large aortic aneurysm; Shoulder fracture or dislocation device and the predicate Briefcase-Triage for AD device (K251406) 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(s). 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: CARE Multi-Triage CT for Pneumothorax; Pericardial effusion; Large aortic aneurysm; Shoulder fracture or dislocation is thus substantially equivalent to the predicate Briefcase-Triage for AD (K251406).