January 7, 2026

Aidoc Medical, Ltd.
Amalia Schreier
SVP of Regulation and Legal
3 Aminadav St.
Tel Aviv, 6706703
Israel

Re: K252970
    Trade/Device Name: BriefCase-Triage: CARE Multi-triage CT Body
    Regulation Number: 21 CFR 892.2080
    Regulation Name: Radiological Computer Aided Triage And Notification Software
    Regulatory Class: Class II
    Product Code: QAS, QFM
    Dated: September 17, 2025
    Received: December 2, 2025

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 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, 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.	K252970	?

Please provide the device trade name(s).	?

BriefCase-Triage: CARE Multi-triage CT Body

Please provide your Indications for Use below.	?

BriefCase-Triage: CARE (Clinical AI Reasoning Engine) Multi-Triage CT Body 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, and/or pelvis, 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. Diverticulitis;
2. Abdominal-pelvic abscess;
3. Appendicitis;
4. Intestinal ischemia and/or pneumatosis;
5. Obstructive renal stone;
6. Small bowel obstruction;
7. Large bowel obstruction;
8. Spleen injury;
9. Liver injury;
10. Kidney injury;
11. Pelvic fracture.

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

510(K) SUMMARY

Aidoc Medical, Ltd.'s BriefCase-Triage: CARE Multi-triage CT Body

Submitter:	Aidoc Medical, Ltd.
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	Tel-Aviv, Israel
Phone:	+972-73-7946870
Contact Person:	Amalia Schreier, LL.M, SVP Regulation and Legal
Date Prepared:	January 5, 2026
Name of Device:	BriefCase-Triage: CARE Multi-triage CT Body ("BriefCase-Triage")
Classification Name:	Radiological computer-assisted triage and notification software device
Regulatory Class:	Class II
Product Code:	QAS, QFM
Predicate Device:	Briefcase-Triage for AD (K251406)

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 images that match meta-data criteria according to BriefCase-Triage: CARE Multi-Triage CT Body's 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 Body 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, and/or pelvis, 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. Diverticulitis;
2. Abdominal-pelvic abscess;
3. Appendicitis;
4. Intestinal ischemia and/or pneumatosis;
5. Obstructive renal stone;
6. Small bowel obstruction;
7. Large bowel obstruction;
8. Spleen injury;
9. Liver injury;
10. Kidney injury;
11. Pelvic fracture.

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 Body device is substantially equivalent to BriefCase-Triage for Aortic Dissection (AD) (K251406). As explained in more detail below, BriefCase-Triage: CARE Multi-triage CT Body 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: CARE Multi-triage CT Body device 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 as safe and effective as 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

	Subject Device Aidoc BriefCase-Triage: CARE Multi-triage CT Body	Predicate Device Aidoc Briefcase-Triage for AD (K251406)
Intended Use / Indications for Use	BriefCase-Triage: CARE (Clinical AI Reasoning Engine) Multi-Triage CT Body 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, and/or pelvis, 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. Diverticulitis; 2. Abdominal-pelvic abscess; 3. Appendicitis; 4. Intestinal ischemia and/or pneumatosis; 5. Obstructive renal stone; 6. Small bowel obstruction; 7. Large bowel obstruction; 8. Spleen injury; 9. Liver injury; 10. Kidney injury; 11. Pelvic fracture. 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)	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.

	Subject Device Aidoc BriefCase-Triage: CARE Multi-triage CT Body	Predicate Device Aidoc Briefcase-Triage for AD (K251406)
	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.	
User population	Hospital networks and appropriately trained medical specialists	Hospital networks and appropriately trained medical specialists
Clinical Indication	1. Diverticulitis; 2. Abdominal-pelvic abscess; 3. Appendicitis; 4. Intestinal ischemia and/or pneumatosis; 5. Obstructive renal stone; 6. Small bowel obstruction; 7. Large bowel obstruction; 8. Spleen injury; 9. Liver injury; 10. Kidney injury;	1. Aortic Dissection

	Subject Device Aidoc BriefCase-Triage: CARE Multi-triage CT Body	Predicate Device Aidoc Briefcase-Triage for AD (K251406)
	11. Pelvic fracture.	
Anatomical region of interest	Chest, abdomen, and/or pelvis	Chest, abdomen, or chest/abdomen
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

	Subject Device Aidoc BriefCase-Triage: CARE Multi-triage CT Body	Predicate Device Aidoc Briefcase-Triage for AD (K251406)
Inclusion/ Exclusion criteria for clinical performance testing	Inclusion Criteria: ● Patient population: CT scans performed on adults/transitional adults ≥ 18 years of age ● Slice thickness: 0.5 mm - 5.0 mm axial ● Contrast-enhanced and non-contrast CT images* Exclusion Criteria ● All studies that have an inadequate field of view. *Contrast and non-contrast CT images of the chest, abdomen, and/or pelvis, as applicable to indication-specific inclusion criteria.	Inclusion Criteria ● Scans performed on adults/transitional adolescents ≥ 18 years of age. ● CT exams with contrast (CTA and CT with contrast) that include at least part of the aorta ● Slice thickness 0.5 mm - 5.0 mm Exclusion Criteria ● All studies that have an inadequate field of view.
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	- 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).	- 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).

Performance Data

Pivotal Study Summary

Aidoc conducted a retrospective, blinded, multicenter study with the Briefcase-Triage software to evaluate the standalone performance analysis individually for each of the 11 clinical indications supported by BriefCase-Triage: CARE Multi-triage CT Body device. 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.

Each of 11-clinical indications had a sample size of N = 280, with 1769 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 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 11-clinical indication exceeded the pre-specified performance goal (PG) of area under the curve (AUC) > 0.95 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: Diverticulitis								
AUC		Sensitivity (Se)		Specificity (Sp)		Case Count		
AUC	95% CI	Se	95% CI	Sp	95% CI	Total	Positive	Negative
99.9	99.7-100	98.6%	95.1%-99.8%	98.5%	94.7%-99.8%	280	146	134
Indication 2: Abdominal-pelvis abscess								
AUC		Sensitivity (Se)		Specificity (Sp)		Case Count		
AUC	95% CI	Se	95% CI	Sp	95% CI	Total	Positive	Negative
99.2	98.5-99.7	95%	89.9%-98%	95.7%	91%-98.4%	280	139	141
Indication 3: Appendicitis								
AUC		Sensitivity (Se)		Specificity (Sp)		Case Count		

AUC	95% CI	Se	95% CI	Sp	95% CI	Total	Positive	Negative
99.5	98.6-100	97.9%	93.9%-99.6%	97.8%	93.8%-99.6%	280	141	139

Indication 4: Intestinal ischemia and/or pneumatosis								
AUC		Sensitivity (Se)		Specificity (Sp)		Case Count		
AUC	95% CI	Se	95% CI	Sp	95% CI	Total	Positive	Negative
98.8	97.5-99.7	96.6%	92.2%-98.9%	96.3%	91.5%-98.8%	280	146	134

Indication 5: Obstructive renal stone								
AUC		Sensitivity (Se)		Specificity (Sp)		Case Count		
AUC	95% CI	Se	95% CI	Sp	95% CI	Total	Positive	Negative
98.6	97.3-99.5	94%	88.9%-97.2%	96.9%	92.3%-99.2%	280	150	130

Indication 6: Small bowel obstruction								
AUC		Sensitivity (Se)		Specificity (Sp)		Case Count		
AUC	95% CI	Se	95% CI	Sp	95% CI	Total	Positive	Negative
97.4	95.2-99.1	95.5%	90.9%-98.2%	96%	91%-98.7%	280	154	126

Indication 7: Large bowel obstruction								
AUC		Sensitivity (Se)		Specificity (Sp)		Case Count		
AUC	95% CI	Se	95% CI	Sp	95% CI	Total	Positive	Negative
99.6	99.1-100	97.9%	94.1%-99.6%	99.3%	95.9%-100%	280	145	135

Indication 8: Spleen injury								
AUC		Sensitivity (Se)		Specificity (Sp)		Case Count		
AUC	95% CI	Se	95% CI	Sp	95% CI	Total	Positive	Negative
100	99.9-100	99.3%	96.1%-100%	98.6%	94.9%-99.8%	280	140	140

Indication 9: Liver injury								
AUC		Sensitivity (Se)		Specificity (Sp)		Case Count		
AUC	95% CI	Se	95% CI	Sp	95% CI	Total	Positive	Negative
99.9	99.7-100	98.6%	94.9%-99.8%	98.6%	94.9%-99.8%	280	140	140

Indication 10: Kidney injury								
AUC		Sensitivity (Se)		Specificity (Sp)		Case Count		
AUC	95% CI	Se	95% CI	Sp	95% CI	Total	Positive	Negative
99.8	99.5-100	98.6%	94.9%-99.8%	99.3%	96.1%-100.0%	280	140	140

Indication 11: Pelvic fracture								
AUC		Sensitivity (Se)		Specificity (Sp)		Case Count		
AUC	95% CI	Se	95% CI	Sp	95% CI	Total	Positive	Negative
98.9	97.6-99.8	96.5%	92.0%-98.9%	96.4%	91.7%-98.8%	280	143	137

Time to Notification

In addition, the time-to-notification metric observed for the BriefCase-Triage: CARE Multi-triage CT Body 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 Body 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 mean time-to-notification for the subject device triage was 45 seconds (95% CI: 43.4-46.5). 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	45	1523	43.4	46.5	38.1	24.7

Thus, the reported similar time-to-notification data demonstrates that when using the subject BriefCase-Triage: CARE Multi-triage CT Body 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: CARE Multi-triage CT Body, 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: Diverticulitis					
Age (Years)					
Mean	**Std**	**Min**	**Median**	**Max**	**N**
57.7	16.7	19	60	90	280

Indication 2: Abdominal-pelvis abscess					
Age (Years)					
Mean	**Std**	**Min**	**Median**	**Max**	**N**
53.6	18.6	18	54.5	90	280

Indication 3: Appendicitis					
Age (Years)					
Mean	**Std**	**Min**	**Median**	**Max**	**N**
50.1	18.5	18	50	90	280

Indication 4: Intestinal ischemia and/or pneumatosis					
Age (Years)					
Mean	**Std**	**Min**	**Median**	**Max**	**N**
61.8	18.6	19	65	90	280

Indication 5: Obstructive renal stone					
Age (Years)					
Mean	**Std**	**Min**	**Median**	**Max**	**N**
53.4	18.5	18	54	90	280

Indication 6: Small bowel obstruction					
Age (Years)					
Mean	**Std**	**Min**	**Median**	**Max**	**N**
60.5	18.8	18	64	90	280

Indication 7: Large bowel obstruction					
Age (Years)					
Mean	**Std**	**Min**	**Median**	**Max**	**N**
61.5	18.3	18	65.5	90	280

Indication 8: Spleen injury					
Age (Years)					
Mean	**Std**	**Min**	**Median**	**Max**	**N**
55.6	19.1	18	56	90	280

Indication 9: Liver injury					
Age (Years)					
Mean	**Std**	**Min**	**Median**	**Max**	**N**
53.9	19.6	18	56	90	280

Indication 10: Kidney injury					

Age (Years)					
Mean	Std	Min	Median	Max	N
58.1	18.7	18	61	90	280
Indication 11: Pelvic fracture					
Age (Years)					
Mean	Std	Min	Median	Max	N
63.0	20.8	18	68	90	280

Table 5. Descriptive Statistics for Gender

Indication 1: Diverticulitis						
Gender						
Ground Truth Results	Female		Male		All	
	N	%	N	%	N	%
Positive	78	27.9%	68	24.3%	146	52.1%
Negative	75	26.8%	59	21.1%	134	47.9%
All	153	54.6%	127	45.4%	280	100.0%
Indication 2: Abdominal-pelvis abscess						
Gender						
Ground Truth Results	Female		Male		All	
	N	%	N	%	N	%
Positive	52	18.6%	87	31.1%	139	49.6%
Negative	79	28.2%	62	22.1%	141	50.4%
All	131	46.8%	149	53.2%	280	100.0%
Indication 3: Appendicitis						
Gender						
Ground Truth Results	Female		Male		All	
	N	%	N	%	N	%
Positive	59	21.1%	82	29.3%	141	50.4%
Negative	75	26.8%	64	22.9%	139	49.6%
All	134	47.9%	146	52.1%	280	100.0%
Indication 4: Intestinal ischemia and/or pneumatosis						
Gender						
Ground Truth Results	Female		Male		All	
	N	%	N	%	N	%
Positive	70	25.0%	76	27.1%	146	52.1%
Negative	77	27.5%	57	20.4%	134	47.9%
All	147	52.5%	133	47.5%	280	100.0%

Indication 5: Obstructive renal stone						
Gender						
Ground Truth Results	**Female**		**Male**		**All**	
	N	%	N	%	N	%
Positive	55	19.6%	95	33.9%	150	53.6%
Negative	78	27.9%	52	18.6%	130	46.4%
All	133	47.5%	147	52.5%	280	100.0%

Indication 6: Small bowel obstruction						
Gender						
Ground Truth Results	**Female**		**Male**		**All**	
	N	%	N	%	N	%
Positive	78	27.9%	76	27.1%	154	55.0%
Negative	79	28.2%	47	16.8%	126	45.0%
All	157	56.1%	123	43.9%	280	100.0%

Indication 7: Large bowel obstruction						
Gender						
Ground Truth Results	**Female**		**Male**		**All**	
	N	%	N	%	N	%
Positive	78	27.9%	67	23.9%	145	51.8%
Negative	79	28.2%	56	20.0%	135	48.2%
All	157	56.1%	123	43.9%	280	100.0%

Indication 8: Spleen injury * 4 cases were unknown for gender, all positive.						
Gender						
Ground Truth Results	**Female**		**Male**		**All**	
	N	%	N	%	N	%
Positive	54	19.6%	82	29.7%	136	49.3%
Negative	84	30.4%	56	20.3%	140	50.7%
All	138	50.0%	138	50.0%	276	100.0%

Indication 9: Liver injury * 7 cases were unknown for gender, all positive.						
Gender						
Ground Truth Results	**Female**		**Male**		**All**	
	N	%	N	%	N	%
Positive	57	20.9%	76	27.8%	133	48.7%
Negative	84	30.8%	56	20.5%	140	51.3%
All	141	51.6%	132	48.4%	273	100.0%

Indication 10: Kidney injury						
Gender						

Ground Truth Results	Female		Male		All	
	N	%	N	%	N	%
Positive	36	13.0%	100	36.2%	136	49.3%
Negative	86	31.2%	54	19.6%	140	50.7%
All	122	44.2%	154	55.8%	276	100.0%

Indication 11: Pelvic fracture
* 9 cases were unknown for gender, all positive.

Gender						
Ground Truth Results	Female		Male		All	
	N	%	N	%	N	%
Positive	86	31.7%	48	17.7%	134	49.4%
Negative	74	27.3%	63	23.2%	137	50.6%
All	160	59.0%	111	41.0%	271	100.0%

Table 6. Frequency Distribution of Manufacturer

Indication 1: Diverticulitis		
Manufacturer	**N**	**%**
Canon	63	22.5%
GE	107	38.2%
Philips	63	22.5%
Siemens	47	16.8%
Total	280	100%
Indication 2: Abdominal-pelvis abscess		
Manufacturer	**N**	**%**
Canon	66	23.60%
GE	96	34.30%
Philips	55	19.6%
Siemens	63	22.5%
Total	280	100%
Indication 3: Appendicitis		
Manufacturer	**N**	**%**
Canon	64	22.9%
GE	101	36.1%
Philips	62	22.1%
Siemens	53	18.9%
Total	280	100%
Indication 4: Intestinal ischemia and/or pneumatosis		
Manufacturer	**N**	**%**

	N	%
Canon	58	20.7%
GE	107	38.2%
Philips	63	22.5%
Siemens	52	18.6%
Total	280	100
Indication 5: Obstructive renal stone		
Manufacturer	**N**	**%**
Canon	58	20.7%
GE	110	39.3%
Philips	62	22.1%
Siemens	50	17.9%
Total	280	100%
Indication 6: Small bowel obstruction		
Manufacturer	**N**	**%**
Canon	59	21.10%
GE	111	39.6%
Philips	61	21.8%
Siemens	49	17.5%
Total	280	100%
Indication 7: Large bowel obstruction		
Manufacturer	**N**	**%**
Canon	58	20.7%
GE	111	39.6%
Philips	58	20.7%
Siemens	53	18.9%
Total	280	100%
Indication 8: Spleen injury		
Manufacturer	**N**	**%**
Canon	60	21.4%
GE	92	32.9%
Philips	73	26.1%
Siemens	55	19.6%
Total	280	100%
Indication 9: Liver injury		
Manufacturer	**N**	**%**
Canon	69	24.6%
GE	94	33.6%
Philips	66	23.6%
Siemens	51	18.2%
Total	280	100%
Indication 10: Kidney injury		

Manufacturer	N	%
Canon	66	23.6%
GE	101	36.1%
Philips	61	21.8%
Siemens	52	18.6%
Total	280	100%
Indication 11: Pelvic fracture		
Manufacturer	**N**	**%**
Canon	66	23.6%
GE	95	33.9%
Philips	60	21.4%
Siemens	59	21.1%
Total	280	100%

Table 7. Frequency Distribution of Slice Thickness

Indication 1: Diverticulitis		
Slice Thickness (mm)	**N**	**%**
0.5-1	38	13.60%
1-2.5	79	28.20%
2.5-5	163	58.20%
Total	280	100%
Indication 2: Abdominal-pelvis abscess		
Slice Thickness (mm)	**N**	**%**
0.5-1	33	11.80%
1-2.5	78	27.90%
2.5-5	169	60.4%
Total	280	100%
Indication 3: Appendicitis		
Slice Thickness (mm)	**N**	**%**
0.5-1	30	10.7%
1-2.5	68	24.3%
2.5-5	182	65.0%
Total	280	100%
Indication 4: Intestinal ischemia and/or pneumatosis		
Slice Thickness (mm)	**N**	**%**
0.5-1	50	17.9%
1-2.5	62	22.1%
2.5-5	168	60.0%

Total	280	100%
Indication 5: Obstructive renal stone		
Slice Thickness (mm)	**N**	**%**
0.5-1	46	16.40%
1-2.5	53	18.9%
2.5-5	181	64.60%
Total	280	100%
Indication 6: Small bowel obstruction		
Slice Thickness (mm)	**N**	**%**
0.5-1	32	11.4%
1-2.5	75	26.8%
2.5-5	173	61.8%
Total	280	100%
Indication 7: Large bowel obstruction		
Slice Thickness (mm)	**N**	**%**
0.5-1	37	13.2%
1-2.5	64	22.9%
2.5-5	179	63.9%
Total	280	100%
Indication 8: Spleen injury		
Slice Thickness (mm)	**N**	**%**
0.5-1	48	17.1%
1-2.5	68	24.3%
2.5-5	164	58.6%
Total	280	100%
Indication 9: Liver injury		
Slice Thickness (mm)	**N**	**%**
0.5-1	56	20.0%
1-2.5	69	24.6%
2.5-5	155	55.4%
Total	280	100%
Indication 10: Kidney injury		
Slice Thickness (mm)	**N**	**%**
0.5-1	47	16.8%
1-2.5	71	25.4%
2.5-5	162	57.9%
Total	280	100%
Indication 11: Pelvic fracture		

Slice Thickness (mm)	N	%
0.5-1	40	14.3%
1-2.5	106	37.9%
2.5-5	134	47.9%
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

Indication 1: Diverticulitis			
AOP1			
Sensitivity (Se)		**Specificity (Sp)**	
Se	**95% CI**	**Sp**	**95% CI**
100%	97.5%-100%	94.8%	89.5%-97.9%
AOP2			
Sensitivity (Se)		**Specificity (Sp)**	
Se	**95% CI**	**Sp**	**95% CI**
97.3%	93.1%-99.2%	99.3%	95.9%-100.0%
AOP3			
Sensitivity (Se)		**Specificity (Sp)**	
Se	**95% CI**	**Sp**	**95% CI**
96.6%	92.2%-98.9%	99.3%	95.9%-100.0%
AOP4			
Sensitivity (Se)		**Specificity (Sp)**	
Se	**95% CI**	**Sp**	**95% CI**
96.6%	92.2%-98.9%	100%	97.3%-100.0%

Indication 2: Abdominal-pelvis abscess			
AOP1			
Sensitivity (Se)		**Specificity (Sp)**	
Se	**95% CI**	**Sp**	**95% CI**
99.3%	96.1%-100.0%	87.2%	80.6%-92.3%
AOP2			
Sensitivity (Se)		**Specificity (Sp)**	
Se	**95% CI**	**Sp**	**95% CI**
97.8%	93.8%-99.6%	90.1%	83.9%-94.5%
AOP3			
Sensitivity (Se)		**Specificity (Sp)**	
Se	**95% CI**	**Sp**	**95% CI**
96.4%	91.8%-98.8%	92.2%	86.5%-96.0%
AOP4			
Sensitivity (Se)		**Specificity (Sp)**	
Se	**95% CI**	**Sp**	**95% CI**
94.2%	89.0%-97.5%	98.6%	95.0%-99.8%
Indication 3: Appendicitis			
AOP1			
Sensitivity (Se)		**Specificity (Sp)**	
Se	**95% CI**	**Sp**	**95% CI**
99.3%	96.1%-100.0%	88.5%	82.0%-93.3%
AOP2			
Sensitivity (Se)		**Specificity (Sp)**	
Se	**95% CI**	**Sp**	**95% CI**
98.6%	95.0%-99.8%	96.4%	91.8%-98.8%
AOP3			
Sensitivity (Se)		**Specificity (Sp)**	
Se	**95% CI**	**Sp**	**95% CI**
97.2%	92.9%-99.2%	98.6%	94.9%-99.8%
AOP4			
Sensitivity (Se)		**Specificity (Sp)**	
Se	**95% CI**	**Sp**	**95% CI**
96.5%	91.9%-98.8%	100%	97.4%-100%
Indication 4: Intestinal ischemia and/or pneumatosis			
AOP1			
Sensitivity (Se)		**Specificity (Sp)**	
Se	**95% CI**	**Sp**	**95% CI**
97.3%	93.1%-99.2%	94.0%	88.6%-97.4%
AOP2			
Sensitivity (Se)		**Specificity (Sp)**	
Se	**95% CI**	**Sp**	**95% CI**
95.2%	90.4%-98.1%	97.8%	93.6%-99.5%
AOP3			

Sensitivity (Se)		Specificity (Sp)	
Se	**95% CI**	**Sp**	**95% CI**
93.2%	87.8%-96.7%	98.5%	94.7%-99.8%

AOP4			
Sensitivity (Se)		Specificity (Sp)	
Se	**95% CI**	**Sp**	**95% CI**
89.7%	83.6%-94.1%	99.3%	95.9%-100.0%

Indication 5: Obstructive renal stone			
AOP1			
Sensitivity (Se)		Specificity (Sp)	
Se	**95% CI**	**Sp**	**95% CI**
96.0%	91.5%-98.5%	93.1%	87.3%-96.8%
AOP2			
Sensitivity (Se)		Specificity (Sp)	
Se	**95% CI**	**Sp**	**95% CI**
94.7%	89.8%-97.7%	94.6%	89.2%-97.8%
AOP3			
Sensitivity (Se)		Specificity (Sp)	
Se	**95% CI**	**Sp**	**95% CI**
90.7%	84.8%-94.8%	98.5%	94.6%-99.8%
AOP4			
Sensitivity (Se)		Specificity (Sp)	
Se	**95% CI**	**Sp**	**95% CI**
88.0%	81.7%-92.7%	100%	97.2%-100%

Indication 6: Small bowel obstruction			
AOP1			
Sensitivity (Se)		Specificity (Sp)	
Se	**95% CI**	**Sp**	**95% CI**
94.8%	90.0%-97.7%	96.8%	92.1%-99.1%
AOP2			
Sensitivity (Se)		Specificity (Sp)	
Se	**95% CI**	**Sp**	**95% CI**
92.9%	87.6%-96.4%	97.6%	93.2%-99.5%
AOP3			
Sensitivity (Se)		Specificity (Sp)	
Se	**95% CI**	**Sp**	**95% CI**
90.3%	84.4%-94.4%	99.2%	95.7%-100.0%
AOP4			
Sensitivity (Se)		Specificity (Sp)	
Se	**95% CI**	**Sp**	**95% CI**
87.7%	81.4%-92.4%	100%	97.1%-100%

Indication 7: Large bowel obstruction			
AOP1			
Sensitivity (Se)		Specificity (Sp)	

Se	95% CI	Sp	95% CI
99.3%	96.2%-100.0%	90.4%	84.1%-94.8%

AOP2			
Sensitivity (Se)		Specificity (Sp)	
Se	95% CI	Sp	95% CI
98.6%	95.1%-99.8%	97.0%	92.6%-99.2%

AOP3			
Sensitivity (Se)		Specificity (Sp)	
Se	95% CI	Sp	95% CI
95.2%	90.3%-98.0%	99.3%	95.9%-100.0%

AOP4			
Sensitivity (Se)		Specificity (Sp)	
Se	95% CI	Sp	95% CI
91.7%	86.0%-95.7%	99.3%	95.9%-100.0%

Indication 8: Spleen injury			
AOP1			
Sensitivity (Se)		Specificity (Sp)	
Se	95% CI	Sp	95% CI
100%	97.4%-100%	95.7%	90.9%-98.4%

AOP2			
Sensitivity (Se)		Specificity (Sp)	
Se	95% CI	Sp	95% CI
98.6%	94.9%-99.8%	99.3%	96.1%-100.0%

AOP3			
Sensitivity (Se)		Specificity (Sp)	
Se	95% CI	Sp	95% CI
96.4%	91.9%-98.8%	100%	97.4%-100%

AOP4			
Sensitivity (Se)		Specificity (Sp)	
Se	95% CI	Sp	95% CI
90.7%	84.6%-95.0%	100%	97.4%-100%

Indication 9: Liver injury			
AOP1			
Sensitivity (Se)		Specificity (Sp)	
Se	95% CI	Sp	95% CI
99.3%	96.1%-100.0%	97.9%	93.9%-99.6%

AOP2			
Sensitivity (Se)		Specificity (Sp)	
Se	95% CI	Sp	95% CI
97.9%	93.9%-99.6%	99.3%	96.1%-100.0%

AOP3			
Sensitivity (Se)		Specificity (Sp)	
Se	95% CI	Sp	95% CI
97.1%	92.8%-99.2%	100%	97.4%-100%

AOP4			
Sensitivity (Se)		**Specificity (Sp)**	
Se	**95% CI**	**Sp**	**95% CI**
90.7%	84.6%-95.0%	100%	97.4%-100%
Indication 10: Kidney injury			
AOP1			
Sensitivity (Se)		**Specificity (Sp)**	
Se	**95% CI**	**Sp**	**95% CI**
99.3%	96.1%-100.0%	95.0%	90.0%-98.0%
AOP2			
Sensitivity (Se)		**Specificity (Sp)**	
Se	**95% CI**	**Sp**	**95% CI**
99.3%	96.1%-100.0%	97.1%	92.8%-99.2%
AOP3			
Sensitivity (Se)		**Specificity (Sp)**	
Se	**95% CI**	**Sp**	**95% CI**
97.1%	92.8%-99.2%	100%	97.4%-100%
AOP4			
Sensitivity (Se)		**Specificity (Sp)**	
Se	**95% CI**	**Sp**	**95% CI**
95.7%	90.9%-98.4%	100%	97.4%-100%
Indication 11: Pelvic fracture			
AOP1			
Sensitivity (Se)		**Specificity (Sp)**	
Se	**95% CI**	**Sp**	**95% CI**
98.6%	95.0%-99.8%	87.6%	80.9%-92.6%
AOP2			
Sensitivity (Se)		**Specificity (Sp)**	
Se	**95% CI**	**Sp**	**95% CI**
97.2%	93.0%-99.2%	94.9%	89.8%-97.9%
AOP3			
Sensitivity (Se)		**Specificity (Sp)**	
Se	**95% CI**	**Sp**	**95% CI**
95.8%	91.1%-98.4%	97.8%	93.7%-99.5%
AOP4			
Sensitivity (Se)		**Specificity (Sp)**	
Se	**95% CI**	**Sp**	**95% CI**
91.6%	85.8%-95.6%	99.3%	96.0%-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 demonstrate that the software is substantially equivalent to the predicate with respect to resilience against cybersecurity threats.

Conclusions

The subject BriefCase-Triage: CARE Multi-triage CT Body and the predicate Briefcase-Triage for AD (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 Body is thus substantially equivalent to the predicate Briefcase-Triage for AD (K251406).