November 6, 2025

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

Re: K253265
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: November 4, 2025
Received: November 4, 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.	K253265

Please provide the device trade name(s).

BriefCase-Triage

Please provide your Indications for Use below.

BriefCase-Triage is a radiological computer aided triage and notification software indicated for use in the analysis of abdominal CT images in adults or transitional adolescents aged 18 and older. The device is intended to assist hospital networks and appropriately trained medical specialists in workflow triage by flagging and communication of suspected positive findings of Intra-abdominal free gas (IFG) pathologies.

BriefCase-Triage uses an artificial intelligence algorithm to analyze images and highlight cases with the detected findings in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected findings. Notifications include compressed preview images that are meant for informational purposes only and not intended for diagnostic use beyond notification. The device does not alter the original medical image and is not intended to be used as a diagnostic device.

The results of BriefCase-Triage are intended to be used in conjunction with other patient information and based on their professional judgment, to assist with triage/prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care.

Please select the types of uses (select one or both, as applicable).

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

510(k) Summary
Aidoc Medical, Ltd.'s Briefcase-Triage
K253265

Submitter:

Aidoc Medical, Ltd.
3 Aminadav St.
Tel-Aviv, Israel

Phone: +972-73-7946870

Contact Person: Amalia Schreier, LL.M

Date Prepared: November 3, 2025

Name of Device: Briefcase-Triage

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

Regulatory Class: Class II

Product Code: QAS

Primary Predicate Device: Briefcase-Triage for IFG (K193298)

Reference 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 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 abdominal CT images in adults or transitional adolescents aged 18 and older. The device is intended to assist hospital networks and appropriately trained medical specialists in workflow triage by flagging and communication of suspected positive findings of Intra-abdominal free gas (IFG) pathologies.

BriefCase-Triage uses an artificial intelligence algorithm to analyze images and highlight cases with the detected findings in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected findings. Notifications include compressed preview images that are meant for informational purposes only and not intended for diagnostic use beyond notification. The device does not alter the original medical image and is not intended to be used as a diagnostic device.

The results of BriefCase-Triage are intended to be used in conjunction with other patient information and based on their professional judgment, to assist with triage/prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care.

Summary of Technological Characteristics

The subject Briefcase-Triage for IFG and the algorithm analysis module for the primary predicate Briefcase-Triage for IFG (K193298) 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 IFG**	**Predicate Device** **Aidoc Briefcase-Triage for IFG (K193298)**
Intended Use / Indications for Use	BriefCase-Triage is a radiological computer aided triage and notification software indicated for use in the analysis of abdominal CT images in adults or transitional adolescents aged 18 and older. The device is intended to assist hospital networks and appropriately trained medical specialists in workflow triage by flagging and communication of suspected positive findings of Intra-abdominal free gas (IFG) pathologies. BriefCase-Triage uses an artificial intelligence algorithm to analyze images and highlight cases with the detected findings in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected findings. Notifications include compressed preview images that are meant for informational purposes only and not intended for diagnostic use beyond notification. The device does not alter the original medical image and is not intended to be used as a diagnostic device. The results of BriefCase-Triage are intended to be used in conjunction with other patient information and based on their	BriefCase is a radiological computer aided triage and notification software indicated for use in the analysis of abdominal CT images. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communication of suspected positive findings of Intra-abdominal free gas (IFG) pathologies. 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 of medical

	Subject Device **Aidoc Briefcase-Triage for IFG**	**Predicate Device** **Aidoc Briefcase-Triage for IFG (K193298)**
	professional judgment, to assist with triage/prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care.	images. Notified clinicians are responsible for viewing full images per the standard of care.
User population	Hospital networks and appropriately trained medical specialists	Hospital networks and appropriately trained medical specialists
Anatomical region of interest	Abdomen	Abdomen
Data acquisition protocol	Abdominal CT images	Abdominal CT images
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 IFG**	**Predicate Device** **Aidoc Briefcase-Triage for IFG (K193298)**
Inclusion/ Exclusion criteria for clinical performance testing	<u>Inclusion criteria</u> ● CT studies of the abdomen. ● Scans performed on adults/transitional adults ≥ 18 years of age. ● Slice thickness 0.6 mm-5 mm. <u>Exclusion Criteria</u> ● All studies that have an inadequate field of view	<u>Inclusion criteria</u> ● Scans performed on adults/transitional adults ≥ 18 years of age. ● Scans performed on CT scanners with 64 or greater number of detectors. ● CT studies of the abdomen. ● Slice thickness 0.625 mm-5 mm axial. <u>Exclusion Criteria</u> ● All scans that are technically inadequate, including motion artifacts, severe metal artifacts, or an inadequate field of view.
Additional Operating Points	4 Additional Operating Points	N/A
Algorithm	Artificial intelligence algorithm with database of images.	Artificial intelligence algorithm with database of images.
Structure	- Integrated with image routing module via image communication platform (ICP) (image acquisition). - Algorithm module (image processing) - Integrated with desktop application for workflow integration (feed and non-diagnostic Image Viewer).	- AHS module (image acquisition); - ACS module (image processing); - Aidoc Desktop Application for workflow integration (Feed/Worklist (alternate names) and non-diagnostic Image Viewer).

Performance Data

Pivotal Study Summary

Aidoc conducted a retrospective, blinded, multicenter study with the Briefcase-Triage software to evaluate the software's performance in identifying abdominal CT images in 394 cases from 6 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. 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 94.2% (95% CI: 89.6%, 97.2%) and Specificity was 94.6% (95% CI: 90.7%, 97.2%) meeting the study's primary endpoints.

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). 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 IFG triage was 10.4 seconds (95% CI: 10.1-10.8) . The time-to-notification for the predicate IFG was 264.4 seconds (95% CI: 222-300).

As can be seen in **Table 2** the mean age of patients whose scans were reviewed for IFG was 56.7 years, with a standard deviation of 18.7 years. Gender distribution was 46.8% male, and 53.2% female (**Table 3**). Scanner and slice thickness distribution can also be found in **Tables 4-5** below.

Device performance has been validated primarily on images acquired from CT scanners with 64 or more detector rows (388 cases from scanners with >=64 detectors and 6 cases from scanners with <64 detectors). Performance may vary with other scanner types**.**

Table 2. Descriptive Statistics for Age

	Mean	Std	Min	Median	Max	N
Age (Years)	56.7	18.7	18	60	90	394

Table 3. Frequency Distribution of Gender

Ground Truth Results	Gender				All	
	Female		Male			
	N	%	N	%	N	%
Positive	77	19.8%	93	23.9%	170	43.7%
Negative	130	33.4%	89	22.9%	219	56.3%
All	207	53.2%	182	46.8%	389	100.0%

Table 4. Frequency Distribution of Manufacturer

Manufacturer	N	%
Philips	133	33.8%
SIEMENS	101	25.6%
GE MEDICAL SYSTEMS	90	22.8%
TOSHIBA	70	17.8%
Total	394	100%

Table 5. Frequency Distribution of Slice Thickness

Slice Thickness (mm)	N	%
0.6-1.5	39	9.9%
1.5-2.5	139	35.3%

Slice Thickness (mm)	N	%
2.5-5	216	54.8%
Total	394	100%

Clinical Subgroups and Confounders:

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

Table 6. Sensitivity Poolability Across Sites and Regions with Associated Two-sided 95% Confidence Limits (Efficacy Population)

Sensitivity					
Site	Total N	Truly Diagnosed	Estimate	Lower Confidence Limit	Upper Confidence Limit
Site 1	32	29	90.6%	75.0%	98.0%
Site 2	26	24	92.3%	74.9%	99.1%
Site 3	29	27	93.1%	77.2%	99.2%
Site 4	29	29	100.0%	88.1%	100.0%
Site 5	29	29	100.0%	88.1%	100.0%
Site 6	28	25	89.3%	71.8%	97.7%
all	173	163	94.2%	89.6%	97.2%

Table 7. Specificity Poolability Across Sites and Regions with Associated Two-sided 95% Confidence Limits (Efficacy Population)

Specificity					
Site	Total N	Truly Diagnosed	Estimate	Lower Confidence Limit	Upper Confidence Limit
Site 1	35	34	97.1%	85.1%	99.9%
Site 2	34	32	94.1%	80.3%	99.3%
Site 3	36	35	97.2%	85.5%	99.9%
Site 4	37	33	89.2%	74.6%	97.0%
Site 5	42	39	92.9%	80.5%	98.5%
Site 6	37	36	97.3%	85.8%	99.9%
all	221	209	94.6%	90.7%	97.2%

Table 8. Sensitivity Poolability Across Slice thicknesses with Associated Two-sided 95% Confidence Limits (Efficacy Population)

Sensitivity					
Slice Thickness [mm]	Total N	Truly Diagnosed	Estimate	Lower Confidence Limit	Upper Confidence Limit
0.6-1.5	22	20	90.9%	70.8%	98.9%
1.5-2.5	61	56	91.8%	81.9%	97.3%
2.5-5	90	87	96.7%	90.6%	99.3%
all	173	163	94.2%	89.6%	97.2%

Table 9. Specificity Poolability Across Slice thicknesses with Associated Two-sided 95% Confidence Limits (Efficacy Population)

Specificity					
Slice Thickness [mm]	Total N	Truly Diagnosed	Estimate	Lower Confidence Limit	Upper Confidence Limit
0.6-1.5	17	16	94.1%	71.3%	99.9%
1.5-2.5	78	75	96.2%	89.2%	99.2%
2.5-5	126	118	93.7%	87.9%	97.2%
all	221	209	94.6%	90.7%	97.2%

Table 10. Sensitivity Poolability Across Contrast Protocol with Associated Two-sided 95% Confidence Limits (Efficacy Population)

Sensitivity					
Protocol	Total N	Truly Diagnosed	Estimate	Lower Confidence Limit*	Upper Confidence Limit
W IV W Oral	38	35	92.1%	78.6%	98.3%
W IV WO Oral	82	78	95.1%	88.0%	98.7%
WO IV W Oral	11	11	100.0%	71.5%	100.0%
WO IV WO Oral	42	39	92.9%	80.5%	98.5%
all	173	163	94.2%	89.6%	97.2%

*Lower confidence bounds may fall below 80% in small subgroups due to limited sample size

Table 11. Specificity Poolability Across Contrast Protocol with Associated Two-sided 95% Confidence Limits (Efficacy Population)

Specificity					
Protocol	Total N	Truly Diagnosed	Estimate	Lower Confidence Limit*	Upper Confidence Limit
W IV W Oral	32	30	93.8%	79.2%	99.2%
W IV WO Oral	107	101	94.4%	88.2%	97.9%
WO IV W Oral	10	10	100.0%	69.2%	100.0%
WO IV WO Oral	72	68	94.4%	86.4%	98.5%
all	221	209	94.6%	90.7%	97.2%

*Lower confidence bounds may fall below 80% in small subgroups due to limited sample size

Table 12. Sensitivity Poolability Across manufacturers with Associated Two-sided 95% Confidence Limits (Efficacy Population)

Sensitivity					
Scanner	Total N	Truly Diagnosed	Estimate	Lower Confidence Limit	Upper Confidence Limit
GE	43	41	95.3%	84.2%	99.4%
Philips	61	56	91.8%	81.9%	97.3%
SIEMENS	40	39	97.5%	86.8%	99.9%
TOSHIBA	29	27	93.1%	77.2%	99.2%
all	173	163	94.2%	89.6%	97.2%

Table 13. Specificity Poolability Across Manufacturers with Associated Two-sided 95% Confidence Limits (Efficacy Population)

Specificity					
Scanner	Total N	Truly Diagnosed	Estimate	Lower Confidence Limit	Upper Confidence Limit
GE	47	46	97.9%	88.7%	99.9%
Philips	72	69	95.8%	88.3%	99.1%
SIEMENS	61	55	90.2%	79.8%	96.3%

Specificity					
Scanner	Total N	Truly Diagnosed	Estimate	Lower Confidence Limit	Upper Confidence Limit
TOSHIBA	41	39	95.1%	83.5%	99.4%
all	221	209	94.6%	90.7%	97.2%

Table 14. Sensitivity by Covariates Levels with Associated Two-sided 95% Confidence Limits (Efficacy Population)

	Sensitivity					
Covariate	Level	Total N	Truly Diagnosed	Estimate	Lower Confidence Limit	Upper Confidence Limit
Age	Age (Years) ≤70	125	120	96.0%	90.9%	98.7%
	Age (Years)>70	48	43	89.6%	77.3%	96.5%
Gender*	Male	93	86	92.5%	85.1%	96.9%
	Female	77	74	96.1%	89.0%	99.2%

* 3 cases were unknown for gender.

Table 15. Specificity by Covariates Levels with Associated Two-sided 95% Confidence Limits (Efficacy Population)

	Specificity					
Covariate	Level	Total N	Truly Diagnosed	Estimate	Lower Confidence Limit	Upper Confidence Limit
Age	Age (Years) ≤70	170	162	95.3%	90.9%	97.9%
	Age (Years)>70	51	47	92.2%	81.1%	97.8%
Gender*	Male	89	81	91.0%	83.1%	96.0%
	Female	130	127	97.7%	93.4%	99.5%

* 2 cases were unknown for gender.

Additional Operating Points:

In addition to the default (balanced) operating point that was selected to maximize both sensitivity and specificity, a total of five additional operating points (AOP1-AOP5) allowing to enhance sensitivity or specificity while maintaining a threshold of >80% for both sensitivity and specificity respectively, demonstrating that the pre-specified performance goals were met. AOP1 corresponds to the highest sensitivity point estimate with acceptable specificity. AOP5 corresponds to the highest specificity point estimate with acceptable sensitivity. AOP2-AOP4 represent operating points between the two, while maintaining acceptable performance.

Table 16. Sensitivity and Specificity with Associated Two-sided 95% Confidence Limits

Operating Point	Parameter	N	Estimate	95% Lower CL	95% Upper CL
AOP1	Sensitivity	173	98.8%	95.9%	99.9%
	Specificity	221	91.9%	87.4%	95.1%
AOP2	Sensitivity	173	96.0%	91.8%	98.4%
	Specificity	221	92.8%	88.5%	95.8%
AOP3	Sensitivity	173	91.9%	86.8%	95.5%
	Specificity	221	95.0%	91.3%	97.5%
AOP4	Sensitivity	173	86.1%	80.1%	90.9%
	Specificity	221	95.9%	92.4%	98.1%
AOP5	Sensitivity	173	82.1%	75.5%	87.5%
	Specificity	221	96.8%	93.6%	98.7%

In summary, performance goals were achieved for the default and five additional operating points. Combined with the comparison results of time-to-notification metric with the predicate device, these

results demonstrate that the subject Briefcase-Triage effectively enables preemptive triage.

Cybersecurity

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

Conclusions

The subject Briefcase-Triage for IFG and the predicate Briefcase for IFG (K193298) 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 IFG is thus substantially equivalent to the primary predicate Briefcase for IFG (K193298).