Aidoc Medical, Ltd.
℅ John Smith
Partner
Hogan Lovells U.S. LLP
555 Thirteenth Street NW
WASHINGTON, DISTRICT OF COLUMBIA 20004

October 30, 2023

Re: K232751
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: September 8, 2023
Received: September 8, 2023

Dear John Smith:

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

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

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

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

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

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
Assistant Director
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023

See PRA Statement below

510(k) Number *(if known)*

K232751

Device Name

BriefCase-Triage

Indications for Use *(Describe)*

BriefCase-Triage is a radiological computer-aided triage and notification software indicated for use in the analysis of CTPA 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 communicating suspected positive cases of Central Pulmonary Embolism (Central PE).

BriefCase-Triage uses an artificial intelligence algorithm 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 Central PE 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.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
Aidoc Medical, Ltd.'s BriefCase-Triage
K232751

Submitter:

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Phone: +972-73-7946870

Contact Person: Amalia Schreier, LL.M.

Date Prepared: October 16, 2023

Name of Device: BriefCase-Triage

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

Regulatory Class: Class II

Product Code: QAS (21 C.F.R. 892.2080)

Primary Predicate Device: Rapid PE Triage and Notification (PETN) (K220499)

Reference Device: BriefCase of Pulmonary Embolism (PE) (K222277)

Device Description

BriefCase-Triage is a radiological computer-assisted triage and notification software device. The software is based on an algorithm programmed component and is intended to run on a linux-based server in a cloud environment.

The BriefCase-Triage receives filtered DICOM images, and processes them chronologically by running the algorithms on each series to detect suspected cases. Following the AI processing, the output of the algorithm analysis is transferred to an image review software (desktop application). When a suspected case is detected, the user receives a pop-up notification and is presented with a compressed, low-quality, grayscale image that is captioned "not for diagnostic use, for prioritization only" which is displayed as a preview function. This preview is meant for informational purposes only, does not contain any marking of the findings, and is not intended for primary diagnosis beyond notification.

Presenting the users with worklist prioritization facilitates efficient triage by prompting the user to assess the relevant original images in the PACS. Thus, the suspect case receives attention earlier than would have been the case in the standard of care practice alone.

The algorithm was trained during software development on images of the pathology. As is customary in the field of machine learning, deep learning algorithm development consisted of training on manually

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

Intended Use / Indications for Use

BriefCase-Triage is a radiological computer-aided triage and notification software indicated for use in the analysis of CTPA 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 communicating suspected positive cases of Central Pulmonary Embolism (Central PE).

BriefCase-Triage uses an artificial intelligence algorithm 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 Central PE 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.

Comparison of Technological Characteristics

The subject BriefCase-Triage of Central Pulmonary Embolism (Central PE) is substantially similar to primary predicate Rapid PE Triage and Notification (PETN) (K220499) and is similar to reference device BriefCase of Pulmonary Embolism (PE) (K222277), as explained below.

The subject, predicate and the reference devices are radiological computer-aided triage and notification software programs. All devices are artificial intelligence, deep-learning algorithms incorporated in software packages for use with DICOM compliant CT scanners, PACS, and radiology workstations. The subject and the reference devices differ in the fact the SW architecture was changed to separate the image communication platform from the BriefCase-Triage SW. The subject device consists of only the algorithm analysis module which can be integrated with image communication platforms that meet the BriefCase-Triage input and output requirements.

All 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. All 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, predicate and reference 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 and reference devices, the subject device neither removes cases from the standard of care reading queue nor de-prioritizes cases. All 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

	Predicate Device Rapid PE Triage and Notification (PETN) (K220499)	**Reference Device BriefCase-Triage for PE triage (K222277)**	**Subject Device Aidoc BriefCase-Triage of Central Pulmonary Embolism (Central PE)**
Intended Use / Indications for Use	Rapid PE Triage and Notification (PETN) is a radiological computer aided triage and notification software indicated for use in the analysis of CTPA images. The device is intended to assist hospital networks and trained clinicians in workflow triage by flagging and communication of suspected positive findings of central pulmonary embolism (PE) pathology in adults. The software is only intended to be used on single-energy exams. Rapid PETN uses an artificial intelligence algorithm to analyze images and highlight cases with detected findings on a server or standalone desktop application in parallel to the ongoing standard of care image interpretation. The	BriefCase is a radiological computer aided triage and notification software indicated for use in the analysis of CTPA 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 Pulmonary Embolism (PE) 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.	BriefCase-Triage is a radiological computer-aided triage and notification software indicated for use in the analysis of CTPA 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 communicating suspected positive cases of Central Pulmonary Embolism (Central PE). BriefCase-Triage uses an artificial intelligence algorithm 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 Central PE findings. Notifications include

	Predicate Device Rapid PE Triage and Notification (PETN) (K220499)	Reference Device BriefCase-Triage for PE triage (K222277)	Subject Device Aidoc BriefCase-Triage of Central Pulmonary Embolism (Central PE)
	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 Rapid PETN 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. Rapid PETN is validated for use on GE, Siemens and Toshiba scanners.	The user is presented with notification 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 images. Notified clinicians are responsible for viewing full images per the standard of care.	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.

	Predicate Device Rapid PE Triage and Notification (PETN) (K220499)	Reference Device BriefCase-Triage for PE triage (K222277)	Subject Device Aidoc BriefCase-Triage of Central Pulmonary Embolism (Central PE)
User population	Hospital networks and trained clinicians	Hospital networks and appropriately trained medical specialists	Hospital networks and appropriately trained medical specialists
Anatomical region of interest	Chest	Chest	Chest
Data acquisition protocol	CTPA	CTPA	CTPA
Notification-only, parallel workflow tool	Yes	Yes	Yes
Interference with standard workflow	No	No	No
Algorithm	Artificial intelligence algorithm with database of images.	Artificial intelligence algorithm with database of images.	Artificial intelligence algorithm with database of images.
Structure	- The Rapid PETN module operates within the integrated Rapid Platform and uses the basic services supplied by the Rapid Platform including DICOM processing, job management, imaging module execution and imaging output.	- AHS module (image acquisition); - ACS module (image processing); - Aidoc Desktop Application for workflow integration (Feed/Worklist (alternate names) 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

	Predicate Device Rapid PE Triage and Notification (PETN) (K220499)	Reference Device BriefCase-Triage for PE triage (K222277)	Subject Device Aidoc BriefCase-Triage of Central Pulmonary Embolism (Central PE)
			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 CTPA images containing Central Pulmonary Embolism (Central PE) in 328 cases from unique patients, 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, using majority voting. The cases collected for the pivotal dataset were all distinct in time or center from the cases used to train the algorithm.

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 and specificity exceeded the 80% performance goal. Sensitivity was 89.2% (95% CI: 82.5%, 93.9%) and specificity was 94.5% (95% CI: 90.3%, 97.2%).

Secondary Endpoint

In addition, the time-to-notification metric observed for the BriefCase-Triage software, when integrated with a compatible image communication platform, was compared to the equivalent metric of the predicate devices. The BriefCase-Triage time-to-notification includes the time to get the DICOM exam, de-identify it, upload it to the cloud, analyze and send a notification on a positive suspect case back to the desktop application.

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

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 Central PE triage was 29.3 seconds (95% CI: 26.8-31.9). The time-to-notification for the predicate Rapid PE Triage and Notification (PETN) was 158.4 seconds (95% CI: 140.4-288).

Table 2. Time-to- Notification Comparison for BriefCase-Triage and Predicate Devices (Seconds)

Time -to-notification	N	Mean Estimate	95% Lower CL	95% Upper CL	Median	IQR
Predicate Rapid PE Triage and Notification (PETN) Processing Time	306	158.4	140.4	288	N/A	N/A
BriefCase-Triage + Image Communication Platform Time-To-Notification	115	29.3	26.8	31.9	28.0	20.2

NPV was 99.2% (95% CI: 98.7%- 99.5%) and PPV was 52.9% (95% CI: 38.6%- 66.6%).

PLR was 16.1 (95% CI: 9.1- 28.7 and NLR was 0.1 (95% CI: 0.1- 0.2).

Thus, the reported similar time-to-notification data demonstrates that when using the subject BriefCase-Triage for Central PE the clinician may have the same benefit in time saving as with the predicate Rapid PE Triage and Notification (PETN).

As can be seen in **Table 3** the mean age of patients whose scans were reviewed for Central PE was 60.3 years, with a standard deviation of 17.4 years. Gender distribution was 44.5% male, and 55.5% female (**Table 4**). Scanner distribution can also be found in **Table 5** below.

Table 3. Descriptive Statistics for Age

	Mean	Std	Min	Median	Max	N
Age (Years)	60.3	17.4	19	63	90	328

Table 4. Frequency Distribution of Gender

Ground Truth Results	Gender				All	
	Male		Female			
	N	%	N	%	N	%
Positive	65	19.8%	64	19.5%	129	39.3%
Negative	117	35.7%	82	25.0%	199	60.6%
All	182	55.5%	146	44.5%	328	100.0%

Table 5. Frequency Distribution of Manufacturer

Manufacturer	N	%
Philips	99	30.2%
GE MEDICAL SYSTEMS	90	27.4%
SIEMENS	78	23.8%
TOSHIBA	61	18.6%
Total	**328**	**100%**

Clinical Subgroups and Confounders:

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

Additional Operating Point:

In addition to the default operating point one additional operating point was selected to maximize sensitivity, while maintaining a lower bound 95% confidence interval of 80% for specificity and sensitivity.

AOP1: Sensitivity was 96.9% (95% CI: 92.3%-99.2%) and specificity was 85.9% (95% CI: 80.3%-90.4%).

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

Conclusions

The subject BriefCase-Triage of Central Pulmonary Embolism (Central PE), the predicate Rapid PE Triage and Notification (PETN) and the reference BriefCase for PE triage devices are intended to aid in prioritization and triage of radiological images for the indications for suspected positive findings of Pulmonary Embolism (the subject and predicate device specifically aid in Central PE). All devices are software packages consisting of deep learning AI algorithms that process images and produce analysis results, which are displayed to the user by a prioritization alert and a compressed, low-quality, grayscale, unannotated preview image. In all 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.

All 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. All 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 of Central Pulmonary Embolism (Central PE) triage is thus substantially equivalent to the predicate Rapid PE Triage and Notification (PETN) and the reference BriefCase for PE triage.