**510(k) Summary**
**Aidoc Medical, Ltd.'s BriefCase (K190072)**

**Submitter:**

Aidoc Medical, Ltd.
92 Yigal Alon St.
Tel-Aviv, Israel
Phone: +972-73-7946870

Contact Person: N. Epstein, Ph.D.

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**Name of Device:** BriefCase

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

**Regulatory Class:** Class II

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

**Predicate Device:** BriefCase (K180647, for ICH triage)

**Device Description**

BriefCase is a radiological computer-assisted triage and notification software device. The software system is based on an algorithm programmed component and is comprised of a standard off-the-shelf operating system, the Microsoft Windows server 2012 64bit, and additional applications, which include PostgreSQL, DICOM module and the BriefCase Image Processing Application. The device consists of the following three modules: (1) Aidoc Hospital Server (AHS); (2) Aidoc Cloud Server (ACS); and (3) Aidoc Worklist Application that is installed on the radiologist' desktop and provides the user interface in which notifications from the BriefCase software are received.

DICOM images are received, saved, filtered and de-identified before processing. Series are processed chronologically by running an algorithm on each series to detect suspected findings and then notifications on flagged series are sent to the Worklist desktop application, thereby prompting preemptive triage and prioritization.

The Worklist Application displays the pop-up text notifications of new studies with suspected findings when they come in. Notifications are in the form of a small pop-up containing patient name, accession number and the relevant pathology (e.g., PE). A list of all incoming cases with suspected findings is also displayed. Hovering over a notification or a case in the worklist pops up a compressed, small black and white, unmarked image that is captioned "not for diagnostic use" and is displayed as a preview function. This compressed 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 radiologist with notification facilitates earlier 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.

**Intended Use / Indications for Use**

BriefCase is a radiological computer aided triage and notification software indicated for use in the analysis of non-enhanced head CT and CTPA images. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communication of Intracranial Hemorrhage (ICH) and Pulmonary Embolism (PE) pathologies. For the PE pathology, the software is only intended to be used on single-energy exams.

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 images. Notified clinicians are responsible for viewing full images per the standard of care.

**Comparison of Technological Characteristics**

The subject BriefCase for PE triage and predicate device BriefCase for ICH triage (K180647) are identical in all aspects and defer only with respect to the training of the algorithm on PE and ICH images, respectively.

Both devices are radiological computer-aided triage and notification software programs. Both devices are artificial intelligence algorithms incorporated software packages for use with CT scanners, PACS, and radiology workstations. As noted above, both devices are intended to aid in triage and prioritization of radiological images. The predicate device processes head CTs and is indicated for intracranial hemorrhage triage, while the subject device also processes CTPA images and is indicated for Pulmonary Embolism triage. Both devices are intended to provide radiologists with notifications and unannotated preview images of suspect studies for the purpose of preemptive triage.

In addition, both software devices notify the attending radiologist of the availability of time sensitive radiological medical images for review based on computer aided image analysis. Both devices send notifications and compressed previews to the radiology workstations' desktop. Notifications are meant to prompt the radiologist to start preemptive triage of a flagged case, upon which he may decide after observing the unannotated, low quality preview on his desktop, to turn to the local PACS to perform evaluation of the original series earlier than would have been the case without BriefCase.

Thus, the subject and predicate BriefCase raise the same types of safety and effectiveness questions, namely, accurate detection of findings within the processed study. It is important to note that, like the predicate, the subject device does not remove cases from the standard of care reading queue. 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 predicate devices is provided below.

**Table 1.** Key feature comparison

| | **Predicate Device**<br>**Aidoc Briefcase for ICH triage (K180647)** | **Subject Device**<br>**Aidoc Briefcase for ICH and PE triage** |
|---|---|---|
| Intended Use / Indications for Use | BriefCase is a radiological computer aided triage and notification software indicated for use in the analysis of non-enhanced head 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 pathologies in head CT images, namely Intracranial Hemorrhage (ICH).<br><br>BriefCase uses an artificial intelligence algorithm to analyze images and highlight cases with detected ICH 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 ICH findings. Notifications include compressed preview images that are meant for informational purposes only and not intended for diagnostic use eyond notification. The device does not alter the original medical image and is not intended to be used as a diagnostic device.<br><br>The results of BriefCase are intended to be used in conjunction with other patient information and based on professional judgment, to assist with triage/prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care. | BriefCase is a radiological computer aided triage and notification software indicated for use in the analysis of non-enhanced head CT and CTPA images. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communication of suspected positive findings of Intracranial Hemorrhage (ICH) and Pulmonary Embolism (PE) pathologies. For the PE pathology, the software is only intended to be used on single-energy exams.<br><br>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.<br><br>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. |
| User population | Radiologist | Radiologist |
| Anatomical region of interest | Head | Head and chest |
| Data acquisition protocol | Non-contrast head CT scan | Non-contrast head CT scan and CTPA (single energy exams only) |
| View DICOM data | DICOM Information about the patient, study and current image | DICOM Information about the patient, study and current image |
| Segmentation of region of interest | No; device does not mark, annotate, or direct users' attention to a specific location in the original image | No; device does not mark, annotate, or direct users' attention to a specific location in the original image |
| Algorithm | Artificial intelligence algorithm with database of images | Artificial intelligence algorithm with database of images |
| Notification/Prioritization | Yes | Yes |

| | | |
|---|---|---|
| Preview images | Presentation of a small, compressed, black and white preview image that is labeled "Not for diagnostic use";<br>The device operates in parallel with the standard of care, which remains the default option for all cases. | Presentation of a small, compressed, black and white preview image that is labeled "Not for diagnostic use";<br>The device operates in parallel with the standard of care, which remains the default option for all cases. |
| Alteration of original image | No | No |
| Removal of cases from worklist queue | No | No |

**Performance Data**

*Pilot Study Summary*
The company conducted a retrospective evaluation of 2,803 CT pulmonary angiogram (CTPA) exams of patients with suspected PE, from a single center. The goal of this study was primarily to demonstrate that the BriefCase software can identify PE with high accuracy. Ground truth was determined by a review of a single radiologist and the radiology report. Another radiologist was used to break ties between the report and the reviewer.

Performance Endpoints: Specificity and sensitivity.

*Pilot Study Results*
Sensitivity was 93.0% (95% CI: 90.2%-95.1%). Specificity was 93.7% (95% CI: 92.7%-94.6%).

*Pivotal Study Summary*
Aidoc conducted a retrospective, blinded, multicenter, multinational study with the BriefCase software with the primary endpoint to evaluate the software's performance in identifying CTPAs containing pulmonary embolism in 184 cases from 3 clinical sites (2 US and 1 OUS). There were approximately an equal number of positive and negative cases (images with PE versus without PE) included in the analysis.

Sensitivity and specificity exceeded the 80% performance goal. Specifically, sensitivity was observed to be 90.6% (95% CI: 82.2%-95.9%) and specificity was observed to be 89.9% (95% CI: 82.2%-95.1%).

In addition, a secondary endpoint measure was Briefcase's potential clinical benefit of worklist prioritization for true positive PE cases. For that purpose, in two medical centers, one in Israel and one in the US, Aidoc compared the standard-of-care metric of time-to-exam-open to the software's time-to-notification metric for PE cases.

The BriefCase time-to-notification includes the time to get the DICOM exam, de-identify it, upload it to the cloud, analyze and send a notification back to the worklist application. The standard of care time-to-open-exam consisted of the time from the initial scan of the patient to when the radiologist first opened the exam for review.

The standard of care time-to-exam-open was compared to the BriefCase time-to-notification for 51 True Positive cases (i.e. identified as positive both by the reviewers as well as the BriefCase device), and the results are reported in the **Table 2** below.

The BriefCase time-to-notification for PE was 3.9 minutes (95% CI: 3.7-4.1). In contrast, standard

of care time-to-exam-open was much longer (64.1 minutes: 95% CI 36.6-91.5). The mean difference of 60.2 minutes (95% CI 32.7-87.6) for these two metrics is statistically significant and assuming the radiologist receives a notification on a true positive PE case and acts on it immediately, it can on average save 60.2 minutes (95% CI 32.7-87.6) compared to the time-to-exam-open in a FIFO reading queue. The value of 60.2 is based on the study of 51 cases, taken from 2 medical centers (1 US, 1 OUS), and may vary in practice.

**Table 2**. Time saving data

| Parameter | N | Mean estimate | Lower Confidence Limit | Upper Confidence Limit | Median | P-value |
|---|---|---|---|---|---|---|
| Time-to-open-exam in the standard of care | 51 | 64.1 | 36.6 | 91.5 | 49.0 | |
| Time-to-notification of BriefCase PE | 51 | 3.9 | 3.7 | 4.1 | 3.9 | |
| Difference | 51 | 60.2 | 32.7 | 87.6 | 45.2 | <0.0001 |

Thus, the reported time savings data demonstrates that radiologists may have the opportunity to be involved in the clinical workflow substantially earlier thanks to the notifications from the BriefCase device.

In summary, performance validation data, combined with real-world evidence, establish the achievement of effective preemptive triage by the BriefCase image analysis algorithm as well as effective notification functionality of the BriefCase application, as compared to the standard of care for improved time-to-exam-open of a notified case.

**Conclusions**

The subject BriefCase for PE triage and the predicate BriefCase for ICH triage devices are both intended to aid in prioritization and triage of radiological medical images for the indications of Pulmonary Embolism and Intracranial Hemorrhage, respectively. The labeling of both devices clearly states that the devices are not for diagnostic use. Both devices are software packages with similar technological characteristics and principles of operation, incorporating deep learning AI algorithms that process images, and software to send notifications and unannotated compressed preview images to the radiologists' workstation. In both devices, the labeling 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, and do not remove images from the standard of care FIFO queue, thus not disturbing standard interpretation of the images by the attending radiologists. Both devices achieve reduction of the standard of care time-to-open-exam to several minutes, which is the BriefCase' time-to-notification, and thus contribute similarly to the standard of care workflow turnaround time reduction through preemptive triage.

The BriefCase device for PE triage is thus substantially equivalent to the BriefCase for ICH triage.