



Aidoc Medical, Ltd.
% John Smith
Regulatory Counsel
Hogan Lovells US LLP
555 Thirteenth Street NW
Washington, District of Columbia 20004

December 20, 2019

Re: K192383

Trade/Device Name: BriefCase
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological Computer Aided Triage And Notification Software
Regulatory Class: Class II
Product Code: QAS
Dated: November 22, 2019
Received: November 22, 2019

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K192383

Device Name

BriefCase

Indications for Use (Describe)

BriefCase is a radiological computer aided triage and notification software indicated for use in the analysis of head CTA images. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communication of suspected positive findings of Large Vessel Occlusion (LVO) 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 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 (K192383)

Submitter:

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Phone: +972-73-7946870

Contact Person: N. Epstein, Ph.D.

Date Prepared: December 16, 2019

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)

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

Secondary Predicate Device: ContaCT (DEN170073)

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) for image acquisition; (2) Aidoc Cloud Server (ACS) for image processing; and (3) Aidoc Worklist Application for workflow integration, 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 user may opt to filter out notifications by pathology, e.g. a chest radiologist may choose to filter out notifications on Large Vessel Occlusion (LVO) cases, and a neuro-radiologist would opt to divert Pulmonary Embolism (PE) notifications. In addition, where several medical centers are linked to a shared PACS, a user may read cases for a certain center but not for another, and thus may opt to filter out notification by center. Activating the filter does not impact the order in which notifications are presented in the Aidoc worklist application.

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., LVO). 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 head CTA images. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communication of suspected positive findings of Large Vessel Occlusion (LVO) 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 images. Notified clinicians are responsible for viewing full images per the standard of care.

Comparison of Technological Characteristics

The subject BriefCase for LVO triage and primary predicate BriefCase for ICH triage (K180647) are identical in all aspects and differ only with respect to the training of the algorithm on LVO and ICH images, respectively. The addition of a notification filter feature to the software platform design is considered a minor change which does not alter the safety and efficacy profile of the device.

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. 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. They differ only with regard to the training on image type, specifically, the predicate device processes head CTs and is indicated for intracranial hemorrhage triage, while the subject device processes head CTA images and is indicated for Large Vessel Occlusion (LVO) triage. Both devices are intended to provide radiologists with notifications and unannotated low-quality preview images of suspect studies for the purpose of preemptive triage.

Both software devices notify the attending radiologist of the availability of time sensitive radiological images for review based on computer aided image analysis. Both devices send notifications within the range of several minutes from the time a case comes in for processing as well as 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 (captioned “not for diagnostic use”), 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 primary 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.

In addition, it is also important to note that the proposed indications for use are substantially equivalent to a secondary predicate, the ContaCT device (DEN170073), which is cleared for LVO triage. Both devices send triage notifications as well as compressed preview images within the range of several minutes from the time a case comes in for processing. A table comparing the key features of the subject and the predicate devices is provided below.

The ContaCT differs from the subject device regarding the party receiving the notifications. While the ContaCT sends notifications on time-sensitive cases with a critical finding to a neurovascular specialist, the subject device sends them to the radiologist who then contacts a specialist (neurologist, neuro-interventionalist or any other clinician capable of treating stroke patients). Yet, there is clinical benefit in the subject workflow similar to alerting a radiologist of an ICH (or an LVO in this case). Thus, it is relevant to report time-to-notification to alert a radiologist, as well as estimate the time-to-open, based on the alert and worst-case assumption for responding. In addition, the subject device features a notification filter that enables the user to refrain from receiving certain notifications, per pathology or per center.

Lastly, again, all three devices do not remove cases from the standard reading queue and are operating in parallel to the standard of care, which remains the default option for all cases.

Table 1. Key feature comparison

	Subject Device Aidoc Briefcase for LVO triage	Primary Predicate Device Aidoc Briefcase for ICH triage (K180647)	Secondary Predicate Device Viz.AI ContaCT Software (DEN170073)
<p>Intended Use / Indications for Use</p>	<p>BriefCase is a radiological computer aided triage and notification software indicated for use in the analysis of head CTA images. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communication of suspected positive findings of Large Vessel Occlusion (LVO) pathologies.</p> <p>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.</p> <p>The results of BriefCase are intended to be used in conjunction with other patient information and based on their professional judgment, to assist with</p>	<p>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).</p> <p>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 beyond notification. The device does not alter the original medical image and is not intended to be used as a diagnostic device.</p> <p>The results of BriefCase are intended to be used in conjunction with other patient information and based on</p>	<p>ContaCT is a notification-only, parallel workflow tool for use by hospital networks and trained clinicians to identify and communicate images of specific patients to a specialist, independent of standard of care workflow.</p> <p>ContaCT uses an artificial intelligence algorithm to analyze images for findings suggestive of a pre-specified clinical condition and to notify an appropriate medical specialist of these findings in parallel to standard of care image interpretation. Identification of suspected findings is not for diagnostic use beyond notification. Specifically, the device analyzes CT angiogram images of the brain acquired in the acute setting and sends notifications to a neurovascular specialist that a suspected large vessel occlusion has been identified and recommends review of those images. Images can be previewed through a mobile application.</p> <p>Images that are previewed through the mobile application are compressed and are for informational purposes only and not intended for diagnostic use beyond notification. Notified clinicians are responsible for viewing</p>

	<p>triage/prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care.</p>	<p>professional judgment, to assist with triage/prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care.</p>	<p>non-compressed images on a diagnostic viewer and engaging in appropriate patient evaluation and relevant discussion with a treating physician before making care-related decisions or requests. ContaCT is limited to analysis of imaging data and should not be used in-lieu of full patient evaluation or relied upon to make or confirm diagnosis.</p>
User population	Radiologist	Radiologist	Clinician (e.g., neurovascular specialist)
Anatomical region of interest	Head	Head	Head
Inclusion/Exclusion criteria	<p>Inclusion criteria</p> <ul style="list-style-type: none"> • Head CTA protocol with a 64-slice scanner or higher; • Scans performed on adults/transitional adults ≥ 18 years of age; • Slice thickness 0.5 mm – 1.0 mm. <p>Exclusion Criteria</p> <ul style="list-style-type: none"> • All scans that are technically inadequate, including motion artifacts, severe metal artifacts, sub-optimal bolus timing or an inadequate field of view. 	<p>Inclusion Criteria</p> <ul style="list-style-type: none"> • Head non-enhanced CT (NECT) with a 64-slice scanner or higher; • Scans performed on adults/transitional adults ≥ 18 years of age; • Slice thickness 0.625 mm to 5.1 mm. <p>Exclusion Criteria</p> <ul style="list-style-type: none"> • All scans that are technically inadequate; including motion artifacts, severe metal artifacts, inadequate field of view, etc. 	<p>Inclusion Criteria:</p> <ul style="list-style-type: none"> • The patient is older than 22 years of age when presenting to the healthcare facility; • The images were from patients who underwent a stroke protocol assessment; <p>and</p> <ul style="list-style-type: none"> • Head and neck CTA. <p>Exclusion Criteria:</p> <p>Series used to identify potential LVOs were axial thin slice CTAs. CTA series may have been excluded because of insufficient technical quality. Exclusion criteria included:</p> <ul style="list-style-type: none"> • Series containing metal artifacts in the soft matter of the brain; • Series that are non-axial; • Series containing missing slices; • Series displaying no visible

			<p>contrast due to bad bolus timing during the series acquisition process;</p> <ul style="list-style-type: none"> • Series containing inconsistent pixel spacing; • Series containing slices thicker than 0.625mm; • Series containing improperly ordered slices (e.g. as a result of manual correction by an Imaging technician); and <p>Series containing an incomplete skull.</p>
View DICOM data	DICOM Information about the patient, study and current image	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.	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.	Artificial intelligence algorithm.
Notification/Prioritization	Yes	Yes	Yes
Preview images	Presentation of a small, compressed, black and white preview image that is labeled "Not for diagnostic use"; 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"; 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".
Alteration of original image	No	No	No
Removal of cases from worklist queue	No	No	No
Structure	- AHS module (image acquisition);	- AHS module (image acquisition);	- Image Forwarding Software

	<ul style="list-style-type: none">- ACS module (image processing);- Aidoc Worklist application for workflow integration (worklist and Image Viewer). <p>Addition of minor changes in the software platform, e.g. notification filter, which neither impacts the order in which notification come in, nor affects the safety and efficacy profile of the device.</p>	<ul style="list-style-type: none">- ACS module (image processing);- Aidoc Worklist application for workflow integration (worklist and Image Viewer).	<ul style="list-style-type: none">- Image Processing and Analysis Software- Non-diagnostic DICOM viewing mobile application
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Performance Data

Pivotal Study Summary

Aidoc conducted a retrospective, blinded, multicenter, study with the BriefCase software to evaluate the software's performance in identifying head CTA images containing Large Vessel Occlusion (LVO) in 383 cases from 3 US-based clinical sites.

Primary Endpoint

Sensitivity and specificity exceeded the 80% performance goal. Sensitivity was 88.8% (95% CI: 81.9%, 93.8 %) and specificity was 87.2% (95% CI: 82.5%, 91.1%).

Secondary Endpoint

The positive likelihood ratio (PLR) and negative likelihood ratio (NLR) are 6.9 (95% CI: 5.0-9.6) and 0.13 (95% CI: 0.1-0.2), respectively. The table below presents the positive predictive value (PPV) and negative predictive value (NPV) with varying prevalence:

Prevalence	PPV	NPV
10%	43.5%	98.6%
15%	55.0%	97.8%
20%	63.4%	96.9%
25%	69.8%	95.9%
30%	74.8%	94.8%
35%	78.9%	93.5%
40%	82.2%	92.1%
45%	85.0%	90.5%
50%	87.4%	88.6%

In addition, the time-to-notification metric observed for the BriefCase software in the three medical centers was compared to the equivalent metric of the predicate devices.

- 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 on a positive suspect case back to the worklist application.

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

The time-to-notification results obtained for the subject BriefCase device show comparability with the primary predicate with regard to time savings to the standard of care review. The BriefCase mean time-to-notification for LVO was 3.8 min (95% CI: 3.6-4.0). The time-to-notification for the BriefCase for ICH triage was 4.46 minutes (95% CL: 4.10-4.83).

Table 2. Time-to- notification comparison for BriefCase devices

Parameter	N	Mean estimate	Lower Confidence Limit	Upper Confidence Limit
Time-to-notification of BriefCase LVO	111	3.8	3.6	4.0
Time-to-notification of BriefCase ICH	59	4.46	4.10	4.83

Thus, the reported similar time-to-notification data demonstrates that when using the subject BriefCase for LVO triage the radiologists may have the same benefit in time saving as with the BriefCase for ICH triage.

In summary, performance validation data, combined with a comparison of time-to-notification metric with the predicate device establish the achievement by the subject BriefCase of preemptive triage in the range of several minutes.

Conclusions

The subject BriefCase for LVO triage, the primary predicate BriefCase for ICH triage and the secondary predicate ContaCT for LVO triage are all intended to aid in prioritization and triage of radiological images for the indications of Large Vessel Occlusion and Intracranial Hemorrhage respectively. The labeling of both the subject and the predicate devices clearly states that the devices are not for diagnostic use. Both devices are software packages with similar technological characteristics and principles of operation (with minor changes in the software platform of the subject device, such as a notification filter), both incorporating deep learning AI algorithms that process images, and software to send notifications and display unannotated compressed low-quality preview images. In all three devices, the labeling instructs the user to further evaluate and diagnose based only on the original images in the local PACS.

All three 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. The subject and the primary predicate achieve performance of time-to-notification metric in the range of several minutes, and thus contribute similarly to triage and early involvement of the radiologist in evaluating suspected images of LVO and ICH respectively.

The BriefCase device for LVO triage is thus substantially equivalent to the primary predicate BriefCase for ICH triage on time-to-notification metric.