



Aidoc Medical, Ltd.
% John J. Smith, M.D., J.D.
Regulatory Counsel/Partner
Hogan Lovells US LLP
555 Thirteenth Street, NW
WASHINGTON DC 20004

August 1st, 2018

Re: K180647

Trade/Device Name: BriefCase
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer aided triage and notification software
Regulatory Class: II
Product Code: QAS
Dated: July 5, 2018
Received: July 5, 2018

Dear Dr. 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. 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.

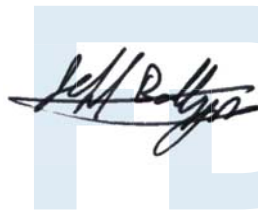
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



Digitally signed by Jeffrey J.
Ballyns -S
DN: c=US, o=U.S. Government,
ou=HHS, ou=FDA, ou=People,
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for
Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known)

K180647

Device Name

BriefCase

Indications for Use (Describe)

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) .

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.

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.

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 (K180647)

Submitter:

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Contact Person: N. Epstein, Ph.D.

Date Prepared: July 31, 2018

Name of Device: BriefCase

Classification Name: Radiological computer aided triage and notification software

Regulatory Class: Class II

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

Predicate Device: Viz.AI's 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); (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 and 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 notifications of new studies with suspected findings when they come in. Notifications are in the form of a small pop-up containing patient name and accession number. A list of all incoming cases with suspected findings is also displayed. In addition, a compressed, small black and white image that is marked "not for diagnostic use" 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 allowing one to assess the available 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 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).

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.

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.

Comparison of Technological Characteristics

The subject and predicate devices are radiological computer-assisted triage and notification software programs. Both devices are artificial intelligence algorithms incorporated software packages for use with CT scanners, PACS, and workstations. Both devices process images intended to aid in prioritization and triage of radiological medical images. The predicate device processes brain CT angiogram images and is indicated for the detection of large vessel occlusion, while the subject device processes head CT images and is indicated for Intracranial Hemorrhage. While the subject device's indications for use differ slightly from the predicate device, both devices are intended to provide notifications and preview head images of potential findings to radiologists and other clinicians for the purpose of treatment planning and follow up.

Both software devices notify a designated list of clinicians (the predicate device - a neurovascular specialist, the subject device – a radiologist) of the availability of time sensitive radiological medical images for review based on computer aided image analysis performed by the device's AI algorithm. The subject device sends notifications and compressed previews to the workstations' desktop of the radiologist. Those notifications work in parallel to the standard of care. They prompt the radiologist to start preemptive triage of a flagged case, upon which he may decide after observing the preview on his desktop, to turn to the local PACS to perform the evaluation. If a notification is rejected, the case still remains in the queue to be handled per the standard of care.

The predicate device also sends notifications and compressed previews, but to the mobile phone of a neuro-specialist independent of the standard of care, thus both devices work in parallel to the standard of care. Both compressed previews are for informational purposes only and not for diagnostic use, and in both cases, the notified clinicians are responsible for using the local imaging system for viewing the original images and engage the referring clinician for diagnosis and treatment decision.

The predicate and subject devices process CT images using similar techniques and a similar artificial intelligence algorithm. Specifically, the subject and predicate software utilize a deep learning algorithm trained on medical images. The deep-learning process allows for high accuracy in the detection of initial suspect locations. As a system, the BriefCase raises the same types of safety and effectiveness questions as the predicate; namely, accurate detection of

findings within the reviewed and processed study on which a physician can base a clinically useful triage/prioritization assessment considering all available clinical information.

It is important to note that, like the predicate, the device does not remove cases from a reading queue. Again, 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.

	Aidoc Briefcase Software	Viz.AI ContaCT Software (DEN170073)
Intended Use / Indications for Use	<p>BriefCase is a radiological computer aided triage and notification software indicated for use in the analysis of non-enhanced head CT images.</p> <p>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 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>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.</p> <p>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. Images that are previewed through the mobile application are compressed and are for informational purposes only and not intended for diagnostic use beyond notification.</p> <p>Notified clinicians are responsible for viewing 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</p>

		not be used in-lieu of full patient evaluation or relied upon to make or confirm diagnosis.
User population	Radiologist	Clinician (e.g. neurovascular specialist)
Anatomical region of interest	Head	Head
Data acquisition protocol	Non contrast CT scan of the head or neck	CT angiogram images of the brain
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, highlight, or direct users' attention to a specific location in the original image	No; device does not mark, highlight, 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 preview of the study for initial assessment not meant for diagnostic purposes The device operates in parallel with the standard of care, which remains the default option for all cases	Presentation of notification and preview of the study for initial assessment not meant for diagnostic purposes 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

Aidoc conducted a retrospective, blinded, multicenter, multinational study with the BriefCase software with the primary endpoint to evaluate the software's performance in identifying non-contrast CT head images containing intracranial hemorrhage (ICH) findings in 198 cases from 3 clinical sites (2 US and 1 OUS). There were approximately an equal number of positive and negative cases (images with ICH versus without ICH) included in the analysis.

Sensitivity and specificity exceeded the 80% performance goal. Specifically, sensitivity was observed to be 93.6% (95% CI: 86.6%-97.6%) and specificity was observed to be 92.3% (95% CI: 85.4%-96.6%).

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

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.

BriefCase time-to-notification has been documented for all 198 cases. Fifty-nine (59) cases have been identified as true positive (i.e., identified as positive by both the BriefCase and the ground truth) and the time-to-exam-open has been also collected for these cases.

As shown in the table below, analysis demonstrated that standard of care time-to-exam-open (72.6 minutes: 95% CI 45.0-100.2) is significantly longer than the parallel time-to-notification of the BriefCase software (4.5 minutes: 95% CI 4.1-4.8). The mean difference of 68.1 minutes (95% CI 40.5-95.7) for these two metrics is statistically significant and assuming the radiologist receives a notification on a true positive ICH case and acts on it immediately, it can on average save 68.1 (95% CI 40.5-95.7) minutes compared to the time-to-exam-open in a FIFO reading queue. The value of 68.1 is based on the study of 59 cases, taken from 2 medical centers (1 US, 1 OUS), and may vary in practice.

Parameter	Mean estimate	Lower Confidence Limit	Upper Confidence Limit	Median	P-value
Time-to-open-exam in the standard of care	72.58	45.02	100.14	41.00	
Time-to-notification of BriefCase	4.46	4.10	4.83	3.95	
Difference	68.11	40.50	95.72	37.42	<0.0001

In summary, performance validation data, combined with real-world evidence, establish the achievement of effective 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 and the ContaCT predicate devices are both intended to aid in prioritization and triage of radiological head medical images for the indications of Intracranial Hemorrhage and large vessel occlusion, 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 compressed preview images to pre-designated clinicians that are instructed to further evaluate the original images in the local PACS and engage the referring clinician for diagnosis.

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 trained clinicians. The minor differences between the subject device and the predicate raise no new issues of safety or effectiveness. In addition, performance testing demonstrates that the BriefCase performs as intended.

The BriefCase device is thus substantially equivalent to the ContaCT predicate.