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

March 21, 2022

Re: K213721
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: February 10, 2022
Received: February 10, 2022

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. 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

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)*

K213721

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 CT Angio (CTA) images. The device is intended to assist hospital networks and appropriately trained medical specialists in workflow triage by flagging and communication of suspected positive cases of Brain Aneurysm (BA) findings above 5 mm size.

BriefCase uses an artificial intelligence algorithm to analyze images and flag suspect cases on a standalone desktop application in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for suspect cases. 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.**

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

**Submitter:**


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

Contact Person: N. Epstein, Ph.D.


Date Prepared: November 24, 2021

**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 (ICH triage) K203508

**Device Description**

BriefCase is a radiological computer-assisted triage and notification software device. The software system is based on an algorithm programmed component and consists 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 user's desktop and provides the user interface in which notifications from the BriefCase software are received and the worklist is presented.

DICOM images are received, saved, filtered and de-identified before processing. Filtration matches metadata fields with keywords. Series are processed chronologically by running the algorithms on each series to detect suspected cases. The software then flags suspect cases by sending notifications to the Worklist desktop application, thereby prompting triage and prioritization by the user. As the BriefCase software platform harbors several triage algorithms, the user may opt to filter out notifications by pathology, e.g., a chest radiologist may choose to filter out notifications on LVO cases, and a neuro-radiologist would opt to divert PE notifications. 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., BA). 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 users with notification facilitates earlier triage by prompting them 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 CT Angio (CTA) images. The device is intended to assist hospital networks and appropriately trained medical specialists in workflow triage by flagging and communication of suspected positive cases of Brain Aneurysm (BA) findings above 5 mm size.

BriefCase uses an artificial intelligence algorithm to analyze images and flag suspect cases on a standalone desktop application in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for suspect cases. 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 BriefCase for BA triage and the predicate device BriefCase for ICH triage (K203508 - initially cleared under K180647) are identical in all aspects and defer only with respect to the training of the algorithm on BA and ICH findings, respectively.

Both devices are radiological computer-aided triage and notification software programs. Both devices are artificial intelligence, deep-learning algorithms incorporated software packages for use with DICOM 3.0 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. They differ only with regard to the training on image type, specifically, the predicate device processes head CTs and is indicated for ICH triage, while the subject device processes head CTA images and is indicated for BA triage. Both devices are intended to provide the specialists with notifications and unannotated low-quality preview images of suspect studies for the purpose of preemptive triage.

The subject and predicate BriefCase devices 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 neither removes cases from the standard of care reading queue nor deprioritized cases. Both devices operate in parallel with the standard of care, which remains the default option for all cases. Following clearance, the company has implemented minor changes to the User Interface of the device to improve user experience and structuring. A table

comparing the key features of the subject and the primary predicate device is provided below.

**Table 1. Key Feature Comparison**

| | **Predicate Device**<br>**Aidoc BriefCase for ICH triage**<br>**(K203508)** | **Subject Device**<br>**Aidoc Briefcase for BA 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 appropriately trained medical specialists 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 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 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 head CT Angio (CTA) images. The device is intended to assist hospital networks and appropriately trained medical specialists in workflow triage by flagging and communication of suspected positive cases of Brain Aneurysm (BA) findings above 5 mm size.<br><br>BriefCase uses an artificial intelligence algorithm to analyze images and flag suspect cases on a standalone desktop application in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for suspect cases. 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 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 | Hospital networks and appropriately trained medical specialists | Hospital networks and appropriately trained medical specialists |

| | **Predicate Device**<br>**Aidoc BriefCase for ICH triage**<br>**(K203508)** | **Subject Device**<br>**Aidoc Briefcase for BA triage** |
|---|---|---|
| Anatomical region of interest | Head | Head |
| Data acquisition protocol | Non-contrast head CT scans | Head CTA |
| 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; the device does not mark, annotate, or direct users' attention to a specific location in the original image. |
| Algorithm | Artificial intelligence Deep-learning algorithm with database of images. | Artificial intelligence Deep-learning 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". | Presentation of a small, compressed, black and white preview image that is labeled "Not for diagnostic use". |
| Alteration of original image | No | No |
| Removal of cases from worklist queue | No. The device operates in parallel with the standard of care, which remains the default option for all cases. | No. The device operates in parallel with the standard of care, which remains the default option for all cases. |
| Structure | - AHS module (image acquisition).<br>- ACS module (image processing).<br>- Aidoc Worklist application (worklist and Image Viewer). | - AHS module (image acquisition).<br>- ACS module (image processing).<br>- Aidoc Worklist application (worklist and Image Viewer). |

**Performance Data**

*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 head CTs (with and without contrast) containing Brain Aneurysm from five study sites. 268 cases were selected, 96 positive cases and 172 negative cases (reports on images with Brain Aneurysm versus without Brain Aneurysm findings) included in the analysis. Performance data were collected on an entirely new data set of Brain Aneurysm images. Cases and reports were selected that have not been previously reviewed using BriefCase software. No patient data were reused between the training and the pivotal datasets. Ground truthing was performed by two US Board-certified radiologists and a third one to resolve inconsistencies.

Primary Endpoint
Sensitivity and specificity exceeded the 80% performance goal. Specifically, sensitivity was 88.5% (95% CI: 80.4%, 94.1%) and specificity was 89.5% (95% CI: 84.0%, 93.7%).

Secondary Endpoint
Briefcase's potential clinical benefit of worklist prioritization for true positive BA cases was evaluated by comparing the standard-of-care metric of time-to-exam-open to the software's time-to-notification metric for BA, in the study sites where the time-to-exam-open information was available.

- 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 suspected positive case back to the worklist application.
- The standard of care time-to-open-exam consists of the time from scan acquisition to when the radiologist first opened the exam for review.

The standard of care metric was compared to the BriefCase time-to-notification in the 2 US-based study sites for 65 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 standard of care time-to-exam-open (89.4 minutes: 95% CI: 56.0-122.7; Median 66.0, IQR 50.7) was significantly longer than the time-to-notification metric of the BriefCase device (4.2 minutes, 95% CI: 3.9-4.5; Median 4.2, IQR 1.8). The mean difference of 85.2 minutes (95% CI: 51.8-118.6; Median 63.1, IQR 50.1) for these two measures was statistically significant and assuming the user receives a notification on a true positive BA case and acts on it immediately, it can on average save more than one hour compared to the time-to-exam-open in a first in first out (FIFO) reading queue. The value of 85.2 is based on the study of 65 cases from 2 study sites and may vary in practice.

**Table 2. Time Saving Data**

| Parameter | N | Mean Estimate | 95% Lower CL | 95% Upper CL | Median | IQR |
|---|---|---|---|---|---|---|
| Standard of care Time-to- exam-open | 65 | 89.4 | 56.0 | 122.7 | 66.0 | 50.7 |
| BriefCase BA Time-to-notification | 65 | 4.2 | 3.9 | 4.5 | 4.2 | 1.8 |
| Difference | 65 | 85.2 | 51.8 | 118.6 | 63.1 | 50.1 |

NPV was 98.9% (95% CI: 98.3%-99.6%) and PPV was 42.4% (95% CI: 30.0%-51.7%).
PLR was 8.46% (95% CI: 5.43%-13.18%) and NLR was 0.13 (95% CI: 0.07%-0.22%).

Thus, the reported time savings data demonstrates that radiologists may have the opportunity to be involved in the clinical workflow substantially earlier due to the notifications from the BriefCase device. Performance validation data suggest that when using the subject BriefCase for Brain Aneurysm triage, the user may have significant benefit in time saving compared to the standard of care alone.

**Conclusions**

The subject BriefCase for BA triage and the predicate BriefCase for ICH triage are intended to aid in prioritization and triage of radiological images for the indications of Brain Aneurysm and Intracranial Hemorrhage respectively. Both devices are software packages with the same technological characteristics and principles of operation, incorporating deep learning AI algorithms that process images, and software to send notifications and display unannotated compressed low-quality preview images. In both devices, the labeling clearly states that the devices are not for diagnostic use and instruct 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 BriefCase device for BA triage is thus substantially equivalent to the primary predicate BriefCase for ICH triage.