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

October 7, 2022

Re: K220709
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: September 8, 2022
Received: September 8, 2022

Dear John J .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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological 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)*

K220709

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 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 complete Large Vessel Occlusion (LVO) - MCA-M1, PCA-P1, ACA-A1, ICA, Basilar; and Medium Vessel Occlusions (MeVO) - MCA-M2, MCA-proximal M3, PCA-P2, PCA-proximal P3, ACA-A2, ACA-proximal A3, and Vertebral-V4.

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.

510(k) Summary
Aidoc Medical, Ltd.'s BriefCase
K220709

K220709

Submitter:

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

Contact Person: Amalia Schreier, LLM

Date Prepared: September 8, 2022

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 (LVO 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/Orchestrator) for image acquisition; (2) Aidoc Cloud Server (ACS) for image processing; and (3) Aidoc Desktop Application for workflow integration.

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 desktop application, thereby facilitating 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 alerts on VO cases, and a neuro-radiologist would opt to divert PE alerts. 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 alerts by center. Activating the filter does not impact the order in which notifications are presented in the Aidoc desktop application.

The desktop application feed displays all incoming suspect cases, each notified case in a line. Hovering over a line in the feed pops up a compressed, low-quality, grayscale, unannotated 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 worklist prioritization 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 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 complete Large Vessel Occlusion (LVO) - MCA-M1, PCA-P1, ACA-A1, ICA, Basilar; and Medium Vessel Occlusions (MeVO) - MCA-M2, MCA-proximal M3, PCA-P2, PCA-proximal P3, ACA-A2, ACA-proximal A3, and Vertebral-V4.

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 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.

Comparison of Technological Characteristics

The subject BriefCase for VO triage and primary predicate BriefCase for LVO triage (K203508) are identical in all aspects and defer only with respect to the training of the algorithm on VO vs LVO (M1) images.

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 of the algorithm - the predicate device is indicated for Large Vessel Occlusions (on M1) triage and the current VO device is indicated for all brain vessel occlusions. In addition, they also differ in the image slice thickness they process (the predicate is indicated with image slice thickness of 0.5 mm – 1.0 mm, and the current VO device is indicated for use with slice thickness of 0.5 mm - 1.25 mm). 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. A table comparing the key features of the subject and the primary predicate devices is provided below.

Table 1. Key feature comparison

	Predicate Device **Aidoc Briefcase (K203508)**	**Subject Device** **Aidoc Briefcase (K220709)**
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 appropriately trained medical specialists 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.	BriefCase is a radiological computer aided triage and notification software indicated for use in the analysis of head CTA 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 complete Large Vessel Occlusion (LVO) - MCA-M1, PCA-P1, ACA-A1, ICA, Basilar; and Medium Vessel Occlusions (MeVO) - MCA-M2, MCA-proximal M3, PCA-P2, PCA-proximal P3, ACA-A2, ACA-proximal A3, and Vertebral-V4. 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 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.

	Predicate Device **Aidoc Briefcase (K203508)**	**Subject Device** **Aidoc Briefcase (K220709)**
		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
Anatomical region of interest	Head	Head
Data acquisition protocol	Head CTA	Head CTA
Notification-only (/notification alerts), parallel workflow tool	Yes	Yes
Images format	DICOM	DICOM
Interference with standard workflow	No. No cases are removed from Worklist or deprioritized.	No. No cases are removed from desktop app or deprioritized
Inclusion/ Exclusion criteria	Inclusion criteria • 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. Exclusion Criteria • All scans that are technically inadequate, including motion artifacts, severe metal artifacts, suboptimal bolus timing or an inadequate field of view.	Inclusion criteria • 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 – 1.25 mm. Exclusion Criteria • All scans that are technically inadequate, including motion artifacts, severe metal artifacts, suboptimal bolus timing or an inadequate field of view.
Algorithm	Artificial intelligence algorithm with database of images.	Artificial intelligence algorithm with database of images.
Structure	- AHS module (image acquisition); - ACS module (image processing));	- AHS module (orchestrator, image acquisition); - ACS module (image processing));

	Predicate Device Aidoc Briefcase (K203508)	Subject Device Aidoc Briefcase (K220709)
	- Aidoc Worklist application for workflow integration (worklist and non-diagnostic Image Viewer).	- Aidoc Desktop application for workflow integration (feed and non-diagnostic Image Viewer).

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 Vessel Occlusion (VO) in 342 cases from 5 US-based clinical sites. The study compared the software's performance to the ground truth, as determined by 3 expert US board certified Neurologists reviewers, 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 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 91.3% (95% CI: 83.6%, 96.2%) and specificity was 85.6% (95% CI: 80.6%, 89.7%).

Secondary Endpoint

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 desktop 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 predicate BriefCase LVO.

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 VO was 2.23 minutes (95% CI: 2.22-2.23). The time-to-notification for the predicate BriefCase LVO was 3.80 minutes (95% CI: 3.60-4.00).

Table 2. Time-to- Notification Comparison for BriefCase Devices (minutes)

Time -to-notification	Mean Estimate	95% Lower CL	95% Upper CL	Median
Predicate K203508Time-to-notification	3.80	3.60	4.00	3.8
BriefCase VO Time-to-notification	2.23	2.22	2.23	2.03

NPV was 98.9% (95% CI: 4.66%- 99.4%) and PPV was 41.3% (95% CI: 34.1%- 49.0%).

PLR was 6.34% (95% CI: 97.9%- 8.63%) and NLR was 0.10% (95% CI: 0.05%- 0.20%).

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

As can be seen in **Table 3** the mean age of patients whose scans were reviewed for VO was 64.8 years, with standard deviation of 17.1 years. Gender distribution was 42.4% male, and 56.4% 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)	64.8	17.1	18	65.0	90	342

Table 4. Frequency Distribution of Gender

Ground Truth Results	Gender						All	
	Male		Female		Other			
	N	%	N	%	N	%	N	%
Positive	37	40.2%	54	58.7%	1	1.1%	92	100
Negative	108	43.2%	139	55.6%	3	1.2%	250	100
All	145	42.4%	193	56.4%	4	1.2%	342	100

Table 5. Frequency Distribution of Manufacturer

Manufacturer	N	%
GE MEDICAL SYSTEMS	124	36%
TOSHIBA	72	21%
Philips	81	24%
SIEMENS	65	19%
Total	342	100.0%

Clinical Subgroups And Confounders:

- Pathologies present in negative cases: Vessel Occlusion (Stenosis/narrowing); Head & neck trauma; Fully negative; Vascular; Vessel Occlusion (anatomically out of product definition), Vessel Occlusion (chronic); Vessel Occlusion (partial).

- Vessel Occlusions: MCA-M1, MCA-M2, MCA-M3, ICA, Basilar, PCA-P1, PCA-P2, PCA-P3, ACA-A1, ACA-A2, ACA-A3, and Vertebral-V4. An additional enriched dataset was collected for vessel segment-subgroup analysis on 165 positive vessel occlusions cases.

Additional Operating Point

In addition to the default operating point that was selected to maximize both sensitivity and specificity, one additional operating point (AOP) was selected to maximize sensitivity while maintaining a lower bound 95% confidence interval of 80%:

AOP1: Sensitivity was 91.3% (95% CI: 83.58%-96.17%) and Specificity was 85.2% (95% CI: 80.18%-89.36%).

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

Conclusions

The subject BriefCase for VO triage and the predicate BriefCase for LVO triage are intended to aid in prioritization and triage of radiological images for the indications of Vessel Occlusions. 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 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, 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 subject BriefCase device for VO triage is thus substantially equivalent to the predicate BriefCase for LVO triage.