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

Re: K222329 September 28, 2022
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: August 2, 2022
Received: August 2, 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)*
K222329

Device Name

BriefCase

Indications for Use *(Describe)*

BriefCase is a radiological computer-aided triage and notification software indicated for use in the analysis of CT exams with contrast (CTA and CT with contrast) that include the chest 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 communicating suspected positive cases of aortic dissection (AD) pathology.

BriefCase uses an artificial intelligence algorithm to analyze images and highlight cases with detected findings on a standalone 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 the user's 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)

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

Submitter: K222329

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Contact Person: Amalia Schreier, LL.M.

Date Prepared: August 2, 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: CINA CHEST (K210237)

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 ICH cases, and a neuro-radiologist would opt to divert AD 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 CT exams with contrast (CTA and CT with contrast) that include the chest 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 communicating suspected positive cases of aortic dissection (AD) pathology.

BriefCase uses an artificial intelligence algorithm to analyze images and highlight cases with detected findings on a standalone 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 the user's 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 and primary predicate CINA CHEST triage (K210237) are very similar, as explained below.

Both devices are radiological computer-aided triage and notification software programs. Both devices are artificial intelligence, deep-learning algorithms incorporating software packages for use with DICOM 3.0 compliant scanners, PACS, and radiology workstations. The predicate CINA CHEST evaluates images from CT scanners as does the proposed Briefcase. The predicate and subject devices differ in the fact that the subject device runs also on CT exams with contrast (CTA and CT with contrast) that include the chest. All image types were included in the standalone performance study.

The proposed device for aortic dissection has very similar technology and design as the predicate device, and similar indications for use, i.e., both devices are intended to aid in prioritization and triage of time-critical radiological images. The subject and predicate CINA CHEST 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 deprioritizes 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 predicate devices is provided below.

Table 1. Key Feature Comparison

	Predicate Device CINA CHEST (K210237)	Subject Device Aidoc Briefcase

Intended Use / Indications for Use	CINA CHEST is a radiological computer aided triage and notification software indicated for use in the analysis of Chest and Thoraco-abdominal CT angiography. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communicating suspected positive findings of (1) Chest CT angiography for Pulmonary Embolism (PE) and (2) Chest or Thoraco-abdominal CT angiography for Aortic Dissection (AD). CINA CHEST uses an artificial intelligence algorithm to analyze images and highlight cases with detected PE and AD on a standalone Web application in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected PE or AD findings. Notifications include compressed preview images that are meant for informational purposes only, and are not intended for diagnostic use beyond notification. The device does not alter the original medical image, and it is not intended to be used as a diagnostic device. The results of CINA CHEST 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 ultimately responsible for reviewing full images per the standard of care.	BriefCase is a radiological computer-aided triage and notification software indicated for use in the analysis of CT exams with contrast (CTA and CT with contrast) that include the chest 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 communicating suspected positive cases of aortic dissection (AD) pathology. BriefCase uses an artificial intelligence algorithm to analyze images and highlight cases with detected findings on a standalone 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 the user's professional judgment, to assist with triage/prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care.

	Predicate Device CINA CHEST (K210237)	**Subject Device Aidoc Briefcase**
User population	Hospital networks and trained radiologists	Hospital networks and appropriately trained medical specialists
Anatomical region of interest	Chest and thoraco-abdominal	Chest, abdomen and thoraco-abdominal
Data acquisition protocol	Chest and Thoraco-abdominal CT angiography	CT exams with contrast (CTA and CT with contrast) that include the chest

Notification-only (notification alerts), parallel workflow tool	Yes	Yes
Images format	DICOM	DICOM
Interference with standard workflow	No	No
Algorithm	Artificial intelligence algorithm with database of images.	Artificial intelligence algorithm with database of images.
Structure	- PE and AD image processing applications - Compatibility of use with the CINA Platform reference device (worklist and Image Viewer)	- AHS module (orchestrator, image acquisition); - ACS module (image processing); - 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 aortic dissection in CT images in 499 cases. The cases were collected from 5 medical centers in the US and are distinct datasets from the ones used to train the algorithm.

Primary endpoints were 80% performance goals for both sensitivity and specificity.

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 93.23% (95% CI: 88.70% - 96.35%) and specificity was 92.83% (95% CI: 89.35% - 95.45%).

Secondary Endpoint

In addition, the time-to-notification metric observed for the BriefCase software in the 5 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 CINA CHEST.

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 aortic dissection was 38 seconds (95% CI: 35.5-40.4). The time-to-notification for the CINA CHEST for AD triage was 36.5 seconds (95% CI: 35.4-37.5).

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

Time-to-notification	N	Mean Estimate	95% Lower CL	95% Upper CL	Median	IQR
BriefCase Aortic Dissection	499	38	35.5	40.4	31.1	32.5
CINA CHEST	298	36.5	35.4	37.5	34.1	n/a

NPV was 99.8% (95% CI: 99.7%- 99.9%) and PPV was 25.0% (95% CI: 18.2%- 19.5%).

PLR was 13.010 (95% CI: 8.682 - 19.494) and NLR was 0.073 (95% CI: 0.043 - 0.123).

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

As can be seen in **Table 3** the mean age of patients whose scans were reviewed for AD was 60.02 years, with a standard deviation of 17.19 years. Gender distribution was 51.9% male, and 47.9% 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)	60.02	17.19	18	62	90	499

Table 4. Frequency Distribution of Gender

Ground Truth Results	Gender				All	
	Male		Female			
	N	%	N	%	N	%
Positive	129	25.9	63	12.6	192	38.6
Negative	130	26.1	176	35.3	306	61.4
All	239	48.0	259	52.0	498*	100.0

* 1 case had gender unknown.

Table 5. Frequency Distribution of Manufacturer

Manufacturer	N	%
Siemens	167	33.47%
GE	145	29.06%
Philips	103	20.64%
Canon	84	16.83%
Total	499	100%

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

Additional Operating Points

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

AOP1: Sensitivity was 96.88% (95% CI: 93.32% - 98.84%) and specificity was 85.02% (95% CI: 80.52% - 88.82%).
AOP2: Sensitivity was 86.46% (95% CI: 80.79% - 90.96%) and specificity was 95.11% (95% CI: 92.07% - 97.24%).

Conclusions

The subject BriefCase for Aortic Dissection triage and the predicate CINA CHEST triage are intended to aid in prioritization and triage of radiological images for the indications of aortic dissection. 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 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 Aortic Dissection triage is thus substantially equivalent to the primary predicate CINA CHEST triage.