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

April 14, 2021

Re: K202992
Trade/Device Name: BriefCase for RibFx Triage
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer aided triage and notification software
Regulatory Class: Class II
Product Code: QFM
Dated: March 1, 2021
Received: March 1, 2021

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,

Michael D. O'Hara 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)*

K202992

Device Name

BriefCase for RibFx Triage

Indications for Use *(Describe)*

BriefCase is a radiological computer aided triage and notification software indicated for use in the analysis of chest CTs (with or without contrast). The device is intended to assist hospital networks and appropriately trained medical specialists in workflow triage by flagging and communication of suspect cases of three or more acute Rib fracture (RibFx) pathologies.

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 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 (K202992)

Submitter:

Aidoc Medical, Ltd.
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Tel-Aviv, Israel
Phone: +972-73-7946870

Contact Person: N. Epstein, Ph.D.

Date Prepared: March 1, 2021

Name of Device: BriefCase for RibFx Triage

Classification Name: Radiological computer-assisted triage and notification software device

Regulatory Class: Class II

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

Predicate Device: BriefCase (K190072, for PE)

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. 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 attending radiologist. 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 suspected studies 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., RibFx). A list of all incoming suspect cases is also displayed. Hovering over a notification or a case in the worklist 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 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 chest CTs (with or without contrast). The device is intended to assist hospital networks and appropriately trained medical specialists in workflow triage by flagging and communication of suspect cases of three or more acute Rib fracture (RibFx) pathologies.

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 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 Rib Fracture (RibFx) triage and predicate device BriefCase for Pulmonary Embolism (PE) triage (K190072) are identical in all aspects and defer only with respect to the training of the algorithm on RibFx and PE images, 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. The predicate device processes CTPAs and is indicated for PE triage, while the subject device processes chest images (with or without contrast) and is indicated for RibFx triage. Both devices are intended to provide radiologists with notifications and unannotated preview images of suspect studies for the purpose of triage.

Both software devices notify the attending radiologist of the availability of radiological images for review based on computer aided image analysis. Both devices send notifications and low-quality compressed previews to the radiology workstations' desktop. Both devices feature a notification filter in the user interface. Notifications are for informational purpose only and are meant to prompt the radiologist to start triage of a flagged case, upon which he may decide after observing the unannotated, low quality preview on his desktop, 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 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 does not modify them and does not de-prioritize unflagged 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 predicate devices is provided below.

Table 1. Key feature comparison

	Predicate Device **Aidoc Briefcase for PE triage** **(K190072)**	**Subject Device** **Aidoc Briefcase for RibFx triage** **(K202992)**
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 and CTPA images. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communication of suspected positive findings of Intracranial Hemorrhage (ICH) and Pulmonary Embolism (PE) pathologies. For the PE pathology, the software is only intended to be used on single-energy exams. 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 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 chest CTs (with or without contrast). The device is intended to assist hospital networks and appropriately trained medical specialists in workflow triage by flagging and communication of suspect cases of three or more acute Rib fracture (RibFx) pathologies. 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 their 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	Radiologist	Appropriately trained medical specialist
Anatomical region of interest	Chest	Chest

	Predicate Device Aidoc Briefcase for PE triage (K190072)	Subject Device Aidoc Briefcase for RibFx triage (K202992)
Inclusion/ Exclusion criteria	Inclusion Criteria - CTPA protocols. - Single energy exams. - Scans performed with 64-slice scanner or greater number of detectors. - Scans performed on adults/transitional adults ≥ 18 years of age. - Slice thickness 0.5 - 3.0 mm axial. Exclusion Criteria - All studies that are technically inadequate, including studies with motion artifacts, severe metal artifacts, sub-optimal bolus or inadequate field of view.	Inclusion criteria - Chest CTs (with or without contrast). - Single energy exams. - Scans performed with a 64 or greater number of detectors. - Scans performed on adults/transitional adults ≥ 18 years of age. - Slice thickness; 0.5 - 5.0 mm axial. Exclusion Criteria - All studies that are technically inadequate, including studies with motion artifacts, severe metal artifacts, or inadequate field of view.
Data acquisition protocol	CTPA protocol	Chest CTs (with or without contrast)
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; 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
Notification/Prioritization	Yes	Yes
Preview images	Presentation of a low-quality, compressed, grayscale preview image that is captioned "Not for diagnostic use".	Presentation of a low-quality, compressed, grayscale preview image that is captioned "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. Unflagged cases are not de-prioritized.	No. The device operates in parallel with the standard of care, which remains the default option for all cases. Unflagged cases are not de-prioritized.
Structure	- AHS module (image acquisition). - ACS module (image processing). - Aidoc Worklist application for workflow integration (worklist and non-diagnostic basic Image Viewer).	- AHS module (image acquisition). - ACS module (image processing). - Aidoc Worklist application for workflow integration (worklist and non-diagnostic basic Image Viewer).

Performance Data

Pivotal Study Summary

Performance data were collected on an entirely new data set of RibFx images in a retrospective, blinded, multicenter, multinational study. 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 radiologists with an additional third radiologist to resolve inconsistencies.

Data was acquired consecutively, without differentiating between patient classes, thus including all patient classes, i.e., ED, inpatients, and outpatients.

Primary Endpoint

The primary endpoint was to evaluate the software's performance in identifying three or more acute rib fractures in chest CTs (with or without contrast), in 279 cases from 3 clinical study sites (2 in the US, one OUS, 70.9% of the cases were collected from the US sites). There were 91 ground truth positive cases (cases with 3 or more rib fractures) and 188 ground truth negative cases included in the analysis.

AUC was 0.976 (95% CI: 0.960, 0.991). Sensitivity was 96.7% (95% CI: 90.6%, 99.4%) and specificity was 90.4% (95% CI: 85.2%, 94.3%). Because the 95% CI lower bound of AUC exceeded 0.95 and sensitivity and specificity both exceeded 80%, the study's primary endpoints were met.

Secondary Endpoint

Briefcase's potential clinical benefit of worklist prioritization for true positive RibFx cases was evaluated by comparing the standard-of-care metric of time-to-exam-open to the software's time-to-notification metric for RibFx, in two US-based 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 two US-based study sites for 67 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 substantially longer than the parallel time-to-notification 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 metrics is substantial and assuming the radiologist receives a notification on a true positive RibFx 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 difference value of 85.2 is based on the study of 67 cases from 2 study sites and may vary in practice.

Table 2. Time saving data

Parameter	N	Mean estimate	Lower Confidence Limit	Upper Confidence Limit	Median	IQR
Time-to- exam-open in the standard of care	67	89.4	56.0	122.7	66.0	50.7
Time-to-notification of BriefCase RibFx	67	4.2	3.9	4.5	4.2	1.8
Difference	67	85.2	51.8	118.6	63.1	50.1

NPV was 99.6% (95% CI: 99.2%-100.0%) and PPV was 52.9% (95% CI: 39.1%-62.1%).

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 RibFx triage, the radiologists may have the same benefit in time saving as with using the BriefCase for PE triage.

Conclusions

The subject BriefCase for RibFx triage and the predicate BriefCase for PE triage devices are both intended to aid in prioritization and triage of radiological images for the indications of rib fractures and Pulmonary Embolism, respectively. Both devices are software packages with similar technological characteristics and principles of operation, both incorporating deep learning AI algorithms that process images, and software to send notifications and unannotated compressed preview images to the radiologists' workstation. In both devices, the labeling states that the device is 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, and do not remove images from the standard of care FIFO queue, thus not disturbing standard interpretation of the images by the attending radiologists. 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 RibFx triage is thus substantially equivalent to the BriefCase for PE triage.