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

February 1, 2023

Re: K230020
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: QFM
Dated: January 3, 2023
Received: January 3, 2023

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
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)*

K230020

Device Name

BriefCase

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) 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 communicating suspect cases of three or more acute Rib fracture (RibFx) pathologies.

BriefCase uses an artificial intelligence algorithm to analyze images and highlight cases with detected findings in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected RibFx 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human
Services Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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

K230020

Submitter:

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

Contact Person: Amalia Schreier, LL.M

Date Prepared: January 3, 2023

Name of Device: BriefCase

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

Regulatory Class: Class II

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

Primary Predicate Device: BriefCase (RibFx triage, K202992)

Device Description

BriefCase is a radiological computer-assisted triage and notification software device. The software is based on an algorithm programmed component and is intended to run on a linux-based server in a cloud environment.

The BriefCase receives filtered DICOM Images, and processes them chronologically by running the algorithms on each series to detect suspected cases. Following the AI processing, the output of the algorithm analysis is transferred to an image review software (desktop application). When a suspected case is detected, the user receives a pop-up notification and is presented with a compressed, low-quality, grayscale image that is captioned "not for diagnostic use, for prioritization only" which is displayed as a preview function. This 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 efficient 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) 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 communicating suspect cases of three or more acute Rib fracture (RibFx) pathologies.

BriefCase uses an artificial intelligence algorithm to analyze images and highlight cases with detected findings in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected RibFx 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 RibFx triage and the algorithm analysis module for the primary predicate BriefCase for RibFx triage (K202992) are identical in most aspects and differ with respect to their algorithm performance, due to training the subject device on a larger data set. Additional operating points have been added to the pivotal study endpoints. In addition, the SW architecture was changed to separate the image communication platform from the BriefCase SW. The new device consists of only the algorithm analysis module which can be integrated with image communication platforms that meet the BriefCase input and output requirements.

Both the primary predicate and subject devices are radiological computer-aided triage and notification software programs. Both devices are artificial intelligence, deep-learning algorithms incorporated in software packages for use with DICOM 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. Both devices are intended to provide the specialists with notifications and unannotated, compressed, low-quality, and grayscale 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 for RibFx triage (K202992)**	**Subject Device** **Aidoc Briefcase for RibFx triage**
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.	BriefCase is a radiological computer aided triage and notification software indicated for use in the analysis of chest CTs (with or without contrast) 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 communicating suspect cases of three or more acute Rib fracture (RibFx) pathologies. BriefCase uses an artificial intelligence algorithm to analyze images and highlight cases with detected findings in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected RibFx 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.
User population	Hospital networks and appropriately trained medical specialists	Hospital networks and appropriately trained medical specialists

	Predicate Device Aidoc Briefcase for RibFx triage (K202992)	Subject Device Aidoc Briefcase for RibFx triage
Anatomical region of interest	Chest	Chest
Data acquisition protocol	Chest CTs (with or without contrast)	Chest CTs (with or without contrast)
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 for clinical performance testing	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.	Inclusion criteria - chest CT with or without contrast - Single energy exams. - Performed on CT scanners with 64 or greater number of detectors - Scans performed on adults/transitional adults ≥ 18 years of age - Slice thickness; 0.5 mm to 5.0 mm axial slices Exclusion Criteria - All studies that are technically inadequate, including studies with motion artifacts, severe metal artifacts, or 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)); - Aidoc Worklist application for workflow integration (worklist and non-diagnostic Image Viewer).	- Integrated with image routing module via image communication platform (ICP) (image acquisition). - Algorithm module (image processing) - Integrated with 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 Chest CTs (with or without contrast) images containing three or more acute Rib fractures (RibFx) in 308 cases from 5 US-based clinical sites. The study compared the software's performance to the ground truth, as determined by three senior board-certified radiologists, 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 pre-specified standalone performance goal (PG) of area under the curve (AUC) > 0.95 for the study level receiver operating characteristic (ROC) curve. 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

AUC was 0.98 (95% CI: 0.966, 0.994), Sensitivity was 98.08% (95% CI: 93.23%, 99.77%) and Specificity was 93.14% (95% CI: 88.75%, 96.20%). As the AUC exceeded 0.95 and sensitivity and specificity both exceeded 80%, the study's primary endpoints were met.

Lower confidence limits for AUC, sensitivity and specificity were all above the pre-specified performance goals, demonstrating that the pre-specified performance goals were met.

Secondary Endpoint

In addition, the time-to-notification metric observed for the BriefCase software, when integrated with a compatible image communication platform, 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 RibFx.

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 the subject RibFx triage was 70.1 seconds (95% CI: 64.9-75.4). The time-to-notification for the predicate RibFx triage was 252 seconds (95% CI: 234-270).

Table 2. Time-to- notification comparison for BriefCase devices (Seconds)

Time -to-notification	Mean Estimate (seconds)	N	95% Lower CL	95% Upper CL	Median	IQR
Predicate K202992 Processing Time	252	67	234	270	252	108
BriefCase + Image Communication Platform Time-To-Notification	70.1	104	64.9	75.4	66	59

NPV was 99.8% (95% CI: 99.1% - 99.9%) and PPV was 61.4% (95% CI: 48.9% - 72.5%).

PLR was 14.2912 (95% CI: 8.614 - 23.710) and NLR was 0.0206 (95% CI: 0.005 - 0.082).

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

As can be seen in **Table 3** the mean age of patients whose scans were reviewed for RibFx was 65.1 years, with a standard deviation of 15.5 years. Gender distribution was 51.3% male, and 45.5% 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)	65.1	15.5	20	66	90	308

Table 4. Frequency Distribution of Gender *

Ground Truth Results	Gender				All	
	Female		Male			
	N	%	N	%	N	%
Positive	36	12.1%	61	20.5%	97	32.6%
Negative	104	34.9%	97	32.6%	201	67.4%
All	140	47.0%	158	53.0%	298	100.0%

* 10 cases were unknown for gender (3 negative and 7 positive).

Table 5. Frequency Distribution of Manufacturer

Manufacturer	N	%
GE MEDICAL SYSTEMS	150	48.7%
Philips	64	20.8%
SIEMENS	53	17.2%
TOSHIBA	41	13.3%
Total	**308**	**100%**

Clinical Subgroups and Confounders:

Pathologies present in negative cases: Fully negative; Neoplastic; Heart & vascular; Chronic diseases; Inflammatory; Trauma; None of the above.

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 88.46% (95% CI: 80.71%, 93.89%) and specificity was 95.1% (95% CI: 91.17%, 97.62%).
AOP2: Sensitivity was 99.04% (95% CI: 94.76%, 99.98%) and specificity was 90.20% (95% CI: 85.27%, 93.91%).

In summary, performance goals were achieved for the default and two additional operating points.

Combined with the comparison results of time-to-notification metric with the predicate device, these data establish the achievement by the subject BriefCase of preemptive triage in the range of several minutes.

Conclusions

The subject BriefCase for RibFx triage and the predicate BriefCase for RibFx triage are intended to aid in prioritization and triage of radiological images for the indications for suspected positive findings of Rib Fracture (RibFx) pathologies. Both devices are software packages consisting of deep learning AI algorithms that process images and produce analysis results, which are displayed to the user by a prioritization alert and a compressed, low-quality, grayscale, unannotated preview image. 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 RibFx triage is thus substantially equivalent to the primary predicate BriefCase for RibFx.