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

December 29, 2020

Re: K203508
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: November 30, 2020
Received: November 30, 2020

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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR

803) for devices or post-marketing 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)*

K203508

Device Name

BriefCase

Indications for Use *(Describe)*

BriefCase is a radiological computer aided triage and notification software indicated for use in the analysis of cervical spine 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 linear lucencies in the cervical spine bone in patterns compatible with fractures.

BriefCase uses an artificial intelligence algorithm to analyse 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.

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

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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)*

K203508

Device Name

BriefCase

Indications for Use *(Describe)*

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 Haemorrhage (ICH).

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.

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)*

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510(k) Number *(if known)*

K203508

Device Name

BriefCase

Indications for Use *(Describe)*

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 appropriately trained medical specialists 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 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)*

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See PRA Statement below

510(k) Number *(if known)*

K203508

Device Name

BriefCase

Indications for Use *(Describe)*

BriefCase is a radiological computer aided triage and notification software indicated for use in the analysis of abdominal 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 Intra-abdominal free gas (IFG) 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. .

Type of Use *(Select one or both, as applicable)*

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Food and Drug Administration

Indications for Use

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Expiration Date: 06/30/2023
See PRA Statement below

510(k) Number *(if known)*

K203508

Device Name

BriefCase

Indications for Use *(Describe)*

BriefCase is a radiological computer aided triage and notification software indicated for use in the analysis of contrast enhanced chest CT images (but not dedicated CTPA protocol) CT. 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 Incidental Pulmonary Embolism (iPE) pathologies. For the iPE pathology, the software is only intended to be used on single-energy exams. The device in intended to work with GE and Siemens scanners only.

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)

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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)*

K203508

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. 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.

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 (K203508)

Submitter:	Aidoc Medical, Ltd. 3 Aminadav St. Tel-Aviv, Israel
Phone:	+972-73-7946870
Contact Person:	N. Epstein, Ph.D.

Date Prepared:	December 17, 2020
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 (K190896)

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); (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.

DICOM images are received, saved, filtered and de-identified before processing. Series are processed chronologically by running an algorithm on each series to detect suspected findings and then notifications on flagged series are sent to the Worklist desktop application, thereby prompting preemptive triage and prioritization.

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., CSF). 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 user 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 cervical spine CT images. The device is intended to assist hospital networks and appropriately trained medical specialists in workflow triage by flagging and communication of linear lucencies in the cervical spine bone in patterns compatible with fractures.

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.

Substantial Equivalence

The subject and predicate devices have an identical intended use, technological characteristics, and principles of operation. The only difference is that the subject device has a broadened intended use population of appropriately trained medical specialists, whereas the predicate device is indicated for use by radiologists. Both devices are intended to provide the users with notifications and unannotated preview images of suspect studies for the purpose of preemptive triage, and are therefore substantially equivalent.

A table comparing the key features of the subject and predicate devices is provided below.

Table 1. Key feature comparison

	Predicate Device **Aidoc Briefcase (K190896)**	**Subject Device** **Aidoc Briefcase (K203508)**
Intended Use / Indications for Use	BriefCase is a radiological computer aided triage and notification software indicated for use in the analysis of cervical spine CT images. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communication of suspected positive findings of linear lucencies in the cervical spine bone in patterns compatible with fractures. 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	BriefCase is a radiological computer aided triage and notification software indicated for use in the analysis of cervical spine 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 linear lucencies in the cervical spine bone in patterns compatible with fractures. 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

	Predicate Device Aidoc Briefcase (K190896)	Subject Device Aidoc Briefcase (K203508)
	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.	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.
User population	Radiologist	Appropriately trained medical specialists
Anatomical region of interest	Cervical spine	Cervical spine
Data acquisition protocol	Non-contrast cervical spine CT scan	Non-contrast cervical spine CT scans
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 small, compressed, black and white preview image that is labeled "Not for diagnostic use"; The device operates in parallel with the standard of care, which remains the default option for all cases.	Presentation of a small, compressed, black and white preview image that is labeled "Not for diagnostic use"; The device operates in parallel with the standard of care, which remains the default option for all cases.
Alteration of original image	No	No
Removal of cases from worklist queue	No	No

Performance Data

Performance data was not needed to support this modification to BriefCase. The 510(k) Summary for K190896 describes the data that was used to support initial clearance of BriefCase.

Conclusions

The subject BriefCase is as safe and effective as the predicate BriefCase, with the same intended use, technological characteristics, and principles of operation. Broadening the intended user population does not raise new or different questions of safety or effectiveness.

510(k) Summary

Aidoc Medical, Ltd.'s BriefCase (K203508)

Submitter:

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

Contact Person: N. Epstein, Ph.D.

Date Prepared: December 17, 2020

Name of Device: BriefCase

Classification Name: Radiological computer aided triage and notification software

Regulatory Class: Class II

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

Predicate Device: Aidoc Medical BriefCase (K180647)

Reference Device: Qure.ai Technologies qER (K200921)

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); (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.

DICOM images are received, saved and filtered and de-identified before processing. Series are processed chronologically by running an algorithm on each series to detect suspected findings and then notifications on flagged series are sent to the Worklist desktop application, thereby prompting preemptive triage and prioritization.

The Worklist Application displays the pop-up notifications of new studies with suspected findings when they come in. Notifications are in the form of a small pop-up containing patient name and accession number. A list of all incoming cases with suspected findings is also displayed. In addition, a compressed, small black and white image that is marked "not for diagnostic use" 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 user with notification facilitates earlier triage by allowing one to assess the available 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 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).

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.

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.

Substantial Equivalence

The subject and predicate devices have identical intended use, technological characteristics, and principles of operation. The only difference is that the subject device has a broadened intended use population of appropriately trained medical specialists, whereas the predicate device is indicated for use by radiologists. Both devices are intended to provide notifications and preview head images of potential findings to the user for the purpose of treatment planning and follow up, and are therefore substantially equivalent. The reference qER device is also intended for use by trained medical specialists.

A table comparing the key features of the subject and predicate devices is provided below.

Table 1. Key feature comparison

	Subject Device Aidoc Briefcase (K203508)	**Predicate Device Aidoc Briefcase (K180647)**
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 specialist in workflow triage by flagging and communication of suspected positive findings of pathologies in head CT images, namely Intracranial Hemorrhage (ICH). BriefCase uses an artificial intelligence algorithm to	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 trained radiologists in workflow triage by flagging and communication of suspected positive findings of pathologies in head CT images, namely Intracranial Hemorrhage (ICH). BriefCase uses an artificial intelligence algorithm to analyze images and highlight

	Subject Device Aidoc Briefcase (K203508)	Predicate Device Aidoc Briefcase (K180647)
	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. 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.	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. 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	Appropriately trained medical specialist	Radiologist
Anatomical region of interest	Head	Head
Data acquisition protocol	Non contrast CT scan of the head or neck	Non contrast CT scan of the head or neck
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, highlight, or direct users' attention to a specific location in the original image	No; device does not mark, highlight, 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 preview of the study for initial assessment not meant for diagnostic purposes The device operates in parallel with the standard of	Presentation of notification and preview of the study for initial assessment not meant for diagnostic purposes The device operates in parallel with the standard of

	Subject Device Aidoc Briefcase (K203508)	Predicate Device Aidoc Briefcase (K180647)
	care, which remains the default option for all cases	care, which remains the default option for all cases
Alteration of original image	No	No
Removal of cases from worklist queue	No	No

Performance Data

Performance data was not needed to support this modification to BriefCase. The 510(k) Summary for K180647 describes the data that was used to support initial clearance of BriefCase.

Conclusions

The subject BriefCase is as safe and effective as the predicate BriefCase, with the same intended use, technological characteristics, and principles of operation. Broadening the intended user population does not raise new or different questions of safety or effectiveness.

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Aidoc Medical, Ltd.'s BriefCase (K203508)

Submitter:

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

Contact Person: N. Epstein, Ph.D.

Date Prepared: December 17, 2020

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 (K190072)

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); (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.

DICOM images are received, saved, filtered and de-identified before processing. Series are processed chronologically by running an algorithm on each series to detect suspected findings and then notifications on flagged series are sent to the Worklist desktop application, thereby prompting preemptive triage and prioritization.

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., PE). 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 user 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 non-enhanced head CT and CTPA images. The device is intended to assist hospital networks and appropriately trained medical specialists in workflow triage by flagging and communication 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 their professional judgment, to assist with triage/prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care.

Substantial Equivalence

The subject and predicate device have identical intended use, technological characteristics, and principles of operation. The only difference is that the subject device has a broadened intended use population of appropriately trained medical specialists, whereas the predicate device is indicated for use by radiologists. Both devices are intended to provide the users with notifications and unannotated preview images of suspect studies for the purpose of preemptive triage, and are therefore substantially equivalent.

A table comparing the key features of the subject and predicate devices is provided below.

Table 1. Key feature comparison

	Predicate Device **Aidoc Briefcase (K190072)**	**Subject Device** **Aidoc Briefcase (K203508)**
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	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 appropriately trained medical specialists 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

	Predicate Device Aidoc Briefcase (K190072)	Subject Device Aidoc Briefcase (K203508)
	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.	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.
User population	Radiologist	Appropriately trained medical specialists
Anatomical region of interest	Head and chest	Head and chest
Data acquisition protocol	Non-contrast head CT scan and CTPA (single energy exams only)	Non-contrast head CT scan and CTPA (single energy exams only)
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 small, compressed, black and white preview image that is labeled "Not for diagnostic use"; The device operates in parallel with the standard of care, which remains the default option for all cases.	Presentation of a small, compressed, black and white preview image that is labeled "Not for diagnostic use"; The device operates in parallel with the standard of care, which remains the default option for all cases.

	Predicate Device Aidoc Briefcase (K190072)	Subject Device Aidoc Briefcase (K203508)
Alteration of original image	No	No
Removal of cases from worklist queue	No	No

Performance Data

Performance data was not needed to support this modification to BriefCase. The 510(k) Summary for K190072 describes the data that was used to support initial clearance of BriefCase.

Conclusions

The subject BriefCase is as safe and effective as the predicate BriefCase, with the same intended use, technological characteristics, and principles of operation. Broadening the intended user population does not raise new or different questions of safety or effectiveness.

510(k) Summary
Aidoc Medical, Ltd.'s BriefCase (K203508)

Submitter:

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

Contact Person: N. Epstein, Ph.D.

Date Prepared: December 17, 2020

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 (K193298)

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 user's 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. Series are processed chronologically by running an algorithm on each series to detect suspected findings and then notifications on flagged series are sent to the Worklist desktop application, thereby prompting preemptive triage and prioritization. The user may opt to filter out notifications by pathology, e.g. a chest radiologist may choose to filter out notifications on Large Vessel Occlusion (LVO) cases, and a neuro-radiologist would opt to divert Pulmonary Embolism (PE) notifications. In addition, 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., IFG). 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 user 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 abdominal CT images. The device is intended to assist hospital networks and appropriately trained medical specialists in workflow triage by flagging and communication of suspected findings of Intra-abdominal Free Gas (IFG) 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.

Substantial Equivalence

The subject and predicate devices have an identical intended use, technological characteristics, and principles of operation. The only difference is that the subject device has a broadened intended use population of appropriately trained medical specialists, whereas the predicate device is indicated for use by radiologists. Both devices are intended to provide the users with notifications and unannotated preview images of suspect studies for the purpose of preemptive triage, and are therefore substantially equivalent.

A table comparing the key features of the subject and predicate devices is provided below.

Table 1. Key feature comparison

	Predicate Device **Aidoc Briefcase (K193298)**	**Subject Device** **Aidoc Briefcase (K203508)**
Intended Use / Indications for Use	BriefCase is a radiological computer aided triage and notification software indicated for use in the analysis of abdominal CT images. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communication of suspected positive findings of Intra-abdominal Free Gas (IFG) pathologies. BriefCase uses an artificial intelligence algorithm to analyze images and highlight cases with detected findings on a standalone desktop application in parallel to	BriefCase is a radiological computer aided triage and notification software indicated for use in the analysis of abdominal 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 Intra-abdominal Free Gas (IFG) pathologies. BriefCase uses an artificial intelligence algorithm to analyze images and highlight

	Predicate Device Aidoc Briefcase (K193298)	Subject Device Aidoc Briefcase (K203508)
	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.	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.
User population	Radiologist	Appropriately trained medical specialists
Anatomical region of interest	Abdomen	Abdomen
Data acquisition protocol	Abdominal CT scan	Abdominal CT scan
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 small, compressed, black and white preview image that is labeled "Not for diagnostic use"; The device operates in parallel with the standard of care, which remains the default option for all cases.	Presentation of a small, compressed, black and white preview image that is labeled "Not for diagnostic use"; The device operates in parallel with the standard of care, which remains the default option for all cases.
Alteration of original image	No	No

	Predicate Device Aidoc Briefcase (K193298)	Subject Device Aidoc Briefcase (K203508)
Removal of cases from worklist queue	No	No

Performance Data

Performance data was not needed to support this modification to BriefCase. The 510(k) Summary for K193298 describes the data that was used to support initial clearance of BriefCase.

Conclusions

The subject BriefCase is as safe and effective as the predicate BriefCase, with the same intended use, technological characteristics, and principles of operation. Broadening the intended user population does not raise new or different questions of safety or effectiveness.

510(k) Summary
Aidoc Medical, Ltd.'s BriefCase (K203508)

Submitter:

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Tel-Aviv, Israel
Phone: +972-73-7946870

Contact Person: N. Epstein, Ph.D.

Date Prepared: December 17, 2020

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 (K201020)

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 user's 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 preemptive 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 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., iPE). 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 user 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 contrast-enhanced chest CTs (but not dedicated CTPA protocol). The device is intended to assist hospital networks and appropriately trained medical specialists in workflow triage by flagging and communication of suspect cases of incidental Pulmonary Embolism (iPE) pathologies. For the iPE pathology, the software is only intended to be used on single-energy exams. The device is intended to work with GE and Siemens scanners only.

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.

Substantial Equivalence

The subject and predicate devices have an identical intended use, technological characteristics, and principles of operation. The only difference is that the subject device has a broadened intended use population of appropriately trained medical specialists, whereas the predicate device is indicated for use by radiologists.

Both devices are intended to provide the users with notifications and unannotated preview images of suspect studies for the purpose of preemptive triage, and are therefore substantially equivalent.

A table comparing the key features of the subject and predicate devices is provided below.

Table 1. Key feature comparison

	Predicate Device **Aidoc Briefcase (K201020)**	**Subject Device** **Aidoc Briefcase (K203508)**
Intended Use / Indications for Use	BriefCase is a radiological computer aided triage and notification software indicated for use in the analysis of contrast-enhanced chest CTs (but not dedicated CTPA protocol). The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communication of suspected positive cases of incidental Pulmonary Embolism (iPE) pathologies. For the iPE	BriefCase is a radiological computer aided triage and notification software indicated for use in the analysis of contrast-enhanced chest CTs (but not dedicated CTPA protocol). 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 incidental Pulmonary Embolism (iPE)

	Predicate Device Aidoc Briefcase (K201020)	Subject Device Aidoc Briefcase (K203508)
	pathology, the software is only intended to be used on single-energy exams. The device is intended to work with GE and Siemens scanners only. 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.	pathologies. For the iPE pathology, the software is only intended to be used on single-energy exams. The device is intended to work with GE and Siemens scanners only. 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 specialists
Anatomical region of interest	Chest	Chest
Inclusion/ Exclusion criteria	<u>Inclusion Criteria</u> - Contrast-enhanced chest CTs (but not dedicated CTPA protocol. - Single energy exams. - Scans performed with a 64 slice or greater number of detectors. - Scans performed on adults/transitional adults ≥ 18 years of age.	<u>Inclusion criteria</u> - Contrast-enhanced chest CTs (but not dedicated CTPA protocol. - Single energy exams. - Scans performed with a 64 slice or greater number of detectors. - Scans performed on adults/transitional adults ≥ 18 years of age.

	Predicate Device Aidoc Briefcase (K201020)	Subject Device Aidoc Briefcase (K203508)
	- Slice thickness: 0.5mm – 2.0mm axial. <u>Exclusion Criteria</u> - -All studies that are technically inadequate, including studies with motion artifacts, severe metal artifacts, or inadequate field of view..	- Slice thickness: 0.5mm – 2.0mm axial. <u>Exclusion Criteria</u> - All studies that are technically inadequate, including studies with motion artifacts, severe metal artifacts, or inadequate field of view.
Data acquisition protocol	Contrast-enhanced chest CTs (but not dedicated CTPA protocol)	Contrast-enhanced chest CTs (but not dedicated CTPA protocol)
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

Performance data was not needed to support this modification to BriefCase. The 510(k) Summary for K201020 describes the data that was used to support initial clearance of BriefCase.

Conclusions

The subject BriefCase is as safe and effective as the predicate BriefCase, with the same intended use, technological characteristics, and principles of operation. Broadening the intended user population does not raise new or different questions of safety or effectiveness.

510(k) Summary
Aidoc Medical, Ltd.'s BriefCase (K203508)

Submitter:

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Tel-Aviv, Israel
Phone: +972-73-7946870

Contact Person: N. Epstein, Ph.D.

Date Prepared: December 17, 2020

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 (K192383)

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 user's 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. Series are processed chronologically by running an algorithm on each series to detect suspected findings and then notifications on flagged series are sent to the Worklist desktop application, thereby prompting preemptive triage and prioritization. The user may opt to filter out notifications by pathology, e.g. a chest radiologist may choose to filter out notifications on Large Vessel Occlusion (LVO) cases, and a neuro-radiologist would opt to divert Pulmonary Embolism (PE) notifications. In addition, 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., LVO). 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 user 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 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.

Substantial Equivalence

The subject and predicate devices have an identical intended use, technological characteristics, and principles of operation. The only difference is that the subject device has a broadened intended use population of appropriately trained medical specialists, whereas the predicate device is indicated for use by radiologists. Both devices are intended to provide the users with notifications and unannotated low-quality preview images of suspect studies for the purpose of preemptive triage, and are therefore substantially equivalent.

A table comparing the key features of the subject and predicate devices is provided below.

Table 1. Key feature comparison

	Subject Device Aidoc Briefcase (K203508)	**Predicate Device Aidoc Briefcase (K192383)**
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	BriefCase is a radiological computer aided triage and notification soft-ware indicated for use in the analysis of head CTA images. The device is intended to assist hospital networks and 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

	Subject Device Aidoc Briefcase (K203508)	Predicate Device Aidoc Briefcase (K192383)
	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.	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.
User population	Appropriately trained medical specialists	Radiologist
Anatomical region of interest	Head	Head
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, sub-optimal 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 – 1.0 mm. Exclusion Criteria • All scans that are technically inadequate, including motion artifacts, severe metal artifacts, sub-optimal bolus timing or an inadequate field of view.

	Subject Device Aidoc Briefcase (K203508)	Predicate Device Aidoc Briefcase (K192383)
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 small, compressed, black and white preview image that is labeled "Not for diagnostic use"; The device operates in parallel with the standard of care, which remains the default option for all cases.	Presentation of a small, compressed, black and white preview image that is labeled "Not for diagnostic use"; The device operates in parallel with the standard of care, which remains the default option for all cases.
Alteration of original image	No	No
Removal of cases from worklist queue	No	No
Structure	- AHS module (image acquisition); - ACS module (image processing); - Aidoc Worklist application for workflow integration (worklist and Image Viewer). Addition of minor changes in the software platform, e.g. notification filter, which neither impacts the order in which notification come in, nor affects the safety and efficacy profile of the device.	- AHS module (image acquisition); - ACS module (image processing); - Aidoc Worklist application for workflow integration (worklist and Image Viewer). Addition of minor changes in the software platform, e.g. notification filter, which neither impacts the order in which notification come in, nor affects the safety and efficacy profile of the device.

Performance Data

Performance data was not needed to support this modification to BriefCase. The 510(k) Summary for K192383 describes the data that was used to support initial clearance of BriefCase.

Conclusions

The subject BriefCase is as safe and effective as the predicate BriefCase, with the same intended use, technological characteristics, and principles of operation. Broadening the intended user population does not raise new or different questions of safety or effectiveness.