Aidoc Medical, Ltd.
% John Smith
Partner
Hogan Lovells US LLP
555 Thirteenth Street NW
Washington, District of Columbia 20004

November 22,2024

Re: K242203
Trade/Device Name: BriefCase-Quantification
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: July 26, 2024
Received: October 22, 2024

Dear John 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
Assistant Director
Imaging Software Team
DHT8B: Division of Radiologic 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242203

Device Name

BriefCase-Quantification

Indications for Use *(Describe)*

BriefCase-Quantification is a radiological image management and processing system software indicated for use in the analysis of contrast-enhanced CT exams that include the aorta in adults or transitional adolescents aged 18 and older.

BriefCase-Quantification of Aortic Measurement (M-Aorta) is intended to assist hospital networks and appropriately trained medical specialists by providing the user with aortic diameter measurements across the aorta. BriefCase-Quantification is indicated to evaluate normal and aneurysmal aortas and is not intended to evaluate post-operative aortas.

The device provides the following assessments:
- Aortic measurements at 10 anatomical landmarks;
- Maximum aortic diameter of the abdominal aorta, descending aorta and ascending aorta.

The BriefCase-Quantification results are not intended to be used on a stand-alone basis for clinical decision-making or otherwise preclude clinical assessment of cases. These measurements are unofficial, are not final, and are subject to change after review by a radiologist. For final clinically approved measurements, please refer to the official radiology report. 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-Quantification

Submitter:

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Contact Person: Amalia Schreier, LL.M.

Date Prepared: November 21, 2024

Name of Device: BriefCase-Quantification

Classification Name: Medical image management and processing system

Regulatory Class: Class II

Product Code: QIH (21 C.F.R. 892.2050)

Primary Predicate Device: BriefCase-Quantification of M-AbdAo (K241112)

Reference **Device:**AI-Rad Companion (Cardiovascular) (K222360)

Device Description

BriefCase-Quantification is a radiological medical image management and processing device. The software consists of a single module based on an algorithm programmed component and is intended to run on a linux-based server in a cloud environment.

The BriefCase-Quantification receives filtered DICOM Images, and processes them chronologically by running the algorithm on relevant series to measure the maximum abdominal aortic diameter. Following the AI processing, the output of the algorithm analysis is transferred to an image review software (desktop application), and forwarded to user review in the PACS.

The BriefCase-Quantification produces images and tabular views of the landmarks and segments selected per installation to be displayed in the image review software, provided by the Image Communication Platform integrated with Briefcase-Quantification. The diameter marking is not intended to be a final output, but serves the purpose of visualization and measurement. The original, unmarked series remains available in the PACS as well. The preview image presents an unofficial and not final measurement, and the user is instructed to review the full image and any other clinical information before making a clinical decision. The image includes a disclaimer: "Not for diagnostic use. The measurement is unofficial, not final, and must be reviewed by a radiologist."

BriefCase-Quantification is not intended to evaluate post-operative aortas.

Intended Use / Indications for Use

BriefCase-Quantification is a radiological image management and processing system software indicated for use in the analysis of contrast-enhanced CT exams that include the aorta in adults or transitional adolescents aged 18 and older.

BriefCase-Quantification of Aortic Measurement (M-Aorta) is intended to assist hospital networks and appropriately trained medical specialists by providing the user with aortic diameter measurements across the aorta. BriefCase-Quantification is indicated to evaluate normal and aneurysmal aortas and is not intended to evaluate post-operative aortas.

The device provides the following assessments:

- Aortic measurements at 10 anatomical landmarks;
- Maximum aortic diameter of the abdominal aorta, descending aorta and ascending aorta.

The BriefCase-Quantification results are not intended to be used on a stand-alone basis for clinical decision-making or otherwise preclude clinical assessment of cases. These measurements are unofficial, are not final, and are subject to change after review by a radiologist. For final clinically approved measurements, please refer to the official radiology report. Clinicians are responsible for viewing full images per the standard of care.

Comparison of Technological Characteristics

The subject BriefCase-Quantification of Aortic Measurement (M-Aorta) is substantially similar to primary predicate BriefCase-Quantification of the Abdominal Aortic Measurement (M-AbdAo) (K241112) and is similar to the reference device AI-Rad Companion (Cardiovascular) (K222360), as explained below.

All three devices are radiological computer-aided medical image management and processing software. All devices are artificial intelligence, deep-learning algorithms incorporating software packages for use with compliant scanners, PACS, and radiology workstations. The primary predicate BriefCase-Quantification of M-AbdAo and the reference AI-Rad Companion (Cardiovascular) evaluate images from CT scanners as does the proposed device for BriefCase-Quantification of Aortic Measurement (M-Aorta). The devices produce similar outputs that include a diameter measurement image series of certain segments of the aorta (abdominal, ascending and descending aorta; abdominal aorta; ascending and descending aorta - respectively).

The proposed device for BriefCase-Quantification of Aortic Measurement (M-Aorta) has similar technology and design as the primary predicate device and the reference device, and similar indications for use, i.e., all three devices are intended to aid in measurement of the aorta in radiological images. The subject, the predicate BriefCase-Quantification of M-AbdAo and the reference AI-Rad Companion (Cardiovascular) devices raise the same types of safety and effectiveness questions. A table comparing the key features of the subject device, the primary predicate device and the reference predicate device is provided below.

Table 1. Key feature comparison

	Predicate Device BriefCase-Quantification of the Abdominal Aortic Measurement (M-AbdAo) (K241112)	**Reference Device AI-Rad Companion (Cardiovascular) (K222360)**	**Subject Device Aidoc BriefCase-Quantification of Aortic Measurement (M-Aorta)**
Intended Use / Indications for Use	BriefCase-Quantification is a radiological image management and processing system software indicated for use in the analysis of CT exams with contrast, that include the abdominal aorta, in adults or transitional adolescents aged 18 and older. The device is intended to assist appropriately trained medical specialists by providing the user with the maximum abdominal aortic axial diameter of cases that includes the abdominal aorta (M-AbdAo). BriefCase-Quantification is indicated to evaluate normal and aneurysmal abdominal aortas and is not intended to evaluate post-operative aortas. The BriefCase-Quantification results are not intended to be	AI-Rad Companion (Cardiovascular) is image processing software that provides quantitative and qualitative analysis from previously acquired Computed Tomography DICOM images to support radiologists and physicians from emergency medicine, specialty care, urgent care, and general practice in the evaluation and assessment of cardiovascular diseases. It provides the following functionality: - Segmentation and volume measurement of the heart - Quantification of the total calcium volume in the coronary arteries - Segmentation of the aorta - Measurement of maximum diameters of the aorta at typical landmarks	BriefCase-Quantification is a radiological image management and processing system software indicated for use in the analysis of contrast-enhanced CT exams that include the aorta in adults or transitional adolescents aged 18 and older. BriefCase-Quantification of Aortic Measurement (M-Aorta) is intended to assist hospital networks and appropriately trained medical specialists by providing the user with aortic diameter measurements across the aorta. BriefCase-Quantification is indicated to evaluate normal and aneurysmal aortas and is not intended to evaluate post-operative aortas.

	Predicate Device BriefCase-Quantification of the Abdominal Aortic Measurement (M-AbdAo) (K241112)	**Reference Device AI-Rad Companion (Cardiovascular) (K222360)**	**Subject Device Aidoc BriefCase-Quantification of Aortic Measurement (M-Aorta)**
	used on a stand-alone basis for clinical decision-making or otherwise preclude clinical assessment of cases. These measurements are unofficial, are not final, and are subject to change after review by a radiologist. For final clinically approved measurements, please refer to the official radiology report. Clinicians are responsible for viewing full images per the standard of care.	- Threshold-based highlighting of enlarged diameters The software has been validated for non-cardiac chest CT data with filtered backprojection reconstruction from Siemens Healthineers, GE Healthcare, Philips, and Toshiba/Canon. Additionally, the calcium detection feature has been validated on non-cardiac chest CT data with iterative reconstruction from Siemens Healthineers. Only DICOM images of adult patients are considered to be valid input.	The device provides the following assessmnets: ● Aortic measurements at 10 anatomical landmarks; ● Maximum aortic diameter of the abdominal aorta, descending aorta and ascending aorta. The BriefCase-Quantification results are not intended to be used on a stand-alone basis for clinical decision-making or otherwise preclude clinical assessment of cases. These measurements are unofficial, are not final, and are subject to change after review by a radiologist. For final clinically approved measurements, please refer to the official radiology report. Clinicians are responsible for viewing

	Predicate Device BriefCase-Quantification of the Abdominal Aortic Measurement (M-AbdAo) (K241112)	**Reference Device AI-Rad Companion (Cardiovascular) (K222360)**	**Subject Device Aidoc BriefCase-Quantification of Aortic Measurement (M-Aorta)**
			full images per the standard of care.
User population	Appropriately trained medical specialists	Radiologists and physicians from emergency medicine, specialty care, urgent care, and general practice	Hospital networks and appropriately trained medical specialists
Anatomical region of interest	Abdominal aorta	Heart, coronary arteries and aorta	Aorta
Data acquisition protocol	CT exams with contrast that include the abdominal aorta	non-cardiac chest CT	contrast-enhanced CT exams that include the aorta
Diameter Measurement	Yes	Yes	Yes
Images format	DICOM	DICOM	DICOM
Interference with standard workflow	No	No	No
Algorithm	Artificial intelligence algorithm with database of images.	Artificial intelligence algorithm with database of images.	Artificial intelligence algorithm with database of images.
Structure	-BriefCase-Quantification, is hostedon a cloud server, analyzes applicable CT images that are acquired on CT scanner that are forwarded to BriefCase-Quantification.	- The system remains hosted in the teamplay digital health platform and remains driven by the AI-Rad Companion Engine. - The edge deployment the processing of clinical	- BriefCase-Quantification is hosted on a cloud server, analyzes applicable CT images that are forwarded to BriefCase-Quantification. - The results of the analysis are exported

	Predicate Device BriefCase-Quantification of the Abdominal Aortic Measurement (M-AbdAo) (K241112)	Reference Device AI-Rad Companion (Cardiovascular) (K222360)	Subject Device Aidoc BriefCase-Quantification of Aortic Measurement (M-Aorta)
	- The results of the analysis are exported in DICOM format, and are sent to a PACS destination for review by medical specialists, to assist in the measurement of the abdominal aorta.	data and the generation of results are performed within the customer environment. - This system remains fully connected to the cloud for monitoring and maintenance of the system from a remote setup.	in DICOM format, and are sent to a PACS destination for review by medical specialists, to assist in the measurement of the abdominal aorta.

Performance Data

Pivotal Study Summary

Aidoc conducted a retrospective, blinded, multicenter study with the BriefCase-Quantification software to evaluate the software's performance in providing quantitative diameter measurements across a set of 10 aorta landmarks and measurements of the maximum aortic diameter at three segments - abdominal ascending, and descending in contrast-enhanced CT exams that include the aorta in 212 cases, from 6 US-based clinical sites, both academic and community centers, compared to the ground truth, as determined by three US board-certified radiologists. The cases collected for the pivotal dataset were all distinct in time and/or center from the cases used to train the algorithm.

Primary Endpoint

The algorithm performance showed that the mean absolute error between the ground truth measurement and algorithm across all landmarks and across all studies was 1.88 mm (95% CI: 1.78 mm, 1.99 mm). Because the mean absolute error estimate was below the prespecified performance goal, the study's primary endpoint was achieved.

The reported similar mean absolute error [the subject device: 1.88 mm (95% CI: 1.78 mm, 1.99 mm); the predicate device: 1.95 mm (95% CI: 1.59 mm, 2.32 mm)] demonstrates comparable performance.

As can be seen in **Table 2,** the mean age of patients whose scans were reviewed for BriefCase-Quantification of Aortic Measurement (M-Aorta) was 63.2 years, with a standard deviation of 19.3 years. Gender distribution was 49.8% male, and 50.2% female (**Table 3**). Scanner distribution can also be found in **Table 4** below.

Table 2. Descriptive Statistics for Age

	Mean	Std	Min	Median	Max	N
Age (Years)	63.0	19.3	18.0	67.0	90.0	212

Table 3. Frequency Distribution of Gender

Gender	N*	%
Male	106	50%
Female	106	50%

Table 4. Frequency Distribution of Manufacturer

Manufacturer	N	%
Siemens	58	27.4%
GE	49	23.1%
Philips	50	23.6%
Toshiba	55	25.9%
Total	212	100%

Clinical Subgroups and Confounders: Aortic Aneurysm; Vasculitis, penetrating atherosclerotic ulcer, and mural thrombus; Aortic calcification/atherosclerosis; Aortic dissection; Retroperitoneal lymphadenopathy / enlarged para-aortic nodes and None of the above.

Performance testing results for the Bland-Altman analysis is reported below:

The mean difference between the ground truth compared to the algorithm output is 0.1 mm, indicating that there is little to no bias between the two measurements, demonstrating the study's secondary endpoint was achieved.

In summary, performance validation data, combined with a comparison of mean absolute error metric with the primary predicate device demonstrated equivalent performance.

Conclusions

The subject BriefCase-Quantification of Aortic Measurement (M-Aorta), the primary predicate BriefCase-Quantification of the Abdominal Aortic Measurement (M-AbdAo) and the reference device

AI-Rad Companion (Cardiovascular) are intended to aid in medical image management and processing of radiological images in CT. The devices are not intended to be used as diagnostic devices. All three devices are software packages with similar technological characteristics and principles of operation, incorporating deep learning AI algorithms that process images. They additionally operate in parallel to the standard of care workflow in the sense that they have the potential to allow accurate measurement and facilitate the standard manual workflow.

In all devices, the labeling instructs the user that the results are not intended to be used on a stand-alone basis for clinical decision making or otherwise preclude clinical assessment. The subject and predicate device have similar clinical indications and show substantially similar performance.

The BriefCase-Quantification of Aortic Measurement (M-Aorta) device demonstrates substantial equivalence to the BriefCase-Quantification of the Abdominal Aortic Measurement (M-AbdAo) and AI-Rad Companion (Cardiovascular).