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

May 15, 2024

Re: K241112
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: April 22, 2024
Received: April 22, 2024

Dear John J. Smith:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (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.

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,

for

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241112

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 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 diameter measurement of cases that include the abdominal aorta (M-AbdAo). BriefCase-Quantification is indicated to evaluate normal and aneurysmal abdominal aortas and is not intended to evaluate postoperative aortas.

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.

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

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

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

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

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

510(K) SUMMARY

Aidoc Medical, Ltd.'s

BriefCase-Quantification

Submitter

Aidoc Medical, Ltd.

3 Aminadav St.
Tel-Aviv, Israel
6706703

Phone: +972-73-7946870

Contact Person: Amalia Schreier, VP of Regulatory Affairs

Date Prepared: 2024-05-13

Name of Device: BriefCase-Quantification

Common or Usual Name: 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 Devices BriefCase-Quantification (K230534)

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.

BriefCase-Quantification produces a preview image annotated with the maximum diameter measurement. 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 measurement which is not final, 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 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 diameter measurement of cases that include 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 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.

Summary of Technological Characteristics

The subject BriefCase-Quantification device is substantially similar to the predicate device BriefCase-Quantification (K230534). Both devices are radiological computer-aided medical image management and processing software devices, intended to aid in measurement of radiological images.

Both devices are artificial intelligence, deep-learning algorithms incorporating software packages for use with compliant scanners, PACS, and radiology workstations. Both are intended to assist appropriately trained medical specialists by providing the user with the maximum abdominal aortic diameter measurement. The subject device presents key slice with the long and short axis of the aorta in the reformatted slice with the maximum measurement, while the predicate device presents key slice in axial format.

The main difference between the subject and predicate device is the performance, due to its training on a larger data set, in that the subject device demonstrates improved performance over the predicate device. With regards to the indications for use, for the predicate device the indications refer to axial measurement of cases that include the abdominal aorta. For the subject device, measurement is orthogonal to the blood flow, therefore the word axial was omitted from the indications for use statement.

Both devices raise the same types of safety and effectiveness questions. A table comparing the key features of the subject and predicate devices is provided below:

Table 1: Comparison between Predicate and Subject Devices

	Predicate Device: BriefCase-Quantification (K230534)	Subject Device: BriefCase-Quantification
Indications for Use/ Intended 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 measurement of cases that include 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 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.	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 diameter measurement of cases that include 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 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.
User Population	Appropriately trained medical specialists.	Appropriately trained medical specialists.
Anatomical region of interest	Abdominal aorta	Abdominal aorta

	Predicate Device: BriefCase-Quantification (K230534)	Subject Device: BriefCase-Quantification
Data acquisition protocol	CT exams with contrast that include the abdominal aorta	CT exams with contrast that include the abdominal aorta
Diameter Measurement	Yes	Yes
Measurement Method	Axial	Orthogonal
Images Format	DICOM	DICOM
Interference with standard workflow	No	No
Preview images	Presentation of a compressed, grayscale preview image that is captioned “Not for diagnostic use”.	Presentation of a compressed, grayscale preview image that is captioned “Not for diagnostic use”.
Output	Maximum abdominal aortic diameter with preview image that contains the measurement and key slice with the long and short axis of the aorta in the slice with the maximum measurement.	Maximum abdominal aortic diameter with preview image that contains the measurement and key slice with the long and short axis of the aorta in the reformatted slice composed of the plane that is orthogonal to the blood flow and not on the original axial slice.
Algorithm	Artificial intelligence algorithm with database of images	Artificial intelligence algorithm with database of images
Structure	- 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 in DICOM format, and are sent to a PACS destination for review by medical specialists, to assist in the measurement of the abdominal aorta.	- 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 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 maximum diameter measurements of the abdominal aorta in CT images in 162 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 was 1.52 mm (95% CI: 1.20 mm, 1.83 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: 1.52 mm (95% CI: 1.20 mm, 1.83 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 the Abdominal Aortic Measurement was 62.8 years, with a standard deviation of 19.6 years. Gender distribution was 46.9% male, and 53.1% 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)	62.8	19.6	18.0	67.5	90.0	162

Table 3. Frequency Distribution of Gender

Gender	N*	%
Male	76	46.9%
Female	86	53.1%

* 2 cases had unknown gender defined in the DICOM metadata header and were excluded from the gender distribution

Table 4. Frequency Distribution of Manufacturer

Manufacturer	N	%
Philips	43	26.5%
Canon	41	25.3%
Siemens	39	24.1%
GE	39	24.1%
Total	162	100%

Clinical Subgroups and Confounders: Preoperative abdominal 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 0.58 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 reference device demonstrated equivalent performance.

Conclusions

The subject and predicate BriefCase-Quantification for Abdominal Aortic Measurement (M-AbdAo) devices are intended to aid in medical image management and processing of radiological images in CT.

BriefCase-Quantification of M-AbdAo is as safe and effective as the predicate device cleared under K230534. BriefCase-Quantification has similar intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in the indications for use and in the technological characteristics do not alter the intended use of the device and do not affect its safety and effectiveness when used as labeled. Performance data demonstrate that the subject device is as safe and effective as the predicate device. Thus, BriefCase-Quantification of M-AbdAo is substantially equivalent to the previously cleared BriefCase-Quantification of M-AbdAo device (K230534).