Aidoc Medical, Ltd.
℅ John Smith
Partner
Hogan & Lovells U.S. LPP
555 Thirteenth Street NW
Washington, DC 20004

Re: K232083 November 13, 2023
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: October 17, 2023
Received: October 17, 2023

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.

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
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: 06/30/2023

See PRA Statement below

510(k) Number *(if known)*

K232083

Device Name

BriefCase-Quantification

Indications for Use *(Describe)*

BriefCase-Quantification of Midline Shift (MLS) is a radiological image management and processing system software intended for automatic measurement of brain midline shift in non-contrast head CT (NCCT) images, in adults or transitional adolescents aged 18 years and older.

The device is intended to assist appropriately trained medical specialists by providing the user with an automated current manual process of measuring midline shift.

The device provides midline shift measurement from NCCT images acquired at a single time point, and can additionally provide an output with comparative analysis of two or more images that were acquired in the same individual at multiple time points.

The device does not alter the original medical image and is not intended to be used as a diagnostic device. 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. 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
K232083

Submitter:

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Contact Person: Amalia Schreier, LL.M.

Date Prepared: November 10, 2023

Name of Device: BriefCase-Quantification

Classification Name: Medical image management and processing system

Regulatory Class: Class II

Product Code: QIH (21 CFR 892.2050)

Primary Predicate Device: qER-Quant (K211222)

Device Description

BriefCase-Quantification is a radiological 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 quantify the extent of midline shift. Following the AI processing, the output of the algorithm analysis is transferred to an image review software (the PACS or a desktop application).

The device generates a summary report that includes a preview image of the slice with the largest midline shift. The preview image includes the measured shift, the annotation of the midline, and the annotation of the largest perpendicular distance between the midline and septum pellucidum. Also, the summary report includes a table and a graph showing the measured midline shift over time for patients with multiple scans.

Intended Use / Indications for Use

BriefCase-Quantification of Midline Shift (MLS) is a radiological image management and processing system software intended for automatic measurement of brain midline shift in non-contrast head CT (NCCT) images, in adults or transitional adolescents aged 18 years and older.

The device is intended to assist appropriately trained medical specialists by providing the user with an automated current manual process of measuring midline shift.

The device provides midline shift measurement from NCCT images acquired at a single time point, and can additionally provide an output with comparative analysis of two or more images that were acquired in the same individual at multiple time points.

The device does not alter the original medical image and is not intended to be used as a diagnostic device. 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. Clinicians are responsible for viewing full images per the standard of care.

Comparison of Technological Characteristics

The subject BriefCase-Quantification of Midline Shift (MLS) is substantially equivalent to the predicate qER-Quant (K211222), as explained below.

The subject device and the predicate device are both radiological image management and processing system software. Both devices are artificial intelligence, deep-learning algorithms incorporating software packages for use with compliant scanners, PACS, and radiology workstations. The predicate qER-Quant evaluates images from CT scanners as does the proposed device for BriefCase-Quantification of Midline Shift (MLS). The predicate and subject devices differ in the fact that the predicate device analyzes additional two brain structures, which are Intracranial Hyperdensities and Lateral Ventricles.

The proposed device for BriefCase-Quantification of Midline Shift (MLS) has similar technology and design as the primary predicate device, and similar indications for use as both devices are intended to aid in automation of the current manual process of measuring midline shift. The subject and predicate qER-Quant devices raise the same types of safety and effectiveness questions. A table comparing the key features of the subject device and the predicate device is provided below.

Table 1: Key Feature Comparison

	Predicate Device **qER-Quant (K211222)**	**BriefCase-Quantification of Midline Shift (MLS)**
Intended Use / Indications for Use	The qER-Quant device is intended for automatic labeling, visualization and quantification of segmentable brain structures from a set of Non-Contrast head CT (NCCT) images. The software is intended to automate the current manual process of identifying, labeling and quantifying the volume of segmentable brain structures identified on NCCT images.	BriefCase-Quantification of Midline Shift (MLS) is a radiological image management and processing system software intended for automatic measurement of brain midline shift in non-contrast head CT (NCCT) images, in adults or transitional adolescents aged 18 years and older.

	Predicate Device qER-Quant (K211222)	BriefCase-Quantification of Midline Shift (MLS)
	qER-Quant provides volumes from NCCT images acquired at a single time point and provides a table with comparative analysis for two or more images that were acquired on the same scanner with the same image acquisition protocol for the same individual at multiple time points. The qER-Quant software is indicated for use in the analysis of the following structures: Intracranial Hyperdensities, Lateral Ventricles and Midline Shift.	The device is intended to assist appropriately trained medical specialists by providing the user with an automated current manual process of measuring midline shift. The device provides midline shift measurement from NCCT images acquired at a single time point, and can additionally provide an output with comparative analysis of two or more images that were acquired in the same individual at multiple time points. The device does not alter the original medical image and is not intended to be used as a diagnostic device. 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. Clinicians are responsible for viewing full images per the standard of care.
Anatomical region of interest	Brain	Brain
Target structures analyzed on NCCT scans	Midline shift, Intracranial hyperdensities, and lateral ventricles	Midline shift
Data acquisition protocol	Non-contrast head CT (NCCT) images	Non-contrast head CT (NCCT) images
Midline Shift Measurement	Yes	Yes
Interference with standard workflow	No	No
Time point	Single or multiple time points	Single or multiple time points
Output	Multiple electronic reports with volumetric information of brain structures and midline shift and Annotated DICOM Images	A Summary report with measurement information of midline shift and annotated images

	Predicate Device qER-Quant (K211222)	BriefCase-Quantification of Midline Shift (MLS)
Algorithm	Artificial intelligence algorithm with database of images.	Artificial intelligence algorithm with database of images.
Structure	- The qER-Quant software interacts with the user's picture archiving and communication system (PACS) to receive scans and returns the results to the same destination. - The core processing component is coupled with a pre-processing module to prepare input digital imaging and communications in medicine (DICOMs) for processing by the CNNs and a post-processing module to convert the output into visual and tabular output for users.	- BriefCase-Quantification is hosted on a cloud server and analyzes applicable CT images that are acquired on CT scanner that are forwarded to BriefCase-Quantification - The results of the analysis are exported and presented to medical specialists for review , to assist in the measurement of MLS.

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 adequate measurements of the midline shift in non-contrast head CT images in 284 cases from 228 unique patients from 6 US-based clinical sites, both academic and community centers, compared to the ground truth, as determined by three neuroradiologists, who independently measured the midline shift, the reference standard was created as the mean of all three measurements. The cases collected for the pivotal dataset were all distinct in time or center from the cases used to train the algorithm.

Primary Endpoints

The algorithm performance showed that the mean absolute error between the ground truth measurement and algorithm was 0.94 mm (95% CI: 0.74 mm, 1.14 mm) mm. Because the mean absolute error estimate is lower than the prespecified performance goal, the study's primary endpoint was achieved.

Secondary Endpoints

A Bland-Altman plot demonstrated an agreement between the ground truth compared to the algorithm output. The mean difference between the two measurements was -0.15 mm, indicating that there is little to no bias between the two measurements, demonstrating the study's secondary endpoint was achieved.

The mean absolute error in midline shift between the device and the reference for multiple time point testing for the same patient was 1.16 mm (95% CI: 0.61 mm, 1.71 mm) for the first case and 1.28 mm (95% CI: 0.68 mm, 1.88 mm) for the follow-up cases. Because the mean absolute error estimate is lower than the prespecified performance goal, the study's secondary endpoint was achieved.

Thus, the reported similar mean absolute error [the subject device: 0.94 (1.54) mm 0.51 (0.09 - 1.75) mm; the predicate device: 1.37 (1.23) mm 1.15 (0.23 - 2.59) mm] demonstrates that when using the subject BriefCase-Quantification of Midline Shift (MLS) the radiologists may have the same benefits with the qER-Quant.

As can be seen in **Table 2** the mean age of patients whose scans were reviewed for BriefCase-Quantification of Midline Shift (MLS) was 64.4 years, with a standard deviation of 20.1 years. Gender distribution was 48.3% male, and 48.8% 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)	64.4	20.2	18	68	90	228

Table 3: Frequency Distribution of Gender

Gender	N*	%
Male	110	48.3%
Female	111	48.8%

* 7 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	%
Siemens	47	20.6%
GE	58	25.4%

Manufacturer	N	%
Philips	65	28.5%
Toshiba	58	25.4%
Total	228	100%

Clinical Subgroups and Confounders: Heart and Vascular, Chronic diseases, Neoplasm, Trauma, Inflammatory, None of the above and Fully Negative.

In summary, performance validation data, combined with a comparison of overall agreement metric with the predicate device demonstrated equivalent performance.

Conclusions

The subject BriefCase-Quantification of Midline Shift (MLS) and the predicate qER-Quant are intended to aid in medical image management and processing of radiological images of the brain. The subject and predicate devices are both software devices with similar technological characteristics and principles of operation, incorporating deep learning AI algorithms that process images. The predicate and subject devices both provide an automated current manual process of measuring midline shift. Both devices provide a summary report and quantitative measurements from NCCT images acquired at a single time point and provide a table with comparative analysis for two or more images that were acquired for the same individual at multiple time points. The BriefCase-Quantification of Midline Shift (MLS) device is thus substantially equivalent to the qER-Quant device (K211222).