



Qure.ai Technologies
% Pooja Rao
Head, Research and Development
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INDIA

June 17, 2020

Re: K200921
Trade/Device Name: qER
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer-assisted triage and notification software
Regulatory Class: Class II
Product Code: QAS
Dated: June 11, 2020
Received: June 11, 2020

Dear Pooja Rao:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

Indications for Use

510(k) Number (if known)

K200921

Device Name

qER

Indications for Use (Describe)

qER is a radiological computer aided triage and notification software indicated for use in the analysis of non-contrast head CT images.

The device is intended to assist hospital networks and trained medical specialists in workflow triage by flagging the following suspected positive findings of pathologies in head CT images: intracranial hemorrhage, mass effect, midline shift and cranial fracture.

qER uses an artificial intelligence algorithm to analyze images on a standalone cloud-based application in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected findings. Notifications include non-diagnostic preview images that are meant for informational purposes only. The device does not alter the original medical image and is not intended to be used as a diagnostic device.

The results of the device 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)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

Qure.ai's qER

Submitter:

K200921

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Contact Person: Pooja Rao

Date Prepared: June 11, 2010

Name of Device: qER

Common or Usual Name: Radiological Computer-Assisted Triage and Notification Software

Classification Name: Radiological Computer-Assisted Triage and Notification Software

Regulatory Class: Class II

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

Predicate Device: Aidoc's Briefcase Software (K180647)

Reference Device: Aidoc's Briefcase Software (for CSF Triage) (K190896)

Device Description:

Qure.ai Head CT scan interpretation software, qER, is a deep-learning-based software device that analyses head CT scans for signs of intracranial hemorrhage, midline shift, mass effect or cranial fractures in order to prioritize them for clinical review. The standalone software device consists of an on-premise module and a cloud module. qER accepts non-contrast adult head CT scan DICOM files as input and provides a priority flag indicating critical scans. Additionally, the software has the capability to send the preview of critical scans to the medical specialist.

Intended Use / Indications for Use:

The qER device is a radiological computer aided triage and notification software indicated for use in the analysis of non-contrast head CT images.

The device is intended to assist hospital networks and trained medical specialists in workflow triage by flagging the following suspected positive findings of pathologies in head CT images: intracranial hemorrhage, mass effect, midline shift and cranial fracture.

qER uses an artificial intelligence algorithm to analyze images on a standalone cloud-based application in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected findings. Notifications include non-diagnostic preview images that are meant for informational purposes only. The device does not alter the original medical image and is not intended to be used as a diagnostic device.

The results of the device 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.

Technological Characteristics

The qER software consists of two major components: 1) a configurable gateway as an interface with the client systems such as the PACS and worklist; and 2) analysis module that hosts the pre-trained artificial intelligence algorithms. qER software can be deployed completely on client premises (on-premise) or on cloud servers (on-cloud). For on-cloud processing mode, an on-premise gateway is deployed that interfaces with the HIPAA-compliant cloud server(s) where the analysis is performed.

Additionally, a configuration module allows control over triage settings and output formats.

The deep learning analysis module underlying qER consists of a set of 4 independent algorithms. The core component of each algorithm is a pre-trained classification convolutional neural network (CNN) that has been trained to detect a specific abnormality from head CT scan images. This core component is coupled with a pre-processing module that transforms the CT scan series to a set of images and a post-processing module that combines slice-level outputs to a scan-level triage result for each abnormality.

A predefined threshold is applied to each of the 4 scan-level outputs, to determine the presence (positive, 1) or absence (negative, 0) of the abnormality for purposes of triage for further review. If one or more of the 4 abnormalities are present, the scan is positive for 'critical abnormality' and is triaged by placing an indicator on the worklist with the condition for which it was triaged identified.

Principles of Operation

qER is an artificial intelligence software device that screens head CT scans for signs of ICH, mass effect, midline shift and cranial fractures in order to prioritize them for clinical review. Each target abnormality is detected using an independent underlying pre-trained deep learning algorithm. Users can control the triage process by selecting one or more of the four target critical abnormalities identified by the software and can turn triage on or off for each abnormality. A dedicated, secure user settings webpage is to be made accessible to users for this purpose

The qER device is intended for use in parallel to the standard of care workflow. With the addition of the subject device to the workflow, the user is able to prioritize scans based on a suspected critical abnormality detected and flagged by qER.

Once deployed in conjunction with a PACS or CT scanner, the device automatically processes incoming CT scans and produces triage results that appear on the user's worklist as a priority flag. For every head CT scan identified by qER as containing one or more target abnormalities, a notification is sent to the worklist. For positive head CT scans, non-diagnostic preview images are returned to the PACS. These preview images are smaller in size than the original CT scan image and have a limited dynamic range. The notification and the preview image may be used as a reference by the end-user when deciding which study to read next.

Substantial Equivalence

The above indications for use statement for the subject device is substantially similar to the cleared indications for Aidoc's Briefcase device. Although the subject device is intended to flag mass effect, midline shift and cranial fractures in addition to ICH whereas the predicate flags intracranial hemorrhages only, this difference does not raise new questions of safety or effectiveness. Additionally, the reference device, Aidoc's Briefcase (for CSF Triage) (K190896) is indicated for use in the analysis of cervical spine CT images and is intended to assist radiologists by flagging linear lucencies in the cervical spine bone in patterns compatible with fractures. The overall effect of both the subject and predicate devices, namely the workflow triaging of CT images by flagging and communication of suspected findings of pathologies found in head CT images, remains the same.

Further, although the predicate device is intended to assist radiologists specifically as compared to the subject device, which is intended to assist trained medical specialists more generally, this difference does not raise new questions of safety or effectiveness as the function of the device is to simply triage CT images with the ultimate clinical decision making function continuing to the radiologists. The subject device triages head CT scans with any of the target findings; the user is provided with full control over which critical findings will be flagged through a settings menu.

In addition, the technological characteristics of both devices are very similar and the patient populations that the qER could be used for can be expected to overlap with that of the predicate device (i.e., patients suspected of having ICH abnormalities could also have mass effect, midline shift and/or a cranial fracture). In short, the target populations for which the qER and the predicate would be used for are largely the same.

In summary, the differences in the indications for use for the qER do not alter the intended effect of the device as compared to the predicate device or raise any new questions of safety or effectiveness. Thus, the company maintains that the qER meets the first requirement of substantial equivalence.

Both the subject and predicate device consist of a module that handles the incoming studies, de-identifies and pushes them to the cloud module, receives results after processing on the analysis module, and re-identifies the studies and sends the results to the radiology PACS and worklist used by medical specialist. Both devices also consist of a module that performs the analysis using a pre-trained artificial intelligence algorithm.

The qER software and the predicate device are radiological computer aided triage and notification software systems that are indicated for use in the analysis of non-contrast-enhanced head CT images. Both devices are intended to assist hospital networks and trained medical specialists in workflow triage by flagging and communication of suspected positive findings of pathologies identified in head CT images.

At a high level, the subject and predicate devices are based on the following same technological elements:

- Both the subject and predicate device use an artificial intelligence algorithm to analyze images and highlight cases with detected pathologies in parallel to the ongoing standard of care image interpretation. As part of both the subject and predicate software, the user is presented with notifications for cases with suspected findings. Notifications include preview images that are meant for informational purposes only and not intended for diagnostic use beyond notification.
- Further, both the subject and predicate device process CT images using similar techniques and a similar artificial intelligence algorithm. Specifically, the subject and predicate device utilize a deep

learning algorithm which has been trained on medical images. The deep-learning process allows for high accuracy in the detection of initial suspect locations. As a system, the qER raises the same types of safety and effectiveness questions as the predicate device, namely, accurate detection of findings within the reviewed and processed study on which a physician can base a clinically useful triage/prioritization assessment considering all available clinical data.

- Importantly, like the predicate, the device does not remove cases from a reading queue. It is also important to note that, similar to predicate, the subject device does not mark, highlight, or direct users' attention to a specific location in the original image. Further, both the subject and predicate software does not alter the original medical image, is not intended to be used as a diagnostic device and are to be used in parallel with the standard of care, which remains the default option for all cases.

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

Table 1. Comparison of Technical Characteristics with Predicate Device

Parameter	qER Device Subject Device	Aidoc Briefcase Software (K180647)
Indications For Use	<p>qER is a radiological computer aided triage and notification software indicated for use in the analysis of non-contrast head CT images.</p> <p>The device is intended to assist hospital networks and trained medical specialists in workflow triage by flagging the following suspected positive findings of pathologies in head CT images: intracranial hemorrhage, mass effect, midline shift and cranial fracture.</p> <p>qER uses an artificial intelligence algorithm to analyze images on a standalone cloud-based application in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected findings. Notifications include non-diagnostic preview images that are meant for informational purposes only. The device does not alter the original medical image and is not intended to be used as a diagnostic device.</p> <p>The results of the device 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.</p>	<p>BriefCase is a radiological computer aided triage and notification software indicated for use in the analysis of non-enhanced head CT images.</p> <p>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).</p> <p>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.</p> <p>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.</p>
Classification / Product Code	21 CFR 892.2080/QAS	21 CFR 892.2080/QAS
Device Components	<ol style="list-style-type: none"> 1. An on-premise module that: <ol style="list-style-type: none"> a. Performs de-identification of studies and pushes them to the cloud module. b. Receives results after processing on the cloud module. c. Re-identifies the studies and sends them to the radiology PACS and radiology worklist. 2. A cloud module that performs the analysis using a pre-trained artificial intelligence algorithm. 	<ol style="list-style-type: none"> 1. An on-premise module that: <ol style="list-style-type: none"> a. Performs de-identification of studies and pushes them to the cloud module. b. Receives results after processing on the cloud module. c. Re-identifies the studies and sends them to the radiology PACS and radiology worklist. 2. A cloud module that performs the analysis using a pre-trained artificial intelligence

Parameter	qER Device Subject Device	Aidoc Briefcase Software (K180647)
		algorithm.
Anatomical region of interest	Head	Head
Data acquisition protocol	Non contrast CT scan of the head	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, with controls for the user to select the finding or combination of findings for triage	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 care, which remains the default option for all cases.	Presentation of a preview of the study for initial assessment not meant for diagnostic purposes. 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
Abnormalities triaged	Four findings: Intracranial haemorrhage, Mass effect, midline shift, cranial fracture and ICH	One finding: Intracranial hemorrhage
User control over triage	Triages non-contrast CT scan when any of the 4 abnormalities are identified Notification/ prioritization with user provided control for configuring the triage finding or combination of finding(s)	Non contrast CT scan of the head or neck Single configuration
Preview image information	Preview images returned to the PACS Preview images are reduced in size and their dynamic range is limited	Preview images on hover over the worklist Preview images are compressed and/or reduced in size

Performance Data:

A retrospective, multicenter, blinded clinical study was conducted to test the accuracy of qER at triaging head CT scans containing one of the conditions listed below and to establish the clinical benefit of such triage.

The study used 1320 head CT scans from multiple United States sites containing one or more of the following conditions: Intracranial hemorrhage (n=629), cranial fractures (n=248), mass effect (n=471), midline shift (n=414), and none of the target abnormalities (n=501) with 3 board-certified radiologists reading the scans to obtain ground truth. Overall, 48.03% of scans in the testing dataset had a slice thickness less than or equal to 3.5 mm.

Sensitivity and specificity exceeded the predefined success criteria, as well as the required performance criteria for triage and notification software as per the special controls for QAS, for all the 4 conditions independently and in combination, demonstrating the ability of the qER device to effectively triage studies containing one of these conditions.

Table 2. Primary Endpoint Results in qER Standalone Performance Study

Abnormality	Sensitivity (95% CI), TP/P	Specificity (95% CI), TN/N	AUC (95% CI)
Intracranial Hemorrhage	96.98 (95.32 - 98.17), 610/629	93.92 (91.87 - 95.58), 649/691	98.53 (98.00 - 99.15)
Cranial Fracture	96.77 (93.74 - 98.60), 240/248	92.72 (91.00 - 94.21), 994/1072	97.66 (96.88 - 98.57)
Mass Effect	96.39 (94.28 - 97.88), 454/471	96.00 (94.45 - 97.21), 815/849	99.09 (98.73 - 99.52)
Midline Shift	97.34 (95.30 - 98.67), 403/414	95.36 (93.79 - 96.64), 864/906	99.09 (98.74 - 99.51)
Any of the 4 target abnormalities	98.53 (97.45 - 99.24), 807/819	91.22 (88.39 - 93.55), 457/501	NA

The control group for specificity calculations and AUC includes all scans in the dataset not containing the target abnormality listed in that row. Control groups contain the other 3 target abnormalities and non-target abnormalities. TP = true positives, P = all positives, TN = true negatives, N = all negatives

The clinical benefit of using qER to prioritize these scans was quantified by comparing the time before the scan was opened by a radiologist in the Standard of Care (TTO) versus the time that qER notification was received (TTN) for all the eligible head CT scans included in the standalone study.

Since scans not containing any target abnormality would not be prioritized by qER, scans containing one or more of the target abnormalities were used for this analysis. Of the 819 studies containing one or more target abnormalities, the requisite timestamp data was available for 386 scans, of which 378 were correctly identified and notified by qER, and 8 were false negatives. These timestamps were collected and used for the clinical benefit analysis (n=386).

The mean TTO was 65.54 mins (95% CI 59.14 – 71.76 mins) for Standard of Care and the mean TTN was 2.11 mins (95% CI 1.45 - 2.61 mins) for qER. qER TTN was substantially lower than standard of care TTO. Thus, study prioritization by qER could substantially shorten the time that elapses before a critical head CT scan is read and diagnosed.

Table 3. Comparison between Standard of Care Time-to-Open and qER Time-to-Notify a Head CT Scan Containing One of the Target Abnormalities

Parameter	Mean (95% CI) in minutes	Median (95% CI) in minutes
Time to open exam in the standard of care	65.54 (59.14 - 71.76)	60.01 (54.57 - 77.63)
Time-to-notification with qER	2.11 (1.45 - 2.61)	1.21 (1.12 - 1.25)

Conclusion:

qER is as safe and effective as Aidoc’s Briefcase software. qER has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the intended use of the device and do not affect its safety and effectiveness when used as labeled. Thus, qER is substantially equivalent to the predicate device.