



DeepHealth, Inc.
A. Gregory Sorensen, M.D.
President and CEO
1000 Massachusetts Ave
CAMBRIDGE MA 02138

April 16, 2021

Re: K203517
Trade/Device Name: Saige-Q
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological Computer aided triage and notification software
Regulatory Class: Class II
Product Code: QFM
Dated: March 19, 2021
Received: March 19, 2021

Dear Dr. Sorensen:

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 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)
K203517

Device Name
Saige-Q

Indications for Use (Describe)

Saige-Q is a software workflow tool designed to aid radiologists in prioritizing exams within the standard-of-care image worklist for compatible full-field digital mammography (FFDM) and digital breast tomosynthesis (DBT) screening mammograms. Saige-Q uses an artificial intelligence algorithm to generate a code for a given mammogram, indicative of the software's suspicion that the mammogram contains at least one suspicious finding. Saige-Q makes the assigned codes available to a PACS/EPR/RIS/workstation for worklist prioritization or triage.

Saige-Q is intended for passive notification only and does not provide any diagnostic information beyond triage and prioritization. Thus, it is not intended to replace the review of images or be used on a stand-alone basis for clinical decision-making. The decision to use Saige-Q codes and how to use those codes is ultimately up to the interpreting radiologist. The interpreting radiologist is responsible for reviewing each exam on a diagnostic viewer and evaluating each patient according to the current 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**DeepHealth's Saige-Q****501(k) Submission Number K203517****Submitter:**

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Contact Person: A. Gregory Sorensen

Date Prepared: November 30, 2020

Name of Device: Saige-Q™

Common or Usual Name: Medical Imaging Software

Classification Name: Radiological Computer-Assisted Triage and Notification Software

Regulatory Class: Class II (21 CFR 892.2080)

Product Code: QFM

Predicate Devices

CureMetrix, Inc., cmTriage, K183285

Device Description

Saige-Q is a software workflow device that processes Digital Breast Tomosynthesis (DBT) and Full-Field Digital Mammography (FFDM) screening mammograms using artificial intelligence to act as a prioritization tool for interpreting radiologists. By automatically indicating whether a given mammogram is suspicious for malignancy, Saige-Q can help the user prioritize or triage cases in their worklist (or queue) that may benefit from prioritized review.

Saige-Q takes as input a set of x-ray mammogram DICOM files from a single screening mammography study (FFDM or DBT). The software first checks that the study is appropriate for Saige-Q analysis and then extracts, processes and analyses the DICOM images using an artificial intelligence algorithm. As a result of the analysis, the software generates a Saige-Q code indicating the software's suspicion of the presence of findings suggestive of breast cancer. For mammograms given a Saige-Q code of "Suspicious," the software also generates a compressed preview image, which is for informational purposes only and is not intended for diagnostic use.

The Saige-Q code can be viewed by radiologists on a picture archiving and communication system (PACS), Electronic Patient Record (EPR), and/or Radiology Information System (RIS) worklist and can be used to reorder the worklist. As a software-only device, Saige-Q can be hosted on a compatible host server connected to the necessary clinical IT systems such that DICOM studies can be received and the resulting outputs returned where they can be incorporated into the radiology worklist.

The Saige-Q codes can be used for triage or prioritization. For example, "Suspicious" studies could be given prioritized review. With a worklist that supports sorting, batches of mammograms could also be sorted based on the Saige-Q code.

Intended Use / Indications for Use

Saige-Q is a software workflow tool designed to aid radiologists in prioritizing exams within the standard-of-care image worklist for compatible full-field digital mammography (FFDM) and digital breast tomosynthesis (DBT) screening mammograms. Saige-Q uses an artificial intelligence algorithm to generate a code for a given mammogram, indicative of the software's suspicion that the mammogram contains at least one suspicious finding. Saige-Q makes the assigned codes available to a PACS/EPR/RIS/workstation for worklist prioritization or triage.

Saige-Q is intended for passive notification only and does not provide any diagnostic information beyond triage and prioritization. Thus, it is not intended to replace the review of images or be used on a stand-alone basis for clinical decision-making. The decision to use Saige-Q codes and how to use those codes is ultimately up to the interpreting radiologist. The interpreting radiologist is responsible for reviewing each exam on a diagnostic viewer and evaluating each patient according to the current standard of care.

Summary of Technological Characteristics

Saige-Q is a software only device that consists of several core components that perform the following functions: 1) receive mammogram study data as DICOM files, 2) preprocess the DICOM files and check that the study is appropriate for analysis, 3) analyze the study images using an artificial intelligence algorithm, 4) generate outputs based on the analysis and 5) send the outputs to the appropriate clinical IT system for viewing on a radiology worklist.

The receiving and sending components are configured at the time of installation in conjunction with clinical IT staff. The software should be installed on a compatible host machine that is connected to the appropriate clinical IT systems (e.g., RIS, PACS and/or EPR) that enable the device to receive DICOM studies and return Saige-Q outputs.

The preprocessing component of the device performs two functions. The first function is to check that the study is appropriate for analysis. For example, if the study is not a mammogram, Saige-Q will not proceed with analysis. Saige-Q is compatible with FFDM and DBT mammogram studies acquired using Hologic mammography equipment. The second function is to preprocess the images to be analyzed. The preprocessed images become the input to the AI algorithm, which generates the Saige-Q code using deep neural networks that have been trained on large numbers of mammograms where cancer status is known.

The technical components described above are also found in the predicate device, though the exact implementation may vary. One difference relative to the predicate device is Saige-Q's ability to process DBT mammograms, which requires an additional AI model. A comprehensive comparison with the predicate device is provided in the following table:

	Subject device	Predicate device	Summary
	Saige-Q DeepHealth Inc.	cmTriage CureMetrix. K183285	
Regulation number	21 CFR 892.2080 - Radiological Computer- Assisted Prioritization	21 CFR 892.2080 - Radiological Computer- Assisted Prioritization Software	Same

	Software		
Product code	QFM	QFM	Same
Class	II	II	Same
Intended use	<p>Saige-Q is a software workflow tool designed to aid radiologists in prioritizing exams within the standard-of-care image worklist for full-field digital mammography (FFDM) and digital breast tomosynthesis (DBT) screening mammograms. Saige-Q uses an artificial intelligence algorithm to generate a code for a given mammogram, indicative of the software's suspicion that the mammogram contains at least one suspicious finding. Saige-Q makes the assigned codes available to a PACS/EPR/RIS/workstation for worklist prioritization or triage.</p> <p>Saige-Q is intended for passive notification only and does not provide any diagnostic information beyond triage and prioritization. Thus, it is not intended to replace the review of images or be used on a stand-alone basis for clinical decision-making. The decision to use Saige-Q codes and how to use those codes is ultimately up to the interpreting radiologist. The interpreting radiologist is responsible for reviewing each exam on a diagnostic viewer and evaluating each patient according to the current standard of care.</p>	<p>cmTriage is a passive prioritization-only, parallel-workflow software tool used by radiologists to prioritize specific patients within the standard-of-care image worklist for 2D FFDM screening mammograms. cmTriage uses an artificial intelligence algorithm to analyze 2D FFDM screening mammograms and flags those that are suggestive of the presence of at least one suspicious finding at the exam level. These flags are viewed by the radiologist via their PACS worklist. The decision to use cmTriage codes and how to use cmTriage codes is ultimately up to the radiologist. cmTriage does not send a proactive alert directly to the radiologist.</p> <p>Radiologists are responsible for reviewing each exam on a diagnostic viewer according to the current standard of care.</p> <p>cmTriage is limited to the categorization of exams, does not provide any diagnostic information beyond triage and prioritization, does not remove images from the radiologist's worklist, and should not be used in lieu of full patient evaluation, or relied upon to make or confirm diagnosis.</p> <p>cmTriage is for prescription use only.</p>	Both devices have the same intended use per 21 CFR 892.2080
Technical Method	The device provides triage or notification that is informed by artificial intelligence algorithms.	The device provides triage or notification that is informed by artificial intelligence algorithms.	Same

Anatomical Site	Breast	Breast	Same
Clinical condition	Breast cancer	Breast cancer	Same
Notification-only, parallel workflow tool	Yes	Yes	Same
Alert to finding	Passive notification flagged for review	Passive notification flagged for review	Same
Preview Image	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.	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.	Same
Multiple operating points	Yes; 3 operating points	Yes; a continuous range of operating points.	Similar but Saige-Q uses a more conservative approach by pre-specifying a discrete number of operating points.
Independent of standard of care workflow	Yes; no cases are removed from worklist	Yes; no cases are removed from worklist	Same
End users	Radiologists	Radiologists	Same
Type of mammograms	FFDM and DBT screening mammograms.	FFDM screening mammograms.	Both devices operate on screening mammograms (x-ray images), but cmTriage is intended for FFDM cases only whereas Saige-Q is intended for both FFDM and DBT cases.
Deployment	On-premise	On-premise with cloud processing	Different, but does not raise any new questions regarding safety and effectiveness.
Output device	The end user interacts with	The end user interacts with the	There is no

	the output of the device in the facility's PACS/EPR/RIS software (worklist).	output of the device in the facility's PACS software (worklist).	significant difference.
Software levels of concern	Moderate	Moderate	Same

Performance Data

DeepHealth conducted two retrospective, blinded, multi-center studies to evaluate the standalone performance of Saige-Q, one study using FFDM and a separate study using DBT mammograms. The primary objective was the same for each study: to assess the sensitivity and specificity of Saige-Q relative to radiologist performance, as estimated by BCSC. The secondary objective was to assess the processing time performance when executing Saige-Q software on FFDM and separately on DBT mammograms to ensure processing times are within clinically acceptable ranges.

Data for the FFDM study was collected from eight clinical sites across two states in the United States with 501 malignant exams and 832 normal exams. Data for the DBT study was collected from six clinical sites across two states in the United States, with 517 malignant exams and 1011 normal exams. The test dataset excludes screening BI-RADS 0 cases that were determined to be benign after diagnostic workup. DeepHealth had never collected data from the clinical sites previous to this study either for training or testing. Malignant exams were confirmed using pathology reports from biopsied lesions and normal cases were confirmed with a negative clinical interpretation (BIRADS 1 or 2) followed by another negative clinical interpretation at least two years later. Each case was reviewed by two independent expert radiologists (and an adjudicator if discordance was observed) to establish the reference standard for each case.

In the FFDM study, Saige-Q achieved an overall area under the receiver operating characteristic curve (AUC) of 0.966 (95% CI: [0.957, 0.975]). In the DBT study, Saige-Q achieved an overall AUC of 0.985 (95% CI: [0.979, 0.990]) on the DBT data. This performance meets or exceeds the performance of the predicate device and exceeds the requirement specified for the QFM product code for effective triage with an AUC >0.95.

The primary endpoints of the studies consisted of sensitivity and specificity targets to validate that Saige-Q operates with a 95% CI for both sensitivity and specificity above the 80% CI reported in BCSC data.

The primary endpoint for FFDM was successfully met with Saige-Q demonstrating a specificity at 86.9% sensitivity of 92.2% (95% CI: [90.2%, 93.8%]) and a sensitivity at 88.9% specificity of 91.2% (95%: [88.4%, 93.4%]).

The primary endpoint for DBT was also successfully met with Saige-Q demonstrating a specificity at 86.9% sensitivity: 98.3% (95% CI: [97.3%, 99.0%]) and a sensitivity at 89.9% specificity of 95.7% (95% CI: [93.6%, 97.2%]).

A sub-analysis of performance by lesion type (soft tissue densities vs. calcifications), breast density (dense vs. non-dense), age, and lesion size showed similar performance across sub-categories. For instance, on FFDM, Saige-Q achieved an AUC of 0.964 (95% CI: [0.954,

0.974]) on soft tissue densities and an AUC of 0.973 (95% CI: [0.958, 0.988]) on calcifications. For DBT, Saige-Q achieved an AUC of 0.983 (95% CI: [0.977, 0.990]) on soft tissue densities and an AUC of 0.989 (95% CI: [0.983, 0.996]) on calcifications. For breast density, Saige-Q achieved an AUC of 0.959 (95% CI: [0.945, 0.973]) on dense breasts and an AUC of 0.972 (95% CI: [0.961, 0.984]) on non-dense breasts for FFDM exams. For DBT, Saige-Q achieved an AUC of 0.980 (95% CI: [0.971, 0.988]) on dense breasts and an AUC of 0.988 (95% CI: [0.981, 0.996]) on non-dense breasts.

The secondary endpoints required the processing time for each FFDM and DBT mammogram to be within clinical operational expectations of breast cancer screening. The median processing time for FFDM was 15.5 seconds and was 196.8 seconds for DBT. These processing times are within the clinical expectations for screening mammograms.

Based on the clinical performance as documented in the pivotal clinical study, Saige-Q has a safety and effectiveness profile that is similar to the predicate device.

Conclusions

Saige-Q is as safe and effective as cmTriage. Saige-Q 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. In addition, the minor technological differences between Saige-Q and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that Saige-Q is as safe and effective as cmTriage. Thus, Saige-Q is substantially equivalent to the legally marketed predicate device.