510(k) Summary of MammoSightAI
by
NEUROCAREAI INC

510(k) Approval Number: K252954

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Device Name and Classification

Name of Device: MammoSightAI

Classification Name: Radiological Computer Aided Triage and Notification Software

Common or Usual Name: Radiological Computer Assisted Prioritization Software for Lesions

Classification Panel: Radiology

Regulation Number: 21 CFR 892.2080

Regulatory Class: Class II

Product Code: QFM

Predicate Device:

Manufacturer	Device Name	Product Code	Application Number
DeepHealth Inc.	Saige-Q	QFM	K203517

Device Description:
MammoSightAI is a software that utilizes deep learning techniques to process both DBT and FFDM screening digital mammograms, to act as a prioritization tool for interpreting radiologists. By automatically indicating whether a given mammogram is suspicious for malignancy, MammoSightAI can help the user prioritize or triage cases in their worklist (or queue) of hospital authorized PACS that may benefit from prioritized review.

The software analyzes a single mammogram study by evaluating all appropriate 2D FFDM scans as well as 3D DBT scans to determine suspected critical cases. The software first checks that the study is appropriate for 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 priority tag indicating the software's suspicion of the presence of findings suggestive of breast cancer. Mammograms are given a tag of "Suspicious" for suspected cases and left blank for non-suspicious cases considered by the software. The software also generates two DICOM files as output including a non-diagnostic preview image, which is for informational purposes only and is not intended for diagnostic use. The device's priority code can be viewed by radiologists on a hospital authorized PACS/workstation to enable worklist prioritization.

Intended Use:
The MammoSightAI software is designed to detect and classify the presence of malignancy and features suggestive of breast cancer in DBT and FFDM screening mammograms. The results are presented in the hospital PACS/workstation for prioritized review by interpreting radiologists. Patients are flagged with a "suspicious" tag if malignancy is suspected. Utilizing an artificial intelligence algorithm, the device analyzes images in parallel with the standard of care interpretation workflow, enabling worklist prioritization to facilitate the earlier review and diagnosis of suspected critical patients compared to routine practices.

Indications for Use:
MammoSightAI is a software radiological workflow tool designed to assist radiologists in prioritizing exams within the standard-of-care image worklist for compatible FFDM and DBT screening mammograms. Utilizing an advanced artificial intelligence algorithm, MammoSightAI analyzes each mammogram and assigns a tag indicating the software's suspicion of at least one potentially suspicious finding. These assigned tags are seamlessly integrated into the hospital PACS or workstation, enabling worklist prioritization or triage to help radiologists focus on the most critical cases first.

MammoSightAI 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 interpreting radiologist is responsible for reviewing each exam on a diagnostic viewer and evaluating each patient according to the current standard of care.

The indications for use of the subject device is identical to the cleared indications of use of the predicate device, where both devices are intended to assist radiologists in prioritizing review of critical patients suspected of at least one suspicious finding in the breast. Both devices target the same intended user and patient populations and utilize the same imaging modality, i.e., FFDM and DBT mammograms. Both devices utilize artificial intelligence algorithms to analyze

mammograms and generate a priority tag to enable worklist prioritization. Both devices send the results back to hospital PACS/workstation for prioritized review of suspected critical patients.

Comparison of Technological Characteristics:
Both the MammoSightAI and the predicate device; Saige-Q are software only devices that use Artificial intelligence (AI) algorithms and are intended to aid in triage and prioritization of radiological images.

At a high level, the subject and the predicate devices have the same principle of operation and underlying technological components that perform the following functions:

1. Receive mammogram study data as DICOM files from hospital PACS
2. Filter and preprocess the DICOM studies for analysis
3. Analyze the study images using an artificial intelligence algorithm
4. Generate outputs based on the analysis
5. Send the outputs to appropriate clinical IT system such as PACS for viewing on a radiology worklist

There are no notable technological differences between the subject and the predicate device. Both devices are designed to identify features suggestive of at least one suspicious finding suggestive of breast cancer in mammogram, to prioritize the review of suspected critical cases. They both operate on FFDM and DBT screening mammograms and present results within the appropriate clinical IT system such as PACS to enable worklist prioritization.

Both devices are intended to be used by radiologists, who are experts in the independent review and interpretation of mammograms. As passive notification tools focused on prioritization, neither device provides any diagnostic information beyond triage and notification. Additionally, neither device alters the standard of care image workflow after integration with hospital systems, removes cases from the worklist queue, or marks, highlights, or draws attention to specific regions of the analyzed mammograms.

Neither device is intended to serve as a standalone diagnostic tool. Instead, their outputs are solely for prioritization purposes, with the actual diagnosis relying on radiologists performing standard-of-care image interpretation. As both devices use proprietary AI algorithms and components, there are assumed differences in their implementation, as well as minor differences in the specific formats of the outputs provided to users. However these minor differences do not raise any new questions of safety and effectiveness and therefore do not affect the substantial equivalence claim of the subject device with the predicate device.

A table comparing the key features of the subject and predicate device is provided below:

Parameters	Subject Device MammoSightAI	Predicate Device Saige-Q
Indications for use	MammoSightAI is a software radiological workflow tool designed to assist radiologists in prioritizing exams within the standard-of-care image worklist for compatible FFDM and DBT screening mammograms.	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

	Utilizing an advanced artificial intelligence algorithm, MammoSightAI analyzes each mammogram and assigns a tag indicating the software's suspicion of at least one potentially suspicious finding. These assigned tags are seamlessly integrated into the hospital PACS or workstation, enabling worklist prioritization or triage to help radiologists focus on the most critical cases first. MammoSightAI 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 interpreting radiologist is responsible for reviewing each exam on a diagnostic viewer and evaluating each patient according to the current standard of care.	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.
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.
Anatomical region of interest	Breast	Breast
Intended user	Radiologists	Radiologists
Data acquisition	Acquires data from hospital PACS or FFDM and DBT compliant imaging devices.	Acquires data from appropriate clinical IT systems (such as PACS) or FFDM and DBT compliant imaging devices.
DICOM compatible	Yes	Yes
Image source modality	FFDM and DBT screening mammograms	FFDM and DBT screening mammograms
Design	Software only	Software only
AI used	Yes	Yes

Independent of standard of care workflow	Yes; no cases are removed from worklist	Yes; no cases are removed from worklist
Targeted abnormality	Breast cancer	Breast cancer
Notification only, parallel workflow tool	Yes	Yes
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.
Deployment	On-premise and Cloud	On-premise
Output device	The end user interacts with the output of the device in the facility's PACS software (worklist).	The end user interacts with the output of the device in the facility's PACS/EPR/RIS software (worklist).
Device output in case of positive detection	The software displays the analysis result and priority tag through the worklist interface of PACS/Workstation. No markup on original image. Secondary capture (OT file) containing non-diagnostic preview image and SR report of the finding.	The software displays the analysis result and priority code through the worklist interface of PACS/EPR/RIS/Workstation. No markup on original image. Secondary capture (OT file) containing compressed non-diagnostic preview image.
Performance level- processing time	Median Processing Time FFDM: 25 seconds DBT: 549.5 seconds (9.15 mins)	Median Processing Time FFDM: 15.5 seconds DBT: 196.8 seconds (3.28 mins)
Performance level – accuracy of classification	**Overall:** AUC: 0.963 (95% CI: [0.948, 0.977]) Sensitivity: 89.8% (95% CI: [86.0%, 92.9%]) Specificity: 95.0% (95% CI: [93.1%, 96.5%]) **FFDM:** AUC: 0.975 (95% CI: [0.958, 0.993]) Sensitivity: 89.7% (95% CI: [83.8%, 94.0%]) Specificity: 93.3% (95% CI: [89.9%, 95.8%]) **DBT:** AUC: 0.953 (95% CI: [0.930, 0.976]) Sensitivity: 90.0% (95% CI: [84.5%, 94.1%])	**FFDM:** AUC: 0.966 (95% CI: [0.957, 0.975]) Specificity: 92.2% (95% CI: [90.2%, 93.8%]) at 86.9% sensitivity Sensitivity: 91.2% (95%: [88.4%, 93.4%]) at 88.9% specificity **DBT:** AUC: 0.985 (95% CI: [0.979, 0.990]) Specificity: 98.3% (95% CI: [97.3%, 99.0%]) at 86.9% sensitivity Sensitivity: 95.7% (95% CI: [93.6%, 97.2%]) at 89.9% specificity

	Specificity: 96.3% (95% CI: [93.9%, 98.0%])	

Performance Data:

Software Testing- Non Clinical
Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software documentation level for this device is Basic Documentation.

Performance Testing - Clinical
Two retrospective, blinded, studies were conducted to evaluate the standalone performance of MammoSightAI, one study using FFDM and a separate study using DBT mammograms. The primary objective was the same for each study i.e., to assess the sensitivity, specificity, accuracy and AUC of MammoSightAI relative to the established ground truth based on clinical evidence and histopathological reports. The secondary objective was to assess the processing time performance when executing MammoSightAI software on FFDM and separately on DBT mammograms to ensure processing times are comparable to the predicate device and within clinically acceptable ranges for breast cancer screening.

A total of 1019 mammogram cases (468 cases of FFDM, and 551 cases of DBT) collected from Segmed with recognizable distribution of intended age, malignant cases, variable breast densities, lesion types, lesion sizes, race and other confounders were used in the standalone performance testing and device processing time estimation. We obtained standardized, high-quality, fully de-identified DICOM studies (mammograms) for testing from Segmed Insight Platform, adhering to privacy regulations such as HIPAA and GDPR under a proper research contract. This test dataset was totally separate from the databases (RSNA, VinDr-Mammo, and others) or studies (16364 mammogram images) used for the training of the MammoSightAI breast anomaly classifier and represents the vast US population.

The test dataset was obtained from various device manufacturers to ensure consistent performance and generalizability. FFDM study was conducted with 155 malignant exams, 133 benign exams and 180 normal exams. Whereas DBT study was conducted with 170 malignant exams, 205 benign exams and 176 normal exams. Moreover the entire dataset was well distributed across intended patient population i.e., females of age 35 years and older with a fair distribution of 26.8% mammograms in age group 35 to 50 years, 51.8% mammograms in age group 51 to 70 years and 21.4% mammograms in females over 70 years. The dataset had approximately 40.1% mammograms with dense tissue (density category C and D) and 59.9% mammograms with non-dense tissue (density category A and B). The dataset contained 15.2% mammograms with soft tissue lesions, 45.3% mammograms with calcification and 39.5% mammograms with solid/asymmetry/architectural distortions. The dataset had 5.4% mammograms with lesion size (small invasive) 1mm to 10mm, 19.0% mammograms with lesion size (intermediate and large invasive) 11mm to 50mm, 3% mammograms with lesion size (very large invasive) of greater than 50mm and 72.6% mammograms with undefined edges such that their size was unmeasurable. The dataset had distribution of various scanner manufacturers namely; Hologics Inc. (73.9%), Siemens (23.5%), GE Medical Systems (2.4%), and GE HealthCare (0.2%). Moreover it was spread across various regions of the United States (83.7% of the data belonged to the east region, 8.0% belonged to the midwest region, 7.8% belonged to the southwest region, 0.2% belonged to the northwest region and 0.3% of the scans had no

specific region specified i.e., telerad) and various races (54.9% of the data belonged to the White race, 8.2% of the data belonged to the Black or African American race, 5.2% of the data belonged to the Asian race, and 31.7% of the data had no specific race mentioned i.e, not reported). Malignant exams were confirmed using clinical evidence and histopathology reports from biopsied lesions, benign cases were confirmed using clinical evidence and histopathological reports along with a negative imaging follow-up of at least 12 months confirming no evidence of malignancy or suspicious change has been developed, and negative exams were confirmed with a minimum of 12 months of documented negative imaging follow-up in the clinical record, with no evidence of suspicious findings. Each case along with its clinical documentation was reviewed by two independent MQSA qualified radiologists to establish the reference standard based on histopathological evidence from biopsy results instead of radiologists independent interpretation.

The results obtained for both FFDM and DBT studies are given below:

Performance Metrics	Overall	FFDM	DBT
Sensitivity [95% CI]	89.8% [86.0%, 92.9%]	89.7% [83.8%, 94.0%]	90.0% [84.5%, 94.1%]
Specificity [95% CI]	95.0% [93.1%, 96.5%]	93.3% [89.9%, 95.8%]	96.3% [93.9%, 98.0%]
ROC AUC [95% CI]	0.963 [0.948, 0.977]	0.975 [0.958, 0.993]	0.953 [0.930, 0.976]
Accuracy [95% CI]	93.3% [91.6%, 94.8%]	92.1% [89.3%, 94.4%]	94.4% [92.1%, 96.1%]

In the FFDM study, MammoSightAI achieved an overall area under the receiver operating characteristic curve (AUC) of 0.975. In the DBT study, MammoSightAI achieved an overall AUC of 0.953 on the DBT data. This performance is comparable to the performance of the predicate device i.e., 0.966 for FFDM and 0.985 for DBT data and exceeds the pre-specified performance goal for MammoSightAI (AUC > 0.95) and requirement specified for the QFM product code for effective triage. The sensitivity, specificity, and accuracy values for both FFDM and DBT studies also exceed the pre-specified performance goal criteria of greater than 80%.

A sub-analysis of performance by lesion type, lesion size, breast density (dense vs. non-dense), age, scanner manufacturer and race was also conducted similar to the predicate device to showcase similar performance across subcategories and generalizability of the AI model. The tables below summarize the AUC values obtained for all sub-groups.

Device Performance by Lesion Type		
Lesion Type	**FFDM**	**DBT**
Soft tissue	0.994 [95% CI: (0.977, 0.999)]	1.000 [95% CI: (0.994, 1.000)]
Calcification	0.952 [95% CI: (0.945, 0.958)]	0.952 [95% CI: (0.946, 0.957)]
Solid/Asymmetry/Architectural Distortion	0.968 [95% CI: (0.960, 0.975)]	0.925 [95% CI: (0.918, 0.932)]

Device Performance by Lesion Size		
Lesion Size	**FFDM**	**DBT**
1mm to 10mm	0.982 [95% CI: (0.903, 1.000)]	0.958 [95% CI: (0.897, 0.989)]
11mm to 50mm	0.962 [95% CI: (0.935, 0.980)]	0.958 [95% CI: (0.920, 0.982)]
> 50mm	N/A due to no normal/benign distribution	N/A due to no normal/benign distribution
Undefined	0.950 [95% CI: (0.946, 0.955)]	0.939 [95% CI: (0.935, 0.943)]

Device Performance by Breast Density		
Breast Density	**FFDM**	**DBT**
Dense	0.970 [95% CI: (0.938, 1.000)]	0.945 [95% CI: (0.904, 0.986)]
Non-Dense	0.979 [95% CI: (0.959, 0.999)]	0.956 [95% CI: (0.929, 0.984)]

Device Performance by Age		
Age Range (Years)	**FFDM**	**DBT**
35 to 50	0.977 [95% CI: (0.938, 1.000)]	0.956 [95% CI: (0.906, 1.000)]
51 to 70	0.983 [95% CI: (0.964, 1.000)]	0.934 [95% CI: (0.893, 0.974)]
70+	0.957 [95% CI: (0.911, 1.000)]	0.978 [95% CI: (0.951, 1.000)]

Device Performance by Scanner Manufacturer		
Scanner Manufacturer	**FFDM**	**DBT**
Hologic Inc	0.970 [95% CI: (0.948, 0.993)]	0.963 [95% CI: (0.941, 0.985)]
Siemens	0.974 [95% CI: (0.925, 1.000)]	0.929 [95% CI: (0.849, 1.000)]
GE Medical Systems	1.000 [95% CI: (1.000, 1.000)]	N/A due to no DBT studies in test dataset

Device Performance by Race		
Race	**FFDM**	**DBT**

White	0.975 [95% CI: (0.950, 1.000)]	0.927 [95% CI: (0.883, 0.970)]
Black or African American	0.963 [95% CI: (0.890, 1.000)]	0.945 [95% CI: (0.861, 1.000)]
Asian	1.000 [95% CI: (1.000, 1.000)]	1.000 [95% CI: (1.000, 1.000)]
Not Reported	0.972 [95% CI: (0.942, 1.000)]	0.965 [95% CI: (0.936, 0.995)]

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 mammograms was calculated to be 25 seconds and for DBT mammograms was 549.5 seconds (9.15 mins). These processing times are comparable with the predicate device (showcasing 15.5 seconds for FFDM mammograms and 196.8 seconds for DBT mammograms) and within the clinical expectations for screening mammograms. Therefore, based on the clinical performance as documented in the pivotal clinical study, MammoSightAI has a safety and effectiveness profile that is similar to the predicate device to support the substantial equivalence claim.

Conclusion:
The comparison of the subject and predicate device in the table, along with the software and performance testing presented above, demonstrates that MammoSightAI is substantially equivalent to the predicate device, Saige-Q. Like the predicate, MammoSightAI is a software-only device and is designed to be as safe and effective. It shares the same intended users, similar technological characteristics, principles of operation and indications for use. The minor differences in device output and implementation of technological components do not introduce new safety concerns, nor do they impact the device's safety and effectiveness when used as labeled. Both devices function in parallel with the standard of care workflow. Performance testing confirms that MammoSightAI operates as intended, and software and clinical testing further support that it meets all defined software requirements.