



May 4, 2026

NEUROCAREAI INC (DBA SaveLife.AI)
Junaid Siddiq Kalia
Chief Executive Officer
1740 Lonesome Dove Dr
Prosper, Texas 75078

Re: K252954

Trade/Device Name: MammoSightAI
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological Computer Aided Triage And Notification Software
Regulatory Class: Class II
Product Code: QFM
Dated: April 2, 2026
Received: April 2, 2026

Dear Junaid Siddiq Kalia:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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,

YANNA S. KANG -S

Yanna Kang, Ph.D.

Assistant Director

Mammography and Ultrasound Team

DHT8C: Division of Radiological

Imaging and Radiation Therapy Devices

OHT8: Office of Radiological Health

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K252954

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Please provide the device trade name(s).

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MammoSightAI

Please provide your Indications for Use below.

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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

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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Please select the age group(s) for which the device(s) is to be used.

☐ Neonates/Newborns (Birth to < 29 days old)

☐ Infants (29 days old to < 2 years old)

☐ Children (2 years old to < 12 years old)

☐ Adolescents (12 years old to < 22 years old)

☒ Adults (22 years old and greater)

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**510(k) Summary of MammoSightAI
by
NEUROCAREAI INC**

510(k) Approval Number: K252954

Applicant Name: NEUROCAREAI INC. (DBA SaveLife.AI)
1740 Lonesome Dove Dr
Prosper, TX 75078 USA
Phone Number: +1 (214) 346-6083
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Contact Person: Junaid Kalia
Chief Executive Officer
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Date Prepared: April 1, 2026

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
<i>Indications for use</i>	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.
<i>Technical Method</i>	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.
<i>Anatomical region of interest</i>	Breast	Breast
<i>Intended user</i>	Radiologists	Radiologists
<i>Data acquisition</i>	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.
<i>DICOM compatible</i>	Yes	Yes
<i>Image source modality</i>	FFDM and DBT screening mammograms	FFDM and DBT screening mammograms
<i>Design</i>	Software only	Software only
<i>AI used</i>	Yes	Yes

<i>Independent of standard of care workflow</i>	Yes; no cases are removed from worklist	Yes; no cases are removed from worklist
<i>Targeted abnormality</i>	Breast cancer	Breast cancer
<i>Notification only, parallel workflow tool</i>	Yes	Yes
<i>Preview Image</i>	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.
<i>Deployment</i>	On-premise and Cloud	On-premise
<i>Output device</i>	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).
<i>Device output in case of positive detection</i>	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.
<i>Performance level- processing time</i>	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)
<i>Performance level – accuracy of classification</i>	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% CI: [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%])	
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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.