See-Mode Technologies Pty, Ltd.
Sadaf Monajemi
Co-founder and Director
3/162 Collins St.
Melbourne, VIC 3000
Australia

July 28, 2026

Re: K260303
Trade/Device Name: See-Mode Augmented Reporting Tool, Breast (SMART-B)
Regulation Number: 21 CFR 892.2090
Regulation Name: Radiological Computer-Assisted Detection And Diagnosis Software
Regulatory Class: Class II
Product Code: QDQ, QIH
Dated: June 30, 2026
Received: June 30, 2026

Dear Sadaf Monajemi:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

Digitally signed by Michael D. O'hara -S
Date: 2026.07.28 11:58:08 -04'00'

For

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.	K260303

Please provide the device trade name(s).

See-Mode Augmented Reporting Tool, Breast (SMART-B)

Please provide your Indications for Use below.

See-Mode Augmented Reporting Tool, Breast (SMART-B) is a stand-alone software to assist trained interpreting physicians in analyzing the breast ultrasound images of patients with soft tissue breast lesions who are being referred for diagnostic ultrasound examination.

Output of the device includes regions of interest (ROIs) placed on breast ultrasound images assisting interpreting physicians to localize suspicious soft tissue lesions from two orthogonal views of a single lesion in breast studies. The device also outputs the BI-RADS category as well as the ultrasonographic lexicon-based descriptors based on ACR BI-RADS for breast, including lesion shape, orientation, margin, echo pattern, and posterior features.

See-Mode Augmented Reporting Tool, Breast may also be used as a structured reporting software for further ultrasound studies. The software includes tools for reading measurements and annotations from the images that can be used for generating a structured report.

Patient management decisions should not be made solely on the basis of analysis by See-Mode Augmented Reporting Tool, Breast.

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)

This "510(k) Summary" was prepared per section 807.92(c).

1. ADMINISTRATIVE INFORMATION

Date of Preparation: July 21, 2026

Prepared by: Sadaf Monajemi, PhD.
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2. DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name: See-Mode Augmented Reporting Tool, Breast (SMART-B)
Regulation Number: 21 CFR 892.2090
Regulation Name: Radiological computer-assisted detection and diagnosis software
Classification Name: System, Image Processing, Radiological
Review Panel: Radiology
Regulatory Class: Class II
Product Code: QDQ/QIH

3. INTENDED USE

Localization and characterization of breast ultrasound images.

4. INDICATIONS FOR USE

See-Mode Augmented Reporting Tool, Breast (SMART-B) is a stand-alone software to assist trained interpreting physicians in analyzing the breast ultrasound images of patients with soft tissue breast lesions who are being referred for diagnostic ultrasound examination.

Output of the device includes regions of interest (ROIs) placed on breast ultrasound images assisting interpreting physicians to localize suspicious soft tissue lesions from two orthogonal views of a single lesion in breast studies. The device also outputs the BI-RADS category as well as the ultrasonographic lexicon-based descriptors based on ACR BI-RADS for breast, including lesion shape, orientation, margin, echo pattern, and posterior features.

See-Mode Augmented Reporting Tool, Breast may also be used as a structured reporting software for further ultrasound studies. The software includes tools for reading measurements and annotations from the images that can be used for generating a structured report.

Patient management decisions should not be made solely on the basis of analysis by See-Mode Augmented Reporting Tool, Breast.

5. DEVICE DESCRIPTION

See-Mode Augmented Reporting Tool, Breast (SMART-B) is a stand-alone, web-based image processing and reporting software for localization, characterization and reporting of lesions in breast ultrasound images.

The software analyzes breast ultrasound images and uses machine learning algorithms to extract specific information. The algorithms can identify and localize a single suspicious soft tissue lesion in two orthogonal views, generate the BI-RADS category and lexicon-based descriptors, which are classified according to ACR BI-RADS (shape, orientation, margin, echo pattern, and posterior features).

The software then generates a report based on the image analysis results to be reviewed and approved by a qualified interpreting physician after performing quality control. Any information within this report can be changed and modified by the clinician if needed during quality control and before finalizing the report.

SMART-B may also be used as a structured reporting software for further ultrasound studies. The software includes tools for reading measurements and annotations from the images that can be used for generating a structured report.

The software runs on a standard “off-the-shelf” computer and can be accessed within

the client web browser to perform the reporting of ultrasound images. Input data and images for the software are acquired through DICOM-compliant ultrasound imaging devices.

The data produced by the software is intended to be used by qualified interpreting physicians. The software is not intended to be used as an independent source of medical advice, or to determine or recommend a course of action or treatment for patients.

6. PREDICATE DEVICE

Manufacturer: TaiHao Medical Inc.
Trade Name: BU-CAD
510(k) Identifier: K210670
Regulation Number: 21 CFR 892.2090
Regulation Name: Radiological Computer Assisted Detection/Diagnosis Software For Lesions Suspicious For Cancer
Classification Name: Radiological Computer Assisted Detection/Diagnosis Software For Lesions Suspicious For Cancer
Classification Panel: Radiology
Regulatory Class: Class II
Product Code: QDQ, LLZ
Date Cleared: December 21, 2021

6.1. Tabular Comparison of Features and Specifications of the Subject Device, Predicate Device, and Reference Device

	Subject Device See-Mode Augmented Reporting Tool, Breast (SMART-B)	**Predicate Device BU-CAD (K210670)**	**Reference Device See-Mode Augmented Reporting Tool, Thyroid (SMART-T) (K240697)**
Administrative information			
Regulation	21 CFR 892.2090 Radiological computer-assisted detection and diagnosis software for lesions suspicious for cancer	21 CFR 892.2090 Radiological computer-assisted detection and diagnosis software for lesions suspicious for cancer	21 CFR 892.2090 Radiological computer-assisted detection and diagnosis software for lesions suspicious for cancer
Regulatory Class	Class II	Class II	Class II

	Subject Device **See-Mode Augmented Reporting Tool, Breast (SMART-B)**	**Predicate Device** **BU-CAD (K210670)**	**Reference Device** **See-Mode Augmented Reporting Tool, Thyroid (SMART-T) (K240697)**
Product Code	QDQ, QIH	QDQ, LLZ	QDQ, QIH
510(k) Number	K260303	K210670	K240697
Intended Use			
Indications for Use	See-Mode Augmented Reporting Tool, Breast (SMART-B) is a stand-alone software to assist trained interpreting physicians in analyzing the breast ultrasound images of patients with soft tissue breast lesions who are being referred for diagnostic ultrasound examination. Output of the device includes regions of interest (ROIs) placed on breast ultrasound images assisting interpreting physicians to localize suspicious soft tissue lesions from two orthogonal views of a single lesion in breast studies. The device also outputs the BI-RADS category as well as the ultrasonographic lexicon-based descriptors based on ACR BI-RADS for breast, including lesion shape, orientation, margin, echo pattern, and posterior features. See-Mode Augmented Reporting Tool, Breast may also be used as a structured reporting software for	BU-CAD is a software application indicated to assist trained interpreting physicians in analyzing the breast ultrasound images of patients with soft tissue breast lesions suspicious for breast cancer who are being referred for further diagnostic ultrasound examination. Output of the device includes regions of interest (ROIs) and lesion contours placed on breast ultrasound images assisting physicians to identify suspicious soft tissue lesions from up to two orthogonal views of a single lesion, and region-based analysis of lesion malignancy upon the physician's query. The region-based analysis indicates the score of lesion characteristics (SLC), and corresponding BI-RADS categories in user-selected ROIs or ROIs automatically identified by the software. In addition, BU-CAD also automatically classifies lesion shape, orientation, margin, echo pattern, and posterior features according to BI-RADS descriptors.	See-Mode Augmented Reporting Tool, Thyroid (SMART-T) is a stand-alone reporting software to assist trained medical professionals in analyzing thyroid ultrasound images of adult (>=22 years old) patients who have been referred for an ultrasound examination. Output of the device includes regions of interest (ROIs) placed on the thyroid ultrasound images assisting healthcare professionals to localize nodules in thyroid studies. The device also outputs ultrasonographic lexicon-based descriptors based on ACR TI-RADS. The software generates a report based on the image analysis results to be reviewed and approved by a qualified clinician after performing quality control. SMART-T may also be used as a structured reporting software for further ultrasound studies. The software includes tools for reading measurements and annotations from the images that can be used for

	Subject Device **See-Mode Augmented Reporting Tool, Breast (SMART-B)**	**Predicate Device** **BU-CAD (K210670)**	**Reference Device** **See-Mode Augmented Reporting Tool, Thyroid (SMART-T) (K240697)**
	further ultrasound studies. The software includes tools for reading measurements and annotations from the images that can be used for generating a structured report. Patient management decisions should not be made solely on the basis of analysis by See-Mode Augmented Reporting Tool, Breast.	BU-CAD may also be used as an image viewer of multi-modality digital images, including ultrasound and mammography. The software includes tools that allow users to adjust, measure and document images, and output into a structured report (SR). Patient management decisions should not be made solely on the basis of analysis by BU-CAD.	generating a structured report. Patient management decisions should not be made solely on the basis of analysis by See-Mode Augmented Reporting Tool, Thyroid.
Intended Population	Patients with soft tissue breast lesions who are being referred for ultrasound scan (Prescription only)	Patients with soft tissue breast lesions who are being referred for ultrasound interpreting (Prescription only)	Patients with thyroid nodules who are being referred for ultrasound scan (Prescription only)
Image Source	Ultrasound images	Ultrasound images	Ultrasound images
Rx only?	Yes	Yes	Yes
Technological Characteristics			
Application Description	The subject device is a stand-alone, web-based image processing and reporting software for localization, characterization and reporting of breast ultrasound images. The software analyzes breast ultrasound images and uses machine learning algorithms to extract specific information. The algorithms can identify and localize a single suspicious soft tissue lesion in two orthogonal views, generate the BI-RADS category and lexicon-based descriptors,	BU-CAD is a software system designed to assist users in analyzing breast ultrasound images including identification of regions suspicious for breast cancer and assessment of their malignancy. BU-CAD consists of a viewer, a lesion identification module, and a lesion analysis module. The lesion identification module identifies regions of interest (automated ROIs) of a single suspicious soft tissue lesion in up to two orthogonal views of breast ultrasound images for assisting users in detecting soft tissue lesions. Additionally, the lesion identification module	The reference device is a stand-alone, web-based image processing and reporting software for localization, characterization and reporting of thyroid ultrasound images. The software analyzes thyroid ultrasound images and uses machine learning algorithms to extract specific information. The algorithms can identify and localize suspicious soft tissue nodules and also generate lexicon-based descriptors, which are classified according to ACR TI-RADS (composition, echogenicity, shape, margin, and echogenic foci) with a

	Subject Device **See-Mode Augmented Reporting Tool, Breast (SMART-B)**	**Predicate Device** **BU-CAD (K210670)**	**Reference Device** **See-Mode Augmented Reporting Tool, Thyroid (SMART-T) (K240697)**
	which are classified according to ACR BI-RADS (shape, orientation, margin, echo pattern, and posterior features). The software then generates a report based on the image analysis results to be reviewed and approved by a trained qualified physician after performing quality control. Any information within this report can be changed and modified by the physician if needed during quality control and before finalizing the report.	generates an ROI and a lesion contour on each breast ultrasound image. The lesion analysis module analyzes given ROIs of a breast lesion on ultrasound images, and generates a score of lesion characteristics (SLC) in terms of malignancy or benignity of a lesion, BI-RADS category, and BI-RADS descriptors.	calculated TI-RADS category according to the ACR TI-RADS chart. The software then generates a report based on the image analysis results to be reviewed and approved by a qualified clinician after performing quality control. Any information within this report can be changed and modified by the clinician if needed during quality control and before finalizing the report.
Anatomical Location	Breast	Breast	Thyroid
Input	Medical images provided in a DICOM format	Medical images provided in a DICOM format	Medical images provided in a DICOM format
Output	ROIs placed on breast lesions BI-RADS lexicon descriptors BI-RADS category	ROIs and lesion contours placed on suspicious soft tissue lesion BI-RADS lexicon descriptors A region-based score of lesion malignancy BI-RADS category	ROIs placed on thyroid nodules TI-RADS lexicon descriptors TI-RADS category according to the ACR TI-RADS chart
Operating Platform	Client-server technology	Client-server technology	Client-server technology
Image Format	DICOM	DICOM	DICOM
2D viewing capabilities	Yes	Yes	Yes

	Subject Device **See-Mode Augmented Reporting Tool, Breast (SMART-B)**	**Predicate Device** **BU-CAD (K210670)**	**Reference Device** **See-Mode Augmented Reporting Tool, Thyroid (SMART-T) (K240697)**
Image storage and report generation	Yes	Yes	Yes

6.2. Comparison with Predicate and Reference Devices

Similarities

- **Intended Use:** The intended use and indications for use of the Subject Device are the same as that of the legally marketed predicate device, BU-CAD. Both are intended to be used by trained physicians interpreting radiological images to help them localize and characterize soft tissue lesions in breast ultrasound images. SMART-B and the predicate device are both intended to be used concurrently with the reading of images and are not intended as a replacement for the review of a physician or their clinical judgment.

- **Localization and Characterization:** See-Mode Augmented Reporting Tool, Breast (SMART-B) is similar to BU-CAD, the legally marketed predicate device, in its intent to localize soft tissue lesions in breast ultrasound images. Similarly, the reference device, SMART-T, localizes thyroid nodules in thyroid ultrasound images. All devices (SMART-B, BU-CAD, and SMART-T) have their soft tissue lesions automatically localized by the software. Similar to BU-CAD and SMART-T, our subject device provides automatic regions of interest (ROIs). The ROI highlights the bounding box around the detected lesion for the user to review. The user can't edit the bounding box directly but can remove an ROI from a finding or make changes to the report directly.

  Additionally, similar to the predicate and reference devices, the subject device characterizes the lesions based on lexicon descriptors. The subject device (SMART-B), predicate device (BU-CAD), and reference device (SMART-T) all use established classification systems for their ultrasonographic lexicon descriptors. They all use the American College of Radiology Systems for describing soft tissue lesions. The ACR atlases provide standardized imaging terminology, report organization, assessment structure, and a classification system, which enables radiologists to communicate results clearly and consistently. Both the subject device and the predicate BU-CAD device use ACR BI-RADS for breast ultrasound images. The reference SMART-T device uses ACR TI-RADS for analyzing and reporting of thyroid ultrasound images.

- **Target Population:** SMART-B, BU-CAD, and SMART-T share the same intended population. All devices are intended to be used for assisting trained interpreting physicians in analyzing patients with soft tissue lesions or suspicious nodules that are being referred for diagnostic ultrasound examination.

- **Anatomical Regions:** Both BU-CAD and the subject device are specifically focused on breast ultrasound images, whereas See-Mode Augmented Reporting Tool, Thyroid (SMART-T) analyzes thyroid ultrasound images.

Differences

- **Score of lesion malignancy:** Contrary to BU-CAD, SMART-B only provides ultrasonographic descriptors and BI-RADS category according to the ACR BI-RADS guideline. The subject device does not provide a region-based, stand-alone cancer risk assessment score (suspicion score) for predicting malignancy or benignity of breast lesions.

The technological characteristics of the subject device and its predicate and reference device have been evaluated to determine equivalence. Upon reviewing and comparing intended use, design, materials, principle of operation, and overall technological characteristics, the subject device is determined to be substantially equivalent to predicate (BU-CAD, K210670) and reference (SMART-T, K240697) devices in the table above.

Both devices (subject device and predicate) have the same intended use and are indicated for the same use. The subject device uses standard principles of operation, methods, and algorithms for processing, measurement, and quantification of the images and is intended to be used by trained professionals, which is similar to the predicate and reference devices.

The comparison of technological characteristics, non-clinical performance data, clinical data, and software validation data demonstrate that See-Mode Augmented Reporting Tool, Breast is as safe and effective when compared to the predicate and reference devices that are currently marketed for similar intended use and indications for use.

7. PERFORMANCE DATA - CLINICAL AND BENCH TESTING

The performance of the device has been validated both in a multi-reader multi-case (MRMC) study and a standalone study, as described below:

- MRMC study: The primary endpoint of the MRMC study is to compare the performance of the readers when aided vs. unaided by the device in suspicion level

by measuring the area under the curve (AUC) of the location-specific Receiver Operating Characteristic (LROC) against reference standard of biopsy or appropriate follow-up of benign status using Multi-reader Multi-case (MRMC) analysis.

In the MRMC study, we had 16 US board-certified radiologists read 589 cases from 589 patients twice, once with the aid of the device and once without. There was a one-month washout period in between the two reads.

- Standalone study: To evaluate the standalone performance of our device, where the output of the models are directly compared against ground truth labels. The standalone performance of the device was evaluated on 972 unique patients with breast ultrasound lesions.

To ensure the generalizability and satisfactory performance of our models on new, unseen data, all cases in both the MRMC and standalone studies were sourced from institutions or sources not part of the model training or development datasets.

SMART-B algorithms were trained using diverse datasets of breast ultrasound images acquired from multiple vendors including GE Healthcare, Philips Medical Systems, Toshiba, Hitachi, Samsung, Canon and Siemens. The training data comprised of over 12 institutions and over 35,000 lesions across multiple geographic regions. The datasets included a broad range of imaging protocols, transducer types, and patient demographics to ensure clinical representativeness. The performance of the device was evaluated across different sub-groups of patient age, race, lesion size, ultrasound machine, reader experience, and data sources.

7.1. MRMC Study

7.1.1. Acceptance criteria

The primary endpoint of the MRMC study is to demonstrate improved performance of the readers when aided vs. unaided by the device by measuring the area under the curve (AUC) of the location-specific Receiver Operating Characteristic (LROC) using Multi-reader Multi-case (MRMC) analysis.

7.1.2. Data Selection

The dataset has been collected retrospectively from breast ultrasound images of patients who have been referred for a diagnostic ultrasound examination. As the target population of the product are patients with soft tissue breast lesions who are being referred for

diagnostic ultrasound examination, the data comprised pre-existing images from these studies available in the existing registries in the clinical institutions.

The breast ultrasound images were acquired from commercially available ultrasound systems, including GE Healthcare, Philips Medical Systems, Toshiba Medical Systems, and Mindray. Images were obtained by qualified healthcare professionals using standard breast ultrasound imaging protocols.

The MRMC study consisted of 589 cases from unique patients. The data has been acquired from 9 clinical institutions across the US with a 100% female cohort. The age range is representative of the target population (>= 21 years old) and the patients in the study represented a racially and ethnically diverse population with patients from White, Asian, American Indian or Alaska Native, Black or African American and Native Hawaiian or Other Pacific Islander backgrounds.

The cases in the dataset contained both negative and positive biopsy results with all relevant BI-RADS categories (BI-RADS 2 to BI-RADS 5) represented. The data is sampled such that the distribution of the data accounts for patient age, lesion size, malignancy, a priori clinical ACR BI-RADS category.

7.1.3. Reader Selection

The study consisted of sixteen US board-certified radiologists with experience ranging from 0 to more than 20 years. All radiologists participating in the study use the American College of Radiology guidelines for interpreting breast ultrasound studies and satisfy a predefined set of requirements.

The table below shows the number of readers within each experience level.

Years of experience (post board certification)	**Total number of readers participating in the study**
0-3 years	4 Readers
4-7 years	4 Readers
8-10 years	3 Readers
11+ Years	5 Readers

7.1.4. Establishing ground truth

The performance of the subject device had been evaluated on localization, BI-RADS descriptors, BI-RADS category, and diagnostic outcome. The ground truthing approach for each is described below:

- Ground truth labels of benign or malignant status were assigned to the lesion for each case, sourced from the reference standard of biopsy or 2 year follow-up for benign status.

- The ground truth labels for localization, ACR BI-RADS lexicon descriptors, and BI-RADS category were based on the labels of two expert US-board certified radiologists and an adjudicator.

7.1.5. Performance Testing

Given that our device is intended for both localization and characterization, LROC analysis has been selected as the primary endpoint of the study to evaluate the performance of the device.

The table below shows the results for the primary study endpoint (IOU > 0.5) as well as a supportive analysis for different IOU thresholds. Reader performance improved significantly when aided across all localization thresholds. For the primary LROC definition (IOU > 0.5), average reader AUC had an increase of 0.073 (p=0.001) when aided, with the improvement more pronounced at stricter localization thresholds. Overall AUROC also showed a significant increase from 0.893 to 0.909 when aided (difference: 0.016, p<0.001). These results indicate that the aid of the device enhances both detection and diagnosis. Additionally, all sixteen readers have shown improved performance when aided by the subject device.

LROC Definition	Average Reader AUC (95% CI)			P-value
	Aided	Unaided	Difference (Aided – Unaided)	
IOU > 0.5	0.897 (0.874, 0.919)	0.824 (0.781, 0.867)	0.073 (0.032, 0.113)	0.001
IOU > 0.6	0.846 (0.815, 0.877)	0.752 (0.693, 0.811)	0.094 (0.037, 0.151)	0.003
IOU > 0.7	0.751 (0.710, 0.791)	0.615 (0.544, 0.687)	0.135 (0.065, 0.206)	<0.001

IOU > 0.8	0.484 (0.434, 0.534)	0.380 (0.317, 0.443)	0.104 (0.038, 0.170)	0.003
AUROC	0.909 (0.888, 0.930)	0.893 (0.871, 0.914)	0.016 (0.007, 0.025)	<0.001

Average reader sensitivity increased by 8.0% (95% Cl (4.6%, 12.9%, p-value < 0.001) whilst specificity decreased by -4.4% (95% CI (-8.1%, -0.9%), p-value = 0.014). Average reader positive predictive value (PPV) decreased by -0.5% (95% CI (-3.5%, 2.2%), p-value = 0.692), and negative predictive value (NPV) increased by 8.9% (95% CI (5.3%, 13.4%), p-value < 0.001). When adjusted to a clinically representative malignancy prevalence of 10%, the average aided PPV was 18.6%, compared with 18.7% in the unaided setting, while the adjusted average NPV increased from 97.4% in the unaided setting to 98.8% with device assistance.

The increase in NPV and decreased specificity are reflective of the impact of false positive findings on the reader's image assessments; however, the magnitude of the sensitivity improvement was nearly twice that of the specificity reduction. Although aided specificity was modestly lower than unaided specificity, this trade-off is consistent with established breast imaging practice, where maintaining high sensitivity is prioritized due to the clinical consequences associated with false negative findings and delayed cancer diagnosis.

7.1.6. Localization of breast lesions

To evaluate the localization performance of the device, we have calculated the average accuracy of the readers on localization in aided and unaided scenarios. The results are also reported separately for benign and malignant lesions. Localization accuracy for each reader is calculated as the number of cases where the reader's bounding box has achieved an IOU greater than 0.5 relative to the ground truth ROI, divided by the total number of cases in the corresponding analysis set (overall, benign only, malignant only).

Lesion Type	Number of cases	Average Localization Accuracy (95% CI)			P-value
		Aided	Unaided	Difference (Aided-Unaided)	
Overall	589	98.7% (97.9, 99.4)	93.3% (87.0, 97.0)	5.4% (1.7, 11.8)	<0.001
Malignant	290	98.7% (97.5, 99.6)	92.1% (87.1, 95.5)	6.6% (3.3, 11.6)	<0.001

Benign	299	98.7% (97.5, 99.6)	94.5% (86.5, 98.9)	4.2% (-0.3, 12.2)	0.061

When aided by SMART-B, readers achieved significantly higher localization accuracy overall (5.4% difference, $p < 0.001$), with particularly notable improvement for malignant lesions (6.6% difference, $p < 0.001$). These results indicate that the device enhances the ability of readers to correctly identify and localize clinically relevant lesions, supporting the effectiveness of the device.

7.1.7. BI-RADS Category

Aided assessments influenced agreement across the BI-RADS categories by improving consistency in the classification of clearly benign and clearly malignant cases, while altering reader classification patterns for borderline cases.

Positive percent agreement (PPA) remained high and stable for BI-RADS 2, decreased for BI-RADS 3 as aided readers were more likely to upgrade borderline findings, showed only minor variation across BI-RADS 4 subcategories, and improved substantially for BI-RADS 5, indicating enhanced alignment with reference truth for lesions highly suspicious for malignancy.

Negative percent agreement (NPA) increased for BI-RADS 2, 3, 4A, and 4B, suggesting improved specificity within lower and intermediate-risk categories, but decreased for BI-RADS 4C and BI-RADS 5, consistent with a tendency for the SaMD-assisted assessment to favour higher-risk categorization in equivocal cases. Overall, these findings suggest the device may support improved detection of clinically significant malignancies while modestly increasing conservative risk assignment near upper BI-RADS thresholds.

7.1.8. BI-RADS Descriptors

The table below provides BI-RADS descriptor performance in the aided and unaided modes for each of the descriptors.

		Aided	Unaided
ACR BI-RADS Descriptor	**Descriptor Class**	**Class-wise Accuracy**	**Class-wise Accuracy**
Shape	Round	94.1%	92.6%
	Irregular	76.9%	75.3%
	Oval	77.0%	79.1%

Posterior Features	No Posterior Features	78.0%	77.7%
	Enhancement	90.1%	90.4%
	Shadowing	82.9%	83.6%
	Combined Pattern	90.1%	89.8%
Orientation	Parallel	79.9%	77.6%
	Not Parallel	79.8%	76.3%
Echo Pattern	Anechoic	98.9%	97.8%
	Complex cystic & solid	94.2%	95.0%
	Heterogenous	81.2%	81.5%
	Hyperechoic	99.2%	99.1%
	Hypoechoic	74.7%	75.5%
	Isoechoic	89.5%	94.3%
Margin	Circumscribed	74.3%	75.8%
	Angular	79.6%	79.7%
	Indistinct	55.3%	55.6%
	Microlobulated	85.4%	85.5%
	Spiculated	87.1%	89.1%

Overall, aided assessments had minimal impact on agreement with the consensus ground truth across most BI-RADS descriptors, with improvements observed for one or more sub-categories of Shape, Posterior Features, Orientation and Echo Pattern, satisfying the predefined acceptance criteria for those descriptors. A small decrease was observed for Margin.

7.1.9. Subgroup analyses

Subgroup analysis of patient age (<40, 40-49, 50-59, 60-74, >=75), race (White, Asian, American Indian or Alaska Native, Black or African American, and Native Hawaiian or Other Pacific Islander groups), lesion size (<0.5cm, 0.5-1.0cm, 1.0-1.5cm, >=1.5cm), ultrasound machine (Acuson, GE, Philips, Toshiba and Mindray) and reader experience (0-3 years, 4-6 years, 7-10 years, >=11 years) from the MRMC study was performed. The readers aided by SMART-B achieved consistent improved performance across the subgroups.

7.2. Standalone Study

The standalone study evaluates the independent performance of the SMART-B device without radiologist input, using the 589 cases in the MRMC dataset along with a further 383 cases. This end-to-end evaluation of the 972 cases assesses both localization and

classification capabilities of the device, quantifying its diagnostic accuracy relative to biopsy or two-year benign follow-up.

7.2.1. Acceptance criteria

Standalone performance was considered acceptable if the device demonstrated clinically meaningful diagnostic discrimination for malignancy classification, defined as an AULROC greater than 0.80, with sensitivity at the BI-RADS 4A threshold of at least 85%. Specificity was also evaluated at this threshold and considered acceptable if consistent with the expected performance range of similar FDA-cleared breast ultrasound CADx devices. Localization performance was assessed using the pre-specified localization criterion, and BI-RADS category and descriptor outputs were evaluated descriptively against the established ground truth.

7.2.2. Data Selection

The dataset has been collected retrospectively from breast ultrasound images of patients who have been referred for a diagnostic ultrasound examination. As the target population of the product are patients with soft tissue breast lesions who are being referred for diagnostic ultrasound examination, the data comprised pre-existing images from these studies available in the existing registries in the clinical institutions.

The breast ultrasound images were acquired from commercially available ultrasound systems, including Acuson, Fujifilm Healthcare, GE Healthcare, Hitachi, Philips Medical Systems, Toshiba and Mindray. Images were obtained by qualified healthcare professionals using standard breast ultrasound imaging protocols.

The standalone performance study dataset included the original MRMC study dataset and an additional 383 cases from unique patients. The additional cases were acquired from two U.S. clinical institutions. All patients were female and at least 21 years of age, consistent with the intended patient population. The dataset included cases from institutions located in multiple states, including California, Ohio, and Massachusetts. The study population was representative of the intended use population and included a racially diverse cohort comprising White (64.3%), Asian (9.1%), American Indian or Alaska Native (0.2%), Black or African American (13.0%), and Native Hawaiian or Other Pacific Islander (1.4%).

The dataset included both benign (55%) and malignant (45%) cases and represented the relevant clinical assessment categories (BI-RADS 2 through BI-RADS 5). Cases were sampled to provide representation across patient age, lesion size, malignancy status, and the clinical ACR BI-RADS assessment. The age distribution was <40 years (11.6%), 40–49

years (14.5%), 50–59 years (20.3%), 60–74 years (37.6%), and ≥75 years (15.2%). The lesion-size distribution was <0.5 cm (11.2%), 0.5–<1.0 cm (31.3%), 1.0–<1.5 cm (20.0%), and ≥1.5 cm (36.6%).

7.2.3. Establishing ground truth

The standalone performance was evaluated on localization, BI-RADS descriptors, BI-RADS category, and diagnostic outcome. The ground truthing approach for each is described below:

- Ground truth labels of benign or malignant status were assigned to the lesion for each case, sourced from the reference standard of biopsy or 2 year follow-up for benign status.

- The ground truth labels for localization, ACR BI-RADS lexicon descriptors, and BI-RADS category were based on the labels of two expert US-board certified radiologists and an adjudicator (US-board certified radiologist with the most years of experience).

7.2.4. Performance Testing

The standalone study evaluated the independent performance of the SMART-B device without radiologist input. This end-to-end evaluation assessed both localization and classification capabilities of the device, quantifying its diagnostic accuracy relative to biopsy or two-year benign follow-up.

When assessing the standalone performance, the subject device demonstrated an AUCLROC of 0.901 (95% CI (0.881, 0.923)) with the same localization success criteria of the reader study (IOU > 0.5). When comparing the device to the ground truth of biopsy or 2-year follow-up of benign status, the subject device demonstrated sensitivity of 94.7% (95% CI (92.2%, 96.5%)) and specificity of 51.4% (95% CI (47.2%, 55.6%)).

The unadjusted PPV was 61.4% (95% CI: 57.7%, 65.0%) and the NPV was 92.3% (95% CI: 88.7%, 94.8%). After adjustment to the primary target malignancy prevalence of 10%, the PPV was 17.8% and the NPV was 98.9%, consistent with the expected decrease in PPV and increase in NPV at lower disease prevalence. Across the evaluated prevalence range (5%–20%), the NPV remained consistently high (≥97.5%), supporting performance for ruling out malignant findings across the assumed prevalence range.

These results demonstrate that SMART-B maintained robust diagnostic performance when evaluated on a substantially larger and more diverse dataset designed to improve representation across key clinical subgroups.

Similar standalone performance trends were observed across patient age (<40, 40-49, 50-59, 60-74, >=75), race (White, Asian, American Indian or Alaska Native, Black or African American, and Native Hawaiian or Other Pacific Islander groups), lesion size (<0.5cm, 0.5-1.0cm, 1.0-1.5cm, >=1.5cm), ultrasound manufacturers (Acuson, Fujifilm Healthcare, GE Healthcare, Hitachi, Philips Medical Systems, Toshiba and Mindray), and data sources.

7.2.5. Localization of breast lesions

Standalone localization performance has been assessed by comparing the regions of interest (ROIs) identified by the device against the consensus ground truth. For each case, a localization was classified as a true positive if Intersection over Union (IOU) between the device ROI and the ground-truth ROI is greater than 0.5.

Metric	Score (IOU > 0.5)
Localization Accuracy	98.6%

The standalone device demonstrates consistent lesion localization performance across evaluated cases. These results support reliable localization capability for subsequent classification and diagnostic assessment.

7.2.6. BI-RADS Category

The standalone performance of the device was evaluated by comparing ACR BI-RADS categories against consensus ground-truth labels. Performance was quantified by evaluating the accuracy of the multi-class algorithms against the ground truth labels, reporting the accuracy of each ACR BI-RADS category (BI-RADS 2, 3, 4A, 4B, 4C, and 5).

Performance was assessed using class-wise accuracy, with overall performance calculated as a weighted average across all categories. The device achieved an overall standalone performance of 75.8% (95% CI (74.8%, 76.7%)) with consistent performance across all BI-RADS categories.

7.2.7. BI-RADS Descriptors

The table below provides standalone BI-RADS descriptor performance for each of the descriptor classes.

ACR BI-RADS Descriptor	Descriptor Class	Standalone Class-wise Accuracy
Shape	Round	92.1%
	Irregular	75.4%
	Oval	73.6%
Posterior Features	No Posterior Features	72.4%
	Enhancement	80.2%
	Shadowing	84.0%
	Combined Pattern	91.5%
Orientation	Parallel	82.3%
	Not Parallel	82.4%
Echo Pattern	Anechoic	88.9%
	Complex cystic & solid	94.1%
	Heterogenous	82.7%
	Hyperechoic	98.8%
	Hypoechoic	61.6%
	Isoechoic	80.0%
Margin	Circumscribed	68.6%
	Angular	58.6%
	Indistinct	85.9%
	Microlobulated	82.8%
	Spiculated	85.4%

Class-wise accuracy ranged from 58.6% to 98.8% across all descriptor categories. Performance was generally high for shape, posterior features, orientation, and most echo pattern and margin classes, with the highest accuracies observed for hyperechoic (98.8%) and complex cystic-and-solid (94.1%) echo patterns, round shape (92.1%), and combined posterior pattern (91.5%). Lower class-wise accuracy was observed for hypoechoic (61.6%) and circumscribed (68.6%) and angular (58.6%) classes.

7.3. Text Recognition Algorithm

Image data from medical examinations are often annotated with important information inserted by the practitioner. In the case of ultrasound images, these annotations are often burned into the image itself as pixel-drawn text and inserted by the clinician at the time of image acquisition. The goal of the text recognition algorithm is to use optical character

recognition (OCR) methods to read those annotations from the rendered image and convert them back to computer readable text strings.

7.3.1. Data Selection

The text recognition model was trained and validated using a retrospectively collected dataset of pre-existing ultrasound images obtained from clinical registries. The dataset reflects real-world clinical practice by incorporating images from multiple ultrasound manufacturers and a broad range of sonographer annotation styles, ensuring representation of the imaging conditions encountered in routine ultrasound examinations.

Images were acquired from clinically accepted ultrasound systems, including Philips Medical Systems, GE Healthcare, Samsung, Siemens, Toshiba, and Mindray, and were sourced from 22 clinical institutions across the United States, Australia, New Zealand, Singapore, and Canada.

Performance was evaluated using an external test set of 1,240 images from 12 clinical sites. The test set was completely independent of OCR model development, with no overlap in images or clinical sites between the development datasets and the external test set.

Because the text recognition algorithm is designed solely to extract text embedded within ultrasound images and does not analyze patient anatomy or physiology, patient demographics and disease characteristics were not considered relevant factors for training or validation.

7.3.2. Performance testing

For each image and each annotation within the image, the output of the text recognition algorithm was compared to the label, which is the written annotations on the image by the clinician at the time of image acquisition. For annotations identifying anatomical regions, the text recognition algorithm on an image was considered successful if all the regions are identified accurately (e.g. if the annotations on an image was “Right Breast and the text recognition algorithm correctly returned “Right” AND “Breast”, the algorithm output was considered correct. Conversely, if any of the regions are not returned or returned incorrectly the algorithm is considered unsuccessful for that annotation).

The table below provides the accuracy for the text recognition algorithm.

Annotation type	**Text recognition accuracy**
Anatomy (region) annotations	99.0%

Measurement annotations	98.1%

8. NON-CLINICAL DATA

The design and development of SMART-B has been implemented according to recognised standards. See-Mode Technologies has performed software verification and validation testing for the subject device according to the FDA's guidance document "Content of Premarket Submissions for Device Software Functions," as well as "IEC 62304:2006/AC: 2015 - Medical Device Software - Software Lifecycle Processes". Special Controls were added according to 21 CFR 892.2090.

The risk analysis was completed and the hazard risk analysis has been submitted as part of this application. It has been observed that all the risks identified with the subject device are acceptable and have been reduced as far as possible in accordance with ISO 14971:2019 Medical devices - Application of risk management to medical devices.

9. CONCLUSIONS

The See-Mode Augmented Reporting Tool, Breast (SMART-B) is a stand-alone software device intended to assist trained interpreting physicians in the localization, characterization, and structured reporting of breast ultrasound images. The device provides regions of interest (ROIs), BI-RADS lexicon-based descriptors, and BI-RADS categories in accordance with the American College of Radiology (ACR) BI-RADS guidelines. The device is intended to support clinical interpretation and is not intended to replace clinical judgment.

SMART-B uses machine learning–based image analysis algorithms to process DICOM-formatted breast ultrasound images from commercially available ultrasound systems. Performance and validation testing, including standalone and multi-reader multi-case (MRMC) studies, as well as software verification, validation, and risk management activities, demonstrated that the device performs as intended.

Based on a comparison of intended use, technological characteristics, and performance data, the See-Mode Augmented Reporting Tool, Breast (SMART-B) is substantially equivalent to the legally marketed predicate device, BU-CAD (K210670), and is as safe and effective for its intended use.