BeamWorks, Inc.
MinGi Seo
Regulatory Affairs Manager
B1, 107, Chilgokjungang-Daero 136-Gil, Buk-Gu
Daegu, 41404
Republic Of Korea

August 12, 2026

Re: K260086
Trade/Device Name: CadAI-B Dx
Regulation Number: 21 CFR 892.2090
Regulation Name: Radiological Computer-Assisted Detection And Diagnosis Software
Regulatory Class: Class II
Product Code: QDQ
Dated: July 13, 2026
Received: July 13, 2026

Dear MinGi Seo:

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: 2026.08.12 13:36:49 -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.	K260086

Please provide the device trade name(s).

CadAI-B Dx

Please provide your Indications for Use below.

CadAI-B Dx is a software application indicated to assist 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 lesion indicators placed on breast ultrasound images assisting physicians to identify suspicious soft tissue breast lesions from given B-Mode ultrasound images and the risk analysis of malignancy. The risk analysis of malignancy indicates the malignancy score (CadAI-Score) and corresponding BI-RADS categories. In addition, CadAI-B Dx analyzes the size of the lesions and BI-RADS lexicon descriptors: shape, orientation, margin, echo pattern, and posterior features.
CadAI-B Dx may also be used as an image viewer of digital ultrasound images. The software includes tools that allow users to adjust, measure and document images, and output into a structured report.
Patient management decisions should not be made solely on the basis of analysis by CadAI-B Dx.
Limitations: CadAI-B Dx is not to be used on sites of post-surgical excision, or images with Doppler, elastography, or other overlays present in them.

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)

510(k) Summary: K260086

[As Required by 21 CFR 807.92]

1. Data Prepared

December 31, 2025

2. Submitter's Information

- Name of Manufacturer: BeamWorks Inc.
- Address: B1, 107 Chilgokjungang-daero 136-gil, Buk-gu Daegu, Republic of Korea
- Contact Name: MinGi Seo/Regulatory Affairs
- Telephone No.: +82 53-322-2107
- Email Address: smg@beamworks.co.kr

3. Identification of Proposed Device(s)

510(k) Number	K260086
Trade/Device Name	CadAI-B Dx
Product Name	CadAI-B Dx
Regulation Name	Radiological computer assisted detection and diagnosis software
Regulation Number	21 CFR 892.2090
Classification Product Code	QDQ
Device Class	Class II
510(k) Review Panel	Radiology

4. Identification of Predicate Device(s)

The identified predicate device within this submission is shown as follows;

510(k) Number	K210670
Trade/Device/Model Name	BU-CAD
Product Name	BU-CAD
Regulation Name	Radiological computer assisted detection and diagnosis software
Regulation Number	21 CFR 892.2090
Classification Product Code	Classification Product Code: QDQ Subsequent Product Code: LLZ
Device Class	Class II
510(k) Review Panel	Radiology

These predicate devices have not been subject to a design-related recall.

5. Description of the Device

CadAI-B Dx, developed by BeamWorks Inc., is a Software as a Medical Device (SaMD) designed to assist interpreting physicians by providing Computer-Assisted Detection (CADe) and Diagnosis (CADx) capabilities in breast ultrasound examinations. The software employs artificial intelligence and machine learning (AI/ML) algorithms trained on large databases comprising ultrasound images, along with associated metadata such as radiology and pathology reports.

After the clinical acquisition of ultrasound images is complete, the software analyzes the captured B-Mode images, identifies, and highlights suspicious areas of abnormality to assist the users in localization of breast lesions. This functionality directs the user's attention to potential lesions based on objective spatial correspondence criteria, ensuring that AI highlights are aligned with clinically validated detection standards. Simultaneously, the software provides automated measurements of the detected lesions (Longest and Shortest Diameters) and extracts standardized ACR BI-RADS lexicon descriptors (e.g., shape, orientation, margin, echo pattern, and posterior acoustic features) to support diagnostic consistency.

The software generates a quantitative malignancy score (CadAI-Score) on a scale of 0 to 100, which indicates the degree of clinical suspicion based on the lesion characteristics learned by the AI/ML algorithm. This score is calibrated to the American College of Radiology (ACR) BI-RADS system to provide a suggested BI-RADS category (CadAI-BIRADS). To ensure safe and appropriate use, the display of the malignancy score and BI-RADS category is gated via role-based access control; these diagnostic outputs are intended to be accessible only to authorized interpreting physicians qualified to perform diagnostic interpretation.

The analysis results provided by the software can be reviewed, modified, and saved by the physician based on their independent clinical judgment. If a user adjusts the lesion markings or descriptors, the system is designed to automatically recalculate the associated diagnostic values based on the updated inputs. The final analysis results can be converted into DICOM Secondary Capture files and saved to user-designated storage locations, such as a Picture Archiving and Communication System (PACS), to support integrated clinical decision-making.

6. Indications for Use

CadAI-B Dx is a software application indicated to assist 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 lesion indicators placed on breast ultrasound images assisting physicians to identify suspicious soft tissue breast lesions from given B-Mode ultrasound images and the risk analysis of

malignancy. The risk analysis of malignancy indicates the malignancy score (CadAI-Score) and corresponding BI-RADS categories. In addition, CadAI-B Dx analyzes the size of the lesions and BI-RADS lexicon descriptors: shape, orientation, margin, echo pattern, and posterior features.

CadAI-B Dx may also be used as an image viewer of digital ultrasound images. The software includes tools that allow users to adjust, measure and document images, and output into a structured report.
Patient management decisions should not be made solely on the basis of analysis by CadAI-B Dx.

Limitations: CadAI-B Dx is not to be used on sites of post-surgical excision, or images with Doppler, elastography, or other overlays present in them.

7. Technological Comparison

Provided below is a table that compares technological characteristics of the CadAI-B Dx and the predicate device.

[Table 3. Comparison of Proposed Device to Predicate Devices]

	Proposed Device	**Predicate Device**	**Note**
K Number	K260086	K210670	-
Manufacturer	BeamWorks Inc.	TaiHao Medical Inc.	-
Trade Name	CadAI-B Dx	BU-CAD	-
Product Name	CadAI-B Dx	BU-CAD	-
Product Code	QDQ	QDQ, LLZ	Similar
Regulation Number	21 CFR 892.2090	21 CFR 892.2090	Identical
510(k) Review Panel	Radiology	Radiology	Identical
Intended Use	Intended to be used by physician interpreting radiological images, to help them with localizing and characterizing breast abnormalities.	Intended to be used by clinicians interpreting radiological images, to help them with localizing and characterizing breast abnormalities.	Identical

	Proposed Device	Predicate Device	Note
	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 judgement.	Intended to be used concurrently with the reading of images and are not intended as a replacement for the review of a clinician or their clinical judgement.	
Indications for Use	CadAI-B Dx is a software application indicated to assist 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 lesion indicators placed on breast ultrasound images assisting physicians to identify suspicious soft tissue breast lesions from given B-Mode ultrasound images and the risk analysis of malignancy. The risk analysis of malignancy indicates the malignancy score (CadAI-Score) and corresponding BI-RADS categories. In addition, CadAI-B Dx analyzes the size of the lesions and BI-RADS lexicon descriptors: shape, orientation, margin, echo pattern, and posterior features. CadAI-B Dx may also be used as	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	Similar

	Proposed Device	Predicate Device	Note
	an image viewer of digital ultrasound images. The software includes tools that allow users to adjust, measure and document images, and output into a structured report. Patient management decisions should not be made solely on the basis of analysis by CadAI-B Dx. Limitations: CadAI-B Dx is not to be used on sites of post-surgical excision, or images with Doppler, elastography, or other overlays present in them.	classifies lesion shape, orientation, margin, echo pattern, and posterior features according to BI-RADS descriptors. 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. Limitations: BU-CAD is not to be used on sites of post-surgical excision, or images with Doppler, elastography, or other overlays present in them. BU-CAD is not intended for the primary interpretation of digital mammography images. BU-CAD is not intended for use on mobile devices.	
Characteristics	CADe and CADx software used to assist in localizing suspicious soft tissue lesions and region	CADe and CADx software used to assist in localizing suspicious soft tissue lesions and region	Identical

	Proposed Device	Predicate Device	Note
	based analyze of malignancy using ultrasound image data.	based analyze of malignancy using ultrasound image data.	
Target Population	Patients with soft tissue breast lesions who are being referred for ultrasound interpreting.	Patients with soft tissue breast lesions who are being referred for ultrasound interpreting.	Identical
Anatomical Location	Breast	Breast	Identical
Design	Software-only device	Software-only device	Identical
Modality Used for Analysis	Breast ultrasound data	Breast ultrasound data	Identical
Input	Medical images provided in a DICOM and Image format	Medical images provided in a DICOM format	Similar
Output	ROIs (CadAI-Map) and lesion contours placed on soft tissue breast lesions. A region-based malignancy score (CadAI-Score), a BI-RADS category, lesion size, and BI-RADS lexicon descriptors (shape, orientation, margin, echo pattern, posterior features).	ROIs and lesion contours placed on suspicious soft tissue lesion. A region-based score of lesion malignancy, a BI-RADS category, and BI-RADS descriptors.	Similar
Physical Characteristics	Software Package Operates on off-the shelf hardware	Software Package Operates on off-the shelf hardware	Identical
Comparative Performance Testing (MRMC)	1. Metric: AUC_LROC 2. Cases used: 797 ● 447 Benign ● 350 Malignant 3. Readers: 16	1. Metric: AUC_LROC 2. Cases used: 628 ● 374 Benign ● 254 Malignant 3. Readers: 16 ● 14 Radiologists ● 2 Breast Surgeons	Similar

	Proposed Device	Predicate Device	Note
	● 5 board-certified radiologists with breast imaging fellowship training. ● 3 Breast Surgeons ● 5 board-certified radiologists without breast imaging fellowship training. ● 6 board-certified physicians from specialties other than radiology fulfills the qualification requirements set by the American College of Radiology (ACR). 4. Results: ● AUC improved by 0.107 (0.766 Unaided vs 0.873 Aided)	4. Results: ● AUC improved by 0.037 (0.779 Unaided vs 0.816 Aided)	
Performance Testing (Standalone)	1. Metric: AUC 2. Cases used: 1,285 ● 603 Benign ● 682 Malignant 3. Source of Cases ● South Korea: n=530 (41.25%) ● United States: n=643 (50.04%) ● Kazakhstan: n=112 (8.72%) 4. Performance (Frequency) ● AUC: 0.907 ● Sensitivity: 88.12% (601/682)	1. Metric: AUC 2. Cases used: 1,139 ● 642 Benign ● 497 Malignant 3. Source of Cases ● United States: 531 cases ● Europe: 36 cases ● Taiwan: 572 cases 4. Performance (Frequency) ● AUC: 0.82 ● Sensitivity: 88.3% (439/497) ● Specificity: 57.9% (372/642)	Similar

	Proposed Device	Predicate Device	Note
	● Specificity: 77.11% (465/603)		
Modality Used for Viewing	Breast Ultrasound	Breast Ultrasound and Mammography (FFDM)	Different

- **Intended Use**

  The intended use of CadAI-B Dx is the same as that of the legally marketed predicate device, BU-CAD. Both are intended to be used by physicians interpreting radiological images, to help them with localizing and characterizing breast abnormalities. CadAI-B Dx 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.

- **Indications for Use**

  Both CadAI-B Dx and BU-CAD are software applications indicated to assist physicians in analyzing breast ultrasound images of patients who are being referred for diagnostic ultrasound examination. Both devices identify regions suspicious for breast cancer and provide computer analytics, including malignancy scores (CadAI-Score for CadAI-B Dx and SLC for BU-CAD) and corresponding BI-RADS categories. Furthermore, both devices automatically classify BI-RADS descriptors such as shape, orientation, margin, echo pattern, and posterior features.

- **Intended Use Population and Modality**

  CadAI-B Dx and BU-CAD share identical intended use populations and modality requirements. Both are intended to be used for assisting interpreting physicians in analyzing patients with soft tissue breast lesions using breast ultrasound data. While BU-CAD may also be used as a viewer for multi-modality images including mammography, both devices are strictly not intended for the primary interpretation of digital mammography images.

- **Input**

  Both CadAI-B Dx and the predicate device, BU-CAD, are designed to perform AI-based analysis on a static B-Mode ultrasound image. CadAI-B Dx processes the B-Mode ultrasound images in DICOM and image (RGB) formats.

- **Output**

  The outputs of CadAI-B Dx and BU-CAD are substantially equivalent. Both devices provide highlighted locations consisting of ROIs and lesion contours placed on suspicious soft tissue lesions. The output for both includes a region-based malignancy score, a BI-RADS category, and BI-RADS descriptors. Additionally, CadAI-B Dx provides lesion size analysis to further assist the physician's diagnostic process.

- **Interface**

  Both **CadAI-B Dx** and **BU-CAD** are software-only devices that operate on off-the-shelf hardware. They are intended to be used as image viewers that include tools allowing users to adjust, measure, and document images, subsequently outputting the findings into structured reports or DICOM formats.

- **Performance Testing**

  The clinical validation of CadAI-B Dx followed similar endpoints to those used for BU-CAD. Both devices were evaluated using a Multiple Reader Multiple Case (MRMC) study design with AUC_LROC as the primary metric. The CadAI-B Dx MRMC study evaluated a total of 797 cases (447 benign, 350 malignant) with 16 readers, while the BU-CAD MRMC study evaluated 628 cases with 16 readers. In standalone performance testing, CadAI-B Dx demonstrated robust diagnostic accuracy with an AUC evaluated over 1,285 cases from diverse geographic sources (US, Korea, and Kazakhstan), which is comparable to the 1,139 cases used for BU-CAD's standalone validation. These results demonstrate that CadAI-B Dx performs with substantial equivalence to the predicate device in improving or maintaining reader performance.

- **Discussion of the Comparison to Support Substantial Equivalence (SE) Determination**

  CadAI-B Dx has the same intended use as the legally marketed predicate device, BU-CAD. They are intended to be used by physicians interpreting radiological images, to help them with localizing and characterizing breast abnormalities.

  CadAI-B Dx analyzes a static B-Mode ultrasound image, making the analytical input functionally equivalent to the input image used by the predicate. The output of CadAI-B Dx is similar to that of the predicate device by providing ROIs and lesion contours placed on suspicious soft tissue lesions and region-based malignancy scores (CadAI-Score), while providing BI-RADS category and BI-RADS descriptors (Shape, Orientation, Margin, Echo Pattern, and Posterior Features) is also

consistent with the predicate.

CadAI-B Dx has an identical intended use, compared to the predicate device, that aims to localize and characterize suspicious soft tissue lesions in breast ultrasound image. Artificial intelligence algorithms of the subject device may have different technological characteristics from the predicate device. Therefore, a fully crossed multiple reader multiple case (MRMC) reader study was conducted.

Compared to BU-CAD as the primary predicate, and in consideration of the technological characteristics and test methods used in the clinical validation, CadAI-B Dx does not raise different questions of safety and effectiveness.

8. Clinical Performance Data

8.1. Summary of the Reader Study

The results of this clinical study demonstrate that CadAI-B Dx provides statistically significant improvements in localization-sensitive clinical effectiveness by assisting physicians in both the accurate classification of malignant lesions and the precise identification of lesion location during breast ultrasound interpretation. Notably, the observed reduction in false-positive interpretations, which addresses a well-recognized limitation of breast ultrasound, together with improved inter-reader agreement supporting diagnostic standardization and meaningful gains in reading efficiency, collectively suggest that CadAI-B Dx offers clinical value beyond improvements in performance metrics alone. These findings support the potential of CadAI-B Dx to function as an effective diagnostic aid that enhances clinical decision-making and improves workflow efficiency in real-world breast ultrasound practice.

Dataset Demographic

A total of 797 cases collected from multiple clinical sites were used in the reader study. The source of cases is listed below.

- U.S.: 420 cases
- South Korea: 377 cases

The age distribution included in this study was as follows:

- 22–39 years: 92 cases
- 40–49 years: 220 cases

- 50–59 years: 211 cases
- 60–69 years: 154 cases
- ≥70 years: 120 cases

The number of benign and malignant cases included in this study were listed below.

- Benign cases: 447 cases
- Malignant cases: 350 cases

The race distribution included in this study was as follows:

- Asian: 401 cases
- White: 208 cases
- Hispanic: 112 cases
- Black or African American: 71 cases
- American Indian / Alaska Native: 5 cases

The lesion size distribution included in this study was listed below:

- <10 mm: 324 cases
- 10–20 mm: 364 cases
- >20 mm: 109 cases

The malignancy subtypes included in this study were listed below.

- Invasive ductal carcinoma (IDC): 266 cases
- Invasive lobular carcinoma (ILC): 26 cases
- Invasive carcinoma, NOS: 12 cases
- Ductal carcinoma in situ (DCIS): 24 cases
- Other malignant types: 22 cases

The imaging hardware distribution included in this study were listed below:

- GE Healthcare: 391 cases
- Philips: 304 cases
- Canon/Toshiba: 50 cases
- Siemens Healthineers: 45 cases
- Other manufacturers: 7 cases

The image acquisition years included in this study were listed below:

- 2011–2015: 219 cases
- 2016–2020: 436 cases
- 2021–2023: 142 cases

Primary Endpoint

Reader-averaged localization and diagnostic performance, measured by AULROC, was higher in the AI-aided reading condition compared with the unaided condition. The reader-averaged AULROC increased from 0.766 (95% CI: 0.725–0.808) in the unaided condition to 0.873 (95% CI: 0.847–0.900) in the AI-aided condition. The difference in reader-averaged AULROC between conditions was 0.107 (95% CI: 0.071–0.142), which was statistically significant ($p < 0.001$).

Table. Reader-averaged AULROC for Unaided and AI-Aided Sessions

Metric	Unaided	AI-aided	Aided – Unaided	p-value
AULROC	0.766	0.873	0.106	< 0.001
95% CI	0.725, 0.808	0.847, 0.900	0.071, 0.142	

Note: AULROC = Area under the localization receiver operating characteristic curve

Diagnostic Accuracy Metrics (Sensitivity, Specificity, PPV, NPV)

Reader-averaged diagnostic accuracy metrics, including sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV), were higher in the AI-aided reading condition compared with the unaided condition.

Table. Reader-averaged Diagnostic Accuracy Metrics

Metric	Unaided (%)	AI-aided (%)	ΔAided – Unaided (%)	p-value
Sensitivity	91.29 (89.94, 92.74)	94.23 (92.37, 96.10)	2.94	0.015
Specificity	36.09 (33.67, 38.50)	55.34 (52.21, 58.48)	19.25	< 0.001
PPV (unadjusted)	52.79 (49.16, 56.43)	62.29 (58.59, 66.00)	9.50	< 0.001
PPV_U.S. (adjusted)	77.76 (76.57, 78.96)	83.78 (82.46, 85.54)	6.02 (04.46, 07.47)	
PPV_Korea (adjusted)	48.78 (47.08,50.53)	58.45 (56.15, 61.69)	9.67 (07.14, 12.31)	

NPV (unadjusted)	84.10 (81.06, 87.14)	92.46 (89.96, 94.95)	8.36	< 0.001
NPV_U.S. (adjusted)	62.85 (56.34, 69.90)	79.67 (74.30, 85.45)	16.82 (10.85, 22.69)	
NPV_Korea (adjusted)	86.13 (82.57,89.50)	93.50 (91.39, 95.57)	7.37 (4.57, 10.32)	

Note: PPV = positive predictive value; NPV = negative predictive value. PPV and NPV were adjusted using 5-year breast cancer prevalence rates reported by WHO GLOBOCAN 2022 (0.71% for the U.S. and 0.44% for South Korea).

Subgroup Analysis

Age, race, geographic data source, ultrasound system manufacturer, BI-RADS assessment category, and lesion- and acquisition-related characteristics were evaluated as subgroups using AULROC-based performance metrics. Except for a limited number of subgroups with insufficient sample sizes, AI-aided interpretation with CadAI-B Dx generally demonstrated improved diagnostic performance compared with unaided interpretation. These performance improvements were observed consistently across patient characteristics and technical conditions, supporting the robustness and generalizability of CadAI-B Dx.

9. Non-Clinical Performance Data

9.1. Summary of the Non-Clinical Bench Testing

The non-clinical bench performance testing provides comprehensive and objective evidence that CadAI-B Dx performs as intended for its labeled indications. The evaluation methodology was designed and conducted in accordance with applicable FDA guidance and relevant recognized standards. The test results demonstrate that the device meets all pre-specified performance acceptance criteria and support reasonable generalizability to the intended use population.

Based on the totality of the non-clinical bench performance evidence presented in this section, CadAI-B Dx is considered substantially equivalent to the predicate device (BU-CAD, K210670) and does not raise new questions of safety or effectiveness when used as a standalone computer-assisted detection and diagnosis tool for breast ultrasound imaging.

Dataset Demographic

A total of 1,285 cases were used for the standalone performance evaluation. The source of cases is listed below:

- United States: 643 cases
- South Korea: 530 cases
- Kazakhstan: 112 cases

The age distribution included in this study was as follows:

- 22–39 years: 118 cases
- 40–49 years: 338 cases
- 50–59 years: 372 cases
- 60–69 years: 266 cases
- ≥70 years: 191 cases

The number of benign and malignant cases included in this study were listed below:

- Benign cases: 603 cases
- Malignant cases: 682 cases

The race distribution included in this study was as follows:

- Asian: 556 cases
- White: 412 cases
- Hispanic: 112 cases
- Black or African American: 77 cases
- Other/Not Available: 128 cases

The imaging hardware distribution included in this study were listed below:

- GE Healthcare: 649 cases
- Philips: 426 cases
- Mindray: 112 cases
- Siemens Healthineers: 28 cases
- Others: 69 cases

Test Dataset Independence

The test dataset (N = 1,285) was strictly sequestered from algorithm development. No data from any patient in the test dataset were used for training, tuning, or internal validation, and no institution that contributed training or tuning data was included in the test dataset. Performance was therefore evaluated on an independent dataset.

Reference ground truth

A multi-step expert consensus ground truth dataset was established by three independent, MQSA-certified breast imaging radiologists, each with over 10 years of dedicated clinical experience and including active members of the ACR BI-RADS Committee.

Primary Performance Analysis

The standalone integrated lesion localization and diagnostic performance, measured by AULROC, met the pre-specified acceptance criterion derived from the predicate device. The observed AULROC was 0.907 (95% CI: 0.890–0.924), with the lower bound of the 95% confidence interval exceeding the performance goal of 0.7626.

Table. Standalone AULROC Performance

Metric	Value	95% CI
AULROC	0.907	0.890, 0.924

Note: AULROC: Area under the localization receiver operating characteristic curve

Sensitivity, Specificity, Positive Predictive Value (PPV), and Negative Predictive Value (NPV)

Standalone diagnostic accuracy metrics were evaluated with a localization penalty to ensure clinical relevance. The system demonstrated a sensitivity of 88.12% (95% CI: 85.74–90.55) and a specificity of 77.11% (95% CI: 73.73–80.40). All diagnostic metrics met or exceeded the predefined acceptance criteria derived from the predicate device.

Table. Sensitivity, Specificity, PPV, NPV with Localization Penalty

Metric	Value	Frequency	95% CI
Sensitivity (%)	88.12	601/682	85.74, 90.55
Specificity (%)	77.11	465/603	73.73, 80.40
PPV (%) [unadjusted]	80.35	601/748	77.23, 83.10
PPV_U.S. (%)	2.68	-	2.32, 3.11
PPV_Korea (%)	1.67	-	1.45, 1.94
NPV (%) [unadjusted]	86.59	465/537	83.64, 89.41
NPV_U.S. (%)	99.90	-	99.89, 99.93
NPV_Korea (%)	99.94	-	99.92, 99.95

Note: PPV = positive predictive value; NPV = negative predictive value. PPV and NPV were adjusted using 5-year breast cancer prevalence rates reported by WHO GLOBOCAN 2022 (0.71% for the U.S. and 0.44% for South Korea).

Summary of Subgroup Analysis

Subgroup analyses across demographics (age, race/ethnicity, geographic data source), disease

characteristics, ultrasound systems, acquisition conditions, and BI-RADS assessment category showed consistent standalone discrimination, with AULROC ≥ 0.800 in all interpretable prespecified subgroups and no meaningful degradation versus overall performance.

10. Conclusion

The manufacturer implemented a comprehensive risk management process in accordance with FDA-recognized standards, including ISO 14971, to identify and mitigate risks associated with CadAI-B Dx. Non-clinical bench testing and clinical performance data demonstrated that CadAI-B Dx performs substantially equivalently to the legally marketed predicate device, BU-CAD (K210670), without raising new questions of safety or effectiveness. Accordingly, CadAI-B Dx is determined to be substantially equivalent to the identified predicate device.