March 26, 2026

Lunit, Inc.
Hyeseung Yoo
Sr. RA Specialist, RAC-Devices
4-8f, 374, Gangnam-Daero, Gangnam-Gu
Seoul, 06241
Republic Of Korea

Re: K253796
Trade/Device Name: Lunit INSIGHT DBT (V1.2)
Regulation Number: 21 CFR 892.2090
Regulation Name: Radiological Computer-Assisted Detection And Diagnosis Software
Regulatory Class: Class II
Product Code: QDQ
Dated: November 28, 2025
Received: November 28, 2025

Dear Hyeseung Yoo:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253796

Device Name
Lunit INSIGHT DBT (V1.2)

Indications for Use *(Describe)*
Lunit INSIGHT DBT is a computer-assisted detection and diagnosis (CADe/x) software intended to be used concurrently by interpreting physicians to aid in the detection and characterization of suspected lesions for breast cancer in digital breast tomosynthesis (DBT) exams from compatible DBT systems. Through the analysis, the regions of soft tissue lesions and calcifications are marked with an abnormality score indicating the likelihood of the presence of malignancy for each lesion. Lunit INSIGHT DBT uses screening mammograms of the female population.
Lunit INSIGHT DBT is not intended as a replacement for a complete interpreting physician's review or their clinical judgment that takes into account other relevant information from the image or patient history.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K253796

510(k) Summary
Lunit INSIGHT DBT v.1.2

This 510(k) summary of safety and effectiveness information is prepared in accordance with the requirements of 21 CFR §807.92.

1. Submitter

Applicant Information	Lunit Inc. 4-8 F, 374, Gangnam-daero, Gangnam-gu, Seoul, 06241, Republic of Korea Tel: + 82-2-2138-0827 Fax: +82-2-6919-2702
Primary Correspondent	Hyeseung Yoo, Sr. Regulatory Affairs Specialist Email: hsyoo@lunit.io
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Date Prepared	November 28, 2025

2. Device Names and Classifications

Subject Device

Name of Device	Lunit INSIGHT DBT (V1.2)
Version	1.2
Classification Name	Radiological Computer-Assisted Detection And Diagnosis Software
Regulation	21 CFR 892.2090
Classification	Class II
Product code	QDQ

Predicate Device

Name of Device	Lunit INSIGHT DBT
Version	v1.1
Legal manufacturer	Lunit Inc.
510(k) number	K242652
Classification Name	Radiological Computer Assisted Detection/Diagnosis Software For Suspicious Lesions For Cancer
Regulation	21 CFR 892.2090
Classification	Class II
Product code	QDQ

3. Device Description

Lunit INSIGHT DBT is a computer-assisted detection/diagnosis (CADe/x) Software as a Medical Device that provides information about the presence, location and characteristics of lesions suspicious for breast cancer to assist interpreting physicians in making diagnostic decisions when reading digital breast tomosynthesis (DBT) images. The software automatically analyzes digital breast tomosynthesis slices via artificial intelligence technology that has been trained via deep learning.

For each DBT case, Lunit INSIGHT DBT generates artificial intelligence analysis results that include the lesion type, location, lesion-level/case-level score, and outline of the regions suspected of breast cancer. This peripheral information intends to augment the physician's workflow to better aid in detection and diagnosis of breast cancer.

4. Indication for Use

Lunit INSIGHT DBT is a computer-assisted detection and diagnosis (CADe/x) software intended to be used concurrently by interpreting physicians to aid in the detection and characterization of suspected lesions for breast cancer in digital breast tomosynthesis (DBT) exams from compatible DBT systems. Through the analysis, the regions of soft tissue lesions and calcifications are marked with an abnormality score indicating the likelihood of the presence of malignancy for each lesion. Lunit INSIGHT DBT uses screening mammograms of the female population.

Lunit INSIGHT DBT is not intended as a replacement for a complete interpreting physician's review or their clinical judgment that takes into account other relevant information from the image or patient history.

5. Summary of Substantial Equivalence

Item	Subject Device	Predicate Device
	Lunit INSIGHT DBT v1.2	**Lunit INSIGHT DBT v1.1**
Classification Name	Radiological Computer Assisted Detection/Diagnosis Software For Suspicious Lesions For Cancer	Radiological Computer Assisted Detection/Diagnosis Software For Suspicious Lesions For Cancer
Regulation	21 CFR 892.2090	21 CFR 892.2090
Regulatory Class	Class II	Class II
Product Code	QDQ	QDQ
Indication for Use	Lunit INSIGHT DBT is a computer-assisted detection and diagnosis (CADe/x) software intended to be used concurrently by interpreting physicians to aid in the detection and characterization of suspected lesions for breast cancer in digital breast tomosynthesis (DBT) exams from compatible DBT systems. Through the analysis, the regions of soft tissue lesions and calcifications are marked with an abnormality score indicating the likelihood of the presence of malignancy for each lesion. Lunit INSIGHT DBT uses screening mammograms of the female population. Lunit INSIGHT DBT is not intended as a replacement for a complete interpreting physician's review or their clinical judgment that takes into account other relevant information from the image or patient history.	Lunit INSIGHT DBT is a computer-assisted detection and diagnosis (CADe/x) software intended to be used concurrently by interpreting physicians to aid in the detection and characterization of suspected lesions for breast cancer in digital breast tomosynthesis (DBT) exams from compatible DBT systems. Through the analysis, the regions of soft tissue lesions and calcifications are marked with an abnormality score indicating the likelihood of the presence of malignancy for each lesion. Lunit INSIGHT DBT uses screening mammograms of the female population. Lunit INSIGHT DBT is not intended as a replacement for a complete interpreting physician's review or their clinical judgment that takes into account other relevant information from the image or patient history.
Target patient population	Women undergoing mammography	Women undergoing mammography
Intended user	Physicians interpreting screening mammograms	Physicians interpreting screening mammograms
Input Image Source	DBT	DBT
Fundamental Technological Basis	Lunit INSIGHT DBT is powered by artificial intelligence/machine learning-based software algorithm	Lunit INSIGHT DBT is powered by artificial intelligence/machine learning-based software algorithm

6. Comparison with Predicate Device

The subject device, Lunit INSIGHT DBT v1.2, maintains the same indications for use and core technological characteristics as the predicate device, Lunit INSIGHT DBT v1.1 (K242652). Both devices are radiological computer assisted detection and diagnostic software and use artificial intelligence technologies and deep learning techniques to fulfill its intended purpose to detect and characterize lesions suspected of breast cancer. Both devices analyze DBT scans and outputs of both devices augments the interpreting physicians in the diagnosis of asymptomatic patients.

The primary modifications in Lunit INSIGHT DBT v1.2 include expanded compatibility with additional imaging modalities, enabling the software to process input images from Siemens and Fujifilm systems in addition to those from Hologic and GE Healthcare. Lunit INSIGHT DBT v1.2 also introduces an ordinal Case Abnormality Level output that presents the abnormality level of a case using pre-defined likelihood categories for suspicious findings. Pre-populated report feature can be enabled to automatically generate a report for Case Abnormality Level based on the minimum likelihood level.

The new version further includes user-selected threshold operating points, enabling clinicians to choose from two additional sensitivity levels to help reduce false positive cases as appropriate. Additional auxiliary functions include a Current–Prior Comparison capability for reviewing interval changes over multiple years of patient imaging, and an optional integration with external software to display volumetric breast density information for each breast. These modifications do not change the intended use or the fundamental scientific technology of the device.

7. Performance Data

7.1. Non-clinical Testing Summary

Testing was conducted in accordance with Lunit's design control processes and in compliance with the following FDA-recognized consensus standards:

- IEC 62304: 2006/A1: 2016, Medical device software – software life-cycle processes
- IEC 62366-1:2015+AMD1:2020, Medical devices – Part 1: Application of usability engineering to medical devices.

Based on results of verification, Lunit INSIGHT DBT demonstrated that it fulfilled the software requirements.

7.2. Performance Testing

Standalone performance tests were conducted to demonstrate substantial equivalence with the predicate device. Total of 3,277 DBT exams of female adults were collected at multiple imaging facilities in the US healthcare institutions to broadly cover the US population and maintain balanced demographic and cancer characteristic distributions. DBT images were obtained from Hologic, GE Healthcare, Siemens, and FujiFilm 3D mammography equipment.
For the reference standard, each ground truther classified each DBT exam into non-cancer group or cancer group, then annotated the malignant lesion location in the 3D planes of cancer cases. The effectiveness of standalone performance in detection and diagnosis of breast cancer in 3D mammography was examined as comparing the results between standalone test and the ground truthing on each DBT exam. The scoring method that calculates the intersection-over-union (IoU) of the reference standards' ROI and heatmap region detected by the device, only when they are aligned along the same z-axis, indicating their presence in the same slice was implemented. In addition, the device performance for the characterization of the lesion type was evaluated by comparing the device analysis results with the ground truther's interpretation for the lesion type (mass, calcification, or mixed).

The primary goal of this standalone performance test was to demonstrate that the lower bound of 95% CI of device's ROC AUC in standalone performance was greater than 0.903 and p-value was less than the significance level of 5% (0.05). ROC AUC in the standalone performance analysis was 0.9388 (95% CI: 0.9304, 0.9472) with statistical significance ($p < 0.05$). Thus, the primary endpoint was achieved.

For the secondary endpoints, the result of the JAFROC AUC was 0.9206 (95% CI: 0.9117, 0.9295). Sensitivity at the default operating point (0.1) was 91.11% (95% CI: 89.66, 92.57) and specificity was 77.62% (95% CI: 75.70, 79.54), respectively. Sensitivity at the supplementary '0.3' operating point was 88.38% (95% CI: 86.74, 90.02) and specificity was 83.68% (95% CI: 81.98, 85.38), respectively. Sensitivity at the supplementary '0.6' point was 81.48% (95% CI: 79.49, 83.47) and specificity was 93.44% (95% CI: 92.30, 94.58), respectively. For lesion type agreement analysis, the matching proportion of the agreement between CAD and ground truther in 3-way classification of lesion type agreement was 75.61% (95% CI: 73.40, 77.80).

7.2.1 Demographic distribution

To broadly cover the US population, the data has been comprised of various demographic and clinical information. All clinical data including patients' demographic information such as age, ethnicity, race as well as previous breast cancer history was collected from imaging facilities in the United States.

For baseline demographics information, a total of 3277 cases are female with a mean age of 60.94 (± 13.99). Among the cases with available ethnicity information, the majority were categorized as 'Not Hispanic or Latino' (617, 18.83%)). 2462 cases (75.13%) are 'White', and 647 cases (19.74%) are 'Non-White' in race category.

7.2.2 Clinical subgroups and confounders present in the dataset

- Breast composition categorized according to the density categories defined by American College of Radiology BI-RADS.

- Distribution of BI-RADS assessment categories, with BI-RADS 0 representing the largest proportion of cases, followed (in decreasing frequency) by BI-RADS 1, 4, 5, 2, and 3.

- Lesion type categorized as “mass only,” “calcification only,” or “both.”

- Cancer type categorized as invasive breast cancer (including invasive ductal carcinoma [IDC] and invasive lobular carcinoma [ILC]) and non-invasive breast cancer (including ductal carcinoma in situ [DCIS]).

- Slice thickness distribution including cases with 1 mm slice thickness and cases with slice thickness less than 1 mm.

7.2.3 Equipment information

Out of the total 3277 cases, 1617 (49.34%) DBT exams were taken using Hologic equipment, 585 (17.85%) DBT exams were taken using GE Healthcare equipment, 469 (14.31%) DBT exams were taken using Siemens equipment and 606 (18.49%) DBT exams were taken using Fujifilm equipment

7.2.4 Truthing process

After completion of the dataset screening, each exam will have its own ground truthing by expert breast imaging radiologists who called as a ‘Ground Truther’ in the study. The ground truthers define the reference standard for every DBT exam enrolled in the study. Depending on the dataset, ground truthing will be conducted by either two or three qualified breast imaging radiologists following the same methodology as described in the following.

In datasets where three ground truthers are involved, two ground truthers independently perform the initial review, and the final truther, who is the most experienced, determines the final reference standard considering the results of the other two.

In datasets where two ground truthers are involved, the first truther independently completes the review, and the final truther, who is more experienced, makes the final decision considering the results of the other truther.

Each ground truther classified each DBT exam into non-cancer group or cancer group [STEP A] then annotated the malignant lesion location in the 3D planes of cancer cases [STEP B].

To set the reference standard, the ground truther reviewed the collected study exams using relevant clinical supporting data such as radiology reports and pathology reports acquired from the investigational institution and defined the reference standard based on the radiologic and pathologic clinical evidence. Especially for the biopsy-proven cancer exams, the ground truther can refer to the relevant pathology report containing

the cancer characteristic information (i.e., cancer location, size, shape, presence of calcification, pathologic results, etc.) for the ground truthing.

7.2.5 Independence of test data from training data

The test set used for the clinical validation was completely independent from the datasets used for training, tuning, or calibrating the algorithm.

7.2.6 AI Standalone Vs. Unaided Reader Performance Comparison

In an additional comparative analysis to evaluate the AI standalone performance against the average unaided reader performance, a testing dataset consisting of 258 cases (128 negative cases, 65 benign cases, and 65 cancer cases) with 4 views was utilized. The reading panel included 15 American Board of Radiology and MQSA-certified radiologists.

The AI standalone performance was compared with the average radiologist using the Obuchowski–Rockette (OR) method for a single-treatment, random-reader random-case (RRRC) CAD-vs-radiologist design. The results demonstrated that the AI standalone AUROC (0.9430) was significantly superior to the average reader AUROC (0.8983), with a difference of 0.0446 (95% CI: [0.0115, 0.0777], $p = 0.0083$).

Even at the highest threshold (Score 60), the AI standalone sensitivity was 86.2%, which is equivalent to the average reader's sensitivity of 85.4% ($p = 0.8912$). Furthermore, the AI standalone specificity at this threshold was 95.9%, demonstrating a statistically significant improvement over the average reader's specificity of 77.3% ($p < 0.001$). These results conclude that the ROC AUC of the device is consistently and significantly superior to the average radiologist across thresholds.

7.2.7 Statistical Methods for Confidence Intervals

To ensure accurate assessment of the device's reliability, all confidence intervals reported for performance metrics in this summary were calculated using statistically appropriate methods that do not rely on normal distribution assumptions. Specifically, AUROC confidence intervals were estimated using the stratified bootstrap percentile method to provide robust interval estimation. For binomial proportion metrics, including sensitivity, specificity, and lesion agreement, the Clopper-Pearson exact method was utilized. Additionally, the confidence interval for AFROC AUC was calculated using the Dorfman-Berbaum-Metz (DBM) method for a Fixed-Reader Random-Case (FRRC) variance analysis.

8. Assessment of Benefit-Risk, General Safety and Effectiveness

Risk management of the subject device is conducted via hazard analysis which identifies and mitigates existing and potential hazards. Hazards were controlled throughout the software lifecycle with control measures with

regards to software development, verification, and validation. Furthermore, labeling information consists of instructions for use with necessary cautionary statements for safe and effective use of the software. Lunit finds the use of the software has a positive balance in terms of probable benefits versus foreseeable and identified risks.

9. Conclusion

Lunit INSIGHT DBT v1.2 is substantially equivalent to the predicate device because it has the same intended use and shares the same technological and performance characteristics. The newly introduced features do not change the device's intended use and do not raise new questions of safety or effectiveness. In addition, performance testing demonstrates that the Lunit INSIGHT DBT v.1.2 is as safe and effective as the predicate device in detecting suspicious lesions in DBT exams from compatible DBT systems. Therefore, substantial equivalence has been established.