



April 23, 2026

Lunit, Inc.  
Sulgue Choi  
Regulatory Affairs Team Lead  
4-8f, 374, Gangnam-Daero, Gangnam-Gu  
Seoul, 06241  
Republic Of Korea

Re: K260320

Trade/Device Name: Lunit INSIGHT MMG (v1.1.10)

Regulation Number: 21 CFR 892.2090

Regulation Name: Radiological Computer-Assisted Detection And Diagnosis Software

Regulatory Class: Class II

Product Code: QDQ

Dated: January 30, 2026

Received: January 30, 2026

Dear Sulgue Choi:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**YANNA S. KANG -S**

Yanna Kang, Ph.D.

Assistant Director

Mammography and Ultrasound Team

DHT8C: Division of Radiological

Imaging and Radiation Therapy Devices

OHT8: Office of Radiological Health

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

## Indications for Use

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

K260320

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Please provide the device trade name(s).

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Lunit INSIGHT MMG (v1.1.10)

Please provide your Indications for Use below.

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Lunit INSIGHT MMG is a radiological Computer-Assisted Detection/ Diagnosis (CADe/x) software device based on an artificial intelligence algorithm intended to aid in the detection, localization, and characterization of suspicious areas for breast cancer on mammograms from compatible FFDM systems. As an adjunctive tool, the device is intended to be viewed by interpreting physicians after completing their initial read. It is not intended as a replacement for a complete physician's review or their clinical judgement that takes into account other relevant information from the image or patient history. The Lunit INSIGHT MMG uses screening mammograms of the female population.

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

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

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

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## 510(k) Summary (K260320)

### Lunit INSIGHT MMG v.1.1.10

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

#### 1. Submitter

<b>Applicant Information</b>	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
<b>Primary Correspondent</b>	Sulgue Choi Regulatory Affairs Team Leader Email: <a href="mailto:sulgue@lunit.io">sulgue@lunit.io</a>
<b>Secondary Correspondents</b>	Juyoung Jung, Regulatory Affairs Specialist Email: <a href="mailto:jjyoung@lunit.io">jjyoung@lunit.io</a>
<b>Date Prepared</b>	January 30, 2026

#### 2. Device Names and Classifications

##### Subject Device

<b>Name of Device</b>	Lunit INSIGHT MMG
<b>Version</b>	1.1.10
<b>Classification Name</b>	Radiological Computer Assisted Detection/Diagnosis Software For Suspicious Lesions For Cancer
<b>Regulation</b>	21 CFR 892.2090
<b>Classification</b>	Class II
<b>Product code</b>	QDQ

##### Predicate Device

<b>Name of Device</b>	Lunit INSIGHT MMG
<b>Version</b>	v1.1.6
<b>Legal manufacturer</b>	Lunit Inc.
<b>510(k) number</b>	K211678
<b>Classification Name</b>	Radiological Computer Assisted Detection/Diagnosis Software For Suspicious Lesions For Cancer
<b>Regulation</b>	21 CFR 892.2090
<b>Classification</b>	Class II
<b>Product code</b>	QDQ

### 3. Device Description

The device identifies and classifies suspicious areas for breast cancer on mammograms to be viewed by interpreting physicians. The images in the standard DICOM-format are uploaded to the device and processed by the analysis engine within the device. As an analysis result, the device allows visualization and quantitative estimation of the likelihood of the presence of a malignant lesion. The suspicious areas are marked by the Color Heatmap, the Single-Color map, the Grayscale Heatmap, or the Combined Heatmap with Abnormality Score, which reflects the likelihood of the presence of malignancy, presented for each breast.

### 4. Indication for Use

Lunit INSIGHT MMG is a radiological Computer-Assisted Detection/ Diagnosis (CAdE/x) software device based on an artificial intelligence algorithm intended to aid in the detection, localization, and characterization of suspicious areas for breast cancer on mammograms from compatible FFDM systems.

As an adjunctive tool, the device is intended to be viewed by interpreting physicians after completing their initial read. It is not intended as a replacement for a complete physician's review or their clinical judgement that takes into account other relevant information from the image or patient history. The Lunit INSIGHT MMG uses screening mammograms of the female population.

## 5. Summary of Substantial Equivalence

Item	Subject Device	Predicate Device
	Lunit INSIGHT MMG v1.1.10	Lunit INSIGHT MMG v1.1.6
<b>Classification Name</b>	Radiological Computer Assisted Detection/Diagnosis Software For Suspicious Lesions For Cancer	Radiological Computer Assisted Detection/Diagnosis Software For Suspicious Lesions For Cancer
<b>Regulation</b>	21 CFR 892.2090	21 CFR 892.2090
<b>Regulatory Class</b>	Class II	Class II
<b>Product Code</b>	QDQ	QDQ
<b>Indication for Use</b>	<p>Lunit INSIGHT MMG is a radiological Computer-Assisted Detection/ Diagnosis (CADe/x) software device based on an artificial intelligence algorithm intended to aid in the detection, localization, and characterization of suspicious areas for breast cancer on mammograms from compatible FFDM systems.</p> <p>As an adjunctive tool, the device is intended to be viewed by interpreting physicians after completing their initial read. It is not intended as a replacement for a complete physician’s review or their clinical judgement that takes into account other relevant information from the image or patient history. The Lunit INSIGHT MMG uses screening mammograms of the female population.</p>	<p>Lunit INSIGHT MMG is a radiological Computer-Assisted Detection/ Diagnosis (CADe/x) software device based on an artificial intelligence algorithm intended to aid in the detection, localization, and characterization of suspicious areas for breast cancer on mammograms from compatible FFDM systems.</p> <p>As an adjunctive tool, the device is intended to be viewed by interpreting physicians after completing their initial read. It is not intended as a replacement for a complete physician’s review or their clinical judgement that takes into account other relevant information from the image or patient history. The Lunit INSIGHT MMG uses screening mammograms of the female population.</p>
<b>Target patient population</b>	Women undergoing mammography	Women undergoing mammography
<b>Intended user</b>	Physicians interpreting screening mammograms	Physicians interpreting screening mammograms
<b>Input Image Source</b>	FFDM	FFDM
<b>Fundamental Technological Basis</b>	Lunit INSIGHT MMG is powered by artificial intelligence/machine learning-based software algorithm	Lunit INSIGHT MMG is powered by artificial intelligence/machine learning-based software algorithm

## 6. Comparison with Predicate Device

The subject device, Lunit INSIGHT MMG v1.1.10, maintains the same indications for use and core technological characteristics as the predicate device, Lunit INSIGHT MMG v1.1.6 (K211678). 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 FFDM and outputs of both devices augments the interpreting physicians in the diagnosis of asymptomatic patients.

The primary modifications in Lunit INSIGHT MMG v1.1.10 include the 1) updated AI model and 2) Removal of the 1-view SC output mode from the Secondary Capture AI analysis output.

## **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 MMG 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 2,412 mammograms 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. MMG images were obtained from Hologic, GE Healthcare, and Siemens mammography equipment.

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 0.9104 (95% CI: 0.896, 0.925) with statistical significance ( $p < 0.05$ ). Thus, the primary endpoint was achieved.

For the secondary endpoints, the result of Type I LROC AUC (IoU) was 0.8170 (95% CI: 0.793-0.841), Type II LROC AUC (Max Location) was 0.8730 (95%CI: 0.854, 0.891). Sensitivity at the default operating point (0.1) was 0.8241 (95% CI: 0.7933, 0.8543) and specificity was 0.8154 (95% CI: 0.7978, 0.8331), respectively.

#### **7.2.1 Demographic distribution**

To broadly cover the US population, the data has been comprised with various demographic and clinical information. All clinical data including patient' demographic information such as age, ethnicity, race as well as previous breast cancer history were collected from 28 imaging facilities in the United States.

For baseline demographics information, a total of 2,412 cases are female and fall under the age band of 61.53(±12.44). The majority of ethnicity category is 'Not Hispanic or Latino' (1379, 57.17%). 1396 cases

(57.95%) are 'White' and 282 cases (12.36%) are 'Black or African American', 61 cases (2.53%) are Asian (2.53%) and 9 cases (0.37%) are American Indian/Alaska Native in race category.

### **7.2.2 Clinical subgroups and confounders present in the dataset**

- Distribution of BI-RADS assessment categories (0~6).
- Cancer type categorized as invasive cancer and non-invasive cancer.
- Cancer lesion Shape as irregular, Oval, Round, and irregular+Oval.

### **7.2.3 Information about equipment and protocols used to collect images**

Image collection protocols mandated the inclusion of standard 4-view 2D FFDM images. To guarantee hardware independence, the dataset intentionally covered the three major US mammography equipment vendors: Hologic (1,689 cases), GE Healthcare (482 cases), and Siemens (241 cases). Furthermore, images derived from 2D mammography equipment (1,019 cases) and combo mammography equipment which is mammography equipment performs either 2D and 3D digital mammography (1,393 cases) were cataloged and analyzed.

### **7.2.4 Reference standard derivation (the Truthing process)**

After completion of the dataset screening, each exam will have its own ground truthing by expert breast imaging radiologists who are referenced as a 'Ground Truther' in the study. The ground truthers define the reference standard for every MMG 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 MMG exam into non-cancer group or cancer group [STEP A] then annotated the malignant lesion location in the 2D images 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.

## **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 MMG v1.1.10 is substantially equivalent to the predicate device because it has the same intended use and shares the same technological and performance characteristics. The updated AI engine does not change the device's intended use and does not raise new questions of safety or effectiveness. In addition, non-clinical verification and standalone performance testing demonstrate that the Lunit INSIGHT MMG v.1.1.10 is as safe and effective as the predicate device in detecting suspicious lesions in FFDM exams. Therefore, substantial equivalence has been established.