November 6, 2023

Lunit Inc.
% Hyung Tak Han
Regulatory Affairs Specialist
4-8 F, 374 Gangnam-daero, Gangnam-gu
SEOUL, 06241
SOUTH KOREA

Re: K231470
Trade/Device Name: Lunit INSIGHT DBT
Regulation Number: 21 CFR 892.2090
Regulation Name: Radiological Computer Assisted Detection And Diagnosis Software
Regulatory Class: Class II
Product Code: QDQ
Dated: October 4, 2023
Received: October 4, 2023

Dear Hyung Tak Han:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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.

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

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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K231470

Device Name

Lunit INSIGHT DBT

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.

510(k) Summary

Lunit INSIGHT DBT (K231470**)**

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

1. Submitter

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Date Prepared	2023. 11. 03

2. Device Names and Classifications

Subject Device

Name of Device	Lunit INSIGHT DBT
Classification Name	Radiological Computer Assisted Detection/Diagnosis Software For Suspicious Lesions For Cancer
Regulation	21 CFR 892.2090
Regulatory Class	Class II
Product Code	QDQ

Predicate Device

Name of Device	Lunit INSIGHT MMG
Classification Name	Radiological Computer Assisted Detection/Diagnosis Software For Suspicious Lesions For Cancer
Regulation	21 CFR 892.2090
Regulatory Class	Class II
Product Code	QDQ
Submission Number	K211678

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 an 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	Lunit INSIGHT MMG
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 MMG is a radiological Computer-Assisted Detection and 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.
Target patient population	Women undergoing mammography	Women undergoing mammography
Intended user	Physicians interpreting screening mammograms	Physicians interpreting screening mammograms
Input Image Source	DBT	FFDM
Fundamental Technological Basis	Lunit INSIGHT DBT 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 substantial equivalence table above summarizes the similarities and differences between Lunit INSIGHT DBT and its predicate device, Lunit INSIGHT MMG (K211678). Both devices use artificial intelligence technologies and deep learning techniques to fulfill its intended purpose to detect and characterize lesions suspected of breast cancer. The devices differ in its input file for analysis where Lunit INSIGHT DBT requires DBT scans whereas its predicate analyzes FFDM's. Outputs of both devices augments the interpreting physicians in the diagnosis of asymptomatic patients.

7. Performance Data

7.1. Non-clinical Testing Summary

Software Verification and Validation

Lunit INSIGHT DBT is determined as Moderate level of Concern since a malfunction of, or a latent design flaw in, the software could result in Minor injury. Software was verified through software unit test, software integration test and software system test. Based on results of verification, Lunit INSIGHT DBT demonstrated that it fulfilled the software requirements.

Standalone Performance Testing

A standalone performance study of the Lunit INSIGHT DBT assessed the detection performance of the artificial intelligence algorithm for breast cancer within DBT exams.

Total of 2,202 DBT exams of female adults were collected at multiple imaging facilities in the US using Hologic and GE Healthcare equipment. The data was collected consecutively with the following information: patient information, original radiology report, follow-up biopsy and pathology data, and further imaging diagnostic work-up. The dataset consisted of 1,100 negative and benign cases, and 1,102 cancer cases. In terms of ethnicity and race, the cases were composed of White, American Indian, African American, Asian, and other races, and representative of the general US population. The standalone performance of the Lunit INSIGHT DBT was examined by comparing the analysis results with the reference standards. The reference standards were established through binary classification of each case based on clinical supporting data, particularly pathology reports for cancer and biopsy-proven benign cases, followed by localization which was derived based on the radiologic review and annotation by multiple MQSA qualified ground truthers. The dataset used in the standalone performance test was independent from the dataset used for development of the artificial intelligence algorithm. For generalizability, various subgroup analyses were conducted on the collected dataset including image/radiologic characteristics (e.g. modality manufacturer, slice thickness), demographic information (e.g., age, race), and clinically relevant confounders (e.g. breast density, BI-RADS, breast cancer type).

Standalone Performance Results

The primary endpoint was to demonstrate AUROC in standalone performance greater than 0.903, the mean AUROC of the predicate device (K211678). The subject device's AUROC in the standalone performance analysis was 0.928 (95% CI: 0.917 - 0.939) with statistical significance ($p < 0.0001$), which exceeded the acceptance criteria of the primary endpoint.

7.2. Clinical Assessment Summary

Clinical performance assessment was conducted to evaluate effectiveness of Lunit INSIGHT DBT in the assistance of detection and diagnosis of breast cancer during DBT exam interpretation. A retrospective, multi-reader multi-case (MRMC) study was conducted comparing the reading panel's interpretation performance with and without the use of the Lunit INSIGHT DBT software during the DBT exam interpretation. During the study, every reading panel member, a total of 15 MQSA qualified and US board-certified radiologists, performed interpretation and completed reading sessions, CAD unassisted and CAD assisted, independently using a setting similar to a screening procedure in the US.

Clinical Assessment Primary Objective

The primary objective of the clinical performance assessment was to evaluate the effectiveness of Lunit INSIGHT DBT by comparing the clinical performance of radiologists with CAD and without CAD assistance. If the performance with CAD assistance is superior to that of without CAD assistance with statistical significance, the study was considered to be successful.

Clinical Assessment Data Description

Total of 258 DBT exams were acquired from US clinical centers and were collected using Hologic and GE Healthcare equipment. 65 were cancer cases and 193 were non-cancer cases (128 normal and 65 benign cases).

Clinical Assessment Results

The primary endpoint result of the study was comparison of patient-level Level of Suspicion (LOS) area under the Receiver Operating Characteristic (ROC) curve between CAD-assisted and CAD-unassisted interpretation. AUROC for CAD-unassisted interpretation was 0.897 (95% CI 0.858 - 0.936), when that of CAD-assisted interpretation was 0.915 (95% CI: 0.874 - 0.955) with inter-test difference of 0.017 (95%: CI 0.000 - 0.034, P = 0.0498).

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 is substantially equivalent to Lunit INSIGHT MMG because they are identical with regards to intended use and share similar technological or performance characteristics. The minor differences in technological characteristics do not alter the intended use of the device and do not raise new questions or safety and effectiveness. In addition, non-clinical and clinical testing results demonstrate that the Lunit INSIGHT DBT is as safe and effective as the predicate Lunit INSIGHT MMG. Thus, the substantial equivalence has been demonstrated.