Lunit Inc.
% Colin Jacob
15th Floor, 27 Teheran-ro 2-gil
Gangnam-gu, Seoul
REPUBLIC OF KOREA

November 10, 2021

Re: K211733
Trade/Device Name: Lunit INSIGHT CXR Triage
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer aided triage and notification software
Regulatory Class: Class II
Product Code: QFM
Dated: October 1, 2021
Received: October 1, 2021

Dear Colin Jacob:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics and 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211733

Device Name
Lunit INSIGHT CXR Triage

Indications for Use *(Describe)*
Lunit INSIGHT CXR Triage is a radiological computer-assisted triage and notification software that analyzes adult chest X-ray images for the presence of pre-specified suspected critical findings (pleural effusion and/or pneumothorax). Lunit INSIGHT CXR Triage uses an artificial intelligence algorithm to analyze images for features suggestive of critical findings and provides case-level output available in the PACS/workstation for worklist prioritization or triage.

As a passive notification for prioritization-only software tool within standard of care workflow, Lunit INSIGHT CXR Triage does not send a proactive alert directly to the appropriately trained medical specialists. Lunit INSIGHT CXR Triage is not intended to direct attention to specific portions of an image. Its results are not intended to be used on a stand-alone basis for clinical decision-making.

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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510(k) Summary

K211733

This summary of safety and effectiveness information is submitted in accordance with 21 CFR § 807.92.

Date Prepared: November 3, 2021

Submitter
Lunit Inc.,
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Name of Device:	Lunit INSIGHT CXR Triage
Common or Usual Name:	Lunit INSIGHT CXR Triage
Classification Name:	Radiological Computer-Assisted Prioritization Software for Lesions
Classification Regulation:	21 CFR 892.2080
Regulatory Class:	Class II
Product Code:	QFM

Predicate Device

The Lunit INSIGHT CXR Triage is substantially equivalent to the following devices:

Primary Predicate Device

Manufacturer Name	Zebra Medical Vision, Ltd.
Device Trade Name	HealthCXR
510(k) Number	K192320

Secondary Predicate Device

Manufacturer Name	GE Medical Systems, LLC
Device Trade Name	Critical Care Suite
510(k) Number	K183182

Device Description

Lunit INSIGHT CXR Triage is a radiological computer-assisted prioritization software that utilizes AI-based image analysis algorithms to identify pre-specified critical findings (pleural effusion and/or pneumothorax) on frontal chest X-ray images and flag the images in the PACS/workstation to enable prioritized review by the appropriately trained medical specialists who are qualified to interpret chest radiographs. The software does not alter the order or remove cases from the reading queue.

Chest radiographs are automatically received from the user's image storage system (e.g. Picture Archiving and Communication System (PACS)) or other radiological imaging equipment (e.g. X-ray systems) and processed by the Lunit INSIGHT CXR Triage for analysis. Following receipt of chest radiographs, the software device de-identifies a copy of each chest radiographs in DICOM format (.dcm) and automatically analyzes each image to identify features suggestive of pleural effusion and/or pneumothorax. Based on the analysis result, the software notifies PACS/workstation for the presence of the critical findings as indicating either "flag" or "(blank)". This would allow the appropriately trained medical specialists to group suspicious exams together that may potentially benefit for their prioritization. Chest radiographs without an identified anomaly are placed in the worklist for routine review, which is the current standard of care. Lunit INSIGHT CXR Triage can flag more than one critical finding per radiograph and the user may select the option to turn on and off notification of critical findings (pleural effusion and pneumothorax).

When deployed on other radiological imaging equipment, Lunit INSIGHT CXR Triage automatically runs after image acquisition. It prioritizes and displays the analysis result through the worklist interface of PACS/workstation. Moreover, the analysis result can also be provided in the form of DICOM files containing information on the presence of suspicious radiologic findings. In parallel, the algorithms produce an on-device notification indicating which cases were prioritized by Lunit INSIGHT CXR Triage in PACS. The on-device notification does not provide any diagnostic information and it is not intended to inform any clinical decision, prioritization, or action to the technologist.

Lunit INSIGHT CXR Triage works in parallel to and in conjunction with the standard care of workflow; therefore, the user enables to review the study containing critical findings earlier than others. As a passive notification for prioritization-only software tool within standard of care workflow, the software does not send a proactive alert directly to the appropriately trained medical specialists who are qualified to interpret chest radiographs. Lunit INSIGHT CXR Triage is not intended to direct attention to specific portions or anomalies of an image and it should not be used on a stand-alone basis for clinical decision-making.

In parallel, an on-device, technologist notification is generated 15 minutes after interpretation by the user, indicating which cases were prioritized by Lunit INSIGHT CXR Triage in PACS. The technologist notification is contextual and does not provides any diagnostic information. The on-device, technologist notification is not intended to inform any clinical decision, prioritization, or action.

Intended Use / Indications for Use

> Lunit INSIGHT CXR Triage is a radiological computer-assisted triage and notification software that analyzes adult chest X-ray images for the presence of pre-specified suspected critical findings (pleural effusion and/or pneumothorax). Lunit INSIGHT CXR Triage uses an artificial intelligence algorithm to analyze images for features suggestive of critical findings and provides case-level output available in the PACS/workstation for worklist prioritization or triage.
>
> As a passive notification for prioritization-only software tool within standard of care workflow, Lunit INSIGHT CXR Triage does not send a proactive alert directly to the appropriately trained medical specialists. Lunit INSIGHT CXR Triage is not intended to direct attention to specific portions of an image. Its results are not intended to be used on a stand-alone basis for clinical decision-making.

There is a minor difference between the subject and primary predicate device HealthCXR (K192320) in their indications for use. The primary predicate device is indicated for use to analyze chest X-ray images for the presence of pleural effusion, while Lunit INSIGHT CXR Triage detects pleural effusion as well as pneumothorax. While the specific clinical finding differs, the intended use of the device which is to provide passive notification for triage and prioritization for time sensitive radiologic findings in the chest X-ray is the same. Additionally, the time sensitivity of additional potential finding of pneumothorax has been already established in a secondary predicate device; Critical Care Suite (K183182) and the detection of such potential finding in Lunit INSIGHT CXR Triage is supported by performance testing.

Summary of Technological Characteristics

Both the Lunit INSIGHT CXR Triage and the predicate devices are software only devices that use Artificial intelligence (AI) algorithms and are intended to aid in triage and prioritization of radiological images. At a high level, the subject and the predicate devices are based on the following same technological elements:

- Artificial Intelligence Algorithm(s)
- Triage and prioritization software

The following technological differences exist between the subject and predicate devices:

- Clinical condition(s)

Lunit INSIGHT CXR Triage detects suspected findings, pleural effusion as well as pneumothorax. In comparison, the primary predicate device detects suspected findings of pleural effusion alone. However, both devices identify time sensitive findings and provide passive notification and pleural effusion as well as pneumothorax have been accepted by FDA as appropriate for regulation as CADt devices.

Comparison of the key features of the subject, and predicate devices is provided in **Table 1**.

Performance Data

The performance of Lunit INSIGHT CXR Triage was validated by clinical and nonclinical tests. All verification testing met the acceptance criteria (passed), demonstrating that the software fulfills its requirement specifications.

Nonclinical Tests

The company conducted an internal validation test to assess the standalone performance of Lunit INSIGHT CXR Triage. The validation was completed to determine whether a distinction between target findings is properly completed by the subject device. A total of 1,385 images were collected according to the inclusion and exclusion criteria and classified into positive and negative groups by highly experienced board-certified radiologists. For each target finding, positive includes any case that contains at least one target finding in the image and negative represents the case that does not have the target finding, which includes cases without any findings and cases that contain findings other than the target radiologic finding.

Summary of results: ROC AUC was 0.9864 (95% CI: 0.9815 – 0.9913) with 94.29% sensitivity and 95.72% specificity for pleural effusion. For pneumothorax, 0.9973 ROC AUC (95% CI: 0.9955 – 0.9992), 96.08% sensitivity, and 99.14% specificity were reported. By confirming that the lower bound of ROC AUC exceeds 0.95 and the sensitivity and specificity for both target radiologic findings are above 0.80, the performance of the algorithm of Lunit INSIGHT CXR Triage is validated to demonstrate that the prespecified target performance is satisfied.

Clinical Tests

Two individual clinical pivotal studies were conducted to evaluate the effectiveness of the Lunit INSIGHT CXR Triage. The studies were conducted with NIH chest X-ray dataset that represents the US population and India dataset collected respectively from multiple institutions in India (6 sites for pleural effusion and 3 sites for pneumothorax).

A total of 1,708 anonymized chest radiographs (754 cases for pleural effusion and 954 cases for pneumothorax) collected from NIH chest X-ray dataset and multiple institutions in India were enrolled in the validation dataset for the standalone performance test and device performance time estimation. For pleural effusion, the results are as follow: ROC AUC 0.9686 (95% CI: 0.9547 - 0.9824), sensitivity 89.86% (95% CI: 86.72 - 93.00) and specificity 93.48% (95% CI: 91.06 - 95.91). For pneumothorax, the results are as follows: ROC AUC 0.9630 (95% CI: 0.9521 - 0.9739), Sensitivity 88.92% (95% CI: 85.60 - 92.24) and Specificity 90.51% (95% CI: 88.18 - 92.83). The performance for the primary predicate device indicated for pleural effusion (Zebra Medical Vision, HealthCXR) are as follows: ROC AUC was 0.9885 (95% CI: 0.9815 - 0.9956) with sensitivity 96.74% (95% CI: 92.79 – 96.48) and specificity 93.17% (95% CI: 89.57 – 95.58). The performance data show that the lower bound of ROC AUC exceeds 0.95 and the lower bounds of both sensitivity and specificity are above

0.85 for both pleural effusion and pneumothorax. Accordingly, the Lunit INSIGHT CXR Triage is demonstrated to achieve effective image analysis and triage capabilities.

With regards to the device performance time, the company assessed the performance time of the Lunit INSIGHT CXR Triage that reflects the time it takes for the device to analyze the study and send a notification to the worklist. The performance time of the Lunit INSIGHT CXR Triage was 20.76 seconds (95% CI: 20.23 - 21.28) for pleural effusion and 20.45 seconds (95% CI: 19.99 - 20.92) for pneumothorax. As compared the device performance time of the Lunit INSIGHT CXR Triage with cleared commercial products (HealthCXR (Zebra, K192320) and red dot™ (Behold.AI, K161556)), the result was comparable with the primary predicate device and other 510(k) cleared products.

In summary, the Lunit INSIGHT CXR Triage performed successfully in the clinical pivotal studies. The Lunit INSIGHT CXR Triage established standalone adequate detection performance and device performance time for pleural effusion and pneumothorax as compared to the primary predicate device.

Conclusions

The Lunit INSIGHT CXR Triage is as safe and effective as the predicate devices. The Lunit INSIGHT CXR Triage has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor differences in indications do not alter the intended use of the device and do not affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between the Lunit INSIGHT CXR Triage and its predicate devices raise no new issues of safety or effectiveness. The clinical and non-clinical performance data demonstrates that the Lunit INSIGHT CXR Triage is as safe and effective as the predicate devices. Thus, the Lunit INSIGHT CXR Triage support a decision is substantially equivalent to its predicate devices for triage and notification.

Table 1 Substantial Equivalence Table

Technological Characteristics	Proposed Device: Lunit INSIGHT CXR Triage	Primary Predicate Device: HealthCXR (K192320)	Secondary Predicate Device: Critical Care Suite (K183182)
Device classification	Radiological Computer Assisted Prioritization Software Class II, QFM	Radiological Computer Assisted Prioritization Software Class II, QFM	Radiological Computer Assisted Prioritization Software Class II, QFM
Indication for Use/Intended Use	Lunit INSIGHT CXR Triage is a radiological computer-assisted triage and notification software that analyzes adult chest X-ray images for the presence of pre-specified suspected critical findings (pleural effusion and/or pneumothorax). Lunit INSIGHT CXR Triage uses an artificial intelligence algorithm to analyze images for features suggestive of critical findings and provides case-level output available in the PACS/workstation for worklist prioritization or triage. As a passive notification for prioritization-only software tool within standard of care workflow, Lunit INSIGHT CXR Triage does not send a proactive alert directly to the appropriately trained medical specialists. Lunit INSIGHT CXR Triage is not intended to direct attention to specific portions of an image or to anomalies other than	The Zebra HealthCXR device is a software workflow tool designed to aid the clinical assessment of adult Chest X-Ray cases with features suggestive of pleural effusion in the medical care environment. HealthCXR analyzes cases using an artificial intelligence algorithm to identify suspected findings. It makes case-level output available to a PACS/workstation for worklist prioritization or triage. HealthCXR is not intended to direct attention to specific portions or anomalies of an image. Its results are not intended to be used on a stand-alone basis for clinical decision-making nor is it intended to rule out Pleural Effusion or otherwise preclude clinical assessment of X-Ray cases.	Critical Care Suite is a computer aided triage and notification device that analyzes frontal chest x-ray images for the presence of pre-specified critical findings (pneumothorax). Critical Care Suite identifies images with critical findings to enable case prioritization or triage in the PACS/workstation. Critical Care Suite is intended for notification only and does not provide diagnostic information beyond the notification. Critical Care Suite should not be used in-lieu of full patient evaluation or solely relied upon to make or confirm a diagnosis. It is not intended to replace the review of the x-ray image by a qualified physician. Critical Care Suite is indicated for adult-size patients.

Technological Characteristics	Proposed Device: Lunit INSIGHT CXR Triage	Primary Predicate Device: HealthCXR (K192320)	Secondary Predicate Device: Critical Care Suite (K183182)
	pleural effusion and/or pneumothorax. Its results are not intended to be used on a stand-alone basis for clinical decision-making.		
Notification-only, parallel workflow tool	Yes	Yes	Yes
User	Appropriately trained medical specialists who are qualified to interpret chest radiographs.	Radiologist	Radiologist
Targeted clinical condition, anatomy, and modality	Pleural effusion, pneumothorax Chest/Lung Frontal Chest X-ray	Pleural effusion Chest/Lung Frontal Chest X-ray	Pneumothorax Chest/Lung Frontal Chest X-ray
Algorithm for pre-specified critical findings detection	AI algorithm designed to detect pleural effusion and pneumothorax in chest X-ray images. Lunit INSIGHT CXR Triage uses a vendor agnostic algorithm compatible with DICOM chest X-ray images.	AI algorithm designed to detect pleural effusion in chest X-ray images. HealthCXR employs a vendor agnostic algorithm compatible with DICOM chest X-ray images.	AI algorithm designed to detect pneumothorax in frontal chest X-ray images. Critical Care Suite uses a vendor agnostic algorithm compatible with DICOM frontal chest X-ray images.
Radiological images format	DICOM	DICOM	DICOM
Computational Platform	Lunit INSIGHT CXR Triage is designed as a software module that can be deployed on several	HealthCXR is designed as a software module that can be deployed on	Critical Care Suite is designed as a software module that can be deployed on several computing and

Technological Characteristics	Proposed Device: Lunit INSIGHT CXR Triage	Primary Predicate Device: HealthCXR (K192320)	Secondary Predicate Device: Critical Care Suite (K183182)
	computing and X-ray imaging platforms such as radiological imaging equipment, PACS, On Premise or On Cloud.	PACS and Standalone desktop application, Zebra Worklist.	X-ray imaging platforms such as Digital Projection Radiographic Systems, PACS, On Premise or On Cloud.
Device output in case of positive detection	When deployed on other radiological imaging equipment, Lunit INSIGHT CXR Triage automatically runs after image acquisition and prioritizes and displays the analysis result through the worklist interface of PACS/workstation. No markup on original image. Secondary capture of the finding. Upon image acquisition from other radiological imaging equipment (e.g. X-ray systems), an on-device, technologist notification indicating which cases were flagged by Lunit INSIGHT CXR Triage in PACS, is generated 15 minutes after interpretation by the user. The on-device notification is contextual and does not provide any diagnostic information. It is not intended to	Integration module notifies the PACS/workstation for prioritization through the worklist interface. No markup on original image.	Critical Care Suite enables case prioritization or triage through direct communication of the Critical Care Suite notification during image transfer to the PACS. No markup on original image Upon image acquisition on a Digital Projection Radiographic System, an on-device, technologist notification is generated 15 minutes after exam closure, indicating which cases were prioritized by Critical Care Suite in PACS. The technologist notification is contextual and does not provides any diagnostic information. The on-device, technologist notification is not intended to inform any clinical decision, prioritization, or action.

Technological Characteristics	Proposed Device: Lunit INSIGHT CXR Triage	Primary Predicate Device: HealthCXR (K192320)	Secondary Predicate Device: Critical Care Suite (K183182)
	inform any clinical decision, prioritization, or action to the technologist.		
Notification (i.e., recipient, timing and means of notification)	Passive notification. Images with suspicion of pleural effusion and/or pneumothorax are flagged in PACS/workstation.	Passive notification. Images with suspicion of pleural effusion are flagged in PACS/workstation.	Passive notification. Images with suspicion of pneumothorax are flagged in PACS/workstation.
Where generated results (i.e., DICOM files) are stored	PACS/Workstation	PACS/Workstation	PACS/Workstation
Performance level – Timing of notification	The average time taken for the notification to travel from the Lunit INSIGHT CXR Triage to the point at which the result is displayed in the destination PACS/RIS/EPR worklist is 14.66 seconds.	Passive notification is visible upon transfer to the PACS with a delay of about 22 seconds for image transfer to the cloud, computation, and results transfer.	The average time to acquire, annotate, process and transfer an image from the x-ray system to PACS was measured and found to take 42 seconds on average. Exams arrive on PACS with the passive notification already incorporated, therefore there is no delay for image transfer or computation. The worklist prioritization happens immediately once the exam is received on the PACS.

Technological Characteristics	Proposed Device: Lunit INSIGHT CXR Triage	Primary Predicate Device: HealthCXR (K192320)	Secondary Predicate Device: Critical Care Suite (K183182)
Performance level – accuracy of classification	**Pleural Effusion** ROC AUC > 0.95 AUC: 0.9686 (95% CI: [0.9547, 0.9824]) Sensitivity 89.86% (95% CI: [86.72, 93.00]) Specificity 93.48% (95% CI: [91.06, 95.91]) **Pneumothorax** ROC AUC > 0.95 AUC: 0.9630 (95% CI: [0.9521, 0.9739]) Sensitivity 88.92% (95% CI: [85.60, 92.24]) Specificity 90.51% (95% CI: [88.18, 92.83])	ROC AUC > 0.95 AUC: 0.9885 (95% CI: [0.9815, 0.9956]), **First operating point** Sensitivity 96.74% (95% CI: [92.79; 96.48]) Specificity 93.17% (95% CI: [89.57; 95.58]) **"High-specificity" operating point** Sensitivity 93.84% (95% CI: [90.36;96.12) Specificity 97.12% (95% CI: [94.43;98.53])	ROC AUC > 0.95 AUC: 0.9607 (95% CI [0.9491, 0.9724]) Specificity 93.5% (95% CI [91.1%, 95.8%]) Sensitivity 84.3% (95% CI [80.6%, 88.0%]) AUC on large pneumothorax 0.9888 (95% CI [0.9810, 0.9965]) Sensitivity on large pneumothorax 96.3% (95% CI [93.3%, 99.2%] AUC on small pneumothorax 0.9389 (95% CI [0.9209, 0.9570]) Sensitivity on small pneumothorax 75% (95% CI [69.2%, 80.8%])