

Korea's Lunit gets FDA nod for AI-based chest X-ray triage solution

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First FDA 510(k) clearance from its AI software product lineup for radiology, specialized in triaging emergent cases found in chest x-ray

South Korea-based startup Lunit has received US Food and Drug Administration (FDA) 510(k) clearance for its AI-powered chest x-ray triaging solution, 'Lunit INSIGHT CXR Triage'.

With this first FDA clearance, the company is now able to commercially provide the AI solution to medical professional and healthcare institutions in the U.S.

Lunit INSIGHT CXR Triage is a computer-assisted triage and notification software that analyzes chest x-ray images for the presence of pre-specified suspected critical findings.

According to the company, the product is designed to triage and prioritize emergent cases such as pleural effusion and pneumothorax immediately after the exam, to have the findings notified to the physicians, thereby reducing the time-to-diagnosis of urgent cases.

The FDA clearance can boost the company's plan to accelerate its sales expansion in the US market. As Lunit INSIGHT CXR Triage is best applied with mobile-based x-ray devices that are often used in urgent care settings, the company can maximize current partnerships with global medical device companies like Philips, and Fujifilm.