

## Gleamer Receives FDA Clearance for ChestView, Revolutionizing Chest X-ray Interpretation with CADe in the U.S.

CAMBRIDGE, MA, UNITED STATES, March 25, 2025 /EINPresswire.com/ -- <u>Gleamer</u>, a leading innovator in artificial intelligence-powered medical imaging solutions, announced today that its advanced chest X-ray interpretation solution, ChestView, has received clearance from the U.S. Food and Drug Administration (FDA).

This announcement marks a groundbreaking advancement in chest X-Ray interpretation, with a Computer-Aided Detection (CADe) model cleared by the FDA for simultaneously detecting multiple pathologies, enabling direct highlighting of abnormalities on images. This capability significantly enhances explainability and confidence in diagnoses compared to traditional triage-focused CADt solutions on chest X-rays, setting a new standard in Al-assisted radiological diagnostics.

This is Gleamer's second announcement of an FDA clearance, following the successful introduction of BoneView in April 2022, reflecting the expanding footprint of the Gleamer Copilot® suite in the U.S. market. The application is enhanced by a unified UX/UI experience with BoneView, ensuring seamless integration and ease of adoption for healthcare providers. This milestone paves the way for ChestView's immediate launch across the United States, offering healthcare providers a powerful tool for faster, more accurate diagnoses. With the U.S. already contributing 30% of Gleamer's revenue from BoneView, ChestView is expected to significantly accelerate this growth.

ChestView leverages cutting-edge artificial intelligence algorithms to assist radiologists and clinicians by automatically detecting key radiological findings in chest X-rays. ChestView further solidifies Gleamer's leadership in AI medical imaging, uniquely covering all core imaging modalities, including X-Ray, Mammography, CT, and MRI. By identifying anomalies such as pleural space abnormalities, lung nodules, and other critical pathologies, ChestView aims to significantly enhance diagnostic accuracy, reduce diagnostic delays, and improve patient outcomes. The introduction of CADe technology, such as ChestView, represents a significant advancement in medical imaging, enabling healthcare providers to manage increasing workloads efficiently, reduce oversight errors, and enhance the overall quality of patient care.

"Securing FDA clearance is a major achievement for Gleamer and underscores our commitment to advancing medical imaging through innovative AI technology. This comes after Gleamer's

recent acquisition of FDA-cleared Neuro MRI AI developer, Pixyl, further accelerating our growth and expansion within the U.S. market," said Christian Allouche, CEO at Gleamer. "We believe ChestView will transform how chest X-rays are analyzed, making healthcare delivery faster, safer, and more effective for millions of patients."

ChestView has already demonstrated exceptional performance in clinical studies, significantly improving diagnostic sensitivity and reducing time-to-diagnosis. The application integrates seamlessly into existing clinical workflows, providing radiologists with critical insights in seconds. With this FDA clearance, Gleamer is set to roll ChestView out across its existing install-base and partner with new healthcare institutions nationwide, helping clinicians leverage AI to deliver superior patient care.

For more information about ChestView and Gleamer's innovative imaging solutions, visit <a href="https://www.gleamer.ai">www.gleamer.ai</a>.

## **About Gleamer**

Founded in 2017, Gleamer considers AI to be a key solution for addressing the sharp rise in demand for medical imaging, stemming from the challenges of an ageing population, the increasing prevalence of chronic diseases, and the problems of access to healthcare. The company's suite of AI-powered solutions, across X-Ray, Mammography, CT and now, MRI, supports radiologists and clinicians in their diagnoses, thereby improving reliability and reducing the time taken to read and process examinations. The relevance and exceptional performance of these solutions have been recognised worldwide thanks to 30 publications in highly regarded peer-reviewed journals. With 35 million exams analysed across over 2,000 institutions, spanning 45 countries across all continents, Gleamer's solutions are now widely acclaimed within the medical imaging industry. <a href="https://www.gleamer.ai">www.gleamer.ai</a>

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