# Lumea’s Digital Pathology Viewer is now FDA Cleared

*Lumea’s Digital Diagnostic Suite™ (Viewer+™) Receives FDA 510(k) Clearance for Clinical Diagnosis*


LEHI, UT, UNITED STATES, March 18, 2025 /EINPresswire.com/ -- Lumea, a leader in digital pathology solutions, is proud to announce that its Viewer+™ software has received FDA 510(k) clearance, solidifying its role as a cutting-edge, centralized diagnostic hub for pathologists. This clearance ensures that Viewer+, our Digital Diagnostic Suite™, meets the highest standards of safety and effectiveness, allowing it to be used for primary diagnosis in clinical settings.

Precision in medicine isn’t a luxury—it’s a necessity. Pathology data informs nearly 70% of medical decisions, yet inconsistencies in tissue handling can compromise accuracy. Lumea’s holistic workflow solutions address these challenges by optimizing every step of the pathology journey, from tissue collection to diagnosis. Viewer+ plays a pivotal role in this workflow, offering pathologists a seamless digital experience that enhances efficiency and diagnostic accuracy.

With FDA clearance, Viewer+ sets a new standard in digital pathology, offering a robust suite of tools tailored to the modern pathologist’s needs, including:

+ Highest Quality Whole Slide Images: Digital slide images are rendered with precision so high that they are visually equivalent to traditional microscope views.

+ Comprehensive Case Management: Pathologists can manage slide orders, review gross images, access patient history, and track previous biopsy results—all in one place.

+ Integrated Tools: All essential tools are built directly into the viewer, eliminating the need for multiple screens and manual test ordering.

+ Instant Second Opinions: Pathologists can consult peers within and outside their network

instantly, ensuring confident diagnoses.

Designed with efficiency and usability in mind, Viewer+ enables pathologists to sign out cases up to 50% faster while keeping the whole slide image always in view.

“The FDA clearance of Viewer+ is great recognition of the exceptional quality of Lumea’s digital pathology solution,” said Andy Ivie, Lumea CTO. “With this approval, we’re not just offering another digital pathology viewer—we’re providing an all-in-one diagnostic powerhouse that transforms the way pathologists work, improving efficiency, accuracy, and ultimately, patient outcomes.”

With Viewer+, pathologists no longer need to rely on stacks of slides, multiple screens, and fragmented workflows. Instead, they have everything they need—on one screen, in one intuitive system.

To learn more about how Viewer+ is setting a new standard in digital pathology, visit LumeaDigital.com/viewerplus.

About Lumea
By placing patients at the core, Lumea is transforming pathology for a more precise and efficient future. Lumea is the U.S. leader in primary clinical digital pathology, processing the highest volume of primary digital diagnoses nationwide. With over a decade of expertise, its innovative tissue-handling technology and AI-driven workflows set a new standard for efficiency, quality, and cancer diagnostics. With a global presence spanning five continents, Lumea supports over half of the U.S. urology market and top dermatology and gastroenterology groups, optimizing tissue integrity, boosting detection rates, and delivering measurable ROI.

*Badrick T. Evidence-based laboratory medicine. Clin Biochem Rev. 2013;34(2):43-46.

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