

Press Release

Tribun Health Achieves FDA Clearance for CaloPix® Digital Pathology Platform with Dual Scanner Compatibility

Paving the way for U.S. Market Entry and Global Expansion

Paris, France – May 21, 2025 – [Tribun Health](#), a leader in digital pathology, proudly announces that its flagship web-based image management system, CaloPix®, has received FDA 510(k) clearance for use with two leading whole slide imaging scanners: the Hamamatsu NanoZoomer S360MD and the Leica Aperio GT450 DX. This double clearance is representing a major step forward for the U.S. adoption of vendor-agnostic, enterprise-grade solutions.

This clearance builds on CaloPix's strong regulatory track record: the solution is CE-marked, Health Canada-approved, and trusted by more than 100 hospitals and laboratories across Europe and Canada. With over 1,000 active users of CaloPix® worldwide, this milestone underscores the platform's scalability, performance, and rapid adoption across diverse healthcare systems. Now, with FDA clearance secured, Tribun Health is ready to bring its proven enterprise solution to hospitals and labs across the United States.

Besides these regulatory achievements, CaloPix® has also been recognized three times as "Best in KLAS" for digital pathology, a global benchmark for excellence in healthcare IT. This prestigious recognition highlights Tribun Health's commitment to customer satisfaction, operational excellence, and product innovation.

"This is a major commercial and clinical milestone for us," said [Jean-François Pomerol](#), CEO of Tribun Health. "We're entering the U.S. with a solution that has already proven its value in demanding, high-throughput clinical environments. With CaloPix®, we offer a platform trusted by top-tier institutions, awarded Best in KLAS multiple times — and now validated by the FDA. As the market accelerates toward widespread clinical adoption, we're thrilled to expand our reach and solidify our position as a truly global player."

Built for Enterprise, Designed for Performance, Ready for Cloud

CaloPix® goes far beyond a traditional image viewer—it's a powerful, all-in-one digital pathology platform tailored for the needs of modern healthcare systems, large hospital networks, and academic institutions.

Key capabilities include:

- Web-based, cloud-ready, zero-footprint architecture—no local installation required
- High-throughput case management and diagnostic reporting to streamline daily workflows
- Seamless integration with LIS and VNA systems for unified data access across the enterprise
- Built-in telepathology and remote collaboration tools for second opinions and network-wide consultations
- Archiving, export, and quality control features to support regulatory compliance and research initiatives



Meeting the Moment: Solving U.S. Market Challenges

The U.S. faces a growing mismatch between rising pathology case volumes and a shrinking workforce. At the same time, there is a clear push for multi-site collaboration, integrated diagnostics, and precision medicine initiatives.

With this FDA clearance, CaloPix® empowers U.S. hospitals and labs to:

- Digitize pathology workflows at scale
- Reduce turnaround times and improve reporting accuracy
- Collaborate remotely across institutions
- Prepare for AI adoption with structured, interoperable data

Building on our success with public health networks, cancer centers, academic hospitals and private laboratory groups across Europe and Canada, we are now ready to scale in the world's largest healthcare market—the United States.

* CaloPix® is CE-marked, Health Canada–approved, and FDA 510(k) cleared. Please refer to the Instructions for Use (IFU) for intended purpose and regulatory indications.

About Tribun Health

Tribun Health is a global leader in digital pathology, offering award-winning solutions that improve workflow efficiency, diagnostic accuracy, and patient outcomes. We assist hospitals and laboratories in transitioning from glass slide pathology to fully digital solutions, leveraging AI and data-driven technology to enhance precision and reduce turnaround times. Our mission is simple: to ensure every cancer patient receives a timely and informed diagnosis—because every moment counts. By advancing pathology with cutting-edge innovations, we are shaping the future of cancer care. For more information, visit [Tribun Health](#) and follow us on [LinkedIn](#) and [X](#).

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