

Vigilant Ops Ensures SBOM and Cybersecurity Compliance for Epredia's Recent FDA Clearance

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Recent FDA Clearance for E1000 Dx Digital Pathology Solution

PITTSBURGH, PA, UNITED STATES, May 7, 2025 /EINPresswire.com/ -- Vigilant Ops, a leader in

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Ken Zalevsky, CEO at Vigilant Ops

SBOM (Software Bill of Materials) lifecycle management, is proud to announce its role in supporting cybersecurity compliance efforts for <u>Epredia</u>'s groundbreaking E1000 Dx™ Digital Pathology Solution. The E1000 Dx recently received U.S. Food and Drug Administration (FDA) 510(k) clearance, a critical milestone for advancing digital pathology in cancer diagnostics.

Epredia, a global leader in precision cancer diagnostics, developed the E1000 Dx to digitize up to 1,500 tissue samples per day, enabling high-speed, automated whole-slide imaging for enhanced diagnostic accuracy. To ensure regulatory compliance and software security throughout

the product's lifecycle, Epredia leveraged Vigilant Ops' industry-leading <u>SBOM management</u> <u>platform</u>.

"As regulatory bodies, including the FDA, continue to emphasize software transparency and cybersecurity in medical devices, ensuring a robust SBOM lifecycle is no longer optional—it's essential," said Ken Zalevsky, CEO of Vigilant Ops. "We are honored to support Epredia in managing SBOM compliance for the E1000 Dx. Ensuring software security and regulatory alignment for such an innovative technology is critical to advancing patient care."

With evolving cybersecurity threats in the healthcare sector, medical device manufacturers must proactively manage their software supply chains. Vigilant Ops' SBOM Lifecycle Management platform provides end-to-end visibility into software components, vulnerabilities, and compliance requirements, empowering manufacturers like Epredia with automation to meet FDA expectations and streamline product approvals.

The successful FDA 510(k) clearance of the E1000 Dx underscores the importance of integrating cybersecurity risk management into medical device development. Epredia's commitment to patient safety and regulatory excellence sets a high standard for medical device security in digital pathology. By collaborating with Vigilant Ops, Epredia ensured a secure and compliant software ecosystem, reinforcing the safety and reliability of Epredia's next-generation digital pathology technology.

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Leader in SBOM Lifecycle Management

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