

OptraSCAN System Receives FDA Clearance

FDA 510(k) clearance (K260755) for the OptraSCAN System, an integrated platform featuring the OS-Ultra Scanner and ImagePath software with HER2 Image Analysis.

SAN JOSE, CA, UNITED STATES, July 9, 2026 /EINPresswire.com/ -- [OptraSCAN](#), Inc., a California-

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Devika Gholap, Chief Product Officer

headquartered [digital pathology](#) and image analysis product company, today announced that it has received clearance from the U.S. Food and Drug Administration (FDA) for the OptraSCAN System. This 510(k) clearance (K260755) covers the OptraSCAN System as an integrated system - comprising the OS-Ultra Scanner, a color display monitor, and a workstation running the company's ImagePath image management software, including [HER2](#) Image Analysis Software.

“This first clearance further strengthens OptraSCAN's

mission to make Digital Pathology genuinely affordable through its pay-per-use model,” says Devika Gholap, Chief Product Officer. She adds, “Digital images generated by the OS-Ultra Scanner can now be evaluated at a fraction of conventional costs, eliminating the need for upfront capital investment, through OptraSCAN's Digital Lab as a service model. As OptraSCAN systems are being deployed across laboratories nationally, Digital Pathology becomes accessible, scalable, and economically sustainable for institutions of every size.”

“By integrating high-quality whole-slide imaging with validated HER2 image analysis, OptraSCAN provides pathologists with a reliable platform that supports both efficiency and diagnostic confidence. This clearance underscores the value of expanding digital pathology solutions that are practical for laboratories of all sizes, ultimately helping ensure that more patients benefit from timely and precise diagnostic evaluation”, says Dr. Jiaoti Huang, Chair of Medical Advisory Board at OptraSCAN and Chair of the Department of Pathology at Duke University.

About OptraSCAN, Inc.

Headquartered in California, USA, OptraScan is a leader in On-Demand Digital Pathology, with 165+ global installations across hospitals, reference laboratories, research institutions, and life sciences organizations in 30+ countries worldwide. Dedicated to making digital pathology accessible, affordable, and scalable, OptraScan delivers end-to-end solutions that enable laboratories of all sizes to seamlessly transition from conventional microscopy to fully digital

workflows through flexible deployment models, including a pay-per-use offering.

The company's portfolio includes high-performance whole slide scanners, image management software, image analysis, telepathology, and workflow automation solutions that enhance interpretation efficiency, collaboration, and patient care. Supporting applications across routine histopathology, oncology, cytology, infectious diseases, and translational research, OptraScan is committed to advancing precision healthcare through innovation, quality, and regulatory excellence, empowering pathologists with intelligent, cost-effective solutions that improve patient outcomes worldwide.

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