

Hamamatsu Receives FDA 510(k) Clearance for NanoZoomer S20MD and S540MD Slide scanner systems

New FDA clearances expand Hamamatsu's FDA-cleared NanoZoomer portfolio with compact benchtop and high-throughput digital pathology solutions.

HAMAMATSU, Japan, Sept. 2, 2026 — Hamamatsu Photonics K.K. today announced that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the NanoZoomer S20MD and NanoZoomer S540MD Slide scanner systems. Building on the previously cleared NanoZoomer S360MD, these additions broaden the availability of FDA-cleared NanoZoomer systems in the United States, giving clinical pathology laboratories greater choice when selecting a NanoZoomer system that aligns with their operational requirements.

With FDA-cleared systems spanning compact, routine, and high-throughput laboratory operations, Hamamatsu now offers a comprehensive NanoZoomer platform that provides a consistent user experience across the NanoZoomer product family.

The FDA-cleared NanoZoomer portfolio now includes:

- **NanoZoomer S20MD** - Compact benchtop deployment
- **NanoZoomer S360MD** - Routine laboratory workflows
- **NanoZoomer S540MD** - High-throughput laboratory operations

"The FDA clearances of the NanoZoomer S20MD and the NanoZoomer S540MD represent an important milestone for Hamamatsu as we continue to expand our FDA-cleared portfolio," said Scott Blakely, Business Development Manager, Americas. "These clearances reflect our commitment to providing laboratories with a range of solutions that deliver the image quality, reliability, and long-term performance that define the NanoZoomer platform."

Together, the NanoZoomer S20MD, S360MD, and S540MD Slide scanner systems provide pathology laboratories with a family of FDA-cleared solutions spanning compact benchtop, routine, and high-throughput laboratory operations.

About Hamamatsu Photonics K.K.

Hamamatsu Photonics K.K. is a global leader in the design and manufacture of photonics devices, including advanced imaging detectors. Our optical sensors, light sources, cameras, photometry systems, and measurement and analysis systems deliver critical photonics components for a broad range of demanding applications and markets. For more than two decades, our NanoZoomer series of digital scanners has been a pioneer solution in whole slide imaging scanner technology for pathology research.

For more information, visit www.nanozoomer.com.