FDA clears Aperio AT2 DX for clinical diagnosis

June 11, 2019–Leica Biosystems received clearance from the Food and Drug Administration to market its Aperio AT2 DX System for clinical diagnosis in the United States.

A multicenter study supporting this clearance was conducted at five clinical study sites: University of California Davis, Pacific Rim Pathology, Dignity Health, TriCore Reference Laboratories, and Intermountain Healthcare. The participating pathologists read approximately 16,000 cases.

“We are very grateful for the hard work of our clinical partners, including the adjudicators and advisors, as well as the pathologists and staff of our study sites,” Colin White, global vice president of Leica Biosystems advanced staining and imaging business, said in a press release. “This is a momentous step forward in the integration of digital pathology into routine patient care.”

The Aperio AT2 DX is a high-throughput automated scanning and viewing platform. It will be launched commercially with clinical image management software for an integrated digital pathology workflow solution.