BioSpectrum the business of Bio & Health Sciences

Leica Biosystems to sell its digital pathology system for Primary Diagnosis

30 May 2019 | News

Leica Biosystems Receives FDA 510(k) Clearance to Market its Aperio AT2 DX System for Primary Diagnosis

Leica Biosystems, the global leader in pathology workflow solutions, announced that it has received clearance from the U.S. Food and Drug Administration (FDA) to market its Aperio AT2 DX System for clinical diagnosis in the U.S.

A multi-center study supporting this clearance was conducted with pathologists at 5 clinical study sites in the U.S.: University of California Davis, Pacific Rim Pathology, Dignity Health, TriCore Reference Laboratories, and Intermountain Healthcare. One of the largest clinical concordance studies ever completed on digital whole slide images, the participating pathologists read approximately 16,000 cases. The study compared reads of pathology slides under a microscope with on-screen digital reads.

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