

[Paige Prostate software receives FDA approval](#)

written by CAP TODAY

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Sept. 23, 2021—The FDA authorized marketing of [Paige](#)'s software Paige Prostate, a prostate cancer detection solution that identifies foci suspicious for cancer and provides the information to a pathologist. The software is the first AI-based pathology product to receive de novo approval from the FDA, allowing in vitro diagnostic use via the company's FDA-cleared FullFocus digital pathology viewer.

The FDA evaluated data from a clinical study in which 16 pathologists examined 527 slide images of prostate biopsies (171 cancer, 356 benign) that were digitized using a scanner. The study found that Paige Prostate improved detection of cancer on individual slide images by 7.3 percent on average when compared with pathologists' unassisted reads for whole slide images of individual biopsies, with no impact on the read of benign slide images.



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