Paige Lymph Node gets FDA breakthrough device designation

Nov. 7, 2023—Paige announced that the FDA has granted breakthrough device designation for Paige Lymph Node, an AI application used to detect breast cancer metastases in lymph node tissue. Paige Lymph Node is an in vitro diagnostic medical device software, derived from a deep learning model that has been trained with more than 32,000 digitized hematoxylin & eosin lymph node slides. If the lymph node tissue is suspicious for cancer, the software will highlight each area of concern for further review by the pathologist.

“Pathologic assessment of lymph nodes in breast cancer patients is critically important for prediction of outcome and treatment, yet the process is time-consuming and error prone,” David Klimstra, MD, founder and CMO at Paige, said in a press release. “Paige Lymph Node uses the power of AI to help the pathologist identify even small lymph node metastases rapidly and accurately, ensuring that breast cancer patients receive the optimal management of their disease.”

Paige Lymph Node is the first AI application of its kind to receive breakthrough device designation.