FDA OKs Ultrasound Device for Dense Breast Screening

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By Diagnostic Imaging Staff [2]

U-Systems' somo•v Automated Breast Ultrasound (ABUS) system is approved for use in combination with mammography for women with dense breast tissue.

The FDA has approved an automated breast ultrasound system for use in combination with mammography for women with dense breast tissue.

U-Systems' somo•v Automated Breast Ultrasound (ABUS) system is the only approved ultrasound device designed especially for screening women with dense breast tissue who have negative mammograms and no symptoms of disease, the FDA said. These women must also have no previous history of clinical breast intervention.

Ultrasound breast imaging uses a transducer to direct high-frequency sound waves throughout the breast. The uniquely-shaped somo•v Automated Breast Ultrasound system transducer scans the entire breast in approximately one minute and produces several images.

The FDA reviewed clinical study results that asked board-certified radiologists to analyze mammograms alone or along with somo•v ABUS images. The agency reviewed image interpretations from 200 women with dense breasts and negative mammograms.

Masses detected through somo•v ABUS were biopsied, and results revealed a statistically significant increase in breast cancer detection when ABUS images are analyzed alongside mammograms.

Included in the device's approval, the agency is mandating U-Systems properly train physicians and technologists in using the ABUS transducer, as well as provide each facility with a manual that details the system tests necessary for initial, periodic, and yearly quality-control measures.

Previous research published in the journal European Radiology revealed breast cancer detection doubled among study participants when ABUS was used with mammography. Detection rates also tripled for cancers smaller than 10 mm.

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