

Hologic reçoit l'approbation FDA pour le premier système 3-D de mammographie digitale (Tomosynthèse de la poitrine)



Hologic, Inc., a leading developer, manufacturer and supplier of premium diagnostic products, medical imaging systems and surgical products dedicated to serving the healthcare needs of women, today announced the Company received approval from the U.S. Food and Drug Administration (FDA) for its Selenia Dimensions digital breast tomosynthesis system (Dimensions 3-D).

Mammography systems using conventional 2-D imaging have limitations caused by tissue overlapping tissue in the breast that may hide lesions or cause benign areas to appear suspicious. Clinical trials using Hologic's Dimensions 3-D system showed measurable improvement in clinical performance over conventional mammography. These trials also showed significant gains in specificity - the confidence to rule out cancer without recalling the patient for further study - and other benefits including improved lesion and margin visibility and the ability to accurately localize structures in the breast. The combination of measurable improvements in accuracy and detection, and improved sensitivity, makes the Dimensions 3-D system a superior system vs. conventional digital mammography systems.

"We are extremely proud to be the first company to receive FDA approval of a 3-D digital mammography system and to offer women this groundbreaking, superior imaging technology," said Rob Cascella, President and Chief Executive Officer.

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