FDA to review expanded approval for Hologic's breast cancer imaging systems

Mass Device

Hologic gets a date with the FDA to explore expanded indication for its already-approved 3D digital mammography systems.

Massachusetts-based women's health devices maker Hologic [1] (NSDQ:HOLX [2]) has got a date with the FDA.

Later this year the federal watchdog agency's Radiological Devices Panel will meet in Washington D.C. to discuss expanding approval for Hologic's 1st-of-its-kind Selenia Dimensions 3D digital mammography system.

The device, which originally won FDA approval in February 2011 [3] after winning a unanimous panel recommendation in September 2010 [4], incorporates 3D imaging with 2D imaging in breast exams by digitally combining multiple X-rays to help radiologists get a view unobstructed by distortion, tissue shadowing or density.

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http://www.mdtmag.com/news/2012/08/fda-review-expanded-approval-hologics-breast-cancer-imaging-systems?qt-video_of_the_day=0

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