Breast cancer: FDA panel votes to expand PMA for Hologic's mammography system

Mass Device

The FDA's Radiological Devices Panel votes to approve expanded indication for Hologic's Selenia 3D digital mammography system.

The FDA's Radiological Devices Panel this week voted to grant Hologic's [1] (NSDQ:HOLX [2]) expanded approval for its 1st-of-its-kind Selenia Dimensions 3D digital mammography system.

Selenia Dimensions is currently approved for breast cancer screening and diagnosis with full-field digital mammography alone or paired with digital breast tomosynthesis. The company is eying expanded indication that includes use of its new C-View software, which generates synthetic 2D images using digital breast tomosynthesis.

Links:
[1] http://www.massdevice.com/company/hologic-inc
[2] http://www.google.com/finance?q=holx