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US approves first 3-D mammogram

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The first three-dimensional mammogram device was approved Friday by the US Food and Drug Administration, in the hopes that the new technology would improve early breast cancer detection.

Currently the only technology on the market produces two-dimensional X-ray images of the breast.

"Physicians can now access this unique and innovative 3-D technology that could significantly enhance existing diagnosis and treatment approaches," said Jeffrey Shuren, director of the FDA's Center for Devices and Radiological Health.

A pair of studies reviewed by the FDA showed a seven percent improvement in the ability of radiologists to "distinguish between cancerous and non-cancerous cases as compared to viewing 2-D images alone," the regulatory agency said.

The new device, called the Selenia Dimensions System, is made by the Massachusetts-based company Hologic and functions as an upgrade to its current 2-D FDA approved system.

The new technology "produces three-dimensional images which are intended to reveal the inner architecture of the breast, free from the distortion typically caused by tissue shadowing or density," the company said in a statement.

"The examination, which includes a 3-D tomosynthesis image in

combination with a 2-D image, takes only seconds longer than a conventional 2-D digital mammogram at a total exam dose within current FDA guidelines."

The FDA said the time it takes to capture the 2-D and 3-D images "approximately doubled the radiation dose the patient received" but that any additional risk was believed to be low.

"There is uncertainty for radiation risk estimates; however, the increase in cancer risk from having both a 2-D and 3-D exam is expected to be less than 1.5 percent compared to the natural cancer incidence, and less than one percent compared to the risk from conventional 2-D mammography," the FDA said.

The US agency also noted the 3-D approach "improved the accuracy with which radiologists detected cancers, decreasing the number of women recalled for a diagnostic workup."

The National Cancer Institute recommends that women over 40 get mammograms to screen for breast cancer every one or two years.

Hologic stock rose just over two percent following the FDA approval.