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Hologic

Hologic, Inc. announced at the RSNA that they have received an approvable letter from the U.S. Food and Drug Administration (FDA) for the Selenia Dimensions 3-D digital mammography tomosynthesis system. Final approval of the company's pre-market approval application for the system remains subject to satisfactory review and inspection of their manufacturing facility, methods and controls. The company plans to work closely with the FDA to complete this final inspection.

"We are extremely pleased to have received the FDA's approvable letter, which represents an important step forward in the commercialisation of our Selenia Dimensions tomosynthesis system," said Rob Cascella, President and Chief Executive officer. "The Selenia Dimensions technology is designed to provide radiologists with enhanced screening and diagnostic capabilities through the incorporation of fast, high-quality 3-D imaging in combination with 2- D imaging. We believe this new technology will address many of the limitations present in standalone 2-D imaging and improve upon both sensitivity and specificity. We look forward to working with the FDA to complete the remaining steps in the approval process."

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