FDA Clears Volpara™ Breast Imaging Software for Automatic Calculation of Volumetric Breast Density

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WELLINGTON, New Zealand, Nov. 18, 2010 /PRNewswire/ -- Offering radiologists a reliable and cost-effective tool to generate automatic volumetric breast density values, Volpara, Ltd., announced today that it has received clearance from the U.S. Food & Drug Administration (FDA) for its Volpara™ breast imaging software. Volpara, a subsidiary of Matakina Technology, Limited of New Zealand, is responsible for commercial operations in the United States.

Automatically computing volumetric breast tissue density from screening mammograms, Volpara software assists radiologists by providing objective, automatic and robust measurement of volumetric breast tissue density. Cleared for use with digital mammography systems, Volpara is currently available for Hologic and GE digital mammography systems with other systems undergoing validation.

Breast tissue density has not only been linked to an increased risk of breast cancer, it also decreases the sensitivity of the mammogram and thereby may impact early detection. Several large studies have confirmed that as tissue density increases the accuracy of mammography decreases. Thirty-five percent of breast cancer goes undetected by mammography in women with dense breasts, as density masks the appearance of tumors (*Boyd et al 2007, NEJM*). Since both dense breast tissue and cancer appear white on a mammogram, finding cancers can be analogous to looking for a snowball in a snow storm.

"Radiologists and imaging scientists have known for years the challenges that tissue density presents to mammography, but there haven't been the means to objectively and automatically quantify the actual amount of breast density from the screening mammogram," said Dr Ralph Highnam, CEO, Volpara, Ltd. "Volpara will improve radiologists' understanding of breast composition and assist them in helping patients to make appropriate screening decisions."

Radiologists currently use the Breast
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SOURCE [1]

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[1] http://www.bio-medicine.org/medicine-technology-1/FDA-Clears-Volpara-u2122-Breast-Imaging-Software-for-Automatic-Calculation-of-Volumetric-Breast-Density-12937-1/