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FDA Clearance for Planmed Digital Mammography (FFDM)

On September 23, 2011 the U.S. Food and Drug Administration (FDA) issued 510(k) approval letter for the Planmed Nuance Excel full-field digital mammography system. Planmed Nuance Excel FFDM System combines fast examination time, low radiation dose, and outstanding image quality. The system includes Planmed's proprietary MaxView Breast Positioning System for enhanced tissue visibility, and Side Access patient positioning for optimal working ergonomics.

"We are excited that we can now provide our unique, innovative digital mammography solutions also for women in the U.S., contributing to the fight against breast cancer. We are confident that our patient-centered design will be well received and will encourage more women to participate in breast cancer screening," says Vesa Mattila, Vice President of Planmed Oy.

Planmed's products are well known for their exquisite design and user ergonomics. The Planmed Nuance Excel features a large 24x31 cm amorphous selenium (a-Se) detector. It is intended for both screening and diagnostic mammography.

Planmed's analog mammography units are widely used in the U.S. and supported by Planmed's subsidiary Planmed, Inc. located in Roselle, Illinois. "We are very pleased to extend our mammography equipment line to also cover full-field digital mammography. Many of our customers have been looking forward to this clearance," says Chris Oldham, Director of Sales of Planmed, Inc.

Planmed Nuance Excel full-field digital mammography system will be on display at the Radiology Society of North America (RSNA) meeting starting on November 27, 2011 in Chicago.

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